## Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES Division 60—Missouri Health Facilities Review Committee Chapter 50—Certificate of Need Program

#### 19 CSR 60-50.200 Purpose and Structure

PURPOSE: This rule describes the purpose of the Certificate of Need (CON) statute and the structure of the Missouri Health Facilities Review Committee.

(1) The Certificate of Need (CON) statute, sections 197.300–197.366, RSMo, became effective September 28, 1979, except those sections which were not effective until October 1, 1980 or later. CON had its origin in the federal Public Law 93-641, 1974, and was initially intended to address issues of need, cost, and distribution of health services, as well as other factors which impact the health of the population.

(2) The purpose of the CON statute is to achieve the highest level of health for Missourians through cost containment, reasonable access, and public accountability. The goals are to—

- (A) Review proposed health care services;
- (B) Contain health costs;
- (C) Promote economic value;
- (D) Evaluate competing interests;
- (E) Prevent unnecessary duplication; and
- (F) Disseminate health-related information to affected parties.

(3) The CON statute is administered by the nine (9)-member Missouri Health Facilities Review Committee (committee). Five (5) members are appointed by the governor, two (2) by the president pro tem of the senate, and two (2) by the speaker of the house, each serving two (2)-year terms or until replaced.

(4) On behalf of the committee, the CON Program provides technical and administrative services as shown in rule 19 CSR 60-50.900.

AUTHORITY: section 197.320, RSMo 2000.\* Original rule filed June 2, 1994, effective Nov. 30, 1994. Emergency rescission and rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Rescinded and readopted: Filed Aug. 29, 1997, effective March 30, 1998. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Rescinded and readopted: Filed Dec. 14, 2001, effective June 30, 2002. Amended: Filed Oct. 1, 2010, effective May 30, 2011.

\*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.

## 19 CSR 60-50.300 Definitions for the Certificate of Need Process

PURPOSE: This rule defines the terms used in the Certificate of Need (CON) review process.

(1) Affiliate means an organization:

(A) That owns five percent (5%) or more of the ownership interests in the operator; or

(B) In which the operator owns five percent (5%) or more of the ownership interests. Affiliates include, without limitation, a parent organization, joint venture, partner, or general partner.

(2) Applicant means all owner(s) and operator(s) of any new institutional health service.

(3) By or on behalf of a health care facility includes any expenditures made by the facility itself as well as capital expenditures made by other persons that assist the facility in offering services to its patients/residents.

(4) Cost means—

(A) Price paid or to be paid by the applicant for a new institutional health service to acquire, purchase, or develop a health care facility or major medical equipment; or

(B) Fair market value of the health care facility or major medical equipment as determined by the current selling price at the date of the application as quoted by builders or architects for similar facilities, or normal suppliers of the requested equipment; or

(C) Fair market value of the existing land(s) and building(s) to be converted as determined by the current selling price at the date of the application or a current appraisal.

(5) Construction of a new hospital means the establishment of a newly licensed facility at a specific location under the Hospital Licensing Law, section 197.020.2, RSMo, as the result of building, renovation, modernization, and/or conversion of any structure.

(6) Expedited application means a shorter than full application and review period as defined in 19 CSR 60-50.420 and 19 CSR 60-50.430 for any long-term care replacement as defined in section 197.318.4.-6., RSMo, long-term care renovation and modernization, or the replacement of any major medical equipment as defined in section (13) of this rule.

(7) Full review means the complete analytical period for applications as described in 19 CSR 60-50.420 and 19 CSR 60-50.430 for the development of health care facilities and acquisition of major medical equipment.

(8) Generally accepted accounting principles pertaining to capital expenditures include, but are not limited to-

(A) Expenditures related to acquisition or construction of capital assets;

(B) Capital assets are investments in property, plant, and equipment used for the production of other goods and services approved by the committee; and

(C) Land is not considered a capital asset until actually converted for that purpose with commencement of aboveground construction approved by the committee.

(9) Health care facility means those described in section 197.366, RSMo.

(10) Health care facility expenditure includes the capital value of new construction or renovation costs, architectural/engineering fees, equipment not in the construction contract, land acquisition costs, consultants'/legal fees, interest during construction, predevelopment costs as defined in section 197.305(12), RSMo, in excess of one hundred fifty thousand dollars (\$150,000), any existing land and building converted to the applicant's medical use for the first time, and any other capitalizable costs incurred over a twelve- (12-) month period as listed on the "Proposed Project Budget" (Form MO 580-1863), included herein.

(11) LTC bed expansion review means a facility licensed pursuant to chapter 198 may increase its licensed bed capacity by submitting a Letter of Intent documenting the expansion, certification from the department of health and senior services and health facilities review committee that the facility has had no patient care class I deficiencies within the last eighteen (18) months, and has maintained a ninety-percent (90%) average occupancy rate for the previous six (6) quarters as shown by CON's most recent Six-Quarter Occupancy of Intermediate Care and Skilled Nursing Facility (or Residential Care and Assisted Living Facility) Licensed Beds only report published on the CON website.

(12) Health maintenance organizations means entities as defined in section 354.400(10), RSMo, except for activities directly related to the provision of insurance only.

(13) Major medical equipment means any piece of equipment and collection of functionally related devices acquired to operate the equipment and additional related costs such as software, shielding, and installation, acquired over a twelve- (12-) month period with an aggregate cost of one (1) million dollars or more, when the equipment is intended to provide the following diagnostic or treatment services and related variations, including, but not limited to:

- (A) Cardiac catheterization;
- (B) Computed tomography;
- (C) Gamma knife;
- (D) Lithotripsy;
- (E) Magnetic resonance imaging;
- (F) Linear accelerator;
- (G) Positron emission tomography/computed tomography; or
- (H) Evolving technology.

(14) Non-applicability review means a Letter of Intent process to document that a CON is not needed for a proposal when the capital expenditure is less than the expenditure minimum in section 197.305(6), RSMo; the proposal is to increase the number of beds by ten (10) or ten percent (10%) of total bed capacity, whichever is less, over a two- (2-) year period since any long-term care beds were last licensed, the facility has had no resident care class I deficiencies within the last eighteen (18) months and has maintained at least an eighty-five percent (85%) average occupancy rate for the previous six (6) quarters as shown by CON's most recent Six-Quarter Occupancy of Intermediate Care and Skilled Nursing Facility (or Residential Care and Assisted Living Facility) Licensed Beds report published on the CON website, and the capital expenditure is less than the expenditure minimum in section 197.305(6), RSMo; an exemption or exception is found in accordance with section 197.312, RSMo; or the proposal meets the definition of a non-substantive project.

(15) Nonsubstantive project includes but is not limited to at least one (1) of the following situations:

(A) An expenditure which is required solely to meet federal or state requirements or involves predevelopment costs or the development of a health maintenance organization;

(B) The construction or modification of nonpatient care services, including parking facilities, sprinkler systems, heating or air-conditioning equipment, fire doors, food service equipment, building maintenance, administrative equipment, telephone systems, energy conservation measures, land acquisition, medical office buildings, and other projects or functions of a similar nature; or

(C) Expenditures for construction, equipment, or both, due to an act of God or a normal consequence of maintenance, but not replacement, of health care facilities, beds, or equipment.

(16) "Request to relicense," a health care facility licensed under Chapter 197 or Chapter 198 that ceases offering health services may seek verification to relicense the facility within twelve (12) months from the date of closure under the same general licensure conditions at the time the facility ceased offering health services. Beds must be relicensed in the same category of care at the time of closure and cannot exceed the licensed bed capacity at the time of closure.

(17) Offer, when used in connection with health services, means that the applicant asserts having the capability and the means to provide and operate the specified health services.

(18) Predevelopment costs mean expenditures as defined in section 197.305(12), RSMo, including consulting, legal, architectural, engineering, financial, and other activities directly related to the proposed project, but excluding the application fee for submission of the application for the proposed project.

(19) Substantial capital expenditure means significant progress completed towards the above-ground construction or renovations approved within in a CON application has been achieved. When applicants incur capital expenditures exceeding ten percent of their approved construction or renovation costs, and provide supporting documentation, such capital expenditures shall be presumed substantial except for good cause shown.

(20) For new hospitals or major medical equipment projects, service area means a geographic region made up of an area such as a county or contiguous areas such as a set of contiguous counties or zip codes, appropriate to the proposed service, documented by the applicant and approved by the committee. For long-term care projects, the fifteen- (15-) mile radius calculation must be used.

AUTHORITY: section 197.320, RSMo 2016.\* Original rule filed June 2, 1994, effective Nov. 30, 1994. Emergency rescission and rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Rescinded and readopted: Filed Aug. 29, 1997, effective March 30, 1998. Emergency amendment filed Oct. 20, 1998, effective Oct. 30, 1998, expired April 27, 1999. Amended: Filed Oct. 20, 1998, effective April 30, 1999. Amended: Filed Jan. 4, 2000, effective July 30, 2000. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Emergency rescission and rule filed Dec. 16, 2002, effective Jan. 1, 2003, expired June 29, 2003. Rescinded and readopted: Filed Dec. 14, 2001, effective June 30, 2002. Amended: Filed April 12, 2004, effective Nov. 30, 2004. Emergency amendment filed Aug. 14, 2006, effective Aug. 28, 2006, expired Feb. 23, 2007. Amended: Filed Aug. 14, 2006, effective March 30, 2007. Amended: Filed Oct. 1, 2010, effective May 30, 2011. Amended: Filed Aug. 9, 2019, effective March 30, 2020. Amended: Filed June 29, 2022, effective Jan. 30, 2023.

\*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.

#### **19 CSR 60-50.310 Guidelines for Specific Health Services** (Rescinded June 30, 2002)

AUTHORITY: section 197.320, RSMo Supp. 1999. Emergency rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Original rule filed Aug. 29, 1997, effective March 30, 1998. Amended: Filed Oct. 19, 1999, effective May 30, 2000. Emergency rescission filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Rescinded: Filed Dec. 14, 2001, effective June 30, 2002.

### 19 CSR 60-50.400 Letter of Intent Process

PURPOSE: This rule delineates the process for submitting a Letter of Intent to begin the Certificate of Need (CON) review process and outlines the projects subject to CON review.

(1) Applicants shall submit by mail, fax, or email a Letter of Intent (LOI) to begin the Certificate of Need (CON) review process so that it is received at the CON office at least thirty (30) days prior to the submission of the CON application and will remain valid in accordance with the following time frames:

(A) A LOI is valid for six (6) months..

(2) Once filed, a LOI may be amended, except for project address, not later than ten (10) days in advance of the CON application filing, or it may be withdrawn at any time without prejudice.

(3) A LTC bed replacement sought pursuant to sections 197.318.4 through 197.318.6, RSMo, requires a CON application if the capital expenditure for such bed replacement exceeds six hundred thousand dollars (\$600,000) but allows for shortened information requirements and review time frames.

(4) The CONP staff, as an agent of the Missouri Health Facilities Review Committee (committee), will review LOIs according to the following provisions:

(A) Major medical equipment is reviewed as an expenditure on the basis of cost, regardless of owners or operators, or location (mobile or stationary);

(B) The CONP staff shall test the LOI for applicability in accordance with statutory provisions for expenditure minimums, exemptions, and exceptions;

(C) If the test verifies that a statutory exception or exemption is met on a proposed project, or the proposed cost is below all applicable expenditure minimums, the committee chair may issue a Non-Applicability CON letter indicating the application review process is complete; otherwise, the CONP staff shall add the proposal to a list of Non-Applicability proposals to be considered at the next regularly scheduled committee meeting;

(D) If an exception or exemption is not verified, and if the proposal is above any applicable expenditure minimum, then a CON application will be required for the proposed project;

(E) A Non-Applicability CON letter will be valid subject to the following conditions:

1. Any change in the project scope, including change in type of service, cost, operator, ownership, or site, could void the effectiveness of the letter and require a new review; and

2. Final project costs with third-party verification must be provided on a Periodic Progress Report (Form MO 580-1871), included herein; and

(F) A CON application must be made if-

1. The project involves the development of a new hospital costing one (1) million dollars or more, except for a facility licensed under Chapter 197, RSMo, meeting the requirements described in 42 CFR, section 412.23(e);

2. The project involves the acquisition or replacement of major medical equipment in any setting not licensed under Chapter 198, RSMo, costing one (1) million dollars or more;

3. The project involves the acquisition or replacement of major medical equipment for a health care facility licensed under Chapter 198, RSMo, costing four hundred thousand dollars (\$400,000) or more;

4. The project involves the acquisition of any equipment or beds in a long-term care hospital meeting the requirements found in 42 CFR section 412.23(e) at any cost;

5. The project involves a capital expenditure for renovation or modernization, but not additional beds, by or on behalf of an existing health care facility licensed under Chapter 198, RSMo, costing six hundred thousand dollars (\$600,000) or more; or

6. The project involves additional LTC (licensed or certified residential care facility, assisted living facility, intermediate care facility, or skilled nursing facility) beds licensed under Chapter 198, RSMo,. that either—

A. Costs six hundred thousand dollars (\$600,000) or more; or

B. Exceeds ten (10) beds or ten percent (10%) of that facility's existing licensed capacity, whichever is less.

(5) Nonsubstantive projects are waived from review by the authority of section 197.330.1(8), RSMo, and any applicant seeking such a determination shall submit information through the LOI process. A project meeting the definition of a nonsubstantive project shall be posted for review on the CON website at least twenty (20) days in advance of the committee meeting when the project is scheduled to be confirmed by the committee.

AUTHORITY: section 197.320, RSMo 2016.\* Original rule filed June 2, 1994, effective Nov. 30, 1994. Emergency amendment filed Nov. 16, 1995, effective Nov. 26, 1995, expired May 23, 1996. Amended: Filed Nov. 15, 1995, effective April 30, 1996. Emergency amendment filed Nov. 26, 1996, effective Dec. 6, 1996, expired June 3, 1997. Emergency rescission filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Emergency rule filed Aug. 29, 1997, effective Sept. 8, 1997, terminated Sept. 21, 1997. Emergency rule filed Sept. 11, 1997, effective Sept. 21, 1997, expired March 19, 1998. Rescinded and readopted: Filed Aug. 29, 1997, effective March 30, 1998. Emergency rescission and rule filed June 29, 1999, effective July 9, 1999, expired Jan. 5, 2000. Rescinded and readopted: Filed June 29, 1999, effective Jan. 30, 2000. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Emergency amendment filed Dec. 16, 2002, effective Jan. 1, 2003, expired June 29, 2003. Rescinded and readopted: Filed Aug. 14, 2006, effective Aug. 28, 2006, expired Feb. 23, 2007. Amended: Filed Aug. 14, 2006, effective March 30, 2007. Amended: Filed Oct. 1, 2010, effective May 30, 2011. Amended: Filed Aug. 9, 2019, effective March 30, 2020. Amended: Filed June 29, 2022, effective Jan. 30, 2023.

\*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.

#### 19 CSR 60-50.410 Letter of Intent Package

PURPOSE: This rule provides the information requirements and the details of how to complete the Letter of Intent package to begin the Certificate of Need (CON) review process.

(1) The Letter of Intent (LOI) (Form MO 580-1860), included herein, shall be completed as follows:

(A) Project Information: sufficient information to identify the intended service, such as the name of the existing or proposed facility, whichever is applicable, and address or if address is unknown or not yet established, a specific description or the latitude and longitude identifying a specific site rather than a general area (county designation alone is not sufficient);

(B) Applicant Identification: the full legal name of all owner(s) and operator(s) which compose the applicant who, singly or jointly, propose to develop, offer, lease, or operate a new institutional health service within Missouri; provide the corporate entity, not individual names, of the corporate board of directors or the facility administrator;

(C) Type of Review: the applicant shall indicate if the review is for a full review, expedited review, non-applicability review, or a LTC bed expansion review pursuant to section 197.318.4;

(D) Project Description: information which provides details of the number and type of beds to be added, removed, or replaced, square footage of new construction and/or renovation, services affected, and equipment to be acquired. If a replacement project, information which provides details of the facilities or equipment to be replaced, including name, location, distance from the current site, and its final disposition. If replacing equipment previously approved, provide the CON project number of existing equipment;

(E) Estimated Project Cost: total proposed expenditures necessary to achieve the application's objectives—not required for long-term care (LTC) bed expansions pursuant to section 197.318.4(1), RSMo;

(F) Authorized Contact Person Identification: the full name, title, address (including association), telephone number, email, fax number, signature, and date of signature;

(G) Applicability: page 2 of the LOI must be filled out by applicants requesting a non-applicability review or LTC bed expansion pursuant to section 197.318.4, to provide the reason and rationale for the non-applicability or LTC bed expansion review request; and

(2) If a non-applicability review is sought, the applicant shall submit the following additional information:

(A) Proposed Expenditures (Form MO 580-2375), included herein;

(B) Information which details all methods and assumptions used to estimate project costs. Documentation of costs may be requested;

(C) Schematic drawings and evidence of site control, with appropriate documentation;

(D) Evidence of submission of architectural plans to the Division of Regulation and Licensure Engineering Consultation Unit, Department of Health and Senior Services, for long-term care projects and other facilities; and

(E) In addition to the above information, for exceptions or exemptions, documentation of other provisions in compliance with the Certificate of Need (CON) statute, as described in sections (3) through (8) below of this rule.

(3) If a LTC bed expansion review is sought pursuant to section 197.318.4, the applicant shall submit the following additional information:

(A) Purchase Agreement (Form MO 580-2352), included herein;

(B) Schematic drawings and evidence of site control, with appropriate documentation;

(4) When an LOI for a LTC bed expansion review pursuant to section 197.318.4 is filed, the Certificate of Need Program (CONP) staff shall immediately review that facility's average licensed bed occupancy for the most recent six (6) consecutive calendar quarters, and request certification that the facility had no patient care Class I deficiencies within the last eighteen (18) months from the Division of Regulation and Licensure (DRL), Department of Health and Senior Services, through a LTC Facility Expansion Certification (Form MO 580-2351, incorporated by reference), to verify compliance with occupancy and deficiency requirements pursuant to section 197.318.4(1), RSMo. Occupancy data shall be taken from the CON's most recent Six-Quarter Occupancy of Intermediate Care and Skilled Nursing Facility (or Residential Care and Assisted Living Facility) Licensed Beds only report published on the CON website.

(5) For a LTC bed expansion review pursuant to section 197.318.4; the sellers and purchasers shall be defined as the owner(s) and operator(s) of the respective facilities, which includes building, land, and license. On the Purchase Agreement (Form MO 580-2352), both the owner(s) and operator(s) of the purchasing and selling facilities shall sign

(6) Upon staff verification that the statutory requirements are met described in sections (3) through (5) above in this rule, staff will notify the applicant and request the applicant to submit either:

(A) If an agreement is reached by the selling and purchasing entities, provide a copy of the selling facility's reissued license verifying surrender of beds sold; or

(B) If no agreement is reached by the selling and purchasing entities and effort(s) to purchase have been unsuccessful, provide Purchase Agreement Form(s) (MO 580-2352), included herein, and additional documentation verifying unsuccessful effort(s) to purchase.

(7) If an exemption is sought for a residential care or assisted living facility (RCF/ALF) pursuant to section 197.312, RSMo, the applicant shall submit documentation that this facility had previously been owned or operated for or on behalf of St. Louis City.

(8) The LOI must have an original signature for the contact person, which can be an electronic signature.

AUTHORITY: section 197.320, RSMo 2016.\* Emergency rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Original rule filed Aug. 29, 1997, effective March 30, 1998. Emergency rescission and rule filed June 29, 1999, effective July 9, 1999, expired Jan. 5, 2000. Rescinded and readopted: Filed June 29, 1999, effective Jan. 30, 2000. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Rescinded and readopted: Filed Dec. 14, 2001, effective June 30, 2002. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2003, expired June 29, 2003. Emergency rescission and rule filed Aug. 14, 2006, effective Aug. 28, 2006, expired Feb. 23, 2007. Amended: Filed Aug. 14, 2006, effective March 30, 2011. Amended: Filed March 10, 2014, effective Oct. 30, 2014. Amended: Filed Aug. 9, 2019, effective March 30, 2020. Amended: Filed June 29, 2022, effective Jan. 30, 2023.

\*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.

## 19 CSR 60-50.420 Review Process

*PURPOSE:* This rule delineates the process for submitting a Certificate of Need (CON) application for a CON review.

(1) The Certificate of Need (CON) filing deadlines are as follows:

(A) For full applications, at least seventy-one (71) days but not more than one hundred (100) days prior to each Missouri Health Facilities Review Committee (committee) meeting;

(B) For expedited applications, the tenth day of each month or date set by program staff, or the next business day thereafter if that day is a holiday or weekend;

(C) For non-applicability and LTC bed expansion reviews, the Letter of Intent (LOI) filing may occur at any time.

(2) A CON application filing that does not substantially conform with the LOI, including but not limited to any change in owner(s), operator(s), project site, increase in requested beds, or scope of services, shall not be considered a CON application and shall be subject to the following provisions:

(A) The Certificate of Need Program (CONP) staff shall return any nonconforming submission; or

(B) The committee may issue an automatic denial unless the applicant withdraws the attempted application.

(3) All filings must be received at the principal office of the committee during regular business hours. The CONP staff, as an agent of the committee, shall provide notification of applications received through publication of the Application Review Schedule (schedule) as follows:

(A) For full and expedited applications, the schedule shall include the filing date of the application, a brief description of the proposed service, the time and place for filing comments and requests for a public hearing, and the tentative date of the meeting at which the application is scheduled for review. Publication of the schedule shall occur within two (2) business days after the filing deadline. The publication of the schedule shall be posted on the CON website; and

(B) For non-applicability reviews, the listing of non-applicability letters to be confirmed shall be posted on the CON website at least twenty (20) days prior to each scheduled meeting of the committee where confirmation is to take place.

(4) If an application is incomplete, the CONP staff shall notify the applicant in writing or by email within twenty (20) calendar days of filing a full or expedited application.

(5) Verbal information or testimony shall not be considered part of the application.

(6) Subject to statutory time constraints, the CONP staff shall post its written analysis on the CON website and immediately notify the committee of the posting by email as follows:

(A) For full CON applications, the CONP staff shall post the analysis and immediately notify the committee at least twenty (20) days in advance of the first committee meeting following the seventieth day after the CON application is filed. The written analysis of the CONP staff shall be sent to the applicant no less than fifteen (15) days before the meeting;

(B) For expedited applications which meet all statutory and rules requirements and which have no opposition, the CONP staff shall send its written analysis to the committee and the applicant within two (2) working days following the expiration of the thirty- (30-) day public notice waiting period or the date upon which any required additional information is received, whichever is later; and

(C) Expedited applications which do not meet all statutory and rules requirements or those which have opposition will be considered at the earliest scheduled committee meeting where the written analysis by the CONP staff can be sent to the committee and the applicant at least seven (7) days in advance.

(8) An applicant may withdraw an application without prejudice by written notice by mail or email at any time prior to the committee's decision. Later submission of the same application or an amended application shall be handled as a new application with a new fee.

(9) An applicant may decrease the number of beds requested in the CON application and provide an applicable explanation at least ten (10) calendar days before the scheduled CON meeting.

(10) In addition to using the Community Need Criteria and Standards as guidelines, the committee may also consider other factors to include, but not be limited to, the needs of residents based upon religious considerations, residents with HIV/AIDS, or mental health diagnoses, and special exceptions to the Community Need Criteria and Standards.

AUTHORITY: section 197.320, RSMo 2016.\* Emergency rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Original rule filed Aug. 29, 1997, effective March 30, 1998. Emergency rescission and rule filed June 29, 1999, effective July 9, 1999, expired Jan. 5, 2000. Rescinded and readopted: Filed June 29, 1999, effective Jan. 30, 2000. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Emergency amendment filed Dec. 16, 2002, effective Jan. 1, 2003, expired Jan. 29, 2003. Rescinded and readopted: Filed Dec. 14, 2001, effective June 30, 2002. Amended: Filed Dec. 1, 2010, effective May 30, 2011. Amended: Filed March 10, 2014, effective Oct. 30, 2014. Amended: Filed Aug. 9, 2019, effective March 30, 2020. Amended: Filed June 29, 2022, effective Jan. 30, 2023.

\*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.

## 19 CSR 60-50.430 Application Package

PURPOSE: This rule provides the information requirements and the application format of how to complete a Certificate of Need (CON) application for a CON review.

(1) A Certificate of Need (CON) application package shall be accompanied by an application fee which shall be a nonrefundable minimum amount of one thousand dollars (\$1,000) or one-tenth of one percent (0.1%), which may be rounded up to the nearest dollar, of the total project cost, whichever is greater, made payable to the "Missouri Health Facilities Review Committee."

(2) A written application package consisting of an electronic file in PDF format or a paper original shall be prepared and organized as follows:

- (A) The CON Applicant's Completeness Checklists and Table of Contents shall be used as follows:
  - 1. Include at the front of the application;
  - 2. Check the appropriate "done" boxes to assure completeness of the application;
  - 3. Number all pages of the application sequentially and indicate the page numbers in the appropriate blanks;

4. Check the appropriate "N/A" box if an item in the Review Criteria is "not applicable" to the proposal type; and

5. Restate the Review Criteria (preferably in bold type) and answer all Review Criteria items.

(B) The application package shall be based on one (1) of the following CON Applicant's Completeness Checklists and Table of Contents appropriate to the proposed project type, as follows:

1. New Hospital Application (Form MO 580-2501), included herein. Use this for a new or replacement hospital project;

2. New or Additional Long-Term Care (LTC) Bed Application (Form MO 580-2502), included herein. Use this form for a Residential Care Facility project, Assisted Living Facility project, Intermediate Care Facility project, or Skilled Nursing Facility project or Long-Term Care Hospital project;

3. New or Additional Long-Term Care Hospital (LTCH) Bed Application (also use Form MO 580-2502), included herein;

- 4. New or Additional Equipment Application (Form MO 580-2503), included herein;
- 5. Expedited LTC Bed Replacement Application (Form MO 580-2504), included herein;
- 6. Expedited LTC Renovation/Modernization Application (Form MO 580-2505), included herein; or

7. Equipment Replacement Application (Form MO 580-2506), included herein.

(C) The application shall be divided into these sections:

- 1. Divider I. Application Summary;
- 2. Divider II. Proposal Description;
- 3. Divider III. Service-Specific Criteria and Standards; and
- 4. Divider IV. Financial Feasibility (only required for full applications).

(D) Support Information shall be included at the end of each section to which it pertains, and shall be referenced in the section narrative. For applicants anticipating having multiple applications in a year, master file copies of such things as maps, population data (if applicable), board memberships, IRS Form 990, or audited financial statements may be submitted once, and then referred to in subsequent applications, as long as the information remains current.

(E) The application package shall document the need or meet the additional information requirements in 19 CSR 60-50.450(4)–(5) for the proposal by addressing the applicable Community Need Criteria and Standards using the standards in 19 CSR 60-50.440 through 19 CSR 60-50.460 plus providing additional documentation to substantiate why any proposed alternative Criteria and Standards should be used.

(3) An Application Summary shall be composed of the completed forms in the following order:

(A) Applicant Identification and Certification (Form MO 580-1861), included herein. Additional specific information about board membership may be requested, if needed.

1. Provide documentation from the Missouri Secretary of State that the proposed owner(s) and proposed operator(s) are registered to do business in Missouri.

2. For new or additional long-term care bed and new hospital projects-

A. State if the license of the proposed operator or any affiliate of the proposed operator has been revoked within the previous five (5) years;

B. If the license of the proposed operator or any affiliate of the proposed operator has been revoked within the previous five (5) years, provide the name and address of the facility whose license was revoked;

C. State if the Medicare and/or Medicaid certification of any facility owned or operated by the proposed operator or any affiliate of the proposed operator has been revoked within the previous five (5) years; and

D. If the Medicare and/or Medicaid certification of any facility owned or operated by the proposed operator or any affiliate of the proposed operator has been revoked within the previous five (5) years, provide the name and address of the facility whose Medicare and/or Medicaid certification was revoked;

(B) A completed Representative Registration (Form MO 580-1869), included herein, for the contact person and any others as required by section 197.326.1, RSMo;

(C) A detailed Proposed Project Budget (Form MO 580-1863), included herein; and

(D) An attachment which details how each line item was determined, including all methods and assumptions used. If a third-party vendor or contractor was used to determine costs, provide documentation of costs..

(4) The Proposal Description shall include documents which-

(A) Provide a complete detailed description and scope of the project, and identify all institutional services or programs which will be directly affected by this proposal;

(B) Describe the developmental details including:

1. A timeline of anticipated events for the proposal from the time of the CON application review through project completion, including the commencement and completion of new construction or renovation, or purchase and installation of equipment;

2. A legible street or road map showing the exact location of the facility or health service, and a copy of the site plan showing the relation of the project to existing structures and boundaries;

3. Preliminary schematics for the project on an eight and one-half inch by eleven inch ( $8 1/2" \times 11"$ ) format (not required for replacement equipment projects). The function for each space, including the location of each existing and proposed bed before and after construction or renovation, shall be clearly identified and all space shall be assigned;

4. Evidence of submission of architectural plans to the Division of Regulation and Licensure, Department of Health and Senior Services, for long-term care projects and other facilities (not required for equipment projects);

5. For long-term care proposals, existing and proposed gross square footage for the entire facility and for each institutional service or program directly affected by the project. If the project involves relocation, identify what will go into vacated space;

6. Documentation that the proposed owner owns the project site, or that the proposed owner has an executed option to purchase or lease the site; and

7. Proposals which include major medical equipment shall include an equipment list with prices and also documentation in the form of bid quotes, purchase orders, catalog prices, or other sources to substantiate the proposed equipment costs;

(C) Proposals for major medical equipment must define the community to be served and geographic service area;

(D) Proposals for new hospitals or new or additional long-term care (LTC) beds must define the community to be served—

1. Describe the service area(s) population using year 2025 populations and projections provided by the Bureau of Health Care Analysis and Data Dissemination (BHCADD), which can be obtained by contacting:

Chief, Bureau of Health Care Analysis and Data Dissemination (BHCADD) Department of Health and Senior Services PO Box 570, Jefferson City, MO 65102 Telephone: (573) 751-6272

There will be a charge for any of the information requested, and seven to fourteen (7-14) days should be allowed for a response from BHCADD. Information requests should be made to BHCADD such that the response is received at least two (2) weeks before it is needed for incorporation into the CON application;

2. Use the maps and population data received from BHCADD with the CON Applicant's Population Determination Method to determine the estimated population for LTC projects, as follows:

A. Utilize all of the population for zip codes entirely within the fifteen- (15-) mile radius for LTC beds or geographic service area for hospitals and major medical equipment;

B. Reference a state highway map (or a map of greater detail) to verify population centers (see BHCADD) within each zip code overlapped by the fifteen- (15-) mile radius or geographic service area;

C. Categorize population centers as either "in" or "out" of the fifteen- (15-) mile radius or geographic service area and remove the population data from each affected zip code categorized as "out";

D. Estimate, to the nearest five percent (5%), the portion of the zip code area that is within the fifteen-(15-) mile radius or geographic service area by "eyeballing" the portion of the area in the radius (if less than five percent (5%), exclude the entire zip code);

E. Multiply the remaining zip code population (total population less the population centers) by the percentage determined in subparagraph (4)(D)2.D. (Due to numerous complexities, population centers will not be utilized to adjust overlapped zip code populations in Jackson, Clay, St. Louis, and St. Charles counties or St. Louis City; instead, the total population within the zip code will be considered uniform and multiplied by the percentage determined in subparagraph (4)(D)2.D.);

F. Add back the population center(s) "inside" the radius or region for zip codes overlapped; and

G. The sum of the estimated zip codes, plus those entirely within the radius, will equal the total population within the fifteen- (15-) mile radius or geographic service area;

3. Provide other statistics, such as studies, patient origin, or discharge data, Hospital Industry Data Institute's information, or consultants' reports, to document the size and validity of any proposed user-defined "geographic service area";

(E) Identify specific community problems or unmet needs which the proposed or expanded service is designed to remedy or meet;

(F) Provide historical utilization for each existing service affected by the proposal for each of the past three (3) full years;

(G) Provide utilization projections through at least three (3) full years beyond the completion of the project for all proposed and existing services directly affected by the project;

(H) If an alternative methodology is added, specify the method used to make need forecasts and describe in detail whether projected utilizations will vary from past trends; and

(I) Provide the current and proposed number of licensed beds by type for projects which would result in a change in the licensed bed complement of the LTC facility.

(5) Document that consumer needs and preferences have been included in planning this project. Describe how consumers have had an opportunity to provide input into this specific project, and include in this section all petitions, letters of acknowledgement, support or opposition received.

(6) Document that providers of similar health services in the proposed service area have been notified of the application by a public notice in the local newspaper of general circulation before it was filed with the CON Program from the applicant. The public notice shall include a contact person's name and phone number and/or email for the project.

(7) For proposed full or expedited CON applications, excluding equipment replacement applications, document that administrators or directors of all affected facilities in the proposed fifteen- (15-) mile radius or service area were addressed letters regarding the application.

(8) In addition to using the Community Need Criteria and Standards as guidelines, the committee may also consider other factors to include, but not be limited to, the needs of residents based upon religious considerations, residents with HIV/AIDS, or mental health diagnoses, and special exceptions to the Community Need Criteria and Standards.

AUTHORITY: section 197.320, RSMo 2016.\* Emergency rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Original rule filed Aug. 29, 1997, effective March 30, 1998. Emergency rescission and rule filed June 29, 1999, effective July 9, 1999, expired Jan. 5, 2000. Rescinded and readopted: Filed June 29, 1999, effective Jan. 30, 2000. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Rescinded and readopted: Filed Dec. 14, 2001, effective Jan. 1, 2002, expired June filed Dec. 16, 2002, effective Jan. 1, 2003, expired June 29, 2003. Amended: Filed June 9, 2003, effective Nov. 30, 2003. Emergency amendment filed June 8, 2005, effective Dec. 30, 2005. Emergency amendment filed June 8, 2005, effective Aug. 28, 2006, expired Feb. 23, 2007. Amended: Filed Aug. 14, 2006, effective March 30, 2007. Amended: Filed Oct. 1, 2010, effective March 30, 2011. Amended: Filed March 10, 2014, effective Oct. 30, 2014. Amended: Filed Aug. 9, 2019, effective March 30, 2020. Amended: Filed June 29, 2022, effective Jan. 30, 2020. Amended: Filed Aug. 9, 2019, effective March 30, 2020. Amended: Filed Aug. 9, 2019, effective March 30, 2020. Amended: Filed June 29, 2022, effective Jan. 30, 2023.

\*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.

#### 19 CSR 60-50.440 Criteria and Standards for Equipment and New Hospitals

PURPOSE: This rule lists the service-specific criteria and standards used in the Certificate of Need (CON) review process.

(1) For new units or services in the service area, use the following:

(A) Provide the minimum annual utilization for each of the other providers in the service area for the most recent three (3) full years, if applicable. The provider(s) should achieve at least the following community need rates as follows by the final year:

- 1. Magnetic resonance imaging procedures: 2,000
- 2. Positron emission tomography/computed tomography procedures: 1,000
- 3. Lithotripsy treatments: 1,000
- 4. Linear accelerator treatments: 3,500
- 5. Cardiac catheterization procedures (include coronary angioplasties): 500
- 6. Gamma knife treatments: 200
- 7. Computed tomography: 3,500
- 8. Robotic surgery system: 240

(B) For long-term care hospitals (such as a hospital-within-a-hospital or long-term acute care hospital), the applicant should comply with the standards as described in 42 CFR, section 412.23(e), and the bed need should meet the applicable population-based bed need methodology in 19 CSR 60-50.450;

(C) Alternate methodologies may also be provided.

(2) For additional units or services, provide the applicant's annual utilization for the most recent three (3) full years, if applicable. The applicant should achieve at least the following community need rates as follows, by the final year:

(A) Magnetic resonance imaging procedures: 3,000

- (B) Positron emission tomography/computed tomography procedures: 1,000
- (C) Lithotripsy treatments: 1,000
- (D) Linear accelerator treatments: 6,000
- (E) Cardiac catheterization procedures: 750
- (F) Gamma knife treatments: 200
- (G) Computed tomography: 4,000
- (H) Robotic surgery system: 240

(3) For replacement equipment, utilization standards are not used, but rather the following questions shall be answered:

(A) What is the financial rationale for the replacement?

(B) How has the existing unit exceeded its useful life in accordance with American Hospital Association guidelines?

(C) How does the replacement unit affect quality of care, utilization, and operational efficiencies compared to the existing unit?

- (D) Is the existing unit in constant need of repair?
- (E) Has the current lease on the existing unit expired?
- (F) What technological advances and capabilities will the new unit include?
- (G) How will patient satisfaction be improved?
- (H) How will the new unit improve outcomes and/or clinical improvements?
- (I) By what percentage will this replacement increase patient charges?

(4) For the construction of a new hospital, the following questions shall be answered:

(A) What methodology was utilized to determine the need for the proposed hospital?

(B) Provide the most recent three (3) full years of evidence that the average occupancy of the same type(s) of beds at each other hospital in the proposed service area exceeds eighty percent (80%).

(C) What impact would the proposed hospital have on utilization of other hospitals in the service area?

(D) What is the unmet need according to the following population-based bed need formula using (Unmet Need =  $(R \times P) - U$ ), where:

- P = Year 2025 population in the service area;
- U = Number of licensed and approved beds in the service area; and
- R = Community need rate of one (1) bed per population in the service area as follows:
  - 1. Medical/surgical bed: 570
  - 2. Pediatric bed: 8,330
  - 3. Psychiatric bed: 2,080
  - 4. Substance abuse/chemical dependency bed: 20,000
  - 5. Inpatient rehabilitation bed: 9,090
  - 6. Obstetric bed: 5,880

AUTHORITY: section 197.320, RSMo 2016.\* Emergency rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Original rule filed Aug. 29, 1997, effective March 30, 1998. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Rescinded and readopted: Filed Dec. 14, 2001, effective June 30, 2002. Amended: Filed Oct. 1, 2010, effective May 30, 2011. Amended: Filed March 10, 2014, effective Oct. 30, 2014. Amended: Filed Aug. 9, 2019, effective March 30, 2020. Amended: Filed June 29, 2022, effective Jan. 30, 2023.

\*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.

### 19 CSR 60-50.450 Criteria and Standards for Long-Term Care

PURPOSE: This rule outlines the criteria and standards against which a project involving a long-term care facility would be evaluated in a Certificate of Need (CON) review.

(1) The following population-based long-term care bed need methodology for the fifteen- (15-) mile radius shall be used to determine the need:

(A) Approval of additional intermediate care facility/skilled nursing facility (ICF/SNF) beds will be based on:

1. A service area need determined to be fifty-three (53) beds per one thousand (1,000) year 2025 population age sixty-five (65) and older minus the current supply of ICF/SNF beds shown in the most recent Six-Quarter Occupancy of Hospital and Nursing Home Licensed and Available Beds report as provided by the Certificate of Need Program (CONP) which includes licensed and Certificate of Need (CON)-approved beds;

(B) Approval of additional residential care facilities/assisted living facilities (RCF/ALF) beds will be based on:

1. A service area need determined to be twenty-five (25) beds per one thousand (1,000) year 2025 population age sixty-five (65) and older minus the current supply of RCF/ALF beds shown in the most recent Six-Quarter Occupancy of Residential Care and Assisted Living Facility Licensed and Available Beds as provided by the CONP which includes licensed and CON-approved beds; and

(C) Approval for Long-Term Care Hospital (LTCH) beds, as described in 42 CFR, section 412.23(e), will be based on a service area need determined to be one-tenth (0.1) bed per one thousand (1,000) year 2025 population minus the current supply of LTCH beds shown in the most recent Six-Quarter Occupancy of Long-Term Care Hospital Facility Licensed and Available Beds as provided by the CONP which includes licensed beds and CON-approved beds.

(D) If the project is to add beds to an existing long-term care facility, the applicant shall state whether or not the facility received any resident care Class I deficiencies within the last eighteen (18) months as a result of a survey, inspection, or complaint investigation and the reason for and status of the deficiencies.

(2) Replacement Chapter 198 beds may qualify for an exception to the LTC bed minimum occupancy requirements (MOR) plus shortened information requirements and review time frames if an applicant proposes to—

(A) Relocate RCF/ALF beds within a six (6)-mile radius pursuant to section 197.318.4(4), RSMo;

(B) Replace one-half (1/2) of its licensed beds within a thirty (30)-mile radius pursuant to section 197.318.5, RSMo; or

(C) Replace a facility in its entirety within a fifteen (15)-mile radius pursuant to section 197.318.6, RSMo, under the following conditions:

1. The existing facility's beds shall be replaced at only one (1) site;

2. The existing facility and the proposed facility shall have the same owner(s), regardless of corporate structure; and

3. The owner(s) shall stipulate in writing that the existing facility's beds to be replaced will not be used later to provide long-term care services by any person or entity; or if the facility is operated under a lease, both the lessee and the owner of the existing facility shall stipulate the same in writing.

(3) An exception to the CON application filing fee will be recognized for any proposed facility which is designed and operated exclusively for persons with acquired human immunodeficiency syndrome (AIDS).

(4) For LTC renovation or modernization projects which do not include increasing the number of beds, the applicant shall document the following, if applicable:

(A) The proposed project is needed to comply with current facility code local, state, or federal government requirements for licensure, certification, or accreditation;

(B) Operational efficiencies will be attained through reconfiguration of space and functions;

(C) The methodologies used for determining need and the reallocation of space and functions; and

(D) The benefits to the facility because of its age or condition.

AUTHORITY: section 197.320, RSMo 2016.\* Emergency rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Original rule filed Aug. 29, 1997, effective March 30, 1998. Emergency rescission and rule filed June 29, 1999, effective July 9, 1999, expired Jan. 5, 2000. Rescinded and readopted: Filed June 29, 1999, effective Jan. 30, 2000. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Emergency amendment filed Dec. 16, 2002, effective Jan. 1, 2003, expired June 29, 2003. Rescinded and readopted: Filed Dec. 14, 2001, effective June 30, 2002. Emergency amendment filed Dec. 14, 2001, effective Jan. 1, 2003, expired June 29, 2003. Rescinded and readopted: Filed Dec. 14, 2001, effective June 30, 2002. Emergency amendment filed Aug. 14, 2006, effective Aug. 28, 2006, expired Feb. 23, 2007. Amended Filed Aug. 14, 2006, effective March 30, 2007. Amended: Filed Oct. 1, 2010, effective May 30, 2011. Amended: Filed Aug. 9, 2019, effective March 30, 2020. Amended: Filed June 29, 2022, effective Jan. 30, 2023.

\*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.

#### 19 CSR 60-50.460 Criteria and Standards for Evolving Technology

PURPOSE: This rule outlines the criteria and standards against which a project involving new technology would be evaluated in a Certificate of Need (CON) review.

(1) For evolving technology not currently available in the state or not in general usage in the state, the following shall be documented:

(A) The medical effects shall be described and documented in published scientific literature;

(B) The degree to which the objectives of the technology have been met in practice;

(C) Any side effects, contraindications or environmental exposures;

(D) The relationships, if any, to existing preventive, diagnostic, therapeutic or management technologies and the effects on the existing technologies;

(E) Food and Drug Administration approval;

(F) The need methodology used by this proposal in order to assess efficacy and cost impact of the proposal; and

(G) Explain the degree of partnership, if any, with other institutions for the joint use of and financing of the evolving technology.

AUTHORITY: section 197.320, RSMo 2000.\* Emergency rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Original rule filed Aug. 29, 1997, effective March 30, 1998. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Rescinded and readopted: Filed Dec. 14, 2001, effective June 30, 2002.

\*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.

#### 19 CSR 60-50.470 Criteria and Standards for Financial Feasibility

# *PURPOSE:* This rule outlines the criteria and standards against which a project involving a health care facility would be evaluated relative to the financial feasibility of the project in a Certificate of Need (CON) review.

(1) Proposals for any new hospital, skilled nursing facility, intermediate care facility, residential care facility, or assisted living facility construction must include documentation that the proposed costs per square foot are reasonable when compared to the latest RS Means Cost Data Percentile Limit Total New Construction Project Costs (Form MO 580-1866), included herein, available from the Certificate of Need Program (CONP). Any proposal with costs in excess of the three-fourths (3/4) percentile must include justification for the higher costs.

(2) Proposals must document that sufficient financing will be available to assure completion of the project by providing a letter from a financial institution saying it is willing to finance the project including the amount of financing, or an auditor's statement that unrestricted funds are available for the project. Written financial statements from an applicant's employee will not be acceptable to document financial feasibility unless that statement is notarized by a notary public. The committee may, at its own discretion, choose to reject any documentation that does comply with this provision.

(3) Document financial feasibility by including-

(A) The Service-Specific Revenues and Expenses (Form MO 580-1865), included herein, as a financial pro forma for each revenue generating service affected by the project for the past three (3) full years projected through three (3) full years beyond project completion; and

(B) For existing services, a copy of the latest available audited financial statements or the most recent Internal Revenue Service (IRS) 990 Form or similar IRS filing for facilities not having individual audited financial statements.

(4) Show how the proposed service will be affordable to the population in the proposed service area:

(A) Document how the proposal would impact current patient charges, and disclose the method for deriving charges for this service, including both direct and indirect components of the charge; and

(B) Demonstrate that the proposed service will be responsive to the needs of the medically indigent through such mechanisms as fee waivers, reduced charges, sliding fee scales, or structured payments.

(5) If the proposal is for a new skilled nursing or intermediate care facility, provide the percentage of the admissions that would be Medicaid eligible on the first day of admission or become Medicaid eligible within ninety (90) days of admission.

(6) If the proposal is to add new long-term beds to an existing skilled nursing or intermediate care facility, provide the percentage of the admissions that is Medicaid eligible on the first day of admission or becomes Medicaid eligible within ninety (90) days of admission.

AUTHORITY: section 197.320, RSMo 2016.\* Emergency rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Original rule filed Aug. 29, 1997, effective March 30, 1998. Amended: Filed Oct. 19, 1999, effective April 30, 2000. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Rescinded and readopted: Filed Dec. 14, 2001, effective June 30, 2002. Emergency amendment filed Aug. 14, 2006, effective Aug. 28, 2006, expired Feb. 23, 2007. Amended: Filed Aug. 14, 2006, effective March 30, 2011. Amended: Filed Aug. 9, 2019, effective March 30, 2020. Amended: Filed June 29, 2022, effective Jan. 30, 2023.

\*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.

# 19 CSR 60-50.480 Criteria and Standards for Alternatives

(Rescinded June 30, 2002)

AUTHORITY: section 197.320, RSMo Supp. 1997. Emergency rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Original rule filed Aug. 29, 1997, effective March 30, 1998. Emergency rescission filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Rescinded: Filed Dec. 14, 2001, effective June 30, 2002.

## 19 CSR 60-50.500 Additional Information

PURPOSE: This rule describes the process for submitting additional information and for requesting a public hearing on Certificate of Need (CON) applications in the CON review process.

(1) Additional information requested by the Missouri Health Facilities Review Committee (committee) shall be submitted within the time frame specified by the committee.

(2) If an application is determined to be incomplete, the applicant shall be notified within twenty () calendar days after filing a full or expedited application. The applicant's written response shall be received within ten (10) calendar days after receipt of notification.

(3) Support, neutral, and opposing information submitted by affected persons shall be received at the committee's principal office at least three (3) full business days before the scheduled meeting of the committee.

(4) Copies of any additional information sent directly to the committee by applicants or affected persons shall also be sent to the Certificate of Need Program (CONP) for file copies.

(5) When a request in writing or email is filed by any affected person within thirty (30) calendar days from the date of publication of the Application Review Schedule, the committee or CONP staff shall hold a public hearing on any application under the following conditions:

(A) The hearing may be conducted in the city of the proposed project if monetarily feasible;

(B) The CONP staff will present the introductions and orientation for the public hearing;

(C) The applicant may have up to fifteen (15) minutes for a presentation at the public hearing;

(D) Any person may present written testimony and up to five (5) minutes of verbal testimony at the public hearing; and

(E) The testimony shall become a part of the record of the review.

AUTHORITY: section 197.320, RSMo 2016.\* Original rule filed June 2, 1994, effective Nov. 30, 1994. Emergency rescission and rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Rescinded and readopted: Filed Aug. 29, 1997, effective March 30, 1998. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Rescinded and readopted: Filed Dec. 14, 2001, effective June 30, 2002. Amended: Filed Oct. 1, 2010, effective May 30, 2011. Amended: Filed Aug. 9, 2019, effective March 30, 2020. Amended: Filed June 29, 2022, effective Jan. 30, 2023.

\*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.

## 19 CSR 60-50.600 Certificate of Need Decisions

*PURPOSE:* This rule describes the process for making decisions on Certificate of Need (CON) applications in the CON review process.

(1) Decisions on full Certificate of Need (CON) applications and contested expedited applications shall be subject to the following:

(A) Parliamentary procedures for all face-to-face, videographic, telephonic, and computerized meetings shall follow Robert's Rules of Order, incorporated by reference, newly revised edition, 10th edition, published October 2000, Perseus Publishing, 11 Cambridge Center, Cambridge, MA 02142. This rule does not include any later amendments or additions;

(B) The CON Program's analysis becomes the findings of fact for the Missouri Health Facilities Review Committee (committee) decision except to the extent that it is expressly rejected, amended, or replaced by the committee in which case the minutes of the committee will contain the changes and become the amended findings of fact of the committee. The committee's final vote becomes conclusion of law; and

(C) A final decision is rendered on any application after each committee member present is given the opportunity to vote and the chair announces the passage or defeat of the motion on the floor. The chair or acting chair shall vote only in case of a tie.

(2) Decisions on expedited CON applications shall be subject to the following:

(A) In the case of qualifying expedited review applications, committee members will receive a ballot in addition to the written analysis. Members may vote either to approve the application or to have it placed on the next formal meeting agenda for consideration;

(B) Ballots may be returned to the CON office by either mail, email, or fax, but must be received within seven (7) business days from the date they were emailed to committee members; and

(C) A final decision to approve the application will be rendered if all ballots received by the cut-off date (at least five (5) ballots are required) signify a vote to approve the project. If the vote is not unanimous, the application will be subject to the provisions of section (1) of this rule.

(3) The committee shall make a decision on an application within one hundred thirty (130) calendar days after the date the application is filed and subsequently notify the applicant by providing either a legal certificate or denial letter by mail and email.

AUTHORITY: section 197.320, RSMo 2016.\* Original rule filed June 2, 1994, effective Nov. 30, 1994. Emergency rescission and rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Rescinded and readopted: Filed Aug. 29, 1997, effective March 30, 1998. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Rescinded and readopted: Filed Dec. 14, 2001, effective June 30, 2002. Emergency amendment filed Aug. 14, 2006, effective Aug. 28, 2006, expired Feb. 23, 2007. Amended: Filed Aug. 14, 2006, effective March 30, 2007. Amended: Filed Oct. 1, 2010, effective May 30, 2011. Amended: Filed Aug. 9, 2019, effective March 30, 2020.

\*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.

## 19 CSR 60-50.700 Post-Decision Activity

PURPOSE: This rule describes the procedure for filing Periodic Progress Reports after approval of Certificate of Need (CON) applications, CONs subject to forfeiture, and the procedure for requesting a cost overrun.

(1) Applicants who have been granted a Certificate of Need (CON) or a Non-Applicability CON letter shall file reports by mail or email with the Missouri Health Facilities Review Committee (committee), using Periodic Progress Report (Form MO 580-1871), included herein. A report shall be filed within ten (10) days following the end of each six- (6-) month period after CON approval, or issuance of a Non-Applicability CON letter, until the project is complete which includes the licensing of all new beds, installation of equipment, and/or completion of renovations. All Periodic Progress Reports must contain a complete and accurate accounting of all expenditures for the report period. Final project costs with third-party verification must be provided on a Periodic Progress Report (Form MO 580-1871), included herein.

(2) Applicants who have been granted a CON and fail to incur a capital expenditure within six (6) months may request an extension of six (6) months by submitting a written request to the committee outlining the reasons for the failure, with a listing of the actions to be taken within the requested extension period to insure compliance. The Certificate of Need Program (CONP) staff on behalf of the committee will analyze the request and grant an extension, if appropriate. Applicants may request additional extensions by submitting a completed Request for Extension (Form MO 580-1872), included herein, and must provide financial information plus other documentation describing delays.

(3) A Non-Applicability or LTC bed expansion pursuant to 197.318.4 CON letter is valid for six (6) months from the date of issuance. Failure to incur a capital expenditure or purchase the proposed equipment within that time frame shall result in the Non-Applicability CON letter becoming null and void. The applicant may request one (1) six (6)-month extension unless otherwise constrained by statutory changes. Failure to file the required Periodic Progress Report shall result in the Non-Applicability or LTC bed expansion CON letter becoming null and void.

(4) A CON shall be subject to forfeiture for failure to-

(A) Incur a project-specific capital expenditure within twelve (12) months after the date the CON was issued through substantial initiation of project aboveground construction by any of the following: installation of structural support; installation of structural steel; installation of framing; or establishing foundations and a wall. For major medical equipment, applicants must provide a copy of the signed lease/purchase of the proposed equipment which includes the date of purchase, delivery, installation and operational date or proof of physical equipment delivery. For renovation projects, applicants must initiate the detailed renovations outlined in the approved project description. For bed projects with a project cost of zero (0) dollars, the applicant must document appropriate department licensure of the approved bed(s). A capital expenditure, according to generally accepted accounting principles, must be applied to a capital asset; or(B) File the required Periodic Progress Report.

(5) If the CONP staff finds that a CON may be subject to forfeiture—

(A) Not less than thirty (30) calendar days prior to a committee meeting, the CONP shall notify the applicant in writing of the possible forfeiture, the reasons for it, and its placement on the committee agenda for action; and

(B) After receipt of the notice of possible forfeiture, the applicant may submit information to the committee within ten (10) calendar days to show compliance with this rule or other good cause as to why the CON shall not be forfeited.

(6) If the committee forfeits a CON, or a Non-Applicability or LTC bed expansion pursuant to 197.318.4(1) CON letter becomes null and void, CONP staff shall notify all affected state agencies of this action.

(7) Cost overrun review procedures implement the CON statute section 197.315.7, RSMo. Immediately upon discovery that a project's actual costs would exceed approved project costs by more than ten percent (10%), the applicant shall apply for approval of the cost variance. A nonrefundable fee in the amount of one-tenth of one percent (0.1%) of the additional project cost above the approved amount made payable to "Missouri Health Facilities Review Committee" shall be required. The information requirements for a cost overrun review are required as follows:

(A) Amount and justification for cost overrun shall document—

1. Why and how the approved project costs would be exceeded, including a detailed listing of the areas involved;

2. Any changes that have occurred in the scope of the project as originally approved; and

3. The alternatives to incurring this overrun that were considered and why this particular approach was selected; and

(B) Provide a Proposed Project Budget (Form MO 580-1863), included herein, and budget detail including all methods and assumptions used. Documentation of costs may be requested.

(8) Applicants may request a project owner change. The information requirements for an owner change review are as follows:

(A) Reason for owner change;

(B) Statement as to whether or not the proposed owner is an affiliate of the current owner, and explanation of relationship;

(C) Evidence that the existing owner agrees to the change. This can be a statement or a contract;

(D) Documentation that the proposed owner owns the site, or has an executed option to purchase or lease the real property;

(E) Documentation that the proposed owner(s) is registered to do business in Missouri;

(F) Documentation that sufficient financing would be available to assure completion of the project; and

(G) Provide a complete and signed Applicant Identification and Certification (Form MO 580-1861), included herein, with the proposed owner listed.

(9) Applicants may request a project operator change. The information requirements for an operator change review are as follows:

(A) Reason for operator change;

(B) Statement as to whether or not the proposed operator is an affiliate of the current operator, and explanation of relationship;

(C) Evidence that the existing operator agrees to the change. This can be a statement or a contract;

(D) Documentation that the proposed operator(s) is registered to do business in Missouri;

(E) The proposed operator must provide a brief explanation of their ability and experience operating a long-term care facility.

1. State if the license of the proposed operator or any affiliate of the proposed operator has been revoked within the previous five (5) years.

2. If the license of the proposed operator or any affiliate of the proposed operator has been revoked within the previous five (5) years, provide the name and address of the facility whose license was revoked.

3. State if the Medicare and/or Medicaid certification of any facility owned or operated by the proposed operator or any affiliate of the proposed operator has been revoked within the previous five (5) years.

4. If the Medicare and/or Medicaid certification of any facility owned or operated by the proposed operator or any affiliate of the proposed operator has been revoked within the previous five (5) years, provide the name and address of the facility whose Medicare and/or Medicaid certification was revoked; and

(F) Provide a complete and signed Applicant Identification and Certification (Form MO 580-1861), included herein, with the proposed operator listed.

(10) Applicants may request a project site change. The information requirements for a site change review are as follows:

(A) Reason for site change;

(B) Documentation the proposed site is within fifteen (15) miles as the crow flies of the existing site;

(C) Documentation that the owner owns the site, or has an executed option to purchase or lease the real property;

(D) Documentation of the cost of the proposed site;

(E) A legible street or road map showing the exact location of the facility or health service, and a copy of the site plan showing the relation of the project to existing structures and boundaries;

(F) Statement as to whether or not the project cost would change. If the project cost would change, submit a revised -proposed budget and fee if applicable;

(G) Provide the population-based long-term care bed need methodology for the fifteen- (15-) mile radius of the proposed site;

(H) Provide a complete and signed Applicant Identification and Certification (Form MO 580-1861), included herein, with the proposed site listed;

(I) List of any additional changes to the project as originally presented to the committee, such as—

1. Decrease in the number of beds. If a decrease, how many beds would be licensed;

2. Change to the building structure(s). If there would be a change, a description of the change(s), the total square footage, and revised schematics of the proposed building(s) with all use of space marked; and

3. The timeline of events for the project, from site change approval through project completion;

(J) Statement of how consumers were made aware of the proposed site change. All feedback received from consumers regarding the proposed site; and

(K) Documentation that sufficient financing would be available to assure completion of the project.

(11) Any applicant who requests an owner, operator or site change or cost overrun must still comply with sections (1) and (2) of this rule.

(12) At any time during the process from Letter of Intent to project completion, the applicant is responsible for notifying the committee of any change in the designated contact person. If a change is necessary, the applicant must file a Contact Person Correction (Form MO 580-1870), included herein.

AUTHORITY: section 197.320, RSMo 2016.\* Original rule filed June 2, 1994, effective Nov. 30, 1994. Emergency rescission and rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Rescinded and readopted: Filed Aug. 29, 1997, effective March 30, 1998. Amended: Filed Oct. 19, 1999, effective April 30, 2000. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Rescinded and readopted: Filed Dec. 14, 2001, effective June 30, 2002. Emergency rescission and rule filed Dec. 16, 2002, effective Jan. 1, 2003, expired June 29, 2003. Amended: Filed June 9, 2003, effective Nov. 30, 2003. Emergency amendment filed Aug. 14, 2006, effective Aug. 28, 2006, expired Feb. 23, 2007. Amended: Filed Aug. 14, 2006, effective March 30, 2007. Amended: Filed Oct. 1, 2010, effective May 30, 2011. Amended: Filed Aug. 9, 2019, effective March 30, 2020. Amended: Filed June 29, 2022, effective Jan. 30, 2023. \*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.

#### 19 CSR 60-50.800 Meeting Procedures

PURPOSE: This rule describes the meeting format and protocol in a Certificate of Need (CON) review meeting.

(1) The regular meetings of the Missouri Health Facilities Review Committee (committee) to consider Certificate of Need (CON) applications shall be held approximately every eight (8) weeks according to a schedule adopted by the committee before the beginning of each calendar year and modified periodically to reflect changes. A copy of this calendar may be obtained from the CON Program (CONP) staff or CON website.

(2) All new information not previously in the application, shall be received by the CONP staff at least thirty (30) calendar days before the scheduled meeting with one (1) exception. An applicant shall have no less than two (2) business days to respond to the findings of the staff and adverse information received from other parties. An applicant shall respond in writing to an inquiry from a committee member. The response shall be provided to the committee for consideration and a copy shall be sent to the CON office.

(3) Requests for the addition of agenda items including CON modification and extension requests shall be received by the CONP staff at least thirty-five (35) calendar days before the scheduled meeting.

(4) Any committee member may request that an item be added to the agenda up to forty-eight (48) hours before the scheduled meeting, exclusive of weekends and holidays when the principal office is closed.

(5) The tentative agenda for each committee meeting shall be released at least twenty (20) calendar days before each meeting.

(6) The committee may give the applicant and affected persons an opportunity to make brief presentations at the meeting according to the Missouri Health Facilities Review Committee Meeting Format and Missouri Health Facilities Review Committee Meeting Protocol. The applicant and affected persons shall conform to the following procedures:

(A) The applicant's presentation shall be a key points summary based on the written application and shall not exceed ten (10) minutes inclusive of all presenters with five (5) minutes additional time for summation;

(B) Others in support or opposition to the applicant's project (such as political representatives, citizens of the community and other providers) shall be categorized as unrelated parties and shall appear after the applicant's presentation;

(C) Regardless of the number of presenters involved in the presentation, individual presentations by unrelated parties in support of, neutral, or in opposition to the applicant's project shall not exceed three (3) minutes each;

(D) No new material shall be introduced with the exception of materials or information provided in response to the CONP staff or at the request of a committee member;

(E) Rebuttals by applicants of presentations by affected persons are generally allowed;

(F) All presenters shall complete and sign a Representative Registration (Form MO 580-1869), included herein, and give it to the sign-in coordinator prior to speaking;

(G) The reserved area in the hearing room may be used by an applicant only during the applicant's presentation and then vacated for the next group (individuals waiting to present shall remain clear of the podium and staff area until specifically called by the chairman); and

(H) Prescribed time limits shall be monitored by the timekeeper, and presenters shall observe the timekeeper's indications of lapsed time to ensure that each presenter has an opportunity to present within the allotted time.

(7) Additional meetings of the committee may be held periodically. These meetings may include educational workshops for members to gain knowledge, meetings with organizations for cooperative purposes, discussion of rules, seeking legal advice from counsel, and other issues.

AUTHORITY: section 197.320, RSMo 2016.\* Original rule filed June 2, 1994, effective Nov. 30, 1994. Emergency rescission and rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Rescinded and readopted: Filed Aug. 29, 1997, effective March 30, 1998. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Rescinded and readopted: Filed Dec. 14, 2001, effective June 30, 2002. Emergency amendment filed Aug. 14, 2006, effective Aug. 28, 2006, expired Feb. 23, 2007. Amended: Filed Aug. 14, 2006, effective March 30, 2007. Amended: Filed Oct. 1, 2010, effective May 30, 2011. Amended: Filed Aug. 9, 2019, effective March 30, 2020. Amended: Filed June 29, 2022, effective Jan. 30, 2023.

\*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.

## 19 CSR 60-50.900 Administration

PURPOSE: This rule describes the duties and responsibilities of the Certificate of Need (CON) Program staff.

- (1) The role of the Missouri Health Facilities Review Committee (committee) includes the following:
  - (A) Make specific decisions about applications, applicability and administrative matters;
    - (B) Make policy decisions to include the development of rules; and
    - (C) Oversee operations of the Certificate of Need Program (CONP) staff.

(2) The role of the CONP staff includes the following:

- (A) Act as an agent of the committee; and
  - (B) Perform administrative tasks.

(3) The CONP staff shall be staffed as follows:

(A) The committee shall employ a CONP coordinator and additional staff to perform the duties assigned to it by law;

(B) The committee shall designate the CONP coordinator, or his/her designee, to perform any administrative functions that may be required of the committee by law; and

(C) The CONP staff shall be housed at the principal office of the committee.

(4) The committee shall maintain its principal office in Jefferson City where the CONP staff will:

- (A) Accept letters of intent, applications and any other written communication related to the conduct of the CONP;
  - (B) Accept service of legal process;
  - (C) Maintain its records; and
  - (D) Post all notices required by law.

(5) The CONP staff shall provide technical assistance to potential applicants.

(6) The committee and CONP staff shall post information on the CONP website containing the status of reviews being conducted, the reviews completed since the last report, and the decisions made, plus an annual summary of activities for the past calendar year.

AUTHORITY: section 197.320, RSMo 2016.\* Original rule filed June 2, 1994, effective Nov. 30, 1994. Emergency rescission and rule filed Aug. 29, 1997, effective Sept. 8, 1997, expired March 6, 1998. Rescinded and readopted: Filed Aug. 29, 1997, effective March 30, 1998. Emergency rescission and rule filed Dec. 14, 2001, effective Jan. 1, 2002, expired June 29, 2002. Rescinded and readopted: Filed Dec. 14, 2001, effective June 30, 2002. Emergency amendment filed Aug. 14, 2006, effective Aug. 28, 2006, expired Feb. 23, 2007. Amended: Filed Aug. 14, 2006, effective March 30, 2007. Amended: Filed Aug. 9, 2019, effective March 30, 2020.

\*Original authority: 197.320, RSMo 1979, amended 1993, 1995, 1999.