# Rules of Department of Health and Senior Services Division 60—Missouri Health Facilities Review Committee Chapter 50—Certificate of Need Program

### Title

### Page

| 19 CSR | 60-50.010 | State Health Planning and Development Agency (SHPDA)<br>(Rescinded January 12, 1990) |
|--------|-----------|--|
| 19 CSR | 60-50.011 | Certificate of Need (CN) Definitions (Rescinded November 30, 1994)3                  |
| 19 CSR | 60-50.020 | Missouri Health Facilities Review Committee (Rescinded January 12, 1990)3            |
| 19 CSR | 60-50.021 | CN Program Administration (Rescinded November 30, 1994)3                             |
| 19 CSR | 60-50.030 | Review of Health Projects Under SSA-1122 Program<br>(Rescinded January 12, 1990)     |
| 19 CSR | 60-50.031 | Certificate of Need (CN) Applications (Rescinded November 30, 1994)3                 |
| 19 CSR | 60-50.040 | Definitions Relating to Certificate of Need (Rescinded January 12, 1990)3            |
| 19 CSR | 60-50.041 | Information Added to CN Application (Rescinded November 30, 1994)3                   |
| 19 CSR | 60-50.050 | Certificate of Need Necessary (Rescinded January 12, 1990)3                          |
| 19 CSR | 60-50.051 | Information on MHFRC Meetings (Rescinded November 30, 1994)3                         |
| 19 CSR | 60-50.060 | Waiver of Certificate of Need (Rescinded January 12, 1990)3                          |
| 19 CSR | 60-50.061 | Certificate of Need Decisions (Rescinded November 30, 1994)4                         |
| 19 CSR | 60-50.070 | Issuance and Penalties (Rescinded January 12, 1990)4                                 |
| 19 CSR | 60-50.071 | Post-Decision Review (Rescinded November 30, 1994)4                                  |
| 19 CSR | 60-50.080 | Certificate of Need Application Process (Rescinded January 12, 1990)4                |
| 19 CSR | 60-50.081 | Criteria and Standards (Rescinded November 30, 1994)4                                |
| 19 CSR | 60-50.090 | Nonsubstantive Review (Rescinded January 12, 1990)4                                  |



| 19 CSR 60-50.100 | Public Hearings, Reconsideration Hearings (Rescinded January 12, 1990)4                                       |
|------------------|---|
| 19 CSR 60-50.110 | Appeals (Rescinded January 12, 1990)  |
| 19 CSR 60-50.120 | Annual Report, Public Access (Rescinded January 12, 1990)4  |
| 19 CSR 60-50.130 | Forfeiture of Certificate (Rescinded January 12, 1990)4   |
| 19 CSR 60-50.140 | Adoption of Criteria (Rescinded January 12, 1990)4  |
| 19 CSR 60-50.150 | Criteria and Written Findings for Review of<br>Certificate of Need Applications (Rescinded January 12, 1990)5 |
| 19 CSR 60-50.200 | Purpose and Structure   |
| 19 CSR 60-50.300 | Definitions for the Certificate of Need Process   |
| 19 CSR 60-50.310 | Guidelines for Specific Health Services (Rescinded June 30, 2002)6  |
| 19 CSR 60-50.400 | Letter of Intent Process  |
| 19 CSR 60-50.410 | Letter of Intent Package7   |
| 19 CSR 60-50.420 | Review Process  |
| 19 CSR 60-50.430 | Application Package   |
| 19 CSR 60-50.440 | Criteria and Standards for Equipment and New Hospitals10  |
| 19 CSR 60-50.450 | Criteria and Standards for Long-Term Care11   |
| 19 CSR 60-50.460 | Criteria and Standards for Evolving Technology12  |
| 19 CSR 60-50.470 | Criteria and Standards for Financial Feasibility13  |
| 19 CSR 60-50.480 | Criteria and Standards for Alternatives (Rescinded June 30, 2002)13   |
| 19 CSR 60-50.500 | Additional Information13  |
| 19 CSR 60-50.600 | Certificate of Need Decisions   |
| 19 CSR 60-50.700 | Post-Decision Activity14  |
| 19 CSR 60-50.800 | Meeting Procedures15  |
| 19 CSR 60-50.900 | Administration  |



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

#### **19 CSR 60-50.010 State Health Planning and Development Agency (SHPDA)** (Rescinded January 12, 1990)

AUTHORITY: section 197.310, RSMo 1986. This rule previously filed as 13 CSR 60-1.010 and 19 CSR 30-50.010. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Emergency rescission filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

### 19 CSR 60-50.011 Certificate of Need (CN) Definitions

(Rescinded November 30, 1994)

AUTHORITY: sections 197.318, RSMo Supp. 1992 and 197.320, RSMo 1986. Emergency rule filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Original rule filed July 3, 1989, effective Jan. 12, 1990. Amended: Filed Feb. 4, 1993, effective July 8, 1993. Rescinded: Filed June 2, 1994, effective Nov. 30, 1994.

#### **19 CSR 60-50.020 Missouri Health Facilities Review Committee** (Rescinded January 12, 1990)

AUTHORITY: sections 197.310 and 197.320, RSMo 1986. This rule was previously filed as 13 CSR 60-1.020 and 19 CSR 30-50.020. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Emergency rescission filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

### 19 CSR 60-50.021 CN Program Administration

(Rescinded November 30, 1994)

AUTHORITY: section 197.320, RSMo 1986. Emergency rule filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Original rule filed July 3, 1989, effective Jan. 12, 1990. Amended: Filed Nov. 16, 1990, effective June 10, 1991. Amended: Filed April 6, 1992, effective Sept. 6, 1992. Emergency amendment filed July 30, 1992, effective Aug. 9, 1992, expired Dec. 6, 1992. Amended: Filed July 30, 1992, effective April 8, 1993. Amended: Filed April 14, 1993, effective Oct. 10, 1993. Rescinded: Filed June 2, 1994, effective Nov. 30, 1994.

#### **19 CSR 60-50.030 Review of Health Projects Under SSA-1122 Program** (Rescinded January 12, 1990)

AUTHORITY: sections 197.305(2), 197.310(1)6, 197.320 and 536.043, RSMo 1986, P.L. 9-603, 42 U.S.C. 1320a-1; 42 CFR 100; 42 CFR 122, 42 CFR 123 and section 1122 of the Federal Social Security Act. This rule was previously filed as 13 CSR 60-2.010 and 19 CSR 30-50.030. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Emergency rescission filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

### 19 CSR 60-50.031 Certificate of Need (CN) Applications

(Rescinded November 30, 1994)

AUTHORITY: section 197.320, RSMo 1986. Emergency rule filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Original rule filed July 3, 1989, effective Jan. 12, 1990. Amended: Filed Jan. 3, 1990, effective March 26, 1990. Amended: Filed Nov. 16, 1990, effective July 8, 1991. Emergency amendment filed July 30, 1992, effective Aug. 9, 1992, expired Dec. 6, 1992. Amended: Filed July 14, 1992, effective April 8, 1993. Amended: Filed July 30, 1992, effective April 8, 1993. Amended: Filed Feb. 4, 1993, effective July 8, 1993. Rescinded: Filed June 2, 1994, effective Nov. 30, 1994.

## **19 CSR 60-50.040** Definitions Relating to Certificate of Need

(Rescinded January 12, 1990)

AUTHORITY: sections 197.305 and 197.320, RSM0 1986. This rule was previously filed as 13 CSR 60-3.010 and 19 CSR 30-50.040. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Amended: Filed: Oct. 19, 1983, effective May 11, 1984. Emergency rescission filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

## **19 CSR 60-50.041 Information Added to CN Application**

(Rescinded November 30, 1994)

AUTHORITY: section 197.320, RSMo 1986. Emergency rule filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Original rule filed July 3, 1989, effective Jan. 12, 1990. Emergency amendment filed July 30, 1992, effective Aug. 9, 1992, expired Dec. 6, 1992. Amended: Filed July 30, 1992, effective April 8, 1993. Rescinded: Filed June 2, 1994, effective Nov. 30, 1994.

### 19 CSR 60-50.050 Certificate of Need Necessary

(Rescinded January 12, 1990)

AUTHORITY: sections 197.315.1, 197.315.7, 197.315.12, 197.315.14, 197.320 and 197.340, RSMo 1986. This rule was previously filed as 13 CSR 60-3.020 and 19 CSR 30-50.050. Emergency rule Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Emergency amendment filed Feb. 9, 1983, effective March 1, 1983, expired June 28, 1983. Emergency rescission filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

### 19 CSR 60-50.051 Information on MHFRC Meetings

(Rescinded November 30, 1994)

AUTHORITY: section 197.320, RSMo 1986. Emergency rule filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Original rule filed July 3, 1989, effective Jan. 12, 1990. Amended: Filed Nov. 16, 1990, effective June 10, 1991. Emergency amendment filed July 30, 1992, effective Aug. 9, 1992, expired Dec. 6, 1992. Amended: Filed July 30, 1992, effective April 8, 1993. Rescinded: Filed June 2, 1994, effective Nov. 30, 1994.

### 19 CSR 60-50.060 Waiver of Certificate of Need

(Rescinded January 12, 1990)

AUTHORITY sections 197.320 and 197.330(9), RSMo 1986. This rule was previously filed as 13 CSR 60-3.030 and 19 CSR 30-50.060. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Emergency rescission filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

### 19 CSR 60-50.061 Certificate of Need Decisions

(Rescinded November 30, 1994)

AUTHORITY: section 197.320, RSMo 1986. Emergency rule filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Original rule filed July 3, 1989, effective Jan. 12, 1990. Amended: Filed Nov. 16, 1990, effective June 10, 1991. Emergency amendment filed July 30, 1992, effective Aug. 9, 1992, expired Dec. 6, 1992. Amended: Filed July 14, 1992, effective April 8, 1993. Amended: Filed July 30, 1992, effective April 8, 1993. Rescinded: Filed June 2, 1994, effective Nov. 30, 1994.

### **19 CSR 60-50.070 Issuance and Penalties** (Rescinded January 12, 1990)

AUTHORITY: sections 197.315.2, 197.315.3, 197.315.4, 197.315.5, 197.315.6 and 197.320, RSMo 1986. This rule was previously filed as 13 CSR 60-3.040 and 19 CSR 30-50.070. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Emergency rescission filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

#### **19 CSR 60-50.071 Post-Decision Review** (Rescinded November 30, 1994)

AUTHORITY: section 197.320, RSMo 1986. Emergency rule filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Original rule filed July 3, 1989, effective Jan. 12, 1990. Amended: Filed Nov. 16, 1990, effective June 10, 1991. Amended: Filed Feb. 4, 1993, effective July 8, 1993. Rescinded: Filed June 2, 1994, effective Nov. 30, 1994.

#### **19 CSR 60-50.080 Certificate of Need** Application Process

(Rescinded January 12, 1990)

AUTHORITY: sections 197.315.8, 197.315.10, 197.320, 197.325, 197.330(1),

197.330(3), 197.330.4, 197.330.5 and 197.330.6, RSMo 1986. This rule was previously filed as 13 CSR 60-3.050 and 19 CSR 30-50.080. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Emergency rescission filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

### **19 CSR 60-50.081 Criteria and Standards** (Rescinded November 30, 1994)

AUTHORITY: section 197.320, RSMo 1986. Emergency rule filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Original rule filed July 3, 1989, effective Jan. 12, 1990. Amended: Filed March 16, 1990, effective June 28, 1990. Amended: Filed July 17, 1990, effective Dec. 31, 1990. Amended: Filed Nov. 16, 1990, effective June 10, 1991. Amended: Filed April 6, 1992, effective Sept. 6, 1992. Emergency amendment filed July 30, 1992, effective Aug. 9, 1992, expired Dec. 6, 1992. Amended: Filed July 14, 1992, effective April 8, 1993. Amended: Filed July 30, 1992, effective April 8, 1993. Amended: Filed April 14, 1993, effective Oct. 10, 1993. Rescinded: Filed June 2, 1984, effective Nov. 30, 1994.

### **19 CSR 60-50.090 Nonsubstantive Review** (Rescinded January 12, 1990)

AUTHORITY: sections 197.320 and 197.330(3), RSMo 1986. This rule was previously filed as 13 CSR 60-3.060 and 19 CSR 30-50.090. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Emergency rescission filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

## 19 CSR 60-50.100 Public Hearings, Reconsideration Hearings

(Rescinded January 12, 1990)

AUTHORITY: sections 197.320 and 197.330(3), RSMo 1986. This rule was previously filed as 13 CSR 60-3.070 and 19 CSR 30-50.100. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Emergency rescission filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

#### **19 CSR 60-50.110 Appeals** (Rescinded January 12, 1990)

AUTHORITY sections 197.320 and 197.335, RSMo 1986. This rule was previously filed as 13 CSR 60-3.080 and 19 CSR 30-50.110. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Emergency rescission filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

## 19 CSR 60-50.120 Annual Report, Public Access

(Rescinded January 12, 1990)

AUTHORITY: section 197.320, RSMo 1986. This rule was previously filed as 13 CSR 60-3.090 and 19 CSR 30-50.120. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Emergency rescission filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

### **19 CSR 60-50.130 Forfeiture of Certificate** (Rescinded January 12, 1990)

AUTHORITY: sections 197.315.9 and 197.320, RSMo 1986. This rule was previously filed as 13 CSR 60-3.100 and 19 CSR 30-50.130. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Emergency rescission filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

### **19 CSR 60-50.140 Adoption of Criteria** (Rescinded January 12, 1990)

AUTHORITY: sections 197.300–197.365 and 536.043, RSMo 1986. This rule was previously filed as 13 CSR 60-3.100 and 19 CSR 30-50.140. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Emergency rescission filed July 3, 1989, effective July 13, 1989,



expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

#### **19 CSR 60-50.150 Criteria and Written** Findings for Review of Certificate of Need Applications

(Rescinded January 12, 1990)

AUTHORITY: sections 197.315 and 197.320, RSMo 1986. This rule was previously filed as 13 CSR 60-4.010 and 19 CSR 30-50.150. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. Amended: Filed May 3, 1988, effective Aug. 11, 1988. Emergency rescission filed July 3, 1989, effective July 13, 1989, expired Nov. 9, 1989. Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.

#### 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) Negotiate competing interests;

(E) Prevent unnecessary duplication; and(F) Disseminate health-related information

to interested and 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 administra-

tive 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.

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

#### **19 CSR 60-50.300 Definitions for the Cer**tificate of Need Process

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

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

(2) 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.

(3) 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.

(4) 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 not licensed as a hospital.

(5) 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 expansion or replacement as defined in section 197.318.8–10, long-term care renovation and modernization, or the replacement of any major medical equipment as defined in sec-

tion (11) of this rule which holds a Certificate of Need (CON) previously granted by the Missouri Health Facilities Review Committee (committee). Applications for replacement of major medical equipment not previously approved by the committee should apply for a full review.

(6) 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.

(7) 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.

(8) Health care facility means those described in section 197.366, RSMo, which replaces section 197.305.7, RSMo.

(9) 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(13), RSMo, in excess of one hundred fifty thousand dollars (\$150,000), any existing land and building converted to 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.

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

(11) Interested party means any licensed health care provider or other affected person who has expressed an interest in the Certificate of Need (CON) process or a CON application.

(12) 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 million dollars (\$1,000,000) or more, when the equipment is intended to provide the following services:

- (A) Cardiac Catheterization;
- (B) CT (Computed Tomography);

(C) Gamma Knife;

(D) Hemodialysis;

(E) Lithotripsy;

(F) MRI (Magnetic Resonance Imaging);

(G) PET (Positron Emission Tomography);

(H) Linear Accelerator;

(I) Open Heart Surgery;

(J) EBCT (Electron Beam Computed Tomography);

(K) PET/CT (Positron Emission Tomography/Computed Tomography); or

(L) Evolving Technology.

(13) 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;

nonpatient care services, including parking facilities, sprinkler systems, heating or airconditioning 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.

(14) 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.

(15) Predevelopment costs mean expenditures as defined in section 197.305(13), 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.

(16) Related organization means an organization that is associated or affiliated with, has control over or is controlled by, or has any direct financial interest in, the organization applying for a project including, without limitation, an underwriter, guarantor, parent organization, joint venturer, partner or general partner.

(17) Service area means a geographic region 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.

(18) The most current version of Form MO 580-1863 may be obtained by mailing a written request to the Certificate of Need Program (CONP), 915G Leslie Boulevard, Jefferson City, MO 65101, or in person at the CONP Office, or, if technically feasible, by downloading a copy of the form from the CONP website at www.dhss.mo.gov/con.

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 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.

\*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 Öct. 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 a Letter of Intent (LOI) package to begin the Certificate of Need (CON) review process 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) For full reviews, expedited equipment replacements, expedited long-term care (LTC) renovation or modernization reviews and expedited LTC facility replacement reviews, a LOI is valid for six (6) months;

(B) For expedited LTC bed expansion reviews in accordance with section 197.318.8, RSMo, a LOI is valid for twentyfour (24) months; and

(C) For non-applicability reviews, 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 expansion or replacement as sought pursuant to section 197.318.8 through 197.318.10, RSMo, requires a CON application, if the capital expenditure for such bed expansion or replacement exceeds six hundred thousand dollars (\$600,000), but allows for shortened information requirements and review time frames. When a LOI for a LTC bed expansion, except replacement(s), is filed, the Certificate of Need Program (CONP) staff shall immediately request certification for that facility of average licensed bed occupancy and final Class 1 patient care deficiencies for the most recent six (6) consecutive calendar quarters by the Division of Senior Services and Regulation (DSSR), Department of Health and Senior Services, through a LTC Facility Expansion Certification (Form MO 580-2351) to verify compliance with occupancy and deficiency requirements pursuant to section 197.318.8, RSMo. Occupancy data shall be taken from the DSSR's most recently published Six-Quarter Occupancy of Intermediate Care and Skilled Nursing Facility (or Residential Care Facility) Licensed Beds reports. For LTC bed expansions or replacements, 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 should sign.

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

(B) The construction or modification of



(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 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 met, 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 audited project costs must be provided on a Periodic Progress Report (Form MO 580-1871).

(F) A CON application must be made if:

1. The project involves the development of a new hospital costing one million dollars (\$1,000,000) 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 million dollars (\$1,000,000) 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, modernization or replacement, 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; 6. The project involves either additional LTC (licensed or certified residential care facility I or II, intermediate care facility, or skilled nursing facility) beds or LTC bed expansions or replacements licensed under Chapter 198, RSMo, as defined in section (3) of this rule, costing six hundred thousand dollars (\$600,000) or more; or

7. The project involves the expansion of an existing health care facility as described in subdivisions (1) and (2) of section 197.366, 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) For a LTC bed expansion proposal pursuant to section 197.318.8(1)(e), RSMo, the CONP staff shall request occupancy verification by the DSSR who shall also provide a copy to the applicant.

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

(7) The most current version of Forms MO 580-2351, MO 580-2352, and MO 580-1871 may be obtained by mailing a written request to the CONP, 915G Leslie Boulevard, Jefferson City, MO 65101, or in person at the CONP Office, or, if technically feasible, by downloading a copy of the forms from the CONP website at www.dhss.state.mo.us/con.

AUTHORITY: section 197.320, RSMo 2000.\* 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 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, 2001. 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. Amended: Filed April 12, 2004, effective Nov. 30, 2004.

\*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) shall be completed as follows:

(A) Project Information: sufficient information to identify the intended service, such as construction, renovation, new or replacement equipment, and address or plat map 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(s) 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 or a non-applicability review;

(D) Project Description: information which provides details of the number of beds to be added, deleted, 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;

(E) Estimated Project Cost: total proposed expenditures necessary to achieve the application's objectives—not required for longterm care (LTC) bed expansions pursuant to section 197.318.8(1), RSMo;

(F) Authorized Contact Person Identification: the full name, title, address (including association), telephone number, e-mail, and fax number; and

(G) Applicability: Page 2 of the LOI must be filled out by applicants requesting a nonapplicability review to provide the reason and rationale for the exemption or exception being sought. (2) If a non-applicability review is sought, applicants shall submit the following additional information:

(A) Proposed Expenditures (Form MO 580-2375) including information which details all methods and assumptions used to estimate project costs;

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

(C) 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 (6) below of this rule.

(3) If an exemption is sought for an RCF I or II pursuant to section 197.312, RSMo, applicants shall submit documentation that this facility had previously been owned or operated for or, on behalf of St. Louis City.

(4) If an exemption is sought pursuant to section 197.314(1), RSMo, for a sixty (60)-bed stand-alone facility designed and operated exclusively for the care of residents with Alzheimer's disease or dementia and located in a tax increment financing district established prior to 1990 within any county of the first classification with a charter form of government containing a city with a population of over three hundred fifty thousand (350,000) and which district also has within its boundaries a skilled nursing facility (SNF), applicants shall submit documentation that the health care facility would meet all of these provisions.

(5) The LOI must have an original signature for the contact person until the Certificate of Need Program (CONP), when technically ready, shall allow for submission of electronic signatures.

(6) The most current version of Forms MO 580-1860 and MO 580-2375 may be obtained by mailing a written request to the CONP, 915G Leslie Boulevard, Jefferson City, MO 65101, or in person at the CONP office, or, if technically feasible, by downloading a copy of the forms from the CONP website at www.dhss.state.mo.us/con.

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 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. 16, 2002, effective Jan. 1, 2003, expired June 29, 2003. Amended: Filed June 9, 2003, effective Nov. 30, 2003.

\*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 seventyone (71) days prior to each Missouri Health Facilities Review Committee (committee) meeting;

(B) For expedited equipment replacement applications, expedited long-term care (LTC) facility renovation or modernization applications, and expedited LTC bed expansions and replacements pursuant to section 197.318.8 through 197.318.10, RSMo, the tenth day of each month, or the next business day thereafter if that day is a holiday or weekend;

(C) For non-applicability 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 any change in owner(s), operator(s), scope of services, or location, 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 occur 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 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 on the next business day after the filing deadline. The publication of the schedule is conducted through the following actions:

1. The schedule shall be submitted to the secretary of state's office for publication in the next regularly scheduled *Missouri Register*;

2. A press release about the CON application schedule shall be sent to all newspapers of general circulation in Missouri as supplied by the Department of Health and Senior Services (DHSS), Office of Public Information;

3. The schedule shall be posted on the CON website; and

4. The schedule shall be mailed to all affected persons who have registered with the CONP staff as having an interest in such CON applications.

(B) For expedited applications the schedule shall include the filing date of the application, a brief description of the proposed service, including the name and location of all participating facilities, the time and place for filing comments and requests for a public hearing, and the tentative decision date for the application. Publication of the schedule shall occur on the next business day after the filing deadline. The publication of the schedule is conducted through the following actions:

1. The schedule shall be submitted to the secretary of state's office for publication in the next regularly scheduled *Missouri Register*; and

2. The schedule shall be posted on the CON website.

(C) 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) When an application for a full review is filed pursuant to section 197.318.1, RSMo, the CONP staff shall immediately request certification of licensed and available bed occupancy and deficiencies for each of the most recent four (4) consecutive calendar quarters in the county and fifteen (15)-mile radius by the DHSS.

(5) The CONP staff shall review CON applications relative to the Criteria and Standards in the order filed.

(6) The CONP staff shall notify the applicant in writing regarding the completeness of a full CON application within fifteen (15) calendar days of filing or within five (5) working days for an expedited application.



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

(8) Subject to statutory time constraints, the CONP staff shall send its written analysis to the committee as follows:

(A) For full CON applications, the CONP staff shall send the analysis 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.

(C) For expedited applications which do not meet all statutory and rules requirements or those which have opposition, they 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.

(9) See rule 19 CSR 60-50.600 for a description of the CON decision process.

(10) An applicant may withdraw an application without prejudice by written notice 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.

(11) 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 number of patients requiring treatment, the changing complexity of treatment, unique obstacles to access, competitive financial considerations, or the specialized nature of the service.

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 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.

\*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 original and eleven (11) bound copies (comb or three (3)-ring binder) shall be prepared and organized as follows:

(A) The CON Applicant's Completeness Checklists and Table of Contents should 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; and

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

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

1. New Hospital Application (Form MO 580-2501);

2. New or Additional Long-Term Care (LTC) Beds Application (Form MO 580-2502);

3. New or Additional Long-Term Care Hospital (LTCH) Beds Application (use Form MO 580-2502);

4. New or Additional Equipment Application (Form MO 580-2503);

5. Expedited LTC Bed Replacement/Expansion Application (Form MO 580-2504); 6. Expedited LTC Renovation/Modernization Application (Form MO 580-2505); or

7. Expedited Equipment Replacement Application (Form MO 580-2506).

(C) The application should be formatted into dividers using the following outline:

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 if required for full applications).

(D) Support Information should be included at the end of each divider section to which it pertains, and should be referenced in the divider 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 should document the need or meet the additional information requirements in 19 CSR 60-50.450(4)–(6) 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). Additional specific information about board membership may be requested, if needed;

(B) A completed Representative Registration (Form MO 580-1869) for the contact person and any others as required by section 197.326(1), RSMo; and

(C) A detailed Proposed Project Budget (Form MO 580-1863), with an attachment which details how each line item was determined including all methods and assumptions used.

(4) The Proposal Description shall include documents which:

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

(B) Describe the developmental details including:

1. A legible city or county 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;

2. Preliminary schematics for the project that specify the functional assignment of all space which will fit on an eight and onehalf inch by eleven inch ( $8 \ 1/2" \times 11"$ ) format (not required for replacement equipment projects). The Certificate of Need Program (CONP) staff may request submission of an electronic version of the schematics, when appropriate. The function for each space, before and after construction or renovation, shall be clearly identified and all space shall be assigned;

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

4. 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;

5. Documentation of ownership of the project site, or that the site is available through a signed option to purchase or lease; and

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

(C) Proposals for new hospitals, new or additional long-term care (LTC) beds, or new major medical equipment must define the community to be served:

1. Describe the service area(s) population using year 2005 populations and projections which are consistent with those provided by the Bureau of Health Data Analysis which can be obtained by contacting:

Chief, Bureau of Health Data Analysis Center for Health Information Management and Evaluation (CHIME)

Department of Health and Senior Services PO Box 570, Jefferson City, MO 65102 Telephone: (573) 751-6278

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 the CHIME. Information requests should be made to CHIME 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 CHIME with the CON Appli-

cant's Population Determination Method to determine the estimated population, 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 Bureau of Health Data Analysis information) 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 ten percent (10%), 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 (4)(C)2.D. (due to numerous complexities, population centers will not be utilized to adjust overlapped zip code populations in Jackson, 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 (4)(C)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";

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

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

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

(H) 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) The most current version of Forms MO 580-2501, MO 580-2502, MO 580-2503, MO 580-2504, MO 580-2505, MO 580-1861, MO 580-1869 and MO 580-1863 may be obtained by mailing a written request to the Certificate of Need Program (CONP), 915G Leslie Boulevard, Jefferson City, MO 65101, or in person at the CONP Office, or, if technically feasible, by downloading a copy of the forms from the CONP website at www.dhss.state.mo.us/con.

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 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. 16, 2002, effective Jan. 1, 2003, expired June 29, 2003. Amended: Filed June 9, 2003, effective Nov. 30, 2003.

\*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 methodologies:

(A) The population-based need formula should be (Unmet need =  $(R \times P) - U$ ) where:



P=Year 2005 population in the service area(s);

U=Number of service units in the service area(s); and

R=Community need rate of one (1) unit per population listed as follows:

| 1. Magnetic resonance imaging     |           |  |  |
|-----------------------------------|-----------|--|--|
| unit                              | 100,000   |  |  |
| 2. Positron emission tomo-        |           |  |  |
| graphy unit                       | 500,000   |  |  |
| 3. Lithotripsy unit               | 1,000,000 |  |  |
| 4. Linear accelerator unit        | 100,000   |  |  |
| 5. Adult cardiac catheteriza-     |           |  |  |
| tion lab                          | 50,000    |  |  |
| 6. Pediatric cardiac catheteriza- |           |  |  |
| tion lab                          | 50,000    |  |  |
| 7. Adult open heart surgery       |           |  |  |
| rooms                             | 100,000   |  |  |
| 8. Pediatric open heart surge     | ery       |  |  |
| rooms                             | 100,000   |  |  |
| 9. All general surgery            | 10,000    |  |  |

| 9. All general surgery | 10,000    |
|------------------------|-----------|
| 10. Gamma knife        | 7,500,000 |

11. Excimer laser 500,000

(B) The minimum annual utilization for all other providers in the service area should achieve at least the following community need rates as follows:

- 1. Magnetic resonance imaging procedures 2,000
- 2. Positron emission tomography procedures 1,000
- 3. Lithotripsy treatments 1,000
- 4. Linear accelerator treatments 3,500 5. Adult cardiac catheterization
- procedures (include coronary 500 angioplasties)
- 6. Pediatric cardiac catheterization procedures 250

200

100

750

200

- 7. Adult open heart surgery operations
- 8. Pediatric open heart surgery operations
- 9. All general surgery
- 10. Gamma knife treatments
- 11. Hemodialysis treatments 200
- 12. Excimer laser procedures 1,800

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

(D) Alternate methodologies may be provided.

(2) For additional units or services, the applicant's optimal annual utilization should achieve at least the following community need rates as follows:

(A) Magnetic resonance

| imaging procedures                  | 3,000 |  |  |
|-------------------------------------|-------|--|--|
| (B) Positron emission tomo-         |       |  |  |
| graphy procedures                   | 1,000 |  |  |
| (C) Lithotripsy treatments          | 1,000 |  |  |
| (D) Linear accelerator treatments   | 6,000 |  |  |
| (E) Adult cardiac catheterization   |       |  |  |
| procedures                          | 750   |  |  |
| (F) Pediatric cardiac catheteriz-   |       |  |  |
| ation procedures                    | 375   |  |  |
| (G) Adult open heart surgery opera- |       |  |  |
| tions                               | 300   |  |  |
| (H) Pediatric open heart surgery    |       |  |  |
| operations                          | 150   |  |  |
| (I) All other general surgery       | 1,125 |  |  |
| (J) Gamma knife treatments          | 200   |  |  |
| (K) Hemodialysis treatments         | 200   |  |  |

200 (K) Hemodialysis treatments (L) Excimer laser procedures 3,600

(3) For replacement equipment, utilization standards are not used, but rather the following questions should 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 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 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) What impact will the new unit have on utilization and operational efficiencies?

(J) How will the new unit add additional capabilities?

(K) By what percentage will this replacement increase patient charges?

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

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

(B) Provide evidence that the current occupancy of other hospitals 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 2005 population in the service area; U=Number of beds in the service area; and

3,000 R=Community need rate of one (1) bed per population as follows: 1. Medical/surgical bed 570 ,000

| 1. Medical Surgical Dea         | 510    |
|---------------------------------|--------|
| 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 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 60-50.450 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) All additional long-term care (LTC) beds in nursing homes, hospitals, and residential care facilities (RCF), and beds in long-term acute hospitals are subject to the LTC bed minimum occupancy requirements (MOR) pursuant to sections 197.317 and 197.318(1), RSMo, with certain exemptions and exceptions pursuant to sections 197.305(7) and 197.312, RSMo, and LTC bed expansions and replacements pursuant to sections 197.318.8 through 197.318.10, RSMo.

(2) The MOR for additional LTC beds pursuant to section 197.318.1, RSMo, shall be met if the average occupancy for all licensed and available LTC beds located within the county and within fifteen (15) miles of the proposed site exceeded ninety percent (90%) during at least each of the most recent four (4) consecutive calendar quarters at the time of application filing as reported in the Division of Health Standards and Licensure (DHSL), Department of Health and Senior Services, Quarterly Survey of Hospital and Nursing Home (or Residential Care Facility) Bed Utilization and certified through a written finding by the DHSL, in which case the following population-based long-term care bed need methodology for the fifteen (15)mile radius shall be used to determine the maximum size of the need:



(A) Approval of additional intermediate care facility/skilled nursing facility (ICF/-SNF) beds will be based on a service area need determined to be fifty-three (53) beds per one thousand (1,000) population age sixty-five (65) and older minus the current supply of ICF/SNF beds shown in the Inventory of Hospital and Nursing Home ICF/SNF Beds as provided by the Certificate of Need Program (CONP) which includes licensed and Certificate of Need (CON)-approved beds; and

(B) Approval of additional RCF beds will be based on a service area need determined to be sixteen (16) beds per one thousand (1,000) population age sixty-five (65) and older minus the current supply of RCF beds shown in the Inventory of Residential Care Facility Beds as provided by the CONP which includes licensed and CON-approved beds.

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

(A) Relocate RCF beds within a six (6)mile radius pursuant to section 197.318.8(4), RSMo;

(B) Replace one-half (1/2) of its licensed beds within a thirty (30)-mile radius pursuant to section 197.318.9, RSMo; or

(C) Replace a facility in its entirety within a fifteen (15)-mile radius pursuant to section 197.318.10, 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; 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.

(4) LTC bed expansions involving a Chapter 198 facility qualify for an exception to the LTC bed MOR. In addition to the shortened information requirements and review time frames, applicants shall also submit the following information:

(A) If an effort to purchase has been successful pursuant to section 197.318.8(1), RSMo, a Purchase Agreement (Form MO 580-2352) between the selling and purchasing facilities, and a copy of the selling facility's reissued license verifying the surrender of the beds sold; or

(B) If an effort to purchase has been unsuccessful pursuant to section 197.318.8(1), RSMo, a Purchase Agreement (Form MO 580-2352) between the selling and purchasing facilities which documents the "effort(s) to purchase" LTC beds.

(5) An exception to the LTC bed MOR and 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).

(6) An exception to the LTC bed MOR will be recognized for a proposed LTC facility where at least ninety-five percent (95%) of the patients require kosher diets pursuant to section 197.318.5, RSMo.

(7) Any newly-licensed Chapter 198 facility established as a result of the Alzheimer's and dementia demonstration projects pursuant to Chapter 198, RSMo, or aging-in-place pilot projects pursuant to Chapter 198, RSMo, as implemented by the DHSL, may be licensed by the DHSL until the completion of each project. If a demonstration or pilot project receives a successful evaluation from the DHSL and a qualified Missouri school or university, and meets the DHSL standards for licensure, this will ensure continued licensure without a new CON.

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

(A) The proposed project is needed to comply with current facility code requirements of local, state or federal governments;

(B) The proposed project is needed to meet requirements for licensure, certification or accreditation, which if not undertaken, could result in a loss of accreditation or certification;

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

(D) The methodologies used for determining need;

(E) The rationale for the reallocation of space and functions; and

 $(\ensuremath{\mathbf{F}})$  The benefits to the facility because of its age or condition.

(9) The most current version of Form MO 580-2352 may be obtained by mailing a written request to the CONP, 915G Leslie Boulevard, Jefferson City, MO 65101, or in person at the CONP Office, or, if technically feasible, by downloading a copy of the form from

the CONP website at www.dhss.state.mo.us/ con.

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 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.

\*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, nursing home, or residential care facility construction must include documentation that the proposed costs per square foot are reasonable when compared to the latest "RS Means Construction Cost Data" available from 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) 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, or an auditor's statement that unrestricted funds are available for the project.

(3) Document financial feasibility by including:

(A) The Service-Specific Revenues and Expenses (Form MO 580-1865) for each revenue generating service affected by the project for the past three (3) years projected through three (3) years beyond project completion;

(B) The Detailed Institutional Cash Flows (Form MO 580-1866) for the past three (3) years projected through three (3) years beyond project completion; and

(C) 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) The most current version of Forms MO 580-1865 and MO 580-1866 may be obtained by mailing a written request to the Certificate of Need Program (CONP), 915G Leslie Boulevard, Jefferson City, MO 65101, or in person at the CONP Office, or, if technically feasible, by downloading a copy of the forms from the CONP website at www.dhss.state.mo.us/con.

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. 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.

\*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 fifteen (15) calendar days after filing (five (5) working days in the case of an expedited application). The applicant's written response shall be received within fifteen (15) calendar days after receipt of notification.

(3) Information submitted by interested parties should be received at the committee's principal office at least thirty (30) calendar days before the scheduled meeting of the committee.

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

(5) When a request in writing 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 an applicant presentation at the public hearing;

 $(\overline{D})$  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 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.

\*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 meetings shall follow *Robert's Rules of Order*, newly revised 1990 edition, 9th edition.

(B) The Certificate of Need 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.

(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, e-mail, or fax, but must be received within ten (10) days from the date they were mailed to committee members.

(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) signifying 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.

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.

\*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 with the Missouri Health Facilities Review Committee (Committee), using Periodic Progress Report (Form MO 580-1871). A report shall be filed by the end of each six (6)-month period after CON approval, or issuance of a Non-Applicability CON letter, until project construction and/or expenditures are complete. All Periodic Progress Reports must contain a complete and accurate accounting of all expenditures for the report period.

(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 letter 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 who request additional extensions must provide additional financial information or other information, if requested by the CONP staff.

(3) For those long-term care proposals receiving a CON in 2003 for which no construction can begin prior to January 1, 2004, such proposals shall not be subject to forfeiture until July 1, 2004, at which time reporting requirements shall commence. Applicants may request an extension of six (6) months for such proposals.

(4) A Non-Applicability 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.

(5) 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 initiation of project aboveground construction or lease/purchase of the proposed equipment since a capital expenditure, according to generally accepted accounting principles, must be applied to a capital asset; or (B) File the required Periodic Progress Report.

(6) 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.

(7) If the Committee forfeits a CON or a Non-Applicability CON letter becomes null and void, CONP staff shall notify all affected state agencies of this action.

(8) 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%), an 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 original and eleven (11) copies of 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).

(9) 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).

(10) The most current version of Forms MO 580-1871, MO 580-1863, and MO 580-1870 may be obtained by mailing a written request to the CONP, 915G Leslie Boulevard, Jeffer-



son City, MO 65101, or in person at the CONP Office, or, if technically feasible, by downloading a copy of the forms from the CONP website at www.dhss.state.mo.us/-con.

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. 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.

\*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.

(2) The original and eleven (11) copies of all new information not previously in the application or requests for the addition of agenda items 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 fifteen (15) days to respond to the findings of the staff and adverse information received from other parties. An applicant should respond in writing to an inquiry from a committee member at any time, and the response shall be provided to the committee for consideration.

(3) Any committee member may request that an item be added to the agenda up to fortyeight (48) hours before the scheduled meeting, exclusive of weekends and holidays when the principal office is closed. (4) The tentative agenda for each committee meeting shall be released at least twenty (20) calendar days before each meeting.

(5) The committee may give the applicant and interested parties 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 interested parties 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 interested parties are generally allowed;

(F) All presenters shall complete and sign a Representative Registration (Form MO 580-1869) 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.

(6) 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. (7) The most current version of Form MO 580-1869 may be obtained by mailing a written request to the CONP, 915G Leslie Boulevard, Jefferson City, MO 65101, or in person at the CONP Office, or, if technically feasible, by downloading a copy of the form from the CONP website at www.dhss.state.mo.us/con.

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.

\*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 director and additional staff to perform the duties assigned to it by law;

(B) The committee shall designate the CONP director, 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 publish quarterly reports 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 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.

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