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

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**Title 19—DEPARTMENT OF
HEALTH**

**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(Rescinded January 12, 1990)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. 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 Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.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(Rescinded November 30, 1994)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 Rescinded: Filed June 2, 1994, effective Nov. 30, 1994.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(Rescinded January 12, 1990)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. 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 Rescinded: Filed July 3, 1989, effective Jan. 12, 1990.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(Rescinded November 30, 1994)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 Rescinded: Filed June 2, 1994, effective Nov. 30, 1994.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(Rescinded January 12, 1990)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. 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, RSMo 1986. This rule was previously filed as 13 CSR 60-3.010. Emergency rule filed Nov. 20, 1980, effective Dec. 1, 1980, expired April 1, 1981. Original rule filed Sept. 11, 1980, effective April 2, 1981. 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. 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. 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. 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. 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. 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. 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. 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. 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. 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. 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. 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 organization of the Missouri Health Facilities Review Committee relative to the Missouri Certificate of Need (CON) statute.

(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 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 cost containment through health cost management, assurance of community need and the prevention of unnecessary duplication of health care services. CON is based on a goal of public accountability through public review of proposed health care services, value promotion and negotiation among competing interests.

(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 Certificate of Need Program provides technical and administrative services as shown in 19 CSR 60-50.900.

AUTHORITY: section 197.320, RSMo Supp. 1997.* 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.

*Original authority 1979, amended 1993, 1995.

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

PURPOSE: This rule revises the definitions of 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) 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 above-ground construction approved by the committee.

(5) Health care facility means any premises as defined in section 197.305(8), RSMo.

(6) Health maintenance organizations mean entities as defined in section 354.400(6), RSMo, except for activities directly related to the provision of insurance only.

(7) 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.

(8) Major medical equipment means any device or collection of devices and startup cost acquired over a twelve (12)-month period, including equipment, shipping, installation, supplies, and taxes, with an aggregate cost in excess of the expenditure minimum, when the project is intended to provide imag-

ing, diagnostic, treatment, preventive or other health services.

(9) 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;

(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 of a similar nature;

(C) The acquisition of minor x-ray units, computed tomography units, mammography units, and fluoroscopy units, adult day care centers, hospices, and home health care services;

(D) 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; or

(E) Expenditures required to resolve the “Year 2000 Compliance Problem” for computers as part of or related to medical equipment. Documentation from a competent third party is required to verify that the project is required solely to solve the “Year 2000 Compliance Problem” along with an itemized equipment list of computers and/or medical equipment affected.

(10) 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.

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

(12) 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.



(13) Service area means—

(A) A review area which is the geographic region within the fifteen (15)-mile radius of the proposed site; and

(B) A geographic region in excess of the fifteen (15)-mile review area appropriate to the proposed service, documented by the applicant and approved by the committee.

AUTHORITY: section 197.320, RSMo Supp. 1997. 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.*

**Original authority 1979, amended 1993, 1995.*



Certificate of Need Program
LETTER OF INTENT

Project and Applicant Information <small>(this form must be included in the application, see note at end of next page)</small>			
1. Project Title and Location <small>(attach additional pages as necessary to identify multiple project sites.)</small>			
Title of Proposed Project			County
Project Address <small>(Street/City/State/Zip Code or plat map, if no address)</small>			Legislative District Number:
		Senate	House
2. Applicant Identification <small>(attach additional pages as necessary to list all owners and operators)</small>			
List All Owner(s): <small>(list corporate entity)</small>		Address <small>(Street/City/State/Zip Code)</small>	Telephone Number
List All Operator(s): <small>(list entity to be licensed or certified)</small>		Address <small>(Street/City/State/Zip Code)</small>	Telephone Number
Applicant's Authorized Designee <small>(Print or Type)</small>		Designee's Title	
Signature of Designee <small>(Preferably in blue ink)</small>	Date of Signature	Telephone Number	Fax Number
3. Applicability <small>(In accordance with §197.315 RSMo, any new institutional health service requires a CON before being offered or developed)</small>			
<small>(indicate the reason[s] for review or the exception/exemption sought)</small>			
<input type="checkbox"/> If proposed expenditures are less than the minimums in §197.305(12), then attach a Proposed Expenditures form and all necessary supporting documentation to illustrate how those amounts were determined, such as schematic drawings and equipment quotes.			
<input type="checkbox"/> If the proposal meets one of the exemptions in §197.305(8), §197.312, §197.318 or §197.360, then attach detailed documentation substantiating compliance with the statutory provisions.			
<input type="checkbox"/> [If the proposal meets one of the exceptions in §197.305(7)(b) and §197.318.3 which reference §197.305.12 (e) and (g), or §197.313, then attach a Proposed Expenditures form, schematic drawings, a copy of the facility license in effect on July 12, 1996, and a description of how the additional beds meet the the lesser of 10 beds or 10% of licensed bed capacity.] If proposed expenditures are required solely to solve the "Year 2000 Compliance Problem" for computers as part of or related to medical equipment in §197.300(9)(E).			
<input type="checkbox"/> If the proposal does not qualify for an exemption or an exception listed above, complete only this form as the first step in the application process.			
4. Proposed Project Costs Capital: \$ _____ Equipment: \$ _____ Total: \$ _____			
5. Authorized Contact Person Identification <small>(only one per project, regardless of number of owners/operators)</small>			
Name of Contact Person		Title	
Contact Person Address <small>(Company/Street/City/State/Zip Code)</small>			
Signature of Contact Person <small>(Preferably in blue ink)</small>	Date of Signature	Telephone Number	Fax Number

MO 580-1860 (01-99)



6. Project Description *(information should be brief but sufficient to understand scope of project)*

Project description to include 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 this is a replacement proposal, provide details concerning the facilities or equipment to be replaced to include their name, location, distance from the proposal and their final disposition:

NOTE: Because an application must be preceded by a Letter of Intent that accurately describes the project, a filing that does not substantially conform with the Letter of Intent shall not be considered an application.

MO 580-1860 (01-99)

19 CSR 60-50.310 Guidelines for Specific Health Services

PURPOSE: This rule adds new definitions of terms of health services reviewed in the Certificate of Need (CON) review process.

(1) The subsections below are intended to serve as guidelines for the Missouri Health Facilities Review Committee.

(2) Acute care means medical treatment rendered to individuals whose illnesses or health problems are of a short-term and episodic nature and is provided in a variety of hospital settings which are individually defined as—

(A) Inpatient rehabilitation means inpatient hospital care encompassing a comprehensive array of restoration services for the disabled and all services necessary to help patients attain maximum functional capacity;

(B) Long-term acute care means services to patients requiring an average length of stay greater than twenty-five (25) days (these beds are licensed as a separate long-term acute care hospital facility as described in 42 CFR section 412.23);

(C) Medical/surgical means inpatient care to patients in medical and surgical units in hospitals on the basis of physicians' orders and approved nursing care plan;

(D) Obstetrics means inpatient hospital services offered at facilities designated for one (1) of the following three (3) levels of care:

1. Uncomplicated maternity and newborn cases;

2. Uncomplicated cases, the majority of complicated problems, and special neonatal services; or

3. All serious illnesses and abnormalities which are supervised by a full-time maternal/fetal specialist;

(E) Pediatric means care to children on the basis of physicians' orders and approved nursing care plans;

(F) Psychiatric means inpatient acute or long-term care in hospitals to emotionally disturbed patients, including patients admitted for diagnosis and those admitted for treatment of psychiatric problems, on the basis of physicians' orders and approved nursing care plans (long-term care may include intensive supervision to the chronically mentally ill, mentally disordered, or other mentally incompetent persons); or

(G) Substance abuse/chemical dependency means diagnosis and therapeutic services in hospitals to patients with alcoholism or other drug dependencies including care for inpatient and residential treatment for patients whose course of treatment involves more intensive care than provided in an outpatient setting or where patient requires supervised withdrawal.

(3) Cardiac catheterization means the introduction of a catheter into the interior of the heart by way of a vein or artery or by direct needle puncture and practiced in a variety of settings which individually mean—

(A) Full-service laboratory with in-house cardiovascular surgery where both diagnostic and therapeutic procedures are performed on the heart and great vessels for a wide variety of cardiovascular diseases;

(B) Specialized service laboratory with in-house cardiovascular surgery where services are focused on a specific area of interest (e.g., therapeutic (interventional), electrophysiological, and pediatric);

(C) Clinical electrophysiology laboratory where services are focused on electrophysiological studies for patients with any type of cardiac electrical disturbance, and provisions for pacing, defibrillation, and resuscitation must be immediately available;

(D) Pediatric diagnostic and/or therapeutic catheterization laboratory where services are focused on pediatric patients and should be supervised by a pediatric cardiologist and must be supported by pediatric cardiac surgery and pediatric anesthesia (biplane cineangiographic equipment must be available to obtain quality studies while keeping contrast agent volume at safe levels);

(E) Laboratories without in-house cardiovascular surgery where this limited service will see less variety in the condition of patients undergoing evaluation because they must exercise particular caution to not accept unstable, acutely ill, or other high-risk patients for study, and formal arrangements with a hospital offering cardiovascular surgery must be made;

(F) Freestanding cardiac catheterization laboratory where the laboratory is not physically attached to a hospital, and may or may not be under hospital administration, and formal arrangements must be made with a hospital offering cardiovascular surgery; or

(G) Mobile cardiac catheterization laboratory where the entire laboratory, consisting of a single unit or multiple units joined together, is transportable by land, water, or air from one location to another location, and formal arrangements must be made with a hospital offering cardiovascular surgery.

(4) Cardiac catheterization service to be offered should utilize at least the following recommended components:

- (A) Physiological data acquisition;
- (B) Radiographic equipment;
- (C) Optics;
- (D) Cinecamera;
- (E) Video system;
- (F) Patient and equipment support;
- (G) Contrast injectors;

(H) Cineangiographic film and processing (if not digital);

(I) Cinefilm viewing and/or digital imaging;

(J) Support equipment;

(K) Quantitative angiography;

(L) Procedure room;

(M) Control room;

(N) Equipment room; and

(O) Clean utility room.

(5) Computed tomography (CT) means a diagnostic technique in which the combined use of a computer and X-rays, passed through the body at different angles, together produce clear cross-sectional images (slices) of the tissue being examined, using at least the following recommended components:

(A) CT gantry (X-ray generator);

(B) Device electronics and controller;

(C) Central processing unit (CT computer);

(D) Display console (TV screen);

(E) Keyboard; and

(F) Vehicle (if mobile).

(6) Coronary angiography and angioplasty means the process of describing the anatomy of the coronary arteries when such information is needed for patient management, including assessment of the presence, extent, and severity of obstructive atherosclerotic coronary artery disease, coronary artery size, coronary collateral flow, thrombus formation, dynamic obstructions (coronary spasm), or congenital coronary artery anomalies. These procedures may also allow visualization of all chambers of the heart, the aorta, and pulmonary arteries; angioplasty is the procedure of endovascular enlargement of the coronary lumen by a balloon or other device; these services are provided using at least the following recommended components:

(A) The resources of cardiac catheterization and radiographic facilities;

(B) An ample inventory of balloon dilation catheters, calibrated balloon inflation devices, and a complete range of existing guide wires of variable flexibility and steerability;

(C) A high resolution fluoroscopic system and an optimal television chain;

(D) An angulating X-ray tube image intensifier arm that allows three (3)-dimensional determination of the anatomic position of a guide wire or balloon catheter;

(E) A physiologic recording system, a high resolution fluoroscope, cineangiographic and/or digital (subtraction or acquisition) angiographic and/or cut film (analog) angiographic equipment, a complete set of emergency resuscitation instruments, and a full complement of drugs;

(F) Radiation exposure control systems including such items as an X-ray beam with automatic collimation, a carbon fiber scattered radiation grid, carbon fiber tabletop, and a correct tube filter; and

(G) On-site cardiovascular surgical backup (for coronary angioplasties, not angiography).

(7) Diagnostic imaging center means a facility or portion of a facility housing any professional or business undertaking, whether for profit or not for profit, which offers or proposes to offer any clinical radiological diagnostic health service which, at a minimum, uses a specialized collection of imaging equipment made up of any two (2) or more of mammography, X-ray, computerized axial tomography, positron emission tomography, fluoroscopy, ultra-sound, magnetic resonance imaging and related imaging services, and includes related support areas including patient processing, waiting, records, storage, counselling, and other patient support functions.

(8) Excimer laser means a specialized collection of equipment used to correct low to moderate myopia (nearsightedness) through a procedure called photorefractive keratectomy (PRK). This procedure removes microscopic layers of corneal tissue from the surface of the cornea to change its shape and improve the focus of light images, using at least the following components:

- (A) Excimer laser system;
- (B) Patient chair;
- (C) Physician's stool;
- (D) Bottles of argon, fluoride, and other gases;
- (E) Visionkey cards for PRK;
- (F) Slit lamp;
- (G) Topography system;
- (H) Micro keratome; and
- (I) Other miscellaneous supplies/equipment.

(9) Gamma knife means a specialized type of equipment used to perform stereotactic radiosurgery on small brain tumors and vascular malformations which utilizes multiple Cobalt-60 gamma radiation sources which are focused through a collimator helmet, using at least the following recommended components:

- (A) Radiation unit with collimator helmets;
- (B) Operating table;
- (C) Control panel;
- (D) Computer system; and
- (E) Support equipment including, CT and angiography.

(10) Hemodialysis means a process whereby a patient's blood is run through a machine that

acts as an artificial kidney. Patients are connected to the machine two (2) to three (3) times per week for approximately four (4) to six (6) hours per session, using at least the following recommended components:

- (A) Dialysis machine;
- (B) Blood pressure module;
- (C) Dialysis chair;
- (D) Reverse osmosis water system; and
- (E) Crash cart-defibrillator/monitor.

(11) Hospital means an establishment as defined in the Hospital Licensing Law, section 197.020.2, RSMo.

(12) Lithotripsy means a treatment technique using shock waves or ultrasonic waves to break up calculi (kidney stones) for excretion (two common treatment modalities currently are extracorporeal shock wave lithotripsy and percutaneous lithotripsy), using at least the following recommended components:

- (A) Lithotripter system;
- (B) Nephroscope;
- (C) Ultrasonic probe;
- (D) Support equipment (includes an X-ray imager); and
- (E) Vehicle (if mobile).

(13) Magnetic resonance imaging (MRI) means a diagnostic technique that provides high quality cross-sectional images of organs and structures within the body without X-rays or other radiation, through the absorption or emission of electromagnetic energy by nuclei in a static magnetic field after excitation by a suitable radiofrequency magnetic field, using at least the following recommended components:

- (A) MRI gantry (electromagnets);
- (B) Device electronics and controller;
- (C) Central processing unit (MRI computer);
- (D) Display console (TV screen);
- (E) Keyboard; and
- (F) Vehicle (if mobile).

(14) Positron emission tomography (PET) means a diagnostic technique based on the detection of positrons (positively charged particles) that are emitted by labeled substances introduced into the body. PET scanning produces three-dimensional images that reflect the metabolic and chemical activity of tissues being studied and depicts molecular function by the local concentration of an injected radionuclide which decays to a stable form by emitting a positron which a computer processes to produce an image on a TV screen, using at least the following recommended components:

- (A) PET gantry (radiation detectors);
- (B) Device electronics and controller;
- (C) Central processing unit (PET computer);

(D) Display console (TV screen);

(E) Keyboard;

(F) Line printer; and

(G) Cyclotron (an on-site medical cyclotron for radionuclide production and a chemistry unit for labeling radiopharmaceuticals; or an on-site rubidium-82 generator; or access to a supply of cyclotron-produced radiopharmaceuticals from an off-site medical cyclotron and radiopharmaceutical production facility within a two (2)-hour air transport radius; and a diagnostic imaging unit).

(15) Radiation therapy means a treatment technique for cancer and other diseases using X-radiation or other sources of radioactivity in which resultant ionizing radiation retards the progress of the disease, using at least the following recommended components:

- (A) Linear accelerator;
- (B) Simulator with radiographic/fluoroscopic capabilities;
- (C) Treatment planning computer;
- (D) Dosimetry equipment;
- (E) Block cutting machine;
- (F) X-ray film processor; and
- (G) Other (includes calibration equipment).

(16) Radiation therapy utilization shall be expressed in terms of patient visits.

(17) Surgery means the treatment of disease, injury, or deformity by manual or instrumental operations and is practiced in a variety of settings which individually mean—

(A) Ambulatory surgical facility means an establishment as defined in section 197.200(1), RSMo;

(B) Open heart surgery means any operation on the heart which uses extracorporeal circulation, such as coronary artery bypass surgery, cardiac transplantation, cardiac valve repair or replacement, correction of other acquired or congenital heart defects, and/or removal of a cardiac tumor; the services are provided using at least the following recommended components in addition to a normal operating room:

1. Heart-lung bypass unit;
 2. Back-up heart-lung bypass unit;
 3. Intra-aortic balloon pump;
 4. Ventilator for pulmonary support;
 5. Open heart surgery instruments;
 6. Special operating room lights for open heart surgery;
 7. Ability to perform renal dialysis or kidney dialysis;
 8. Cardiac surgery post-operative intensive care unit; and
 9. Cardiac catheterization and angiographic facility; and
- (C) All other surgery means—

1. Scheduled procedures provided to patients who remain in the hospital more than twenty-four (24) hours; or

2. Procedures performed in operating rooms also used for inpatient surgery, specially designated surgical suites for outpatient surgery, or procedure rooms within an outpatient care facility.

(18) Residential care facility I means any premises as defined in section 198.006(15), RSMo.

(19) Residential care facility II means any premises as defined in section 198.006(16), RSMo.

(20) Intermediate care facility means any premises as defined in section 198.006(8), RSMo.

(21) Skilled nursing facility means any premises as defined in section 198.006(17), RSMo.

(22) Long-term care hospital means an establishment as described in 42 CFR section 412.23(e).

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.*

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

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 outlined the projects subject to CON review and adds the following new form: MO 580-2351; the following form was modified: MO 580-2157; and the following forms are refiled without changes: MO 580-1871 and MO 580-2158.

(1) Applicants shall submit a Letter of Intent (LOI) package to begin the Certificate of Need (CON) review process preceding the submission of the CON application according to the following time frames:

(A) For standard proposals, at least thirty (30) days, but no more than six (6) months;

(B) For long-term care (LTC) bed expansion proposals by purchase, at least thirty (30) days, but no more than eighteen (18) months; and

(C) For LTC bed expansion proposals for which an effort to purchase was unsuccessful, at least eighteen (18) months, but no more than twenty-four (24) months.

(2) Once filed, a LOI may be amended once, at least thirty (30) 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 defined in these rules includes all of the provisions pursuant to section 197.318.8 through 197.318.10, RSMo, requiring a CON application, but allowing abbreviated information requirements and review timeframes. When a LOI for a LTC bed expansion (except replacements) 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 Aging (DA), Department of Social 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 DA's most recently published Quarterly Survey of Hospital and Nursing Home (or Residential Care Facility) Bed Utilization 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:

(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 the Expenditure Minimums Applicability Test (Form MO 580-2157); and the Exemptions and Exceptions Applicability Test (Form MO 580-2158);

(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 chairman may issue a nonapplicability CON letter indicating the application review process is complete; otherwise, the CONP staff shall add the pro-

posal to a list of nonapplicability proposals to be considered at a 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 nonapplicability 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, including a notarized project cost verification, must be provided on a Periodic Progress Report (Form MO 580-1871) before any additional beds are licensed or new services offered; and

(F) A CON application must be made if—

1. The project involves the development of a new health care facility costing in excess of one (1) million dollars;

2. The project involves a capital expenditure, excluding major medical equipment, by or on behalf of a health care facility not licensed under Chapter 198, RSMo, costing in excess of one (1) million dollars;

3. The project involves the acquisition or replacement of major medical equipment in an existing or proposed health care facility not licensed under Chapter 198, RSMo costing in excess of one (1) million dollars;

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

5. 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;

6. The project involves a capital expenditure, but not additional beds, by or on behalf of an existing health care facility licensed under Chapter 198, RSMo, costing in excess of one (1) million dollars;

7. The project involves predevelopment costs in excess of one hundred and fifty thousand dollars (\$150,000);

8. For facilities not licensed under Chapter 198, RSMo, the project involves a change in licensed bed capacity of a health care facility or reallocation of an existing health care facility's licensed beds among services, physical facilities, or sites by more than ten (10) beds or ten percent (10%) of the total bed capacity, whichever is less over a two (2)-year period; or



9. Prior to January 1, 2003, the project involves additional long-term care (licensed or certified residential care facility I or II, intermediate care facility, or skilled nursing facility) beds or LTC bed expansions or replacements as defined in section (3) above of this rule, regardless of cost, with certain exemptions and exceptions.

(5) If eighteen (18) months have expired after the filing of an LOI for a LTC bed expansion proposal without the filing of an application, then the CONP staff shall request occupancy verification pursuant to section 197.318.8(1)(e), RSMo, by the DA who shall also provide a copy to the potential applicant.

(6) Nonsubstantive projects are waived from review by the authority of section 197.330.1(8), RSMo.

(7) Special forms are furnished by the CON Program and incorporated into this rule by reference as follows:

- (A) Form MO 580-2351
- (B) Form MO 580-2157
- (C) Form MO 580-2158
- (D) Form MO 580-1871.

AUTHORITY: section 197.320, RSMo Supp. 1998. 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, 2000.*

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