

PUBLIC HEALTH CODE (EXCERPT)

Act 368 of 1978

PART 222

CERTIFICATES OF NEED

333.22201 Meanings of words and phrases; principles of construction.

Sec. 22201. (1) For purposes of this part, the words and phrases defined in sections 22203 to 22207 have the meanings ascribed to them in those sections.

(2) In addition, article 1 contains general definitions and principles of construction applicable to all articles in this code.

(3) The definitions in part 201 do not apply to this part.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988.

Compiler's note: For transfer of certain powers and duties of the division of health facility development in the bureau of health systems from the department of public health to the director of the department of community health, see E.R.O. No. 1996-1, compiled at § 330.3101 of the Michigan Compiled Laws.

Popular name: Act 368

333.22203 Definitions; A to F. [M.S.A. 14.15(22203)]

Sec. 22203. (1) "Addition" means adding patient rooms, beds, and ancillary service areas, including, but not limited to, procedure rooms or fixed equipment, surgical operating rooms, therapy rooms or fixed equipment, or other accommodations to a health facility.

(2) "Capital expenditure" means an expenditure for a single project, including cost of construction, engineering, and equipment that under generally accepted accounting principles is not properly chargeable as an expense of operation. Capital expenditure includes a lease or comparable arrangement by or on behalf of a health facility by which a person obtains a health facility or licensed part of a health facility or equipment for a health facility, the expenditure for which would have been considered a capital expenditure under this part if the person had acquired it by purchase. Capital expenditure includes the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, expansion, addition, conversion, modernization, new construction, or replacement of physical plant and equipment.

(3) "Certificate of need" means a certificate issued pursuant to this part authorizing a new health facility, a change in bed capacity, the initiation, replacement, or expansion of a covered clinical service, or a covered capital expenditure that is issued in accordance with this part.

(4) "Certificate of need review standard" or "review standard" means a standard approved by the commission or the statewide health coordinating council under section 22215.

(5) "Change in bed capacity" means 1 or more of the following:

- (a) An increase in licensed hospital beds.
- (b) An increase in licensed nursing home beds or hospital beds certified for long-term care.
- (c) An increase in licensed psychiatric beds.
- (d) A change from 1 licensed use to a different licensed use.
- (e) The physical relocation of beds from a licensed site to another geographic location.

(6) "Clinical" means directly pertaining to the diagnosis, treatment, or rehabilitation of an individual.

(7) "Clinical service area" means an area of a health facility, including related corridors, equipment rooms, ancillary service and support areas that house medical equipment, patient rooms, patient beds, diagnostic, operating, therapy, or treatment rooms or other accommodations related to the diagnosis, treatment, or rehabilitation of individuals receiving services from the health facility.

(8) "Commission" means the certificate of need commission created under section 22211.

(9) "Covered capital expenditure" means a capital expenditure of \$2,000,000.00 or more, as adjusted by the department under section 22221(g), by a person for a health facility for a single project, excluding the cost of nonfixed medical equipment, that includes or involves the acquisition, improvement, expansion, addition, conversion, modernization, new construction, or replacement of a clinical service

area or a capital expenditure of \$3,000,000.00 or more, as adjusted by the department under section 22221(g), by a person for a health facility for a single project that involves the acquisition, improvement, expansion, addition, conversion, modernization, new construction, or replacement of nonclinical service areas only.

(10) "Covered clinical service", except as modified by the commission pursuant to section 22215 after the effective date of the 1993 amendatory act that amended this subsection, means 1 or more of the following:

- (a) Initiation or expansion of 1 or more of the following services:
 - (i) Neonatal intensive care services or special newborn nursing services.
 - (ii) Open heart surgery.
 - (iii) Extrarenal organ transplantation.
- (b) Initiation, replacement, or expansion of 1 or more of the following services:
 - (i) Extracorporeal shock wave lithotripsy.
 - (ii) Megavoltage radiation therapy.
 - (iii) Positron emission tomography.
 - (iv) Surgical services provided in a freestanding surgical outpatient facility, an ambulatory surgery center certified under title XVIII, or a surgical department of a hospital licensed under part 215 and offering inpatient or outpatient surgical services.
 - (v) Cardiac catheterization.
 - (vi) Fixed and mobile magnetic resonance imager services.
 - (vii) Fixed and mobile computerized tomography scanner services.
 - (viii) Air ambulance services.
- (c) Initiation, replacement, or expansion of a partial hospitalization psychiatric program service.
- (d) Initiation or expansion of a specialized psychiatric program for children and adolescent patients utilizing licensed psychiatric beds.
- (e) Initiation, replacement, or expansion of a service not listed in this subsection, but designated as a covered clinical service by the commission under section 22215(1)(a).

(11) "Fixed equipment" means equipment that is affixed to and constitutes a structural component of a health facility, including, but not limited to, mechanical or electrical systems, elevators, generators, pumps, boilers, and refrigeration equipment.

History: Add. 1988, Act 331, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22205 Definitions; H to M.

Sec. 22205. (1) "Health facility", except as otherwise provided in subsection (2), means:

- (a) A hospital licensed under part 215.
 - (b) A psychiatric hospital, psychiatric unit, or partial hospitalization psychiatric program licensed under the mental health code, 1974 PA 258, MCL 330.1001 to 330.2106.
 - (c) A nursing home licensed under part 217 or a hospital long-term care unit as defined in section 20106(6).
 - (d) A freestanding surgical outpatient facility licensed under part 208.
 - (e) A health maintenance organization issued a license or certificate of authority in this state.
- (2) "Health facility" does not include the following:
- (a) An institution conducted by and for the adherents of a church or religious denomination for the purpose of providing facilities for the care and treatment of the sick who depend solely upon spiritual means through prayer for healing.
 - (b) A health facility or agency located in a correctional institution.
 - (c) A veterans facility operated by the state or federal government.
 - (d) A facility owned and operated by the department of mental health.
- (3) "Initiate" means the initiation of a covered clinical service by a person if the covered clinical service has not been offered in compliance with this part or former part 221 on a regular basis by that person at the location where the covered clinical service is to be offered within the 12-month period immediately preceding the date the covered clinical service will be offered.
- (4) "Medical equipment" means a single equipment component or a related system of components that is used for clinical purposes.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993;—Am. 2000, Act 253, Imd. Eff. June 29, 2000.
Popular name: Act 368

333.22207 Definitions; M to S. [M.S.A. 14.15(22207)]

Sec. 22207. (1) "Medicaid" means the program for medical assistance administered by the department of social services under the social welfare act, Act No. 280 of the Public Acts of 1939, being sections 400.1 to 400.119b of the Michigan Compiled Laws.

(2) "Modernization" means an upgrading, alteration, or change in function of a part or all of the physical plant of a health facility. Modernization includes, but is not limited to, the alteration, repair, remodeling, and renovation of an existing building and initial fixed equipment and the replacement of obsolete fixed equipment in an existing building. Modernization of the physical plant does not include normal maintenance and operational expenses.

(3) "New construction" means construction of a health facility where a health facility does not exist or construction replacing or expanding an existing health facility or a part of an existing health facility.

(4) "Person" means a person as defined in section 1106 or a governmental entity.

(5) "Planning area" means the area defined in a certificate of need review standard for determining the need for, and the resource allocation of, a specific health facility, service, or equipment. Planning area includes, but is not limited to, the state, a health facility service area, or a health service area or subarea within the state.

(6) "Proposed project" means a proposal to acquire an existing health facility or begin operation of a new health facility, make a change in bed capacity, initiate, replace, or expand a covered clinical service, or make a covered capital expenditure.

(7) "Rural county" means a county not located in a metropolitan area as that term is defined pursuant to the "revised standards for defining metropolitan areas in the 1990's" by the statistical policy office of the office of information and regulatory affairs of the United States office of management and budget, 55 F.R. p. 12154 (March 30, 1990).

(8) "Statewide health coordinating council" means the state agency created by section 7 of Act No. 323 of the Public Acts of 1978, being section 325.2007 of the Michigan Compiled Laws, before section 7 was amended by the 1988 amendatory act that created the state health planning council.

(9) "Stipulation" means a requirement that is germane to the proposed project and has been agreed to by an applicant as a condition of certificate of need approval.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22208 Definitions; S, T. [M.S.A. 14.15(22208)]

Sec. 22208. (1) "Short-term nursing care" means nursing care provided in a hospital to a patient who has been discharged or is ready for transfer from a licensed hospital bed other than a hospital long-term care unit bed and cannot be placed in a nursing home bed, county medical care facility bed, or hospital long-term care unit bed located within a 50-mile radius of the patient's residence.

(2) "Title XVIII" means title XVIII of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1395 to 1395b, 1395b-2, 1395c to 1395i, 1395-2 to 1395i-4, 1395j to 1395t, 1395u to 1395w-2, 1395w-4 to 1395zz, and 1395bbb to 1395ccc.

(3) "Title XIX" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to 1396g and 1396i to 1396u.

History: Add. 1988, Act 308, Eff. Oct. 1, 1988;—Am. 1990, Act 260, Imd. Eff. Oct. 15, 1990;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22209 Activities requiring certificate of need; exception; acquisition of existing health facility; certificate of need ombudsman. [M.S.A. 14.15(22209)]

Sec. 22209. (1) Except as otherwise provided in this part, a person shall not do any of the following without first obtaining a certificate of need:

(a) Acquire an existing health facility or begin operation of a health facility at a site that is not currently licensed for that type of health facility.

(b) Make a change in the bed capacity of a health facility.

(c) Initiate, replace, or expand a covered clinical service.

- (d) Make a covered capital expenditure.
- (2) A certificate of need is not required for a reduction in licensed bed capacity or services at a licensed site.
- (3) An applicant seeking a certificate of need for the acquisition of an existing health facility may file a single, consolidated application for the certificate of need if the project results in the acquisition of an existing health facility but does not result in an increase or relocation of licensed beds or the initiation, expansion, or replacement of a covered clinical service. Except as otherwise provided in this subsection, a person acquiring an existing health facility is subject to the applicable certificate of need review standards in effect on the date of the transfer for the covered clinical services provided by the acquired health facility. The department may except 1 or more of the covered clinical services listed in section 22203(10)(b), except the covered clinical service listed in section 22203(10)(b) (iv), from the minimum volume requirements in the applicable certificate of need review standards in effect on the date of the transfer, if the equipment used in the covered clinical service is unable to meet the minimum volume requirements due to the technological incapacity of the equipment. A covered clinical service excepted by the department under this subsection is subject to all the other provisions in the applicable certificate of need review standards in effect on the date of the transfer, except minimum volume requirements.
- (4) The center for rural health created in section 2612 shall designate a certificate of need ombudsman to provide technical assistance and consultation to hospitals and communities located in rural counties regarding certificate of need proposals and applications under this part. The ombudsman shall also act as an advocate for health concerns of rural counties in the development of certificate of need review standards under this part.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1990, Act 260, Imd. Eff. Oct. 15, 1990;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.
Popular name: Act 368

333.22210 Certificate of need for short-term nursing care program; application; criteria; modification; fee prohibited; compliance; discrimination prohibited; exercise of rights; written acknowledgment; forms; additional rights; variation; rules; violation; penalty; certificate required. [M.S.A. 14.15(22210)]

Sec. 22210. (1) A hospital that applies to the department for a certificate of need and meets all of the following criteria shall be granted a certificate of need for a short-term nursing care program with up to 10 licensed hospital beds:

- (a) Is eligible to apply for certification as a provider of swing-bed services under section 1883 of title XVIII, 42 U.S.C. 1395tt.
- (b) Subject to subsection (2), has fewer than 100 licensed beds not counting beds excluded under section 1883 of title XVIII of the social security act.
- (c) Does not have uncorrected licensing, certification, or safety deficiencies for which the department or the state fire marshal, or both, has not accepted a plan of correction.
- (d) Provides evidence satisfactory to the department that the hospital has had difficulty in placing patients in skilled nursing home beds during the 12 months immediately preceding the date of the application.

(2) After October 1, 1990, the criteria set forth in subsection (1)(b) may be modified by the commission, using the procedure set forth in section 22215(3). The department shall not charge a fee for processing a certificate of need application to initiate a short-term nursing care program.

(3) A hospital that is granted a certificate of need for a short-term nursing care program under subsection (1) shall comply with all of the following:

- (a) Not charge for or otherwise attempt to recover the cost of a length of stay for a patient in the short-term nursing care program that exceeds the length of time allowed for post-hospital extended care under title XVIII.
- (b) Admit patients to the short-term nursing care program only pursuant to an admissions contract approved by the department.
- (c) Not discharge or transfer a patient from a licensed hospital bed other than a hospital long-term care unit bed and admit that patient to the short-term nursing care program unless the discharge or transfer and admission is determined medically appropriate by the attending physician.
- (d) Permit access to a representative of an organization approved under section 21764 to patients admitted to the short-term nursing care program, for all of the purposes described in section 21763.

(e) Subject to subsection (8), not allow the number of patient days for the short-term nursing care program to exceed the equivalent of 1,825 patient days for a single state fiscal year.

(f) Transfer a patient in the short-term nursing care program to an appropriately certified nursing home bed, county medical care facility bed, or hospital long-term care unit bed located within a 50-mile radius of the patient's residence within 5 business days after the hospital has been notified, either orally or in writing, that a bed has become available.

(g) Not charge or collect from a patient admitted to the short-term nursing care program, for services rendered as part of the short-term nursing care program, an amount in excess of the reasonable charge for the services as determined by the United States secretary of health and human services under title XVIII.

(h) Assist a patient who has been denied coverage for services received in a short-term nursing care program under title XVIII to file an appeal with the medicare recovery project operated by the office of services to the aging.

(i) Operate the short-term nursing care program in accordance with this section and the requirements of the swing bed provisions of section 1883 of title XVIII, 42 U.S.C. 1395tt.

(j) Provide data to the department considered necessary by the department to evaluate the short-term nursing care program. The data shall include, but is not limited to, all of the following:

(i) The total number of patients admitted to the hospital's short-term nursing care program during the period specified by the department.

(ii) The total number of short-term nursing care patient days for the period specified by the department.

(iii) Information identifying the type of care to which patients in the short-term care nursing program are released.

(k) As part of the hospital's policy describing the rights and responsibilities of patients admitted to the hospital, as required under section 20201, incorporate all of the following additional rights and responsibilities for patients in the short-term nursing care program:

(i) A copy of the hospital's policy shall be provided to each short-term nursing care patient upon admission, and the staff of the hospital shall be trained and involved in the implementation of the policy.

(ii) Each short-term nursing care patient may associate and communicate privately with persons of his or her choice. Reasonable, regular visiting hours, which shall take into consideration the special circumstances of each visitor, shall be established for short-term nursing care patients to receive visitors. A short-term nursing care patient may be visited by the patient's attorney or by representatives of the departments named in section 20156 during other than established visiting hours. Reasonable privacy shall be afforded for visitation of a short-term nursing care patient who shares a room with another short-term nursing care patient. Each short-term nursing care patient shall have reasonable access to a telephone.

(iii) A short-term nursing care patient is entitled to retain and use personal clothing and possessions as space permits, unless medically contraindicated, as documented by the attending physician in the medical record.

(iv) A short-term nursing care patient is entitled to the opportunity to participate in the planning of his or her medical treatment. A short-term nursing care patient shall be fully informed by the attending physician of the short-term nursing care patient's medical condition, unless medically contraindicated, as documented by a physician in the medical record. Each short-term nursing care patient shall be afforded the opportunity to discharge himself or herself from the short-term nursing care program.

(v) A short-term nursing care patient is entitled to be fully informed either before or at the time of admission, and during his or her stay, of services available in the hospital and of the related charges for those services. The statement of services provided by the hospital shall be in writing and shall include those services required to be offered on an as needed basis.

(vi) A patient in a short-term nursing care program or a person authorized in writing by the patient may, upon submission to the hospital of a written request, inspect and copy the patient's personal or medical records. The hospital shall make the records available for inspection and copying within a reasonable time, not exceeding 7 days, after the receipt of the written request.

(vii) A short-term nursing care patient has the right to have his or her parents, if the short-term nursing care patient is a minor, or his or her spouse, next of kin, or patient's representative, if the short-term nursing care patient is an adult, stay at the facility 24 hours a day if the short-term nursing care

patient is considered terminally ill by the physician responsible for the short-term nursing care patient's care.

(viii) Each short-term nursing care patient shall be provided with meals that meet the recommended dietary allowances for that patient's age and sex and that may be modified according to special dietary needs or ability to chew.

(ix) Each short-term nursing care patient has the right to receive a representative of an organization approved under section 21764, for all of the purposes described in section 21763.

(1) Achieve and maintain medicare certification under title XVIII.

(4) A hospital or the owner, administrator, an employee, or a representative of the hospital shall not discharge, harass, or retaliate or discriminate against a short-term nursing care patient because the short-term nursing care patient has exercised a right described in subsection (3)(k).

(5) In the case of a short-term nursing care patient, the rights described in subsection (3)(k)(iv) may be exercised by the patient's representative, as defined in section 21703(2).

(6) A short-term nursing care patient shall be fully informed, as evidenced by the short-term nursing care patient's written acknowledgment, before or at the time of admission and during stay, of the rights described in subsection (3)(k). The written acknowledgment shall provide that if a short-term nursing care patient is adjudicated incompetent and not restored to legal capacity, the rights and responsibilities set forth in subsection (3)(k) shall be exercised by a person designated by the short-term nursing care patient. The hospital shall provide proper forms for the short-term nursing care patient to provide for the designation of this person at the time of admission.

(7) Subsection (3)(k) does not prohibit a hospital from establishing and recognizing additional rights for short-term nursing care patients.

(8) Upon application, the department may grant a variation from the maximum number of patient days established under subsection (3)(e), to an applicant hospital that demonstrates to the satisfaction of the department that there is an immediate need for skilled nursing beds within a 100-mile radius of the hospital. A variation granted under this subsection shall be valid for not more than 1 year after the date the variation is granted. The department shall promulgate rules to implement this subsection including, at a minimum, a definition of immediate need and the procedure for applying for a variation.

(9) A hospital that violates subsection (3) is subject to the penalty provisions of section 20165.

(10) A person shall not initiate a short-term nursing care program without first obtaining a certificate of need under this section.

History: Add. 1988, Act 308, Eff. Oct. 1, 1988;—Am. 1990, Act 260, Imd. Eff. Oct. 15, 1990;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22211 Certificate of need commission; creation; appointment, qualifications, and terms of members; vacancy; laws to which commission members subject. [M.S.A. 14.15(22211)]

Sec. 22211. (1) The certificate of need commission is created in the department. The commission shall be appointed within 3 months after the effective date of this part. The commission shall consist of 5 members appointed by the governor with the advice and consent of the senate. Three appointees shall be members of a major political party, and 2 appointees shall be members of another major political party.

(2) In making appointments, the governor shall, to the extent feasible, assure that the membership of the commission is broadly representative of the interests of all of the people of this state.

(3) Except for initial members, a member of the commission shall serve for a term of 3 years or until a successor is appointed. Of the members initially appointed, 1 of the members shall be appointed for a term of 1 year, 2 of the members shall be appointed for a term of 2 years, and 2 of the members shall be appointed for a term of 3 years. A vacancy on the commission shall be filled for the balance of the unexpired term in the same manner as the original appointment.

(4) Commission members are subject to the following:

(a) Act No. 317 of the Public Acts of 1968, being sections 15.321 to 15.330 of the Michigan Compiled Laws.

(b) Act No. 196 of the Public Acts of 1973, being sections 15.341 to 15.348 of the Michigan Compiled Laws.

(c) Act No. 472 of the Public Acts of 1978, being sections 4.411 to 4.431 of the Michigan Compiled Laws.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988.

Popular name: Act 368

333.22213 Commission; bylaws; removal of member; election of chairperson and vice-chairperson; meetings; quorum; final action; compensation and expenses; duties of department; professional employees. [M.S.A. 14.15(22213)]

Sec. 22213. (1) The commission shall, within 2 months after appointment and confirmation of all members, adopt bylaws for the operation of the commission. The bylaws shall include, at a minimum, voting procedures that protect against conflict of interest and minimum requirements for attendance at meetings.

(2) The governor may remove a commission member from office for failure to attend 3 consecutive meetings in a 1-year period.

(3) The commission annually shall elect a chairperson and vice-chairperson.

(4) The commission shall hold regular quarterly meetings at places and on dates fixed by the commission. Special meetings may be called by the chairperson, by not less than 2 commission members, or by the department.

(5) A majority of the commission members appointed and serving constitutes a quorum. Final action by the commission shall be only by affirmative vote of a majority of the commission members appointed and serving. A commission member shall not vote by proxy.

(6) The legislature annually shall fix the per diem compensation of members of the commission. Expenses of members incurred in the performance of official duties shall be reimbursed as provided in section 1216.

(7) The department shall furnish administrative services to the commission, shall have charge of the commission's offices, records, and accounts, and shall provide secretarial and other staff necessary to allow the proper exercise of the powers and duties of the commission. The department shall make available the times and places of commission meetings and keep minutes of the meetings and a record of the actions of the commission.

(8) The department shall assign professional employees to staff the commission to assist the commission in the performance of its substantive responsibilities under this part.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22215 Duties of commission; purpose; public hearing before final action; submission of proposed final action to standing committees and governor; approval or disapproval; development of review standards; revision of fees. [M.S.A. 14.15(22215)]

Sec. 22215. (1) Pursuant to the requirements of this part, the commission shall do all of the following:

(a) If determined necessary by the commission, revise, add to, or delete 1 or more of the covered clinical services listed in section 22203. If the commission proposes to add to the covered clinical services listed in section 22203, the commission shall develop proposed review standards and make the review standards available to the public not less than 30 days before conducting a hearing under subsection (3).

(b) Approve, disapprove, or revise certificate of need review standards that establish for purposes of section 22225 the need, if any, for the initiation, replacement, or expansion of covered clinical services, the acquisition or beginning the operation of a health facility, making changes in bed capacity, or making covered capital expenditures, including conditions, standards, assurances, or information that must be met, demonstrated, or provided by a person who applies for a certificate of need. A certificate of need review standard may also establish ongoing quality assurance requirements including any or all of the requirements specified in section 22225(2)(c). The statewide health coordinating council may perform the duties of the commission under this subdivision, only until all members of the commission are appointed and confirmed, or until March 1, 1989, whichever is sooner.

(c) Direct the department to prepare and submit recommendations regarding commission duties and functions that are of interest to the commission including, but not limited to, specific modifications of proposed actions considered under this section.

(d) Approve, disapprove, or revise proposed criteria for determining health facility viability under

section 22225.

(e) Annually assess the operations and effectiveness of the certificate of need program based on periodic reports from the department and other information available to the commission.

(f) By October 1, 1992, and every 5 years after October 1, 1992, make recommendations to the standing committees in the senate and the house that have jurisdiction over matters pertaining to public health regarding statutory changes to improve or eliminate the certificate of need program.

(g) Upon submission by the department approve, disapprove, or revise standards to be used by the department in designating a regional certificate of need review agency, pursuant to section 22226.

(h) Approve, disapprove, or revise certificate of need review standards governing the acquisition of new technology.

(i) In accordance with section 22255, approve, disapprove, or revise proposed procedural rules for the certificate of need program.

(j) Consider the recommendations of the department and the department of attorney general as to the administrative feasibility and legality of proposed actions under subdivisions (a), (b), and (c).

(k) Consider the impact of a proposed restriction on the acquisition of or availability of covered clinical services on the quality, availability, and cost of health services in this state.

(l) Appoint ad hoc advisory committees to assist in the development of proposed certificate of need review standards. An ad hoc advisory committee shall complete its duties under this subdivision and submit its recommendations to the commission within the time limit specified by the commission when an ad hoc advisory committee is appointed. The composition of the ad hoc advisory committee shall include all of the following:

(i) Experts with professional competence in the subject matter of the proposed standard, who shall constitute a majority of the ad hoc advisory committee.

(ii) Representatives of health care provider organizations concerned with licensed health facilities or licensed health professions.

(iii) Representatives of organizations concerned with health care consumers and the purchasers and payers of health care services.

(2) The commission shall exercise its duties under this part to promote all of the following:

(a) The availability and accessibility of quality health services at reasonable cost and with reasonable geographic proximity for all people in the state.

(b) Appropriate differential consideration of the health care needs of residents in rural counties in ways that do not compromise the quality and affordability of health care services for those residents.

(3) Not less than 30 days before final action is taken by the commission under subsection (1)(a), (b), (d), or (h), the commission shall conduct a public hearing on its proposed action. In addition, not less than 30 days before final action is taken by the commission under subsection (1)(a), (b), (d), or (h), the commission shall submit the proposed action for comment to the standing committees in the senate and house of representatives with jurisdiction over public health matters.

(4) The commission shall submit the proposed final action to the governor and the standing committee of each house of the legislature with jurisdiction over public health matters. The governor or the legislature may disapprove the proposed final action within 45 days after the date of submission. If the proposed final action is not submitted on a legislative session day, the 45 days commence on the first legislative session day after the proposed final action is submitted. The 45 days shall include not less than 9 legislative session days. Legislative disapproval shall be expressed by concurrent resolution which shall be adopted by each house of the legislature. The concurrent resolution shall state specific objections to the proposed final action. A proposed final action by the commission under subsection (1)(a), (b), (d), or (h) is not effective if it has been disapproved under this subsection. If the proposed final action is not disapproved under this subsection, it is effective and binding on all persons affected by this part upon the expiration of the 45-day period or on a later date specified in the proposed final action. As used in this subsection, "legislative session day" means each day in which a quorum of either the house of representatives or the senate, following a call to order, officially convenes in Lansing to conduct legislative business.

(5) Within 2 years after the effective date of the amendatory act that added this sentence, the ad hoc advisory committee for psychiatric services appointed by the department under section 22221 or by the commission under section 22215 shall develop and submit certificate of need review standards under this section for the covered clinical services described in section 22203(10)(c) and (d). The ad hoc

advisory committee for psychiatric services shall include in the review standards a specific methodology for the determination of need. If the ad hoc advisory committee for psychiatric services does not develop and submit review standards for the covered clinical services described in section 22203(10)(c) and (d) within the 2-year time limit set forth in this subsection, the commission shall delete the covered clinical services described in section 22203(10)(c) and (d) pursuant to subsection (1)(a).

(6) If the reports received under section 22221(f) indicate that the certificate of need application fees collected under section 20161(2) have not been within 10% of 1/2 the cost to the department of implementing this part, the commission shall make recommendations regarding the revision of those fees so that the certificate of need application fees collected equal approximately 1/2 of the cost to the department of implementing this part.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22217 Certificate of need review standards; documents, policies, and guidelines. [M.S.A. 14.15(22217)]

Sec. 22217. (1) Until other certificate of need review standards are approved pursuant to this section or section 22215(1)(b), the following documents, policies, and guidelines shall be used by the department as certificate of need review standards for purposes of this part, but are not incorporated by reference into this part:

(a) For general acute care beds, the subareas described on page 67 and the bed need methodology set forth on pages 72 and 73 and the policies pertaining to general hospitals set forth on pages 26 and 27 of the document entitled "Michigan department of public health administrative guidelines for the certificate of need program", adopted by the department on February 1, 1982.

(b) For long-term care services, the policies in the document entitled "planning policies pertaining to long-term nursing care bed need", approved by the statewide health coordinating council on May 16, 1985, and amended on March 19, 1987, except that the limitation on the number of beds that may be set aside to better meet the needs of special population groups within the long-term care and nursing home populations, as described on page 5 of "planning policies pertaining to long-term nursing care bed need", is changed from 0.5% to 2.0%. Subject to the provisions of this subdivision, the commission shall set aside the additional beds in a statewide pool that shall be used for proposed projects that better meet the religious or health needs for specialized services within the long-term care and nursing home populations including, but not limited to, acquired immunodeficiency syndrome and Alzheimer's disease. Not more than 6 months after the initial appointment and confirmation of all members of the commission, the commission shall define and determine those needs and the pool of additional beds by approving or modifying the recommendations of the office and the department. After a public hearing, but not later than 3 months after the effective date of this part, the office and the department shall submit recommendations to the commission regarding those needs and the pool of additional beds.

(c) For cardiac services, the policies in the document entitled "planning policies pertaining to cardiac services" approved by the statewide health coordinating council on January 16, 1986.

(d) For extrarenal organ transplantation services, the policies in the document entitled "planning policies pertaining to extrarenal organ transplantation" approved by the statewide health coordinating council on January 16, 1986.

(e) For special radiological procedures rooms, but excluding procedure rooms used only for general radiology and fluoroscopy procedures, the policies in the document entitled "planning policies pertaining to diagnostic radiology services" approved by the statewide health coordinating council on January 16, 1986.

(f) For specialized radiation therapy services, including, but not limited to, linear accelerators and cobalt units, the policies in the document entitled "planning policies pertaining to specialized radiation therapy services" approved by the statewide health coordinating council on January 16, 1986.

(g) For neonatal intensive care services, including special newborn nursery services, item number 5 on page 29 of the administrative guidelines for certificate of need adopted by the department on February 1, 1982.

(h) For extracorporeal shock wave lithotripsy, policies in the document entitled "planning policies pertaining to extracorporeal shock wave lithotripsy" approved by the statewide health coordinating council on November 21, 1985.

(i) For magnetic resonance units, the policies in the document entitled "planning policies pertaining to magnetic resonance" as amended and approved by the statewide health coordinating council on March 19, 1987.

(j) For mobile computed tomography scanners, the policies in the document entitled "planning policies pertaining to mobile computed tomography scanner services" approved by the statewide health coordinating council on May 15, 1986.

(k) For fixed computed tomography scanner services, pages 61 to 66 of the administrative guidelines for certificate of need adopted by the department on February 1, 1982.

(l) For psychiatric hospitals and units, the document entitled "psychiatric hospitals and units" on pages 18 to 24 of chapter 2 of volume II of the Michigan state health plan, 1983-87, except that, for purposes of this subdivision only, the term "public patient" means an individual approved for inpatient services by a community mental health service board or an individual who is admitted as a patient under section 423, 429, or 438 of the mental health code, Act No. 258 of the Public Acts of 1974, being sections 330.1423, 330.1429, and 330.1438 of the Michigan Compiled Laws.

(m) For surgical facilities, including surgical facilities in hospital or outpatient settings, the policies entitled "policies pertaining to outpatient and inpatient surgical facilities" on pages 41 and 42 of the administrative guidelines for the certificate of need program adopted by the department on February 1, 1982.

(2) Not later than 3 months after the effective date of this part, the office and the department shall hold a public hearing on the documents, policies, and guidelines set forth in subsection (1). The hearing shall provide interested persons an opportunity to submit information and testimony on the appropriateness of the documents, policies, and guidelines and the need, if any, to revise the documents, policies, and guidelines to promote efficient, accessible, and quality health services. Within 5 months after the effective date of this part, based on the public hearing and other available information, the office and the department shall recommend to the commission 1 of the following in regard to each of the documents, policies, and guidelines set forth in subsection (1):

- (a) Approval as certificate of need review standards.
- (b) Approval with specific modifications as certificate of need review standards.
- (c) Deletion, because the applicable clinical services and medical equipment should no longer be governed under this part, as determined by the commission pursuant to section 22215(1)(a).
- (d) Review and revision.

(3) Before or during its third meeting, and after consideration of the recommendations of the department and the office under subsection (2), the commission shall assign each document, policy, and guideline set forth in subsection (1) to 1 of the categories set forth in subsection (2)(a) to (d). The commission's approval, or approval with specific modifications, of certificate of need review standards shall be considered approval under section 22215(1)(b), and such standards shall be binding on all persons affected by this part. The procedures of sections 22215(3) and 22221(2) do not apply to standards approved, or approved with specific modifications, under this subsection, except that a final commission action under this subsection shall be submitted to the governor and legislature as provided by section 22215(3) before it becomes effective. However, the governor and the legislature shall have 30 days, including not less than 6 session days, in which to disapprove the action of the commission. For a document, policy, or guideline considered appropriate for review and revision, the commission shall, after considering the recommendations of the department and the office, establish a schedule for expeditious review and revision by the commission and shall direct the department and office to adhere to the schedule in the development of proposed or revised certificate of need review standards under this part.

(4) An application submitted on or after the effective date of this part for a proposed project subject to a document, policy, or guideline listed in this section shall be considered submitted as of January 1, 1989, except for applications meeting the requirements of section 22235.

(5) Until all members of the commission are appointed and confirmed, or until 5 months after the effective date of this part, whichever is sooner, the statewide health coordinating council may perform the duties of the commission under this section. During the period described in this subsection, the statewide health coordinating council may approve, disapprove, or revise, as a certificate of need review standard, a policy described in subsection (1)(c), (e), and (i). Action by the statewide health coordinating council under this subsection shall be submitted to the legislature and the governor as provided in subsection (3) before it becomes effective and the standards shall be binding on all parties affected by this part.

(6) The documents, policies, and guidelines set forth in subsection (1) are public information. Upon receipt of a written request, the department shall provide a copy of a document, policy, or guideline to the person making the request.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988.

Popular name: Act 368

333.22221 Duties of department generally. [M.S.A. 14.15(22221)]

Sec. 22221. The department shall do all of the following:

- (a) Promulgate rules to implement its powers and duties under this part.
- (b) Report to the commission at least annually on the performance of the department's duties under this part.
- (c) Develop proposed certificate of need review standards for submission to the commission.
- (d) Administer and apply certificate of need review standards. In applying a review standard that establishes the minimum number of magnetic resonance imaging procedures necessary for a certificate of need for a mobile magnetic resonance imaging service servicing only hospitals located in rural counties, the department shall use an adjustment factor of 2.0. In applying a review standard that establishes the minimum number of magnetic resonance imaging procedures necessary for a certificate of need for a mobile magnetic resonance imaging service servicing hospitals located in both rural and nonrural counties, for a hospital located in a rural county the department shall use an adjustment factor of 1.4.
- (e) Designate adequate staff or other resources to directly assist hospitals and nursing homes with less than 100 beds in the preparation of applications for certificates of need.
- (f) Following the first state fiscal year after October 1, 1988, and annually thereafter, report to the commission regarding the costs to the department of implementing this part and the certificate of need application fees collected under section 20161(2) in the immediately preceding state fiscal year.
- (g) Beginning January 1, 1995 annually adjust the \$2,000,000.00 and \$3,000,000.00 thresholds set forth in section 22203(9) by an amount determined by the state treasurer to reflect the annual percentage change in the consumer price index, using data from the immediately preceding period of July 1 to June 30. As used in this subdivision, "consumer price index" means the most comprehensive index of consumer prices available for this state from the bureau of labor statistics of the United States department of labor.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22223 Application for certificate of need; statement addressing review criteria. [M.S.A. 14.15(22223)]

Sec. 22223. An applicant for a certificate of need shall include as part of the application a statement addressing each of the review criteria listed in section 22225. This section does not apply to an application for a certificate of need made under section 22210.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988.

Popular name: Act 368

333.22224 Certificate of need not required.

Sec. 22224. (1) A health facility required to be licensed as a freestanding surgical outpatient facility by rules promulgated under section 20115(2) is not required to obtain a certificate of need in order to be granted a license as a freestanding surgical outpatient facility.

(2) If a freestanding surgical outpatient facility is applying for a certificate of need to initiate, replace, or expand a covered clinical service consisting of surgical services, the department shall not count abortion procedures in determining if the freestanding surgical outpatient facility meets the annual minimum number of surgical procedures required in the certificate of need standards governing surgical services.

History: Add. 1999, Act 206, Eff. Mar. 10, 2000.

Popular name: Act 368

333.22225 Demonstration of need for proposed project; additional

requirements. [M.S.A. 14.15(22225)]

Sec. 22225. (1) In order to be approved under this part, an applicant for a certificate of need shall demonstrate to the satisfaction of the department that the proposed project will meet an unmet need in the area proposed to be served. An applicant shall demonstrate the need for a proposed project by credible documentation of compliance with the applicable certificate of need review standards. If no certificate of need review standards are applicable to the proposed project or to a portion of a proposed project that is otherwise governed by this part, the applicant shall demonstrate to the satisfaction of the department that an unmet need for the proposed project or portion of the proposed project exists by credible documentation that the proposed project will be geographically accessible and efficiently and appropriately utilized, in light of the type of project and the existing health care system. Whether or not there are applicable certificate of need review standards, in determining compliance with this subsection, the department shall consider approved projects that are not yet operational, proposed projects under appeal from a final decision of the department, or proposed projects that are pending final department decision.

(2) If, and only if, the requirements of subsection (1) are met, in order for an application to be approved under this part, an applicant shall also demonstrate to the reasonable satisfaction of the department all of the following:

(a) With respect to the method proposed to meet the unmet need identified under subsection (1), that the applicant has considered alternatives to the proposed project and that, in light of the alternatives available for consideration, the chosen alternative is the most efficient and effective method of meeting that unmet need.

(b) With respect to the financial aspects of the proposed project, that each of the following is met:

(i) The capital costs of the proposed project will result in the least costly total annual operating costs.

(ii) Funds are available to meet the capital and operating needs of the proposed project.

(iii) The proposed project utilizes the least costly method of financing, in light of available alternatives.

(iv) In the case of a construction project, the applicant stipulates that the applicant will competitively bid capital expenditures among qualified contractors or alternatively, the applicant is proposing an alternative to competitive bidding that will achieve substantially the same results as competitive bidding.

(c) The proposed project will be delivered in compliance with applicable operating standards and quality assurance standards approved under section 22215(1)(b), including 1 or more of the following:

(i) Mechanisms for assuring appropriate utilization of the project.

(ii) Methods for evaluating the effectiveness of the project.

(iii) Means of assuring delivery of the project by qualified personnel and in compliance with applicable safety and operating standards.

(iv) Evidence of the current and historical compliance with federal and state licensing and certification requirements in this state by the applicant or the applicant's owner, or both, to the degree determined appropriate by the commission in light of the subject of the review standard.

(v) Other criteria approved by the commission as appropriate to evaluate the quality of the project.

(d) The health services proposed in the project will be delivered in a health facility that meets the criteria, if any, established by the commission for determining health facility viability, pursuant to this subdivision. The criteria shall be proposed by the department and the office, and approved or disapproved by the commission. At a minimum, the criteria shall specify, to the extent applicable to the applicant, that an applicant shall be considered viable by demonstrating at least 1 of the following:

(i) A minimum percentage occupancy of licensed beds.

(ii) A minimum percentage of combined uncompensated discharges and discharges under title XIX in the health facility's planning area.

(iii) A minimum percentage of the total discharges in the health facility's planning area.

(iv) Evidence that the health facility is the only provider in the health facility's planning area of a service that is considered essential by the commission.

(v) An operating margin in an amount determined by the commission.

(vi) Other criteria approved by the commission as appropriate for statewide application to determine health facility viability.

(e) In the case of a nonprofit health facility, the health facility is in fact governed by a body composed of a majority consumer membership broadly representative of the population served. In the case of a

health facility sponsored by a religious organization, or if the nature of the nonprofit health facility is such that the legal rights of its owners or sponsors might be impaired by a requirement as to the composition of its governing body, an advisory board with majority consumer membership broadly representative of the population served may be construed by the department to be equivalent to the governing board described in this subdivision, if the advisory board meets all of the following requirements:

- (i) The role assigned to the advisory board is meaningful, as determined by the department.
- (ii) The functions of the advisory board are clearly prescribed.
- (iii) The advisory board is given an opportunity to influence policy formulation by the legally recognized governing body, as determined by the department.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22226 Regional certificate of need review agency; standards; designation of person for specific review area; requirements; duration and termination of agency; local certificate of need review agency; application or other information; review; recommendations; decision; convening consumers, providers, purchasers, or payers of health care; relevant written communications; public hearing; meetings; “review area” defined. [M.S.A. 14.15(22226)]

Sec. 22226. (1) The department and the office shall jointly develop standards for the designation by the department of a regional certificate of need review agency for each review area to develop advisory recommendations for proposed projects. The standards shall be based on the requirements for a regional certificate of review agency set forth in subsection (3). The standards developed under this subsection shall be approved by the commission before implementation by the department.

(2) The department, with the concurrence of the commission, shall designate a person to be a regional certificate of need review agency for a specific review area, according to procedures approved by the commission, if the person meets the standards approved under subsection (1), and if a regional certificate of need review agency has not already been designated for that specific review area.

(3) A regional certificate of need review agency shall meet all of the following requirements:

(a) Be an independent nonprofit organization that is not a subsidiary of, or otherwise controlled by, any other person.

(b) Be governed by a board that is broadly representative of consumers, providers, payers, and purchasers of health care in the review area, with a majority of the board being consumers, payers, and purchasers of health care.

(c) Demonstrate a willingness and ability to conduct reviews of all proposed projects requiring a certificate of need that would be located within the review area served by the regional certificate of need review agency.

(d) Avoid conflict of interest in its review of all applications for a certificate of need.

(e) Provide data to the department to enable the department to evaluate the regional certificate of need review agency's performance. The data provided under this subdivision shall be reviewed at periodic meetings between the department and the regional certificate of need review agency.

(f) Not receive more than a designated proportion of its financial support from health facilities and health professionals, as determined by the commission.

(g) Meet other requirements established by the commission that are relevant to the functions of a regional certificate of need review agency, pursuant to this part.

(4) The designation of a regional certificate of need review agency shall be operative for a period of time approved by the commission, but not for more than 24 months. The designation of a regional certificate of need review agency may be terminated by the department at any time for noncompliance with the standards approved under subsection (1). In addition, the designation may be terminated by the regional certificate of need review agency upon the expiration of 60 days after the department receives written notice of the termination.

(5) A local certificate of need review agency that was designated pursuant to a designation agreement authorized under former section 22124 and effective on the effective date of this part is designated as the regional certificate of need review agency for its review area until the expiration of 1 year after the date of final approval of the standards developed under subsection (1), unless the designation is terminated by either the department or the regional certificate of need review agency before that time.

(6) A person applying for a certificate of need under this part shall simultaneously provide a copy of any letter of intent, application, or additional information required by the department to the regional certificate of need review agency designated by the department for the review area in which the proposed project would be located, unless the regional certificate of need review agency determines that it will not review the application or other information, and notifies both the applicant and the department in writing of its determination. The regional certificate of need review agency may review the application and submit its recommendations to the department. If the regional certificate of need review agency determines that it will not review the application, then the regional certificate of need review agency shall notify both the applicant and the department in writing of its determination. In developing its recommendations, the regional certificate of need review agency shall utilize the review procedures and time frames specified for health systems agencies or regional certificate of need review agencies in the rules continued or promulgated under this part, and shall also utilize certificate of need review standards, statutory criteria, and forms identical to those used by the department.

(7) Before developing a proposed decision on an application, the department shall review the recommendations of the regional certificate of need review agency for the review area in which the proposed project would be located, if the recommendations are submitted to the department within the time frames required under subsection (6). If the director makes a final decision that is inconsistent with the recommendations of the regional certificate of need review agency, the department shall promptly provide the regional certificate of need review agency with a detailed statement of the reasons for the director's decision. The statement shall address each instance in which the director's decision is inconsistent with the recommendation of the regional certificate of need review agency regarding a specific certificate of need review standard or criterion.

(8) A regional certificate of need review agency may convene consumers, providers, purchasers, or payers of health care, or representatives of all of those groups, related to activities in its review area for the purpose of achieving the objectives of this part.

(9) In the review of certificate of need applications, the department shall consider relevant written communications from any person.

(10) Before developing a recommendation on a certificate of need application, a regional certificate of need review agency shall hold a public hearing on the proposed project. If a regional certificate of need review agency has not been designated for the review area in which the proposed project will be located, the department may hold a public hearing on the proposed project, if the department determines that local interest merits a public hearing.

(11) A regional certificate of need review agency shall conduct all meetings regarding its activities for the purpose of achieving the objectives of this part in compliance with the open meetings act, Act No. 267 of the Public Acts of 1976, being sections 15.261 to 15.275 of the Michigan Compiled Laws.

(12) As used in this section, "review area" means a geographic area established for a health systems agency pursuant to former section 1511 of the public health service act, or a geographic area otherwise established by the commission for a regional certificate of need review agency, after consideration of the recommendations of the department and the office.

History: Add. 1988, Act 331, Eff. Oct. 1, 1988.

Popular name: Act 368

Administrative rules: R 325.9101 et seq. of the Michigan Administrative Code.

333.22227 Health maintenance organization; purposes for which certificate of need required; capital expenditures; considerations and criteria. [M.S.A. 14.15(22227)]

Sec. 22227. (1) A health maintenance organization is required to obtain a certificate of need only for 1 or more of the following purposes:

(a) The acquisition of, purchase of, new construction of, modernization of, replacement of, or addition to a hospital or other health facility providing inpatient services, if a covered capital expenditure is required.

(b) The initiation, replacement, or expansion of a covered clinical service.

(2) A covered capital expenditure proposed to be undertaken by a health maintenance organization that is not intended principally to serve the needs of the enrollees of the health maintenance organization, as determined by the department, is subject to this part.

(3) In making determinations and conducting reviews for certificates of need for health maintenance

organizations, the department shall consider the special needs and circumstances of health maintenance organizations, and shall apply all of the following criteria:

(a) The availability of the proposed service from a provider of health care other than the health maintenance organization on a long-term basis, at reasonable terms, and in a cost-effective manner consistent with the health maintenance organization's basic method of operation.

(b) The long-term needs of the health maintenance organization, and its current and expected future membership.

(c) The long-term impact of the proposed service on health care costs in the health maintenance organization's service area.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22229 Projects and services subject to comparative review; exceptions; establishment of comparative review or alternative procedure; proposed site for project; utilization and financing of covered clinical services. [M.S.A. 14.15(22229)]

Sec. 22229. (1) The following proposed projects are subject to comparative review:

(a) Proposed projects specified as subject to comparative review in a certificate of need review standard.

(b) New beds in a health facility that is a hospital, hospital long-term care unit, or nursing home if there are multiple applications to meet the same need for projects that, when combined, exceed the need of the planning area as determined by the applicable certificate of need review standards.

(2) Replacement beds in a hospital that are proposed for construction on the original site, on a contiguous site, within a 5-mile radius of the original site if the hospital is located in a county with a population of less than 200,000, or within a 2-mile radius of the original site if the hospital is located in a county with a population of 200,000 or more, are not subject to comparative review.

(3) Replacement beds in a nursing home that is located in a nonrural county that are proposed for construction on the original site, on a contiguous site, or within a 2-mile radius of the original site are not subject to comparative review. Replacement beds in a nursing home that is located in a rural county that are proposed for construction on the original site, on a contiguous site, or within the same planning area are not subject to comparative review.

(4) The commission may approve certificate of need review standards that establish comparative review or an alternative procedure for determining whether 1 or more of several qualified applicants may be approved if the level of need is not sufficient to justify approval of all qualified applicants. If an applicant involves more than 1 health facility, the applicant shall indicate on the application the proposed site or sites for the project and arrangements for the utilization and financing of the covered clinical services.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22230 Participation in medicaid program as distinct criterion. [M.S.A. 14.15(22230)]

Sec. 22230. In evaluating applications for a health facility as defined under section 22205(1)(c) in a comparative review, the department shall include participation in title XIX of the social security act, 42 U.S.C. 1396 to 1396d, 1396f to 1396s, as a distinct criterion, weighted as very important, and determine the degree to which an application meets this criterion based on the extent of participation in the medicaid program.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988.

Popular name: Act 368

333.22231 Decision to grant or deny application for certificate of need; conditions; single decision for all applications; proposed decision; final decision; notice of reversal; hearing; judicial review; review and appeal under former law and rules; effect of exceeding time frames. [M.S.A. 14.15(22231)]

Sec. 22231. (1) The decision to grant or deny an application for a certificate of need shall be made by the director. A decision shall be proposed to the director by a bureau within the department designated by the director as responsible for the certificate of need program. A decision shall be in writing and shall

indicate 1 of the following:

- (a) Approval of the application.
 - (b) Disapproval of the application.
 - (c) Subject to subsection (2), approval of the application with conditions.
 - (d) If agreed to by the department and the applicant, approval of the application with stipulations.
- (2) If an application is approved with conditions pursuant to subsection (1)(c), the conditions shall be explicit, shall be related to the proposed project or to the applicable provisions of this part, and shall specify a time, not to exceed 1 year after the date the decision is rendered, within which the conditions shall be met.
- (3) If the department is conducting a comparative review, the director shall issue only 1 decision for all of the applications included in the comparative review.
- (4) Before a final decision on an application is made, the bureau of the department designated by the director as responsible for the certificate of need program shall issue a proposed decision with specific findings of fact in support of the proposed decision with regard to each of the criteria listed in section 22225. The proposed decision also shall state with specificity the reasons and authority of the department for the proposed decision. If a proposed decision is issued within the application review period specified in the rules promulgated under former part 221, the department is in compliance with the review period requirement of those rules. The department shall transmit a copy of the proposed decision to the applicant.
- (5) The proposed decision shall be submitted to the director on the same day the proposed decision is issued.
- (6) If the proposed decision is other than an approval without conditions or stipulations, the director shall issue a final decision not later than 60 days after the date a proposed decision is submitted to the director unless the applicant has filed a request for a hearing on the proposed decision. If the proposed decision is an approval, the director shall issue a final decision not later than 5 days after the proposed decision is submitted to the director.
- (7) The director shall review the proposed decision before a final decision is rendered.
- (8) If a proposed decision is an approval, and if, upon review, the director reverses the proposed decision, the director immediately shall notify the applicant of the reversal. Within 15 days after receipt of the notice of reversal, the applicant may request a hearing under section 22232. After the hearing, the applicant may request the director to reconsider the reversal of the proposed decision, based on the results of the hearing.
- (9) The final decision of the director may be appealed only by the applicant and only on the record directly to the circuit court for the county where the applicant has its principal place of business in this state or the circuit court for Ingham county. Judicial review is governed by sections 103 to 106 of the administrative procedures act of 1969, Act No. 306 of the Public Acts of 1969, being sections 24.303 to 24.306 of the Michigan Compiled Laws.
- (10) The review and appeal of a certificate of need application submitted with the required filing fee before October 1, 1988 shall be conducted under former part 221 and the rules promulgated under that part. The certificate of need board created by former section 22121(2) shall continue for the purpose of performing the functions vested in it by former part 221, until all appeals lawfully brought under former part 221 are concluded.
- (11) If the department exceeds the time frames set forth in this section for other than good cause, as determined by the commission, upon the written request of an applicant, the department shall return to the applicant all of the certificate of need application fee paid by the applicant under section 20161(2).

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22232 Hearing; written request; appointment and duties of hearing officer; governing law. [M.S.A. 14.15(22232)]

Sec. 22232. (1) The applicant may, within 15 days after receipt by the applicant of the bureau's proposed decision to deny the application or receipt of notice of reversal by the director of a proposed decision that is an approval, submit a written request for a hearing to demonstrate that the application filed by the applicant meets the requirements for approval under this part.

- (2) The department shall appoint a hearing officer for a hearing held under this section. The hearing

officer shall establish a schedule for the hearing, control the presentation of proofs, and take such other action determined by the hearing officer to be necessary to ensure that the hearing is conducted in an expeditious manner and completed within a reasonable period of time. The hearing officer shall convene the hearing within 90 days after receipt of a request for a hearing under this section. Upon written request by a party, a hearing officer may issue subpoenas requiring the attendance and testimony of witnesses and the production of evidence. The department shall establish appropriate qualifications for hearing officers appointed under this section.

(3) If a hearing is requested under this section, chapter 4 of the administrative procedures act of 1969, Act No. 306 of the Public Acts of 1969, being sections 24.271 to 24.287 of the Michigan Compiled Laws, governs.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22233 Waiver of criteria and procedures. [M.S.A. 14.15(22233)]

Sec. 22233. If the department determines that a proposed project is nonsubstantive in nature and does not warrant a full review, the department may waive certain criteria and procedures otherwise required under this part.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988.

Popular name: Act 368

333.22235 Waiver of law and procedural requirements and criteria for review; affidavit; emergency certificate of need. [M.S.A. 14.15(22235)]

Sec. 22235. (1) The department may waive otherwise applicable provisions of this part and procedural requirements and criteria for review upon a showing by the applicant, by affidavit, of all of the following:

(a) The necessity for immediate or temporary relief due to natural disaster, fire, unforeseen safety consideration, or other emergency circumstances.

(b) The serious adverse effect of delay on the applicant and the community that would be occasioned by compliance with the otherwise applicable requirements of this part and rules promulgated under this part.

(c) The lack of substantial change in facilities or services that existed before the emergency circumstances established under subdivision (a).

(d) The temporary nature of the construction of facilities or the services that will not preclude different disposition of longer term determinations in a subsequent application for a certificate of need not made under this section.

(2) The department may issue an emergency certificate of need after necessary and appropriate review. A record of the review shall be made, including copies of affidavits and other documentation. Findings and conclusions shall be made as to an application for an emergency certificate of need, whether the emergency certificate of need is issued or denied.

(3) An emergency certificate of need issued under this section is subject to special limitations and restrictions, in regard to duration and right of extension or renewal and other factors, imposed by the department.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988.

Popular name: Act 368

333.22237 Data and statistics as condition precedent to issuance of certificate of need. [M.S.A. 14.15(22237)]

Sec. 22237. As a condition precedent to the issuance of a certificate of need, the department may require that a health facility provide the department with data and statistics determined necessary by the department to carry out departmental duties required under this part, if the data and statistics have not already been reported to the department in a usable format.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988.

Popular name: Act 368

333.22239 Stipulation. [M.S.A. 14.15(22239)]

Sec. 22239. A certificate of need ceases to be effective if the certificate of need approval was based on a stipulation that the project would participate in title XIX and the project has not participated in title XIX for not less than 12 consecutive months within the first 2 years of operation. A stipulation described in this section is germane to all health facility projects.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22241 “New technology” defined; new technology review period; conditions to acquisition of new technology before end of review period; appointment, composition, and purpose of standing new medical technology advisory committee. [M.S.A. 14.15(22241)]

Sec. 22241. (1) For purposes of this section and sections 22243 and 22245, “new technology” means medical equipment that requires, but has not yet been granted, the approval of the federal food and drug administration for commercial use.

(2) The period ending 12 months after the date of federal food and drug administration approval of new technology for commercial use shall be considered the new technology review period. A person shall not acquire new technology before the end of a new technology review period, unless 1 of the following occurs:

(a) The department, with the concurrence of the commission, issues a public notice that the new technology will not be added to the list of covered medical equipment during the new technology review period. The notice may apply to specific new technology or classes of new technology.

(b) The person complies with the requirements of section 22243.

(c) The commission approves the addition of the new technology to the list of covered medical equipment, and the person obtains a certificate of need for that covered medical equipment.

(3) To assist in the identification of new medical technology or new medical services that may be appropriate for inclusion as a covered clinical service in the earliest possible stage of its development, the commission shall appoint a standing new medical technology advisory committee. A majority of the new medical technology advisory committee shall be representatives of health care provider organizations concerned with licensed health facilities or licensed health professions and other persons knowledgeable in medical technology. The commission also shall appoint representatives of health care consumer, purchaser, and third party payer organizations to the committee.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22243 Acquisition of new technology before approval of federal food and drug administration; notice; requirements; deactivation and removal of new technology from service; conditions to utilizing new technology beyond specified period. [M.S.A. 14.15(22243)]

Sec. 22243. (1) Unless the commission provides otherwise in a standard approved under section 22215(1)(h), a person may acquire new technology before the new technology is approved by the federal food and drug administration if the person notifies the department before acquiring the new technology, and the acquisition of the new technology continuously meets all of the following requirements:

(a) Has been authorized by the federal food and drug administration under an investigational device exemption and approved research project pursuant to 21 C.F.R. part 812.

(b) Is operated consistently with the research protocols established and approved by the federal food and drug administration for the investigational device exemption.

(c) Is solely related to research and testing for purposes of determining the safety and effectiveness of the new technology for use on human subjects.

(d) Is funded so that there will be no recovery of either capital or operating expenses for the use of the new technology either from patients or from third party payers. However, usual and customary charges or other payment arrangements for related services rendered to patients that are consistent with standard nonexperimental treatment, including, but not limited to, room, board, ancillary services, and outpatient services may be charged to patients or third party payers, or both, in accordance with normal billing practices. Each patient upon whom the new technology is used shall be informed of the requirements of this subdivision.

(e) Is maintained under a separate cost center that includes overhead costs, for expenditure reporting

related to the research project.

(f) Is developed so that capital funding for the research project will be obtained from sources other than the Michigan state hospital finance authority or any other governmentally supported financing source. This subdivision does not prohibit a person from using grants for research activities.

(g) Is operated so as to provide, upon request of the department, data obtained from the research project that the department may use in developing certificate of need review standards relative to the new technology. Aggregate data obtained as part of a federally approved data set shall meet the requirements of this part, except that supplemental data may be requested by the department.

(h) Is not marketed or advertised to other health care providers or the public.

(2) A person acquiring new technology under this section shall deactivate and remove the new technology from service on the date of notice that federal approval under the investigational device exemption for the new technology acquired under 21 C.F.R. part 812 has expired or been withdrawn, or the date of receipt of a department compliance order alleging a violation of this section.

(3) A person may continue to utilize new technology acquired under this section beyond the period specified in subsection (2) if any 1 of the following applies:

(a) The continued use is in compliance with section 22243(1)(d) to (h).

(b) The department issues a notice that the new technology will not be added to the list of covered medical equipment pursuant to section 22241(2)(a).

(c) The commission adds the new technology to the list of covered medical equipment, and the continued use is consistent with applicable certificate of need review standards, if any.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988.

Popular name: Act 368

333.22247 Monitoring compliance with certificates of need; investigating allegations of noncompliance; violation; sanctions; refund of charges. [M.S.A. 14.15(22247)]

Sec. 22247. (1) The department may monitor compliance with certificates of need issued under this part and shall investigate allegations of noncompliance with a certificate of need or this part.

(2) If the department determines that the recipient of a certificate of need under this part is not in compliance with the terms of the certificate of need or that a person is in violation of this part or the rules promulgated under this part, the department may do 1 or more of the following:

(a) Revoke or suspend the certificate of need.

(b) Impose a civil fine of not more than the amount of the billings for the services provided in violation of this part.

(c) Take any action authorized under this article for a violation of this article or a rule promulgated under this article, including, but not limited to, issuance of a compliance order under section 20162(5), whether or not the person is licensed under this article.

(d) Request enforcement action under section 22253.

(e) Take any other enforcement action authorized by this code.

(f) Publicize or report the violation or enforcement action, or both, to any person.

(3) A person shall not charge to, or collect from, another person or otherwise recover costs for services provided or for equipment or facilities that are acquired in violation of this part. If a person has violated this subsection, in addition to the sanctions provided under subsection (2), the person shall, upon request of the person from whom the charges were collected, refund those charges, either directly or through a credit on a subsequent bill.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

333.22249 Agreement authorizing hospital to lease space and operate beds in another hospital; conditions. [M.S.A. 14.15(22249)]

Sec. 22249. (1) Subject to subsection (2), if a hospital has a high occupancy rate, as determined by the department, and if the hospital applies for and is issued a certificate of need for an increase in licensed bed capacity, the department may enter into an agreement with the hospital that would authorize the hospital to lease space and operate beds in another hospital in the same planning area, if the other hospital has a low occupancy rate, as determined by the department.

(2) The department may enter into an agreement authorized under subsection (1) only if all of the

following apply:

- (a) The hospital issued a certificate of need has a documented history of high occupancy.
- (b) The alternative of redistributing the beds within the hospital's licensed bed capacity does not exist.
- (c) The agreement will not change the overall supply of beds within the planning area.
- (d) New construction is not required.
- (e) The department determines that the agreement is necessary to protect the public health, safety, and welfare.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988.

Popular name: Act 368

333.22251 Repealed. 1993, Act 88, Imd. Eff. July 9, 1993. [M.S.A. 14.15(22251)]

Compiler's note: The repealed section pertained to plans for reduction of excess hospital beds.

Popular name: Act 368

333.22253 Injunction or other process to restrain or prevent violation. [M.S.A. 14.15(22253)]

Sec. 22253. Notwithstanding the existence and pursuit of any other remedy, the department may request the attorney general or prosecuting attorney of the jurisdiction where a capital expenditure is proposed to be or was made to bring an action in the name of the people of this state for an injunction or other process against a person to restrain or prevent a violation of this part or the rules promulgated under this part.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988.

Popular name: Act 368

333.22255 Rules. [M.S.A. 14.15(22256)]

Sec. 22255. (1) The department, with the approval of the commission, may promulgate procedural rules to implement this part.

(2) Pursuant to section 31 of the administrative procedures act of 1969, Act No. 306 of the Public Acts of 1969, being section 24.231 of the Michigan Compiled Laws, rules promulgated by the department under former part 221 shall remain in effect for review and appeal of applications submitted under former part 221 and for this part until amended or rescinded by the department or as a result of this part.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988.

Popular name: Act 368

333.22257 Certificate of need issued under former part 221. [M.S.A. 14.15(22257)]

Sec. 22257. A certificate of need issued under former part 221 has the same effect as a similar certificate of need issued under this part. The holder of the certificate of need is subject to all of the conditions, stipulations, and agreements pertaining to the certificate of need and to the same authority of the department to limit, suspend, revoke, or reinstate the certificate of need as a holder of a certificate of need issued under this part.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988.

Popular name: Act 368

333.22260 Reports of reviews; preparation and publication; statements; recommendations; public examination of applications and written materials on file. [M.S.A. 14.15(22260)]

Sec. 22260. (1) The department shall prepare and publish at least annually reports of reviews conducted under this part. The reports shall include a statement on the status of each pending review and a statement as to each review completed, including statements of the findings and decisions made in the course of the reviews since the last report, and the recommendations of regional certificate of need review agencies.

(2) The department and, if applicable, the appropriate regional certificate of need review agency shall make available to the public for examination during all business hours the applications received by them and pertinent written materials on file.

History: Add. 1988, Act 332, Eff. Oct. 1, 1988;—Am. 1993, Act 88, Imd. Eff. July 9, 1993.

Popular name: Act 368

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