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.


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 MCL 330.3101 of the Michigan Compiled Laws.

Popular name: Act 368

333.22203 Definitions; A to F.

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 to obtain a health facility, licensed part of a health facility, or equipment for a health facility, if the actual purchase of a health facility, licensed part of a health facility, or equipment for a health facility would have been considered a capital expenditure under this part. 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 under 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.

(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 $2,500,000.00 or more, as adjusted annually 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.

(10) "Covered clinical service", except as modified by the commission under section 22215, 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 or expansion of a specialized psychiatric program for children and adolescent patients utilizing licensed psychiatric beds.

(d) 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.


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 or psychiatric unit 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 community health.

(3) "Initiate” means the offering of a covered clinical service that has not been offered in compliance with this part or former part 221 on a regular basis at that location 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.


Popular name: Act 368

333.22207 Definitions; M to S.

Sec. 22207. (1) "Medicaid” means the program for medical assistance administered by the department of community health under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b.

(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 statistical area or micropolitan statistical areas as those terms are defined under the "standards for defining metropolitan and micropolitan statistical areas" by the statistical policy office of the Office of Information and Regulatory Affairs of the United States Office of Management and Budget, 65 F.R. p. 82238 (December 27, 2000).

(8) "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.


Popular name: Act 368

333.22208 Definitions; T.

Sec. 22208. (1) "Title XVIII" means title XVIII of the social security act, 42 USC 1395 to 1395kkk-1.

(2) "Title XIX" means title XIX of the social security act, chapter 531, 49 Stat. 620, 42 USC 1396 to 1396w-5.


Popular name: Act 368

333.22209 Activities requiring certificate of need; exceptions; requirements; acquisition of existing health facility; relocation; "sharing agreement" defined.

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) Subject to subsection (9) and if the relocation does not result in an increase of licensed beds within that health service area, a certificate of need is not required for any of the following:

(a) The physical relocation of licensed beds from a hospital site licensed under part 215 to another hospital site licensed under the same license as the hospital seeking to transfer the beds if both hospitals are located within a 2-mile radius of each other.

(b) Subject to subsections (7) and (8), the physical relocation of licensed beds from a hospital licensed under part 215 to a freestanding surgical outpatient facility licensed under part 208 if that freestanding surgical outpatient facility satisfies each of the following criteria on December 2, 2002:

(i) Is owned by, is under common control of, or has as a common parent the hospital seeking to relocate its licensed beds.

(ii) Was licensed prior to January 1, 2002.

(iii) Provides 24-hour emergency care services at that site.

(iv) Provides at least 4 different covered clinical services at that site.

(c) Subject to subsections (7) and (8), the physical relocation of licensed beds from a hospital licensed under part 215 to another hospital licensed under part 215 within the same health service area if the hospital receiving the licensed beds is owned by, is under common control of, or has as a common parent the hospital seeking to relocate its licensed beds.

(4) Subject to subsection (5), a hospital licensed under part 215 is not required to obtain a certificate of need to provide 1 or more of the covered clinical services listed in section 22203(10) in a federal veterans health care facility or to use long-term care unit beds or acute care beds that are owned and located in a federal veterans health care facility if the hospital satisfies each of the following criteria:

(a) The hospital has an active affiliation or sharing agreement with the federal veterans health care facility.
(b) The hospital has physicians who have faculty appointments at the federal veterans health care facility or has an affiliation with a medical school that is affiliated with a federal veterans health care facility and has physicians who have faculty appointments at the federal veterans health care facility.

(c) The hospital has an active grant or agreement with the state or federal government to provide 1 or more of the following functions relating to bioterrorism:

(i) Education.

(ii) Patient care.

(iii) Research.

(iv) Training.

(5) A hospital that provides 1 or more covered clinical services in a federal veterans health care facility or uses long-term care unit beds or acute care beds located in a federal veterans health care facility under subsection (4) may not utilize procedures performed at the federal veterans health care facility to demonstrate need or to satisfy a certificate of need review standard unless the covered clinical service provided at the federal veterans health care facility was provided under a certificate of need.

(6) If a hospital licensed under part 215 had fewer than 70 licensed beds on December 1, 2002, that hospital is not required to satisfy the minimum volume requirements under the certificate of need review standards for its existing operating rooms as long as those operating rooms continue to exist at that licensed hospital site.

(7) Before relocating beds under subsection (3)(b), the hospital seeking to relocate its beds shall provide the information requested by the department of consumer and industry services that will allow the department of consumer and industry services to verify the number of licensed beds that were staffed and available for patient care at that hospital as of December 2, 2002. A hospital shall transfer no more than 35% of its licensed beds to another hospital or freestanding surgical outpatient facility under subsection (3)(b) or (c) not more than 1 time after the effective date of the amendatory act that added this subsection if the hospital seeking to relocate its licensed beds or another hospital owned by, under common control of, or having as a common parent the hospital seeking to relocate its licensed beds is located in a city that has a population of 750,000 or more.

(8) The licensed beds relocated under subsection (3)(b) or (c) shall not be included as new beds in a hospital or as a new hospital under the certificate of need review standards for hospital beds. One of every 2 beds transferred under subsection (3)(b) up to a maximum of 100 shall be beds that were staffed and available for patient care as of December 2, 2002. A hospital relocating beds under subsection (3)(b) shall not reactivate licensed beds within that hospital that were unstaffed or unavailable for patient care on December 2, 2002 for a period of 5 years after the date of the relocation of the licensed beds under subsection (3)(b).

(9) No licensed beds shall be physically relocated under subsection (3) if 7 or more members of the commission, after the appointment and confirmation of the 6 additional commission members under section 22211 but before June 15, 2003, determine that relocation of licensed beds under subsection (3) may cause great harm and detriment to the access and delivery of health care to the public and the relocation of beds should not occur without a certificate of need.

(10) 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.

(11) An applicant seeking a certificate of need for the relocation or replacement of an existing health facility may file a single, consolidated application for the certificate of need if the project does not result in an increase of licensed beds or the initiation, expansion, or replacement of a covered clinical service. A person relocating or replacing an existing health facility is subject to the applicable certificate of need review standards in effect on the date of the relocation or replacement of the health facility.

(12) As used in this section, “sharing agreement” means a written agreement between a federal veterans health care facility and a hospital licensed under part 215 for the use of the federal veterans health care facility and a hospital licensed under part 215 for the use of the federal veterans health care facility.
333.22210 Certificate of need for extended care services program; application; criteria; modification; fee prohibited; compliance; discrimination prohibited; exercise of rights; written acknowledgment; forms; additional rights; violation; penalty; certificate required; definitions.

Sec. 22210. (1) Subject to this section, 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 an extended care services program with up to 10 licensed hospital beds:

(a) Is eligible to apply for certification as a provider of extended care services through the use of swing beds under section 1883 of title XVIII, 42 USC 1395tt.

(b) Subject to subsection (2), has fewer than 100 licensed beds not counting beds excluded under section 1883 of title XVIII, 42 USC 1395tt.

(c) Does not have uncorrected licensing, certification, or safety deficiencies for which the department or the bureau of fire services created in section 1b of the fire prevention code, 1941 PA 207, MCL 29.1b, 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 an extended care services program.

(3) A hospital that is granted a certificate of need for an extended care services 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 extended care services program that exceeds the length of time allowed for post-hospital extended care under title XVIII.

(b) Admit patients to the extended care services program only pursuant to an admissions contract approved by the department.

(c) Subject to subdivision (f), 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 extended care services 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 extended care services program, for all of the purposes described in section 21763.

(e) Not allow the number of patient days for the extended care services program to exceed the equivalent of 1,825 patient days for a single state fiscal year.

(f) Not provide extended care services in a swing bed if the hospital owns or operates a hospital long-term care unit that has beds available at the time a patient requires admission for extended care services.

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

(h) Assist a patient who has been denied coverage for services received in an extended care services 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 extended care services program pursuant to this section and the provisions of section 1883 of title XVIII, 42 USC 1395tt, that are applicable to the extended care services program.

(j) Provide data to the department considered necessary by the department to evaluate the extended care services program. The data shall include, but not be limited to, all of the following:

(i) The total number of patients admitted to the hospital’s extended care services program during the period specified by the department.

(ii) The total number of extended care services patient days for the period specified by the department.

(iii) Information identifying the type of care to which patients in the extended care services program are released.

(k) As part of the hospital’s policy describing the rights and responsibilities of patients admitted to the facilities.
hospital, as required under section 20201, incorporate all of the following additional rights and responsibilities for patients in the extended care services program:

(i) A copy of the hospital’s policy shall be provided to each extended care services patient upon admission, and the staff of the hospital shall be trained and involved in the implementation of the policy.

(ii) Each extended care services 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 extended care services patients to receive visitors. An extended care services 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 an extended care services patient who shares a room with another extended care services patient. Each extended care services patient shall have reasonable access to a telephone.

(iii) An extended care services 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) An extended care services patient is entitled to the opportunity to participate in the planning of his or her medical treatment, including the development of the discharge plan under subdivision (m). An extended care services patient shall be fully informed by the attending physician of the extended care services patient’s medical condition, unless medically contraindicated, as documented by a physician in the medical record. Each extended care services patient shall be afforded the opportunity to discharge himself or herself from the extended care services program.

(v) An extended care services 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 an extended care services 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) An extended care services patient has the right to have his or her parents, if the extended care services patient is a minor, or his or her spouse, next of kin, or patient’s representative, if the extended care services patient is adult, stay at the hospital 24 hours a day if the extended care services patient is considered terminally ill by the physician responsible for the extended care services patient’s care.

(viii) Each extended care services 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 extended care services patient has the right to receive a representative of an organization approved under section 21764, for all of the purposes described in section 21763.

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

(m) Establish a discharge plan for each extended care services patient who is admitted to the extended care services program. In the discharge plan, the hospital shall emphasize patient choice in receiving extended care services in the most appropriate and least restrictive setting. The hospital shall provide to the patient or his or her authorized representative a copy of the discharge plan not later than 3 days after the patient is admitted to the extended care services program.

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

(5) In the case of an extended care services patient, the rights described in subsection (3)(k)(iv) may be exercised by the patient’s representative, as defined in section 21703(2).

(6) An extended care services patient shall be fully informed, as evidenced by the extended care services 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 an extended care services 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 extended care services patient. The hospital shall provide proper forms for the extended care services 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 extended care services patients.

(8) A hospital that violates subsection (3) is subject to the penalty provisions of section 20165.
(9) A person shall not initiate an extended care services program without first obtaining a certificate of need under this section.

(10) As used in this section:

(a) "Extended care services program" means a program by a hospital to provide extended care services to a patient through the use of swing beds under section 1883 of title XVIII, 42 USC 1395tt.

(b) "Hospital long-term care unit" means that term as defined in section 20106.


Compiler's note: For transfer of powers and duties of state fire marshal to department of labor and economic growth, bureau of construction codes and fire safety, by type II transfer, see E.R.O. No. 2003-1, compiled at MCL 445.2011.

Popular name: Act 368

333.22211 Certificate of need commission; creation; appointment, qualifications, and terms of members; vacancy; laws to which commission members subject.

Sec. 22211. (1) The certificate of need commission is created in the department. The commission consists of 11 members appointed by the governor with the advice and consent of the senate. The governor shall not appoint more than 6 members from the same major political party and shall appoint 5 members from another major political party. The commission consists of the following 11 members:

(a) Two individuals representing hospitals.
(b) One individual representing physicians licensed under part 170 to engage in the practice of medicine.
(c) One individual representing physicians licensed under part 175 to engage in the practice of osteopathic medicine and surgery.
(d) One individual who is a physician licensed under part 170 or 175 representing a school of medicine or osteopathic medicine.
(e) One individual representing nursing homes.
(f) One individual representing nurses.
(g) One individual representing a company that is self-insured for health coverage.
(h) One individual representing a company that is not self-insured for health coverage.
(i) One individual representing a nonprofit health care corporation operating pursuant to the nonprofit health care corporation reform act, 1980 PA 350, MCL 550.1101 to 550.1704, or a nonprofit mutual disability insurer into which a nonprofit health care corporation has merged as provided in section 5805(1) of the insurance code of 1956, 1956 PA 218, MCL 500.5805.
(j) One individual representing organized labor unions in this state.

(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 and of the various geographic regions.

(3) A member of the commission shall serve for a term of 3 years or until a successor is appointed. A vacancy on the commission shall be filled for the remainder of the unexpired term in the same manner as the original appointment.

(4) Commission members are subject to the following:

(a) 1968 PA 317, MCL 15.321 to 15.330.
(b) 1973 PA 196, MCL 15.341 to 15.348.
(c) 1978 PA 472, MCL 4.411 to 4.431.


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.

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 3 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 at least 2 full-time administrative employees, secretarial staff, 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. The department shall make available a brief summary of the actions taken by the commission.

(8) The department shall assign at least 2 full-time professional employees to staff the commission to assist the commission in the performance of its substantive responsibilities under this part.


Popular name: Act 368

333.22215 Duties of commission; purpose; public hearing before final action; submission of proposed final action to joint committee; approval or disapproval; review standards; revision of fees.

Sec. 22215. (1) 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) Develop, 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). Except for nursing home and hospital long-term care unit bed review standards, by January 1, 2004, the commission shall revise all certificate of need review standards to include a requirement that each applicant participate in title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and 1396r-8 to 1396v.

(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 January 1, 2005, and every 2 years thereafter, make recommendations to the joint committee 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) Develop, 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) If the commission determines it necessary, appoint standard advisory committees to assist in the development of proposed certificate of need review standards. A standard advisory committee shall complete
its duties under this subdivision and submit its recommendations to the commission within 6 months unless a shorter period of time is specified by the commission when the standard advisory committee is appointed. An individual shall serve on no more than 2 standard advisory committees in any 2-year period. The composition of a standard advisory committee shall not include a lobbyist registered under 1978 PA 472, MCL 4.411 to 4.431, but shall include all of the following:

(i) Experts with professional competence in the subject matter of the proposed standard, who shall constitute a 2/3 majority of the standard 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.

(m) In addition to subdivision (b), review and, if necessary, revise each set of certificate of need review standards at least every 3 years.

(n) If a standard advisory committee is not appointed by the commission and the commission determines it necessary, submit a request to the department to engage the services of private consultants or request the department to contract with any private organization for professional and technical assistance and advice or other services to assist the commission in carrying out its duties and functions under this part.

(o) Within 6 months after the appointment and confirmation of the 6 additional commission members under section 22211, develop, approve, or revise certificate of need review standards governing the increase of licensed beds in a hospital licensed under part 215, the physical relocation of hospital beds from 1 licensed site to another geographic location, and the replacement of beds in a hospital licensed under part 215.

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

(a) The availability and accessibility of quality health services at a reasonable cost and within a reasonable geographic proximity for all people in this 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), (h), or (o), 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), (h), or (o), the commission chairperson shall submit the proposed action and a concise summary of the expected impact of the proposed action for comment to each member of the joint committee. The commission shall inform the joint committee of the date, time, and location of the next meeting regarding the proposed action. The joint committee shall promptly review the proposed action and submit its recommendations and concerns to the commission.

(4) The commission chairperson shall submit the proposed final action including a concise summary of the expected impact of the proposed final action to the governor and each member of the joint committee. 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), (h), or (o) 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) The commission shall not develop, approve, or revise a certificate of need review standard that requires the payment of money or goods or the provision of services unrelated to the proposed project as a condition that must be satisfied by a person seeking a certificate of need 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. This subsection does not preclude the requirement that each applicant participate in title XIX of the social security act, chapter 531, 49 Stat. 620, 1396r-6 and 1396r-8 to 1396v, or a requirement that each applicant provide covered clinical services to all patients regardless of his or her ability to pay.

(6) If the reports received under section 22221(f) indicate that the certificate of need application fees collected under section 20161 have not been within 10% of 3/4 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 3/4 of the cost to the department of implementing this part.

(7) As used in this section, “joint committee” means the joint committee created under section 22219.


Popular name: Act 368


Compiler's note: The repealed section pertained to certificate of need review standards.

Popular name: Act 368

333.22219 Joint legislative committee.

Sec. 22219. (1) A joint legislative committee to focus on proposed actions of the commission regarding the certificate of need program and certificate of need standards and to review other certificate of need issues is created. The joint committee shall consist of 6 members as follows:

(a) The chairperson of the senate committee on health policy.
(b) The vice-chairperson of the senate committee on health policy.
(c) The minority vice-chairperson of the senate committee on health policy.
(d) The chairperson of the house of representatives committee on health policy.
(e) The vice-chairperson of the house of representatives committee on health policy.
(f) The minority vice-chairperson of the house of representatives committee on health policy.

(2) The joint committee shall be co-chaired by the chairperson of the senate committee on health policy and the chairperson of the house committee on health policy.

(3) The joint committee may administer oaths, subpoena witnesses, and examine the application, documentation, or other reports and papers of an applicant or any other person involved in a matter properly before the committee.

(4) The joint committee shall review the recommendations made by the commission under section 22215(6) regarding the revision of the certificate of need application fees and submit a written report to the legislature outlining the costs to the department to implement the program, the amount of fees collected, and its recommendation regarding the revision of those fees.

(5) The joint committee may develop a plan for the revision of the certificate of need program. If a plan is developed by the joint committee, the joint committee shall recommend to the legislature the appropriate statutory changes to implement the plan.


Popular name: Act 368

333.22221 Duties of department generally.

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

(a) Subject to approval by the commission, 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 the review of certificate of need applications, the department shall consider relevant written communications from any person.
(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) By October 1, 2003, 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 in the immediately preceding state fiscal year.
(g) Beginning January 1, 2003, annually adjust the $2,500,000.00 threshold 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.
(h) Annually review the application process, including all forms, reports, and other materials that are required to be submitted with the application. If needed to promote administrative efficiency, revise the forms, reports, and any other materials required with the application.
Within 6 months after the effective date of the amendatory act that added this subdivision, create a consolidated application for a certificate of need for the relocation or replacement of an existing health facility.

In consultation with the commission, define single project as it applies to capital expenditures.


### 333.22223 Application for certificate of need; statement addressing review criteria.

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.


### 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) due to the performance of abortions at that facility is not required to obtain a certificate of need in order to be granted a license as a freestanding surgical outpatient facility. However, a health facility described in this subsection is subject to this part for the services performed at that facility other than abortions.

(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.

(3) As used in this section, "abortion" means that term as defined in section 17015.


### 333.22224a Magnetic resonance image units.

Sec. 22224a. (1) A person seeking to initiate, expand, replace, relocate, or acquire a fixed or mobile magnetic resonance imager service within a county that has a population of more than 160,000 but does not have at least 2 magnetic resonance imager units may file a letter of intent with the department prior to the initiation, expansion, replacement, relocation, or acquisition of a fixed or mobile magnetic resonance imager unit within that county instead of obtaining a certificate of need.

(2) Within 30 days after receiving the letter of intent, if the department verifies that the county has a population of more than 160,000 and that the county does not already have 2 magnetic resonance imager units, the department shall send a written acknowledgment to the person approving the initiation, expansion, replacement, relocation, or acquisition of a fixed or mobile magnetic resonance imager unit.

(3) A person shall not initiate, expand, replace, relocate, or acquire a fixed or mobile magnetic resonance imager unit under this section without a certificate of need unless that person receives a written acknowledgment of approval from the department under subsection (2).

(4) A person seeking to initiate, expand, replace, relocate, or acquire a fixed or mobile magnetic resonance imager service under this section shall be a nonprofit organization and shall demonstrate that the service shall be accessible to all patients regardless of his or her ability to pay and shall participate in title XIX of the social security act, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to 1396r-8 to 1396v.


### 333.22225 Demonstration of need for proposed project; additional requirements.

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.

(c) 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.

(d) 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.


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
The statement shall address each instance in which the director's decision is inconsistent with the recommendations of the regional certificate of need review agency, the department shall promptly provide the 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 for the review area in which the proposed project would be located, unless 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 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.

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) 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 the department determines that local interest merits a public hearing and a regional certificate of need review agency has not been designated for the review area in which the proposed project will be located, then the department shall hold a public hearing on the proposed project.

(10) 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, 1976 PA 267, MCL 15.261 to 15.275.

(11) 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.


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.

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.


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.

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 application the proposed site or sites for the project and arrangements for the utilization and financing of the covered clinical services.


Popular name: Act 368

333.22230 Participation in medicaid program as distinct criterion.

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, chapter 531, 49 Stat. 620, 42 U.S.C. 1396 to 1396r-6 and 1396r-8 to 1396v, 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.


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; effect of exceeding time frames.

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 under 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. 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) Within 30 days after the final decision of the director, 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 the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328.
If the department exceeds the time 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.


### 333.22232 Hearing; written request; appointment and duties of hearing officer; governing law.

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.


Popular name: Act 368

### 333.22233 Waiver of criteria and procedures.

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.


Popular name: Act 368

### 333.22235 Waiver of law and procedural requirements and criteria for review; affidavit; emergency certificate of need.

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 a final decision and the applicant is not required to submit a formal application for a second review. A certificate of need issued under this section may be subject to special limitations and restrictions, in regard to duration and right of extension or renewal and other factors, imposed by the department.


Popular name: Act 368
333.22237 Data and statistics as condition precedent to issuance of certificate of need.

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.


Popular name: Act 368

333.22239 Stipulation.

Sec. 22239. (1) 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 at least 12 consecutive months
within the first 2 years of operation or continued to participate annually thereafter, the department shall
revoke the certificate of need. A stipulation described in this section is germane to all health facility projects.

(2) The department shall monitor the participation in title XIX of each certificate of need applicant
approved under this part. Except as otherwise provided in subsection (3), the department shall require each
applicant to provide verification of participation in title XIX with its application and annually thereafter.

(3) The department shall not revoke or deny a certificate of need for a nursing home licensed under part
217 if that nursing home does not participate in title XIX on the effective date of the amendatory act that
added this subsection but agrees to participate in title XIX if beds become available. This section does not
prohibit a person from applying for and obtaining a certificate of need to acquire or begin operation of a
nursing home that does not participate in title XIX.


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.

Sec. 22241. (1) For purposes of this section and section 22243, “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. The commission shall also appoint faculty members
from schools of medicine, osteopathy, and nursing in this state.


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.

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.


Popular name: Act 368

333.22247 Monitoring compliance with certificates of need; investigating allegations of noncompliance; violation; sanctions; refund of charges.

Sec. 22247. (1) The department shall monitor compliance with all 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 shall 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.
(g) Take any other action as determined appropriate by the department.
(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.


**Popular name:** Act 368

### 333.22249 Agreement authorizing hospital to lease space and operate beds in another hospital; conditions.

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.


**Popular name:** Act 368


**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.

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.


**Popular name:** Act 368

### 333.22255 Procedural rules.

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


**Popular name:** Act 368

### 333.22257 Certificate of need issued under former part 221.

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.


**Popular name:** Act 368

### 333.22260 Reports of reviews; preparation and publication; statements; recommendations; public examination of applications and written materials on file; providing copies.

Sec. 22260. (1) The department shall prepare and publish monthly 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 shall make available to the public for examination during all business hours the...
applications received by them and pertinent written materials on file.

(3) The department, upon request, shall provide copies of an application or part of an application. The
department may charge a reasonable fee for the copies.


**Popular name:** Act 368