

CHAPTER 150

REGULATION OF HEALTH CARE INSTITUTIONS

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SUBCHAPTER I

DEFINITIONS AND GENERAL PROVISIONS

150.001 Definitions. In this chapter:

(1) "Ambulatory surgical facility" means a facility, not a part of a hospital, which provides surgical treatment to patients not requiring hospitalization, but does not include the offices of private physicians or dentists whether for individual or group practice.

(3) "Clinical equipment" means equipment required to perform diagnostic or therapeutic procedures.

(4) "Community-based residential facility" has the meaning ascribed in s. 50.01 (1) (a).

(5) "Department" means the department of health and social services.

(6) "Health care institutions" include hospitals, psychiatric hospitals, tuberculosis hospitals, nursing homes, kidney disease treatment centers, including free-standing hemodialysis units, ambulatory surgical facilities, health maintenance organizations, community-based residential facilities for more than 20 persons, home health agencies and other comparable facilities. "Health care institutions" do not include facilities operated solely as part of the practice of an independent practitioner, partnership, unincorporated medical group or service corporation as defined in s. 180.99.

(7) "Health maintenance organization" means a public or private organization organized under the laws of this state which provides or otherwise makes available to enrolled participants health care services, including at least the

following basic health care services: usual physician services, hospitalization, laboratory, X-ray, emergency and preventive services and out-of-area coverage; is compensated (except for copayments) for the provision of the basic health care services to enrolled participants on a predetermined periodic rate basis; and provides physicians' services primarily directly through physicians who are either employees or partners of the organization, or through arrangements with individual physicians or one or more groups of physicians, organized on a group practice or individual practice basis.

(8) "Home health agency" means an organization which offers a program of 2 or more health services in a client's residence or other community setting to people of all ages. Such services may include physician services, nursing services, physical therapy services, occupational therapy services, speech pathology services, home health aid-homemaker services, medically related social services, nutrition counseling services, laboratory services and medical supplies and equipment.

(9) "Hospital" has the meaning ascribed in s. 50.33 (1) but excluding those facilities exempted by s. 50.39 (3).

(10) "Nursing home" has the meaning provided in s. 50.01 (3).

(11) "State health planning and development agency" means the department, as designated under s. 140.82 (1).

(12) "Statewide health coordinating council" means the health policy council, as designated under s. 14.25.

(13) "Substate health planning agency" means a public or private nonprofit agency which meets the requirements of P.L. 93-641,

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and which has been designated as a health systems agency.

History: 1977 c. 29; 1979 c. 124, 221.

150.002 Liability limited. No officer, board member, employe or agent of the department or a substate health planning agency, nor any state employe, may incur personal liability for any action taken in good faith within such person's authority under law for the purpose of carrying out this chapter.

History: 1977 c. 29.

150.003 Rule-making authority. The department may promulgate rules for the administration of this chapter and set standards by rule to carry out this chapter.

History: 1977 c. 29.

150.004 Injunctions. Notwithstanding the existence of pursuit of any other remedy, the department may, upon the advice of the attorney general, maintain an action in the name of the state in the circuit court for injunction or other process against any person to restrain or enjoin the violation of this chapter or rules adopted under this chapter.

History: 1977 c. 29.

SUBCHAPTER II**CERTIFICATE OF NEED**

NOTE: Chapter 29, laws of 1977, which created this subchapter provides in section 1624e that subchapter II, as created by ch. 29, terminates on June 30, 1982, unless extended by legislation prior to that date.

150.01 Definitions. In this subchapter:

(1) (a) "Capital expenditure" means an expenditure by or on behalf of a health care institution which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance and which exceeds \$117,000 if health-related or \$150,000 if nonhealth-related. "Nonhealth-related expenditures" means expenditures for parking facilities; alteration or addition of plumbing, heating, cooling or electrical systems; and projects limited to nonpatient areas, such as gift shops, public waiting areas, cafeterias, dietary departments, central supply, maintenance, storage areas, medical libraries, chapels, laundries, housekeeping departments, medical records, classrooms, meeting rooms, administrative offices and such other projects as the department determines, by rule, to be nonhealth-related.

(b) The cost, if \$150,000 or less, of the studies, surveys, designs, plans, working drawings, specifications and other activities essential to the acquisition, improvement, expansion or

replacement of the plant and equipment with respect to which the capital expenditure is made shall be included in determining the amount of the capital expenditure. Transactions which are separated in time but are components of an overall plan for meeting patient care objectives shall, for purposes of this subsection, be viewed in their entirety without regard to their timing.

(c) The cost of predevelopment activities shall be included in determining the amount of the capital expenditure.

(1m) "Certificate of need" means a written authorization by the department for a person to implement the project under review.

(2) "Health services" mean clinically related services, including but not limited to diagnostic, treatment, rehabilitative, alcohol, drug abuse and mental health services.

(3) "Institutional health services" mean health services provided in or through health care institutions and includes the entities in or through which services are provided.

(4) "Obligation" means any enforceable contract which is entered into for the construction, leasing, acquisition or permanent financing of a capital asset. In this subsection, "acquisition" includes a change in ownership.

(5) "Person" means an individual, a trust or estate, a partnership, a corporation (including associations, joint stock companies and insurance companies), a state, or a political subdivision or instrumentality (including a municipal corporation) of a state.

(5m) (a) "Predevelopment activity" means:

1. Any activity involving an expenditure by or on behalf of a health care institution in excess of \$150,000, in preparation for the offering or the development of a project subject to review under s. 150.02; or

2. Any arrangement or commitment by or on behalf of a health care institution that is made to finance the offering or development of a project subject to review under s. 150.02.

(b) "Predevelopment activity" does not include:

1. Any health maintenance organization feasibility survey funded under 42 USC 300e-2, in effect on April 30, 1980; or

2. Any planning project for a health maintenance organization funded under 42 USC 300e-3, in effect on April 30, 1980.

(6) "Substantial and continuing progress" means:

(a) Expenditure of 20% of the approved capital expenditure;

(b) Commencement of excavation or actual construction of a facility; or

(c) Commitment of staff required to provide the new service.

(7) "Substantial change in health service" means the offering of a health service which was not offered on a regular basis in or through such a health care institution or health maintenance organization within the 12-month period prior to the time the services would be offered. "Substantial change in a health service" also means the deletion or substantial change in the scope or type of an existing health service provided by the health care institution or health maintenance organization.

(8) "To offer" when used in connection with health services, means that the health care institution holds itself out as capable of providing, or as having the means for the provision of, specified health services.

History: 1977 c. 29, 418; 1979 c. 34, 221.

150.02 Applicability. (1) This subchapter applies without limitation to all persons who intend to engage in any of the following activities by or on behalf of a health care institution:

(a) The lease, construction or purchase of a health care institution.

(b) A substantial change in health service.

(c) A change in bed capacity, not including temporary increases in bed capacity, except that transfers of beds between services which do not involve specialized services are exempt unless the transfer involves more than 10 beds or more than 10% of the institution's capacity, whichever is less, over a 2-year period.

(d) An expenditure, not covered by par. (b), of more than \$117,000 for a single piece of clinical equipment, or of more than \$150,000 for 2 or more pieces of related clinical equipment, if there is an expenditure for one of the pieces of more than \$100,000. Two or more pieces of clinical equipment that can perform their normal functions only when used simultaneously or when connected to each other constitute a single piece of equipment for purposes of this subsection. Pieces of equipment are related if the diagnostic or therapeutic services provided with the equipment are normally provided to the same individual as a clinical service.

(e) Any capital expenditure not covered by pars. (a) to (d).

(f) Any predevelopment activity.

(1m) The proposed lease or purchase of an existing health care institution is not subject to this subchapter if the institution will continue to operate under the same category of license or permit as the institution possesses prior to the date of the proposed lease or purchase and none of the other activities described in sub. (1) take place in conjunction with such lease or purchase.

(2) This subchapter also applies without limitation to all persons who intend to engage in any of the following activities by or on behalf of

an independent practitioner, partnership, unincorporated medical group or service group as defined in s. 180.99:

(a) An expenditure for a single piece of clinical equipment of more than \$117,000, or

(b) An expenditure for clinical equipment which exceeds \$150,000 for 2 or more pieces of related equipment, if there is an expenditure for one of the pieces of more than \$100,000. Two or more pieces of clinical equipment that can perform their normal functions only when used simultaneously or when connected to each other constitute a single piece of equipment for purposes of this subsection. Pieces of equipment are related if the diagnostic or therapeutic services provided with the equipment are normally provided to the same individual as a clinical service.

(3) No person may divide a project to avoid the requirements of this subchapter. When any person acquires under a lease or comparable arrangement, or through donation, any health facility or part thereof, equipment for a facility or clinical equipment which would have been subject to this subchapter had it been purchased, that acquisition is subject to this subchapter.

(4) The department shall, if permitted by the secretary of health, education and welfare, exempt from the formal review requirements, projects which meet the criteria listed below. All requests for such a nonsubstantive review by the applicant or the substate health planning agency must be made in writing to the department. The department, after consultation with the appropriate substate health planning agency, shall make a determination within 15 days after receipt of a written request. The department shall issue a certificate on all approved projects declared nonsubstantive within 20 days of this determination. A project which is determined to be subject to review shall be declared nonsubstantive if it meets one of the following criteria:

(a) A one-time capital expenditure of less than \$10,000.

(b) Capital expenditure projects developed pursuant to a plan of correction for code deficiencies previously approved by the department.

(c) Capital expenditure projects which are required to remedy an emergency situation detected not more than 30 days prior to the request for a nonsubstantive review determination and which threatens the safety of patients or the ability of the institution to remain in operation.

(d) Replacement of clinical equipment with equipment of similar capability if the equipment is included in the facility's annual capital expenditure budget or plan.

(e) Predevelopment activities.

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(5) The department may promulgate by rule additional criteria which, if approved by the secretary of health, education and welfare, may be used to declare a project nonsubstantive.

History: 1977 c. 29; 1979 c. 34.

150.03 Compliance required for licensing and approval. No license may be issued or renewed nor may approval be granted for any health care institution which fails to comply with this subchapter.

History: 1977 c. 29.

150.04 Notice of intent requirement. Except as provided in this section, any person intending to undertake a project subject to this subchapter must submit a notice of intent to the department and the appropriate substate health planning agency prior to the submission of an application for a certificate of need. Applications submitted under s. 150.02 (4) (c) and (e) are exempt from this requirement. The department, by rule, shall establish the form and content of a notice of intent and the length of any waiting period between the submission of a notice of intent and the submission of an application.

History: 1977 c. 29; 1979 c. 34.

150.05 Certificate of need requirement.

(1) No person may enter into an obligation in support of a project described in s. 150.02 or engage in activities described in that section unless the obligation or activities are authorized by a valid certificate of need. The department may grant a certificate of need that permits only predevelopment activities, but that does not authorize the offering or development of the project with respect to which the predevelopment activities are proposed.

(2) The department shall prescribe the form to be used in applying for certificates of need and for applying for renewal, modification or amendment. The department shall consult with the substate planning agencies and appropriate governmental and affected parties prior to prescribing the form of the application. A statement of the applicable rules and procedures to be followed in the review of an application shall be issued with each application form. The department may require no information under this section which is not prescribed and published as being required information.

(3) No person may apply for a certificate of need unless that person submits proof of consultation with the substate health planning agency for the area in which the project is to be located relative to need for the project, including plans, specifications and design of the project. It is the responsibility of the substate health planning

agency within the area the project is to be located to notify other agencies potentially impacted by the proposed project. Proof of such consultation shall be submitted in a form prescribed by rule by the department.

(4) An application for a certificate of need shall be filed jointly with the department and the appropriate substate health planning agency.

History: 1977 c. 29; 1979 c. 34.

150.06 Review process. (1) The appropriate substate health planning agency shall review each application for a certificate of need in accord with standards and procedures established under s. 150.07, and for consistency with locally developed plans and standards, and shall submit its comments thereon to the department within 60 days after receipt of a complete application. The comments may include a recommendation to approve the application without modifications, to approve the application subject to specified modifications or to reject the application. Suggested modifications, if any, shall relate directly to the project under review.

(2) (a) The appropriate substate health planning agency shall, during the course of its review, provide an opportunity for a public meeting at which interested persons may introduce testimony and exhibits. Public meetings required by this subsection shall be conducted according to rules promulgated by the department.

(b) Any interested person may file written comments and exhibits concerning a proposal under review with the appropriate substate health planning agency and the department.

(c) For the purposes of this subchapter, the department is exempt from the requirements of s. 227.064.

(3) The department shall, except as provided in sub. (4), issue a certificate of need with or without any specified modifications or reject the application within 30 days after receiving the comments on the application from the substate health planning agency. If the department fails to act within such period, the failure to act shall constitute rejection of the application. Modifications shall relate directly to the project and may not constitute conditional approval based on the addition, alteration or termination of other services or facilities provided by the health care institution requesting the certificate.

(4) If the decision by the department contradicts the recommendations of the substate health planning agency, the department shall issue a certificate of need 30 days after notification of approval has been given, if no appeal has been made under s. 150.09. The department

may promulgate by rule criteria by which certificates of need for contested cases will be withheld for 30 days to permit appeals to be made under s. 150.09.

History: 1977 c. 29; 1979 c. 32 s. 92 (1)

150.065 Extended review. The department shall promulgate rules establishing criteria for determining when it would not be practicable to complete a review within 90 days from receipt of a completed application. If the department finds that these criteria are met for a particular project, it shall extend the review period for a period not to exceed 60 days, except with the consent of the applicant, and provide notice of such extension to all affected persons. The time limitations in s. 150.06 (2) shall be modified accordingly.

History: 1977 c. 29

150.067 Findings. The department shall, within 15 days after it approves or rejects an application under s. 150.02, provide in writing to the applicant, to the appropriate substate health planning agency and, upon request, to affected persons the findings and conclusions on which it based its decision, including but not limited to the criteria under s. 150.07 used by the department in making such decision.

History: 1977 c. 29

150.07 Review criteria and standards.

(1) The department shall by rule promulgate and utilize, as appropriate, specific criteria for conducting its reviews under the subchapter including but not limited to the following general considerations:

(a) The relationship of the health services being reviewed to the applicable health systems plan and annual implementation plan adopted under section 1513 (b) (2) and (3), respectively, of P.L. 93-641.

(b) The relationship of services reviewed to the long-range development plan, if any, of the person providing or proposing the services.

(c) The need that the population served or to be served by the services has for the services.

(d) The availability of less costly or more effective alternative methods of providing the services.

(e) The immediate and long-term financial feasibility of the proposal, as well as the probable impact of the proposal on the costs of and charges for providing health services by the person proposing the new institutional health service.

(f) The relationship of the services proposed to be provided to the existing health care system of the area in which the services are proposed to be provided.

(g) The availability of resources, including but not limited to health manpower, management personnel, and funds for capital and operating needs for the provision of the services proposed to be provided and the availability of alternative uses of those resources for the provision of other health services.

(h) The relationship, including the organizational relationship, of the health services proposed to be provided to ancillary or support services.

(i) Special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service area in which the entities are located or in adjacent health service areas. Such entities may include medical and other health professions schools, multidisciplinary clinics and specialty centers.

(j) The special needs and circumstances of health maintenance organizations for which assistance may be provided under Title XIII of the public health services act. Such needs and circumstances include the needs of and costs to members and projected members of the health maintenance organization in obtaining health services and the potential for a reduction in the use of inpatient care in the community through an extension of preventive health services and the provision of more systematic and comprehensive health services.

(k) The special needs and circumstances of biomedical and behavioral research projects which are designed to meet a national need and for which local conditions offer special advantages.

(L) In the case of a construction project, the costs and methods of the proposed construction, including the costs and methods of energy provision, and the probable impact of the construction project reviewed on the costs of providing health services by the person proposing the construction project.

(2) Each substate health planning agency shall adopt and utilize as appropriate specific criteria for conducting its reviews under this subchapter, including but not limited to the general considerations specified in sub. (1) (a) to (L).

(3) All standards established by the department shall distinguish between rural, urban and metropolitan areas as defined by population density to the extent that variable standards will benefit the development of the most appropriate health care system for the service area. All such standards shall be subject to review and comment by substate health planning agencies, public meetings in each substate health planning

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area, and review by the statewide health coordinating council prior to use in reviewing certificate of need applications.

(4) Before issuing a certificate of need, the department shall consider, in accordance with the appropriate criteria of sub. (1), the need for health care institutions, services related thereto and clinical equipment as projected in various state plans prepared annually by substate health planning agencies and state agencies, including but not limited to the medical facilities construction and modernization program, mental health centers plan, programs for facilities and services for the mentally retarded, rehabilitation services program, the alcoholic and drug abuse programs, and special studies, surveys and information. Information submitted by a religious organization in support of its application, demonstrating a desire on the part of persons in the area to be served by the facility to be cared for in an institution sponsored by that particular religious organization, shall be a significant consideration in determining the need for that facility. This information may consist of waiting lists substantiated by verified applications for admission to the institution, surveys and any other forms of information which the state health planning and development agency requires.

History: 1977 c. 29; 1979 c. 221 s. 2200 (20).

150.08 Forfeiture. Any person who violates this subchapter or any rule adopted under this subchapter shall forfeit not less than \$100 nor more than \$1,000 for each such offense. Each day of violation constitutes a separate offense.

History: 1977 c. 29

150.085 Rehearing. Any affected person may request a rehearing under s. 227.12 on the basis of the grounds specified in s. 227.12 (3) or such other grounds as the department may specify by rule.

History: 1977 c. 29

150.09 Appeals. The department shall promulgate rules establishing procedures by which any person applying for a new, modified or amended certificate of need or a substate health planning agency may appeal a decision by the department. The procedures shall include an opportunity for an appeal to an independent hearing officer, appointed by the governor under s. 753.075 (3). In an appeal of a decision to deny a certificate of need, the department shall bear the burden of proving that the project fails to meet the criteria specified in its written findings under s. 150.067. In an appeal of a decision to grant a certificate of need, the person appealing that decision must prove that the

project fails to meet such criteria. The appeals shall be conducted in the manner described in s. 227.20, except that findings, conclusions and the decision resulting from the hearing shall, to the extent the determinations of the department are reversed or modified, constitute the determinations of the department.

History: 1977 c. 29; 1977 c. 187 s. 135.

150.10 Validity of a certificate. A new, modified or amended certificate of need is valid for a period of one year from the date of issuance and may be renewed at the expiration of this period. The certificate of need may be renewed one or more times for periods of up to one year only if evidence of substantial and continuing progress on the project is submitted or if the applicant demonstrates a commitment to obligate for the proposed project within the extension period. The department may establish rules to assure timely completion of the project.

History: 1977 c. 29

150.12 Fees. Persons applying for certificates of need shall pay application fees according to the schedule in this section.

(1) (a) No fee may be charged for any nonsubstantive project under s. 150.02 (4) or (5).

(b) Notwithstanding par. (a), the department may charge an application fee for nonsubstantive review of project cost overruns. The total amount of application fees for the project may not exceed \$37,000.

(2) For all other expenditures the fee shall be 0.37% of the estimated project cost with a maximum fee of \$37,000 and a minimum fee of \$200.

History: 1977 c. 29, 203; 1979 c. 34, 221.

SUBCHAPTER III**DECERTIFICATION OF SPECIALIZED HOSPITAL SERVICES**

150.41 Definitions. In this subchapter:

(1) "Specialized services" are the specialized facilities, equipment and staff necessary:

(a) To perform heart catheterization studies or cardiac surgery.

(b) To perform radiation therapy treatment of cancer and other diseases.

(c) For hemodialysis treatment of acute or chronic renal insufficiency.

(d) To perform kidney transplants.

(e) For the intensive care and management of high-risk maternal, high-risk fetal patients or high-risk neonatal patients.

(f) To perform computed tomography.

(2) "Certificate" means a written authorization by the department for an institution to provide specialized services.

History: 1977 c. 29.

"Cardiac surgery" refers to total cardiac surgery program as characterized by existing facilities, equipment and staff; both emergency and elective surgery are included. *Wausau Hospitals, Inc. v H&SS Dept. 95 W (2d) 601, 291 NW (2d) 602 (Ct. App. 1980).*

150.42 Administration. The bureau or agency with primary responsibility for activities under subch. II shall be responsible for certifying the need for individual specialized services. After certification, the responsibility for monitoring compliance with standards and rules promulgated under this subchapter shall be the responsibility of the single agency responsible for facility licensing and inspection.

History: 1977 c. 29.

150.44 Regulations. (1) The department shall promulgate all regulations necessary to implement this subchapter and to ensure that the specialized services offered are needed, reasonably accessible, and provided in a manner which is consistent with community-defined quality-of-care standards.

(2) All rules and standards proposed by the department under this subchapter shall be reviewed by the statewide health coordinating council prior to becoming effective.

History: 1977 c. 29.

150.45 Decertification. (1) The department, after due notice, may decertify a specialized service if the service is clearly and demonstrably not needed by the community being served or the resources of the institution are incapable of maintaining the service.

(2) The department shall issue a notice of intent to decertify a service at least 90 days prior to initiating formal action. Such notice shall be in writing and shall specify with particularity the basis on which the department reached its preliminary position. No final determination may be made by the department unless a hearing has been held and written findings and conclusions have been prepared by the presiding officer at the hearing or the hearing has been waived by the institution.

(3) The appropriate substate health planning agency shall be notified of the department's preliminary findings and shall be given a minimum of 60 days to review and comment on the proposed decertification.

(4) If the department determines a service is temporarily not in full compliance with applicable standards and rules promulgated under this subchapter, but the service is needed, the department shall issue a warning to the certificate

holder and work with the hospital to establish a plan of correction with a reasonable timetable. Failure to comply with such a timetable is grounds for decertification. Capital expenditures which are necessitated to meet certification standards shall automatically be considered nonsubstantive projects under subch. II, if the service or facility in question will be in full compliance with all applicable rules and standards upon completion of the project.

(5) The certification review process specified in this subchapter shall, after the initial review, be conducted for each service not more frequently than every 3 years or less frequently than every 5 years. The initial review must be completed within 12 months from the date regulations are published.

(6) The hospital shall be given a reasonable period of time, not to exceed one year, to phase out a specialized service.

History: 1977 c. 29.

150.46 Appeals. The department shall promulgate rules establishing procedures by which a person may appeal a decision by the department. The procedures shall include an opportunity for an appeal to an independent hearing officer appointed by the governor under s. 252.075 (3). In any appeal of a decision by the department, the department shall bear the burden of proving that the decision is in accordance with s. 150.45 and the rules, regulations and standards promulgated under this subchapter. Such appeals shall be conducted in accordance with s. 227.20, except that the findings, conclusions and decisions resulting from the hearing shall, to the extent the determinations of the department are reversed or modified, constitute the determinations of the department.

History: 1977 c. 29.

150.47 Operation without a certificate; penalty. No hospital may maintain or operate a specialized service without a certificate. Any hospital which violates this section shall forfeit not less than \$100 nor more than \$1,000. Each day of violation constitutes a separate offense.

History: 1977 c. 29.

150.48 Inspections. The department shall make inspections as are reasonably necessary under this subchapter, but not more often than annually, to obtain compliance with the rules and standards promulgated under this subchapter. To the maximum extent possible, these inspections shall be coordinated with other regulatory and accrediting bodies, both governmental and private.

History: 1977 c. 29.