CHAPTER 401. CERTIFICATE OF NEED PROGRAM

Sec.

Authority

The provisions of this Chapter 401 issued under the Health Care Facilities Act (35 P. S. §§ 448.101—448.904), unless otherwise noted.

Source

The provisions of this Chapter 401 adopted July 25, 1980, effective August 1, 1980, 10 Pa.B. 3093, unless otherwise noted.

Cross References

This chapter cited in 28 Pa. Code § 9.31 (relating to Certificate of Need requirements); 55 Pa. Code § 1101.42b (relating to Certificate of Need requirement for participation—statement of policy); 55 Pa. Code § 1151.52 (relating to payment for capital costs not included in the base year); 55 Pa. Code § 1163.452 (relating to payment methods and rates); 55 Pa. Code § 1163.453 (relating to allowable and nonallowable costs); 55 Pa. Code § 1181.65 (relating to cost-finding); 55 Pa. Code § 1181.259 (relating to depreciation allowance); 55 Pa. Code § 1181.260 (relating to interest allowance); and 55 Pa. Code § 1187.113 (relating to capital component payment limitations).

§ 401.1. Applicability.

The provisions of this chapter shall be applicable to persons who propose to undertake to offer, develop, construct or otherwise establish, or to undertake to establish, within the Commonwealth a new institutional health service.

§ 401.2. Definitions.

The following words or terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

Act—The Health Care Facilities Act (35 P. S. §§ 448.101—448.904).

Administrative review—An expedited review conducted solely by the Department.

Affected person—A person whose proposal is being reviewed for purposes of certificate of need, the health systems agency for the health service area in which the proposed new institutional health service is to be offered or developed, health systems agencies serving contiguous health service areas, health care facilities and health maintenance organizations located in the health service area which provide institutional health services, and those members of the public who are to be served by the proposed new institutional health services and those agencies, if any, which establish rates for health care facilities and health maintenance organizations located in the health systems area in which the proposed new institutional health service is to be offered or developed.

Ambulatory surgical facility—A facility not located upon the premises of a hospital which provides outpatient surgery to patients who do not require overnight hospitalization but who do require medical supervision following the procedure. An ambulatory surgical facility does not include individual or group practice offices of private physicians or dentists, unless such offices have a distinct part used solely for outpatient surgical treatment on a regular and organized basis.

Annual implementation plan—The latest annual statement of objectives of the health systems agency to achieve the goals of the health systems plan, including the priorities established among the objectives.

Association with—Acting as a director, officer or employe of an organization at the present time or within the last 12 months.

Bed capacity—The total number of licensed or approved beds which are set up and staffed and licensed or approved beds which are out of service. Out of service beds include the following:

(i) Beds which are set up but not staffed due to seasonal fluctuations in demand or construction or renovation of the facility.

(ii) Beds which are not being utilized because of the conversion of a multibed room to a single bed room.

Business days—Days when the Department is open and staffed for regular business.

Certificate of Need—A certificate issued by the Department under this chapter, including those issued as an amendment to an existing Certificate of Need.

Council—The Statewide Health Coordinating Council established under the National Health Planning and Resources Development Act of 1974 (42 U.S.C.A. §§ 300k—300n-6).

Department—The Department of Health of the Commonwealth.

Develop—When used in connection with health services or facilities, means to undertake those activities which on their completion will result in the offering of a new health service or the incurring of a financial obligation in relation to the offering of such a service.

Health care facility—General or special hospitals, including tuberculosis and psychiatric hospitals, rehabilitation facilities, skilled nursing facilities, interme-

diate care facilities, kidney disease treatment centers including free-standing dialysis units and ambulatory surgical facilities. The term includes both profit and nonprofit facilities including those operated by an agency of State or local government. Health care facilities does not include the following:

(i) An office used exclusively for a private or group practice by physicians or dentists does not constitute a health care facility unless the office is located within a health care facility or the services of the practice are offered by or through a health care facility.

(ii) A program which renders treatment or care for drug or alcohol abuse or dependence does not constitute a health care facility unless the office is located within a health care facility or the service is offered in, by or through a health care facility.

(iii) A facility providing treatment solely on the basis of prayer or spiritual means in accordance with the tenets of a religious denomination or church does not constitute a health facility.

(iv) A facility providing health care services exclusively to persons in a religious profession who are members of the religious denomination or church which operate the facility does not constitute a health care facility.

(v) A freestanding home health care agency.

Health maintenance organization (HMO)—An organization defined as a health maintenance organization by 42 U.S.C.A. § 300n (8) or by the Health Maintenance Organization Act (40 P. S. §§ 1551—1567).

Health service area—The area served by a health systems agency designated under the National Health Planning and Resources Development Act of 1974 (42 U.S.C.A. §§ 300k—300n-6).

Health services—Clinically related, that is, diagnostic, treatment or rehabilitative services, including alcohol, drug abuse and mental health services.

Health Systems Agency (HSA)—An entity which has been conditionally or fully designated under the National Health Planning and Resources Development Act of 1974 (42 U.S.C.A. §§ 300k—300n-6).

Health Systems Plan (HSP)—The latest HSA Board approved statement of health service area goals and strategies for achieving the goals.

Hearing Board—The State Health Facility Hearing Board created in the Office of General Counsel under the provisions of the act.

HHS—The United States Department of Health and Human Services.

Home health care—The provision of nursing and other therapeutic services to disabled, injured or sick persons in their place of residence and other health related services provided to protect and maintain persons in their own home.

Hospital—An institution licensed or approved by the Department as a hospital.

Intermediate care facility—A facility or part of a facility in which professionally supervised nursing care and related medical or other health services are provided for a period exceeding 24 hours for two or more individuals who

do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide, but who because of age, illness, disease, injury, convalescence or mental or physical infirmity, need medical or other health services. Intermediate care facilities exclusively for mentally retarded persons are considered intermediate care facilities for the purpose of the act.

Kidney disease treatment facility—A facility, including a free-standing dialysis unit, providing treatment to persons with end-stage renal or other kidney disease. For purposes of the act, dialysis stations will be treated as licensed/approved beds.

Major medical equipment—edical equipment which is used for the provision of medical and other health services and which costs in excess of the minimum expenditure threshold for major medical equipment established by Federal statute or regulations except major medical equipment acquired by or on behalf of a clinical laboratory to provide clinical laboratory services if the clinical laboratory is independent of a physician's office and a hospital and it has been determined under the Medicare program to meet the applicable requirements of the Social Security Act (42 U.S.C.A. §§ 300v—300y-11). In determining whether medical equipment has a value in excess of the threshold, the value of studies, surveys, designs, plans, working drawings, specifications and other activities essential to the acquisition of the equipment shall be included.

National Health Planning and Resources Development Act of 1974—42 U.S.C.A. §§ 300k—300n-6.

Nonsubstantive review—A review which is less comprehensive than a full review but maintains all statutory procedures including third party rights, and an HSA recommendation. Projects may receive a nonsubstantive review as determined by the Department after consultation with the HSA. Projects eligible for a nonsubstantive review should not involve a capital expenditure greater than $2 million and include, but are not limited to, the following:

(i) Change of 10 beds or 10% of capacity or less, whichever is less, if the change conforms to the Health Systems Plan. This subparagraph applies to bed changes to approved projects and to cases in which facilities have already exercised the 10 bed/10% option during a 2-year period.

(ii) Replacement of equipment not involving a substantial change in functional capacity or capability.

(iii) Projects identified as needed in the Health Systems Plan or State Health Plan.

(iv) Renovations necessary to meet code requirements which do not expand the capacity of the facility.

(v) Repairs or reconstruction in cases of emergencies.

(vi) Addition of a new health service if the annual operating expense is less than $500,000.

(vii) Nonclinical projects, such as parking, energy, medical office buildings, and telephone.

(viii) Refinancing.

Due to the relatively insignificant consequences of some of the changes that would require a nonsubstantive review, an administrative review can be substituted if the HSA and the Department agree that only an administrative review is necessary. The Department will render its decision on the project within 30 business days of receipt of the required information.

Offer—ake provision for providing in a regular manner and on an organized basis specified health services.

Organization—A nonprofit corporation or other corporation, partnership, association or other organization.

Person—A natural person, corporation including associations, joint stock companies and insurance companies, partnerships, trusts, estates, associations, the Commonwealth, and any local governmental unit, authority and agency thereof. The term includes all entities owning or operating a health care facility or health maintenance organization.

Persons directly affected—A person whose proposal for certificate of need is being reviewed, members of the public who are to be served by the proposed new institutional health services, health care facilities and health maintenance organizations located in the health service area in which the service is proposed to be offered or developed which provide services similar to the proposed services under review, and health care facilities and health maintenance organizations which prior to receipt by the agency of the proposal being reviewed have formally indicated an intention to provide such similar service in the future and those agencies, if any, which establish rates for health care facilities and health maintenance organizations located in the health systems area in which the proposed new institutional health service is to be offered or developed.

Policy board—The Health Care Policy Board created in the Department under the act.

Predevelopment costs—Expenditures for preparation of architectural designs, working drawings, plans and specifications, and any other preparation directed toward planning, developing, or offering a new institutional health service.

Project—A proposal by a person to offer, develop, construct, or otherwise establish or undertake to establish a new institutional health service as defined in § 401.3 (relating to new institutional health services).

Public Health Service Act—42 U.S.C.A. §§ 201—300z-10.

Public hearing—A meeting open to the public where any person has an opportunity to present testimony held without imposition of fee.

Rehabilitation facilities—An inpatient facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical and other services which are provided under competent professional supervision. These facilities are comprehensive physical rehabilitation facilities. They do not include freestanding treatment facilities for drugs or alcohol or both.

Retroactive review—A review which is conducted after a person has undertaken a reviewable activity without a certificate of need. The reviews are procedurally identical to a regular review specified in this chapter. Such persons are subject to penalties as specified in the act.

Secretary—The Secretary of the Department.

Skilled nursing facility—A facility or part of a facility in which professionally supervised nursing care and related medical or other health services are provided for a period exceeding 24 hours for two or more individuals who are not in need of hospitalization and who are not relatives of the nursing home administrator, but who because of age, illness, disease, injury, convalescence, or physical or mental infirmity, need such care.

State Health Plan (SHP)—A statement of goals for the State health care system based on the Health Systems Plans for the State and approved by the Statewide Health Coordinating Council and the Governor prepared triennially, reviewed annually and revised as necessary. It describes the institutional health services needed to provide for the well-being of persons receiving care within the State, the number and type of resources, including facilities, personnel, major medical equipment, and other resources, including financial resources, required to meet the goals of the plan, states the extent to which existing health care facilities are in need of modernization, conversion to other uses, or closure and the extent to which new health care facilities need to be constructed or acquired.

Statewide Health Coordinating Council—The Council established in compliance with Title XV of the Public Health Service Act.

Substantial implementation of a project—The completion of the following requirements relative to but not limited to the following types of projects. All of the requirements listed in this paragraph must be completed within 1 year after issuance of the certificate or within 18 months after issuance of the certificate if an extension has been granted.

(i) *New construction or renovation projects.* New construction or renovation projects shall conform to all of the following:

(A) The title or long-term lease to the appropriate site has been acquired.

(B) The appropriate State agency has approved the complete set of schematic drawings for the project.

(C) A financial commitment has been obtained for at least 60% of the total approved capital expenditure. The commitment may be any combination of funds, such as the applicant's own funds, grants, gifts, or an enforceable offer and acceptance from a financial institution to provide adequate capital financing for the project.

(D) An enforceable construction contract has been entered into causing the commencement of construction no later than 24 months after issuance of a certificate. Failure to commence construction within this time period

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shall be considered an abandonment of the project, and the certificate issued shall be withdrawn. Erection of the foundation shall constitute commencement of construction.

(ii) *Acquisition of equipment.* The equipment must either be purchased; the lease agreement must be entered into by the proponent; or if acquired by a comparable arrangement, the health care facility or health maintenance organization must have possession of the equipment.

(iii) *Addition of a new service.* A written statement must be submitted to the Department verifying that the service is in operation.

(iv) *Donated property.* In the case of donated property, the date on which title to the donated property is transferred in accordance with applicable State statute.

Third-party payor—A person who makes payments on behalf of patients under compulsion of law or contract who does not supply care or services as a health care provider or who is engaged in issuing any policy or contract of individual or group health insurance or hospital or medical service benefits, but shall not include the Federal, State, or any local government unit, authority or agency thereof or a health maintenance organization.

Authority

The provisions of this § 401.2 issued section 2102(a) and (g) of The Administrative Code of 1929 (71 P. S. § 532 (a) and (g)); and section 201(14) of the Health Care Facilities Act (35 P. S. § 448.201(14)).

Source

The provisions of this § 401.2 amended April 13, 1984, effective April 14, 1984, 14 Pa.B. 1294. Immediately preceding text appears at serial pages (55635) to (55637), and (52906) to (52910).

Cross References

This section cited in 28 Pa. Code § 401.5 (relating to Certificate of Need); 28 Pa. Code § 401.6 (relating to certificate of need—statement of policy); and 55 Pa. Code § 1187.113a (relating to nursing facility replacement beds—statement of policy).

§ 401.3. New institutional health services.

(a) No person shall offer, develop, construct or otherwise establish or undertake to establish within the State a new institutional health service without first obtaining a certificate of need from the Department.

(b) A new institutional health service shall mean the following:

(1) The construction, development or other establishment of a health care facility or health maintenance organization.

(2) An expenditure by or on behalf of a health care facility or Health Maintenance Organization (HMO) in excess of the minimum capital expenditure threshold established by Federal law or regulation which, under generally accepted accounting principles, consistently applied is a capital expenditure.

For the purpose of this subsection, any expenditure which is not properly chargeable under generally accepted accounting principles as an expense of operation and maintenance shall be deemed a capital expenditure. An acquisition of a building, property, or equipment by or on behalf of a health care facility or a HMO under lease or comparable arrangement, or through donation, which would have required review if the acquisition had been by purchase, shall be deemed a capital expenditure subject to review.

(3) An expenditure by or on behalf of a health care facility or a health maintenance organization in excess of the minimum capital expenditure threshold established by Federal law or regulation made in preparation for the offering or development of a new institutional health service and any binding arrangement or commitment by either of them for financing the offering or development of the new institutional health service.

(4) Expenditures for the acquisition of an existing health care facility or health maintenance organization shall not be subject to review if notice has been provided to the Department under subsection (c), and the Department finds within 30 days of receipt of the notice that the services or bed capacity of the facility to be acquired will not be changed in being acquired within 1 year from the date of the change of ownership. This does not prohibit facilities from increasing, redistributing, or relocating beds by 10 beds or 10%, whichever is less, of the bed capacity as allowed by paragraph (6).

(5) The acquisition of major medical equipment not owned by or located in a health care facility if the equipment will be used to provide service for inpatients of a health care facility, or if notice has not been provided to the Department under subsection (c).

(6) The obligation of any capital expenditure by or on behalf of a health care facility which results in the addition of a health service not provided in or through the facility in the previous 12 months or which increases the total number of beds, or redistributes beds among various categories other than levels of care in a nursing home, or relocates such beds from one physical facility or site to another, by more than 10 beds or 10% of total bed capacity, whichever is less, over a 2-year period. For purposes of this paragraph, categories of beds in a hospital are those categories of beds established and defined in the instructions and definitions of the Department's Annual Hospital Questionnaire. Although dialysis stations are not defined as beds in the annual hospital questionnaire, facilities with dialysis stations may increase the number of stations in accordance with this subsection, except that the 10 beds or 10% rule will apply to the number of dialysis stations only. The total bed capacity of the hospital if the dialysis unit is located in a hospital, is separate and distinct from dialysis stations. The 2-year periods shall begin on the date of licensure. Increases not added during a 2-year period cannot be accumulated and carried over to another period, nor will a change in ownership allow increases of more than 10 beds or 10% of total capacity in a 2-year period.

(7) The addition of a health service which is offered in or through a health care facility having an annual operating expense in excess of the minimum operating expense threshold established by Federal law or regulation and which was not offered on a regular basis in or through the health care facility within the 12-month period prior to the time such services would be offered. A health service shall be considered to be offered by or through a health care facility or a health maintenance organization if the service is offered or made available on a regular basis to inpatients or outpatients of a health care facility.

(c) Before any person enters into a contractual arrangement to acquire major medical equipment which will not be owned by or located in health care facility or before any person acquires an existing health care facility, the person shall notify the Department of his intent to acquire such equipment or existing health care facility.

(1) The notice shall be in writing and shall be made at least 30 days before contractual arrangements are entered into to acquire the major medical equipment or the existing health care facility.

(2) In the case of the intended acquisition of major medical equipment, the notice shall contain information regarding the use that will be made of the equipment. In the case of the intended acquisition of an existing health care facility, the notice shall contain information with regard to the services to be offered in the facility and its bed capacity.

(3) Within 30 days after the receipt of the notice, the Department will inform the person providing the notice whether or not the proposed acquisition of either the major medical equipment or the existing health care facility is a new institutional health service. If the Department determines that the acquisition will be a new institutional health service, the acquisition shall be subject to this chapter.

(4) A decision of the Department that an acquisition requires a certificate of need may be appealed to the Hearing Board.

Authority

The provisions of this § 401.3 issued under section 2102(a) and (g) of The Administrative Code of 1929 (71 P. S. § 532(a) and (g)); and section 201(14) of the Health Care Facilities Act (35 P. S. § 448.201(14)).

Source

The provisions of this § 401.3 amended April 13, 1984, effective April 14, 1984, 14 Pa.B. 1294. Immediately preceding text appears at serial pages (52910) to (52911).

§ 401.4. Criteria for Certificate of Need review.

(a) The following criteria, and standards applicable to each criterion, shall be used to review each application for a certificate of need. A certificate of need shall be recommended, approved and issued when the application substantially

meets the following criteria provided that each decision, except in circumstances which pose a threat to public health, shall be consistent with the State Health Plan (SHP):

(1) Whether the relationship of the application to the applicable Health Systems Plan (HSP) and annual implementation plan has been considered.

(2) Whether the services are compatible with the long-range development plan of the applicant.

(3) Whether there is a need by the population served or to be served by the services or facility. Particular consideration shall be given to whether the proposed new institutional health service meets or contributes to the health related needs of members of medically underserved groups.

(4) Whether there is any appropriate, less costly or more effective alternative method of providing the services available.

(5) Whether the service or facility is economically feasible, considering anticipated volume of care, the capability of the service or facility and the availability of reasonable financing.

(6) Whether the proposed service or facility is financially feasible both on an intermediate and long term basis, and whether the impact on the cost of and charges for providing services by the applicant is appropriate.

(7) Whether the proposed service or facility is compatible with the existing health care system in the area. Consideration shall be given to efficiency and appropriateness of the existing services and facilities similar to those proposed.

(8) Whether the service or facility is justified by community need and within the financial capabilities of the institution both on an intermediate and long term basis and whether it will have an inappropriate, adverse impact on the overall cost of providing health services in the area.

(9) Whether there are available resources, including health manpower, management personnel and funds for capital and operating needs to the applicant for the provision of the services proposed to be provided, and whether there is a greater need for alternative uses for such resources for the provision of other health services. The effect on the clinical needs of health professional training programs in the medical service area, the extent to which health professional schools in the medical service area will have access to the services for training purposes and the extent to which the proposed service will be accessible to all the residents of the area to be served by such services shall also be considered in determining resources.

(10) Whether the proposed service or facility will have available to it appropriate ancillary and support services and an appropriate organizational relationship to such services.

(11) Whether the proposed services are consistent with the special needs and circumstances of those entities which provide services or resources both within and without the health service area in which the proposed services are to be

located, including medical and other health professional schools, multidisciplinary clinics and specialty centers.

(12) Whether the proposed services are not incompatible with any biomedical or behavioral research projects designed for national need for which local conditions offer special advantages.

(13) Consideration of the need and availability in the community for services and facilities for allopathic and osteopathic physicians and their patients; and the religious orientation of the facility and the religious needs of the community to be served. This paragraph is not intended to create duplicative systems of care.

(14) Whether competitive factors relating to the supply of the health services being reviewed have been considered. Particular attention shall be given to the existence and capacity of market conditions, current or potential, in advancing the purposes of quality assurance, cost containment, and responsiveness to consumer preference. Particular attention shall also be given to the existence and capacity of utilization review programs and other public and private cost control measures to give effect to consumer preferences and to establish appropriate incentives for capital allocations.

(15) Whether consideration has been given to improvements or innovations in the financing and delivery of health services which would foster competition and serve to promote quality assurance, cost effectiveness, and responsiveness to consumer preferences.

(16) Whether, in the case of existing services for facilities, the quality of care provided by services or facilities in the past have been considered.

(17) Whether the special circumstances of applications with respect to the need for conserving energy have been considered.

(b) [Reserved].

(c) [Reserved].

(d) If the application is for a proposed service or facility which includes a construction project, a certificate of need shall be recommended, approved, and issued when the provisions of subsection (a) are satisfied and the following occur:

(1) The costs and methods of the proposed construction including the costs and methods of providing energy are appropriate.

(2) The impact of the costs of providing health services by the applicant resulting from the construction is found to be appropriate and the impact on the costs and charges to the public of providing health services by other persons is found to be not inappropriate.

(e) Whenever new institutional health services for inpatients are proposed, a finding will be made in writing by the Department:

(1) That the capital and operating costs, efficiency and appropriateness of the proposed new service and its potential impact on patient charges has been considered.

(2) That less costly alternatives which are more efficient and more appropriate to the inpatient service are not available and the development of the alternatives has been studied and found not practicable.

(3) That existing inpatient facilities providing inpatient services similar to those proposed are being used in an appropriate and efficient manner.

(4) That in the case of new construction, alternatives to new construction such as modernization or sharing arrangements have been considered and have been implemented to the maximum extent practicable.

(5) That patients will experience serious problems in terms of cost, availability, accessibility or such other problems as may be identified in the applicable HSP or SHP in obtaining inpatient care of the type proposed if the proposed new services is not approved.

(f) With respect to any application regarding the offering, developing, constructing, or otherwise establishing of a health maintenance organization, all of the criteria applicable in subsection (a) shall apply unless the proposed entity is found to meet the requirements for exemption contained in 42 U.S.C.A. § 300m-6(a)(5) and (b)(1) and regulations adopted thereto.

(g) Notwithstanding subsections (a), (d) and (e), the following types of applications for certificates of need shall be approved unless the Department finds that the project in question is not needed or that it is not consistent with the SHP. Applications described in the following paragraphs will be approved only to the extent necessary to remedy the deficiencies they address:

(1) Application for a project which is necessary to eliminate or prevent imminent safety hazards as defined by the Life Safety Code or other appropriate codes or regulations.

(2) Application for a project which is necessary to comply with State licensure standards.

(3) Application for a project which is necessary to comply with accreditation standards, compliance with which is required to receive reimbursement or payments under Title XVIII or XIX of the Social Security Act (42 U.S.C.A. §§ 300v—300y-11).

Authority

The provisions of this § 401.4 issued under section 2102(a) and (g) of The Administrative Code of 1929 (71 P. S. § 532(a) and (g)); and section 201(14) of the Health Care Facilities Act (35 P. S. § 448.201(14)).

Source

The provisions of this § 401.4 amended April 13, 1984, effective April 14, 1984, 14 Pa.B. 1294. Immediately preceding text appears at serial pages (52911) to (52913).

Notes of Decisions

The Department acted within its discretionary authority by accepting evidence as to the projected percentage of Medicare patients and the extent of the applicant's contribution to medically undeserved groups. *Morrisons Cove Home v. Department of Health*, 593 A.2d 925 (Pa. Cmwlth. 1991); appeal denied 602 A.2d 863 (Pa. 1992).

Cross References

This section cited in 28 Pa. Code § 401.5 (relating to Certificate of Need); and 28 Pa. Code § 401.7 (relating to simultaneous and comparative review).

§ 401.5. Certificate of Need.

(a) *Letter of intent.*

(1) As early as possible, any person desiring to obtain a certificate of need shall submit a letter of intent to the Division of Need Review of the Department and to the Health Systems Agency (HSA) responsible for reviewing applications in the health service area where the proposed project will be located. A letter of intent shall contain at least the following information:

(i) The name and address of the applicant.

(ii) The name and location of the project.

(iii) The reason the project is needed.

(iv) The type of capital expenditure, acquisition, health service, or change in bed capacity involved in the project.

(v) The expected date of project commencement and completion.

(vi) The estimated cost and anticipated source of project financing.

(2) The Department, after consultation with the HSA, will determine whether the project is subject to review and notify the applicant within 30 days of receipt of the letter of intent. Only projects for which letters of nonreviewability are issued will be considered not subject to review. A determination by the Department that a project is subject to review may be appealed to the Hearing Board, under 37 Pa. Code Chapter 197 (relating to practice and procedure). An application may be submitted and reviewed during an appeal to the Hearing Board.

(3) If the project has been inactive for more than 1 year the project proposed by the applicant shall be considered withdrawn.

(b) *Application.*

(1) An applicant for a certificate of need may obtain the necessary application forms from the local HSA. Applications to obtain or amend a certificate of need shall be submitted simultaneously to the Department and the HSA responsible for reviewing applications in the health service area where the proposed project will be located. The HSA shall advise the applicant as to the number of copies of the application the agency will require to conduct a review.

(2) Applications for a certificate of need shall contain all data and information required by the Department and the HSA. The following information shall be submitted in a format published by the Department:

(i) General.

(A) Identifying information.
(B) Type of ownership.
(C) Type of applicant.
(D) Type of application.
(E) Anticipated proposal schedule.
(ii) Synopsis of proposal.
(iii) Proposal planning process.
(A) Description of annual institutional planning process.
(B) Results of planning with other organizations.
(C) Description of institutional long range plan.
(iv) Specific description of proposal.
(A) Service, building, equipment and bed changes.
(B) Personnel requirements.
(C) Projected utilization by service.
(D) Projected costs.
(E) Anticipated financing.
(v) Need for proposal.
(A) Compatibility with institutional long range plan.
(B) Consistency of proposal objectives with the following:
(I) Goals, objectives and recommended actions in the health systems plan and annual implementation plan.
(II) Goals, objectives, and recommended actions in the State health plan.
(C) Consistency of specific criteria used to calculate need with the following:
(I) Criteria in the health systems plan.
(II) Criteria in the State health plan.
(III) Other relevant criteria developed by professional organizations, if available.
(D) Documentation of alternatives studied and found not practicable.
(I) More efficient use of existing services or facilities, or both.
(II) Implementation of modernization or sharing arrangements to the maximum extent feasible.
(vi) Economic feasibility of proposal.
(A) Documentation of financial feasibility.
(I) Past historical financial data.
(II) Pro Forma statements: status quo; proposal; alternatives.
(III) Financing arrangements and assumptions.
(B) Evaluation of economic feasibility.
(I) Adequate volume of care projected.
(II) Availability of financing.
(III) No inappropriate adverse impact on overall areawide cost of providing services.

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(IV) No appropriate, less costly or more effective alternative methods of providing the services available.

(vii) When the HSA, with concurrence of the Department, has adopted additional information requirements, the information requirements shall be published by the HSA in a format approved by the Department, and incorporated into the application. The applicant shall submit this information within the format published by the HSA.

(3) The application for a certificate of need shall specify the time the applicant will need to make the service or equipment available or to complete the project, and a timetable to substantially implement the approved project. The timetable to substantially implement the project must conform with the timetable established at subsection (m).

(4) The appropriate HSA and the Department will review each certificate of need application for completeness. If it is determined that the application is incomplete, the reviewing agency shall send notice to the applicant within 20 business days of the receipt of the application and shall advise such persons in writing of the additional information required to complete the application. Upon receipt of the additional information, the reviewing agency shall determine if the application is complete and send notice within 15 business days of the receipt of same. The application and additional information must be sent to both the Department and the HSA. The time frames for review of the application or additional information will not begin until both the Department and HSA have received the information. If the Department and HSA receive information on different dates, the time frame begins on the later of the two dates. An applicant shall only be required to provide information under paragraph (2).

(5) Any conflicts regarding the completeness of an application will be resolved by the Department. An applicant may notify the Department at any time while an application is under consideration for completeness by an HSA, and request in writing a determination by the Department as to whether the application is complete. The request must indicate the reasons why the HSA determined the application incomplete, and the reasons why the applicant believes the information is contained in the application or in the additional information provided. The Department will notify the applicant of its determination within 14 business days. If the Department determines the application is complete, the HSA shall review the application.

(6) An applicant may, 60 days or more after filing an application, request in writing that the review begin. Requests shall be mailed to the HSA and the Department by certified mail, return receipt requested. Upon receipt of such a request the HSA shall notify the applicant and the Department in writing that the review process will begin on the date of notification in accordance with subsection (d)(1) and shall include at least the same information as required in subsection (c)(3). All subsequent requirements pertinent to a complete application shall apply.

(c) *HSA notification of review.*

(1) After the HSA determines that an application is complete in accordance with subsection (b)(3) or upon expiration of the time to determine that an application is complete, whichever comes first, the HSA shall send a written notice to the applicant stating that the application is deemed complete and that the review process will begin on the date of notification in accordance with subsection (d)(1).

(2) [Reserved].

(3) The HSA shall notify all affected persons of a complete certificate of need application by publishing a notice in at least one newspaper of general circulation serving the locality in which the proposed service or facility will be developed. The notice shall contain the name and address of the applicant, a brief description and an estimate of the cost of the project, the schedule for review by the agency, the date by which a public hearing must be requested, and the manner in which notice will be given if a public hearing is to be held. If this notice states the date and location of the public hearing, it shall satisfy the requirement for public notice of the HSAs. The Department will publish a similar notice in the *Pennsylvania Bulletin.*

(4) The HSA shall also provide written notice of a completed certificate of need application to HSAs serving contiguous health service areas, any health care facilities and health maintenance organizations located in the health service area which provide institutional health services, appropriate third party payors, and public agencies. The written notice shall contain the same information as required in paragraph (3) and may be satisfied if published as part of a newsletter.

(d) *HSA period for review.*

(1) The date of notification begins the time period in which the HSA must complete the review of an application for a certificate of need. The date of notification is the date the HSA publishes a notice in accordance with subsection (c)(3). The HSA shall send the applicant the required notice that the review process will begin and publish such notice within 30 days after either the application is deemed complete in accordance with subsection (b)(4) or after receipt of the applicant's request that review begin in accordance with subsection (b)(6), whichever date first occurs.

(2) The HSA shall have 60 days from the date of notification to complete its review of the application.

(3) The HSA with concurrence of the Department may extend the time for review beyond 60 days from the date of notification only if the applicant agrees in writing to a specific extension of time for the review by the HSA. Any agreed extension of time must indicate the date upon which the running of the 60 day period stops and begins, and the date upon which the 60 day period expires. Copies of agreed extensions must be submitted to the Department. If

there are not agreed extensions in writing, the 60 day period shall not be considered extended, and will expire on the 60th day from the date of notification.

(4) [Reserved].

(5) The HSA, with concurrence from the Department, may establish review cycles for the review of applications. There shall be at least six review cycles per year—one every other month. During a review cycle, all completed applications pertaining to similar types of services, facilities or equipment shall be considered in relation to each other.

(e) *Public hearing and objection procedures.*

(1) A public hearing shall be conducted by the appropriate HSA if any affected person or any appropriate third-party payor submits a written request for a hearing to the HSA within 15 days from the notice published under subsection (c)(3). Timely notification within the 15 day period shall be determined by the postmark. The HSA may require a public hearing during the course of its review of any application for a certificate of need.

(2) Any person directly affected may file an objection to an application within 15 days from the publication of notice in accordance with subsection (c)(3). The date of filing will be determined by the postmark. Such an objection must be filed with the appropriate HSA and set forth specifically the reasons such objection is filed. Persons filing objections shall be parties to the proceeding unless and until such objections are withdrawn. Any person, other than the applicant, or the HSA, who appeals the decision of the Department subsection (j)(1) must have become a party to the proceedings by having filed an objection with the appropriate HSA.

(3) Notice of a public hearing on a certificate of need application shall be published by the HSA in a newspaper of general circulation serving the locality in which the proposed service or facility would be developed. The HSA shall notify affected persons of the hearing at least 14 days prior to the hearing. This requirement may be satisfied as part of subsection (c)(3).

(4) [Reserved].

(5) Each HSA shall adopt and publish specific procedures for conducting public hearings on certificate of need applications. The procedures must be approved by the Department and shall conform to the following:

(i) The applicant and any person shall be afforded the opportunity to submit testimony, oral or written arguments, and relevant evidence at the hearing. Such persons should request the opportunity to testify by notifying the HSA prior to the hearing date or may register to testify at the hearing. Any person shall have the right to be represented by counsel. Any person directly affected may conduct reasonable questioning of persons who make relevant factual allegations. A record of the hearing shall be maintained. A transcript of this record shall be made upon request of a party to the proceedings and at the expense of the requesting party.

(ii) The time allocated to persons wishing to present testimony may be limited under the hearing procedures adopted and published by the HSA governing body.

(iii) The public shall be notified as soon as possible regarding any changes in the scheduled date of a public hearing or any changes in the applications to be heard therein.

(f) *HSA review and recommendations.*

(1) A HSA may, with the approval of the Department, give a nonsubstantive review to a proposed new institutional health service. See § 401.2 (relating to definitions) for definitions of nonsubstantive reviews.

(2) HSAs, in formulating recommendations to the Department on a certificate of need application, shall make their findings regarding the criteria set forth in § 401.4 (relating to criteria for Certificate of Need review) under procedures established by the Department.

(3) The HSA shall concurrently send the applicant notification of the findings and recommendations it submits to the Department. The findings shall be submitted to the Department in such form as the Department requires.

(4) The HSA shall submit its findings and recommendations to the Department within the time period allotted in subsection (d)(2) and (3).

(g) *Department review and findings.*

(1) The Department will consider the timely filed findings and recommendations of the HSA, any information accompanying the application or presented on behalf of the application, any duly promulgated criteria and standards adopted by the Department, and the criteria listed in § 401.4.

(2) If there has been no provision for a public hearing before the HSA, the Department will comply with the requirements of subsection (e).

(3) The Department will approve or disapprove the application within 30 days from the date that the HSA's recommendation is received.

(4) If the Department determines that an application cannot be adequately reviewed within the time periods stated in paragraph (3), it will notify the applicant indicating the reasons why, and request the applicant to agree to an extension of the review period.

(5) If a decision is not made within the required time period, the applicant may bring an action in the Commonwealth Court to require the Department to approve or disapprove the application. If an order is issued by the Court, the Department will promptly, and in accordance with the order, issue its decision. If the decision is adverse to the applicant, the applicant may appeal to the Hearing Board.

(6) Decisions of the Department will be based solely on the record. There shall be no ex parte contacts.

(i) For purposes of this section, an ex parte contact is a contact between an applicant for a certificate of need, any person acting on behalf of the applicant, or any person opposed to the issuance of a certificate, and any

person in the Department who exercises any responsibility respecting the application after the commencement of the public hearing on the applicant's application and before a decision is made with respect to it. A status report shall not be considered an ex parte contact. A contact which is recorded as part of the official application file in accordance with paragraphs (ii) and (iv) shall not be considered an ex parte contact.

(A) For the purpose of this subsection, a person acting on behalf of the applicant for, or holder of, a certificate of need is any person, including an HSA, who favors the issuance of a certificate of need.

(B) For the purpose of this subsection, a person in the Department who exercises any responsibility respecting the application includes any Departmental employe involved in a given review, from the initial reviewer up to and including the Secretary.

(C) For the purpose of this section, status reports are any communications which do not go to the substance of a certificate of need review. They are routine statements of the progress of the review of an application for a certificate of need.

(ii) When the Department receives a written communication from a person who supports or opposes the granting of a certificate of need, the communication shall be made a part of the official project file regarding the issuance of the certificate of need. Any person may review the official project file during the normal business hours of the Department. Any affected person may receive a copy of written communications which have been made part of the official project file by contacting the Division of Need Review. Requests will be considered to be requests for status reports as defined in clause (C).

(iii) When the Department receives a communication either in person or by telephone from a person who supports or opposes the granting of a certificate of need, a summary of the communication will be made part of the file.

(iv) When the Department holds a meeting with an applicant or a person opposing or supporting the issuance of a certificate of need, parties to the proceeding will be notified, in advance of the time and place of the meeting. A summary of the meeting will be made part of the project file.

(7) When the Department approves an application, the certificate of need shall specify the maximum amount of capital expenditures which may be obligated under the certificate.

(8) Certificates of need shall be granted or refused. They shall not be conditioned upon the applicant changing other aspects of its facilities or services or requiring the applicant to meet other specified requirements and no such obligation shall be imposed in granting or refusing approval.

(9) The Department may grant a certificate of need which permits expenditures only for predevelopment of the new institutional health service with respect to which such predevelopment costs are incurred.

(10) When the Department makes a decision regarding the proposed new institutional health service which is inconsistent with the recommendation made with respect thereto by a HSA, or with the applicable health systems plan, or annual implementation plan, the Department will submit to the HSA and all parties to the proceeding a written detailed statement which describes why it has made findings that are inconsistent with the findings of the HSA, the health systems plan or the annual implementation plan.

(11) The Department will make written findings which state the basis for any final decision made by the Department. The findings shall be sent to the applicant, the HSA, and all parties to the proceedings as soon as reasonably possible following its decision, but no later than 10 business days after its decision, and it shall be made available to others upon request.

(12) A person proposing a new institutional health service may withdraw a previously filed application without prejudice by filing written notice of the withdrawal with both the HSA and the Department at any time prior to final approval or disapproval of the required certificate of need.

(13) An applicant may modify a proposal at any time during the review period. When an applicant desires to modify a proposal, the applicant shall submit in writing a detailed statement of the desired changes and an explanation to justify each change to the HSA and the Department. The HSA shall review the proposed changes to determine if a substantial modification to the original application would occur. If it is determined that a substantial modification would occur, the proposed change will be submitted to the HSA for review and a recommendation on the proposed change returned to the Department within 60 days. The Department will approve or disapprove the application within 30 days from the date the HSA recommendation is received. For the purposes of this paragraph, a substantial modification occurs when one of the following occurs:

(i) The proposed bed complement is increased.

(ii) The total costs are increased by more than 20% or $2 million, whichever is less.

(iii) A proposed service is added or deleted.

(iv) The Department and HSA determine there is a significant change in site.

(h) *Emergency certificates.*

(1) The application and review process may be suspended, with the concurrence of the HSA and the Department, for a project limited to a replacement of plant and equipment as a result of natural disaster, fire, unforeseen equipment failure or similar occurrence, which endangers the health and safety of

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patients. Within 5 days of the occurrence, written notification shall be given to the Department and the local HSA.

(2) If the Department suspends the review process, an emergency certificate of need shall be issued subject to any restrictions imposed by the Department. Within 30 days of the issuance of the emergency certificate, the health care provider shall file an application for review of the plant and equipment replaced as a result of the emergency. This application shall be reviewed under the HSA's nonsubstantive review procedures.

(i) *Reconsideration of Department decision.*

(1) Any person may, for good cause shown, request, in writing, a public hearing for the purpose of reconsideration of a decision of the Department within 10 days of the decision of the Department. If such hearing is granted, the Department will set forth the cause for the hearing and the issues to be considered at such hearing. The hearing shall be held no sooner than 6 days and no later than 14 days after a request is made, and may be limited to the issues submitted for reconsideration. Notification of such a public hearing shall be sent at least 5 days prior to the date of the hearing, to the person requesting the hearing, the person proposing the new institutional health service, the HSA for the health service area in which the new institutional health service is proposed to be offered or developed, and shall be sent to others upon request. Within 14 days of the conclusion of the hearing, a summary of the oral testimony shall be made of the hearing, and copies thereof supplied at cost to the person proposing the new institutional health service, the appropriate HSA and any parties to the proceeding, and shall be made available by the Department to others upon request.The Department will affirm or reverse its decision and submit the same to the parties, the person requesting the hearing, and the HSA within 14 days of the conclusion of such hearing. Any change in the decision shall be supported by the reasons therefore.

(2) Where reconsideration hearings are held on more than 2 days, consecutive days of hearings and intervening weekends and holidays shall be excluded in calculating the time permitted for the Department to conduct its review and if briefs are to be filed, 10 days subsequent to the adjournment of the hearing shall also be excluded.

(3) Good cause shall be deemed to have been shown if one of the following occurs:

(i) There is significant, relevant information not previously considered.

(ii) There is significant change in factors or circumstances relied on in making the decision.

(iii) There has been material failure to comply with the procedural requirements of this chapter.

(iv) The Department determines that there is good cause shown for some other reason.

(4) If good cause under paragraph (3)(i) and (ii) is found by the Department, a reconsideration hearing will be conducted under section 704(b) and (c) of the act (35 P. S. § 448.704(b) and (c)).

(j) *Appeals.*

(1) Decisions of the Department on an application for a certificate of need or amendment thereto may be appealed within 30 days by any party or HSA who is involved in the proceeding. The appeal to the Hearing Board shall be commenced within 30 days of receipt of the appeal request and shall be limited to issues raised by the appellant in the specification of objections to the decisions of the Department. Those issues shall be restricted to whether the findings and recommendations of the Department are supported by substantial evidence, and must have been raised or brought to the attention of the HSA or the Department during the course of the review.

(2) The Board shall entertain no evidence that the Hearing Board is satisfied the appellant was able, by the exercise of reasonable diligence, to have submitted before the HSA and the Department.

(k) *Cost increases to certificates.*

(1) A certificate of need shall state the maximum amount of expenditures which may be obligated under it. Applicants proceeding with an approved project may not exceed this level of expenditures except under the following procedures:

(i) When the applicant proposes an expenditure greater than that stated on the certificate, the applicant shall notify the Division of Need Review in writing. The applicant may not proceed with the proposed changes until the appropriate Departmental approvals have been granted. The written notice shall include at least all of the following:

(A) The name and address of the applicant.

(B) The name and location of the project.

(C) The amount of the cost increase.

(D) The primary reasons for the cost increase.

(E) The anticipated source of financing for the cost increase.

(ii) Within 20 days of receipt of the information set forth in subparagraph (i), the Department, after consultation with the HSA, will notify the applicant of the type of review which will be conducted.

(A) A cost increase which exceeds 20% of the originally approved amount shall receive a full review as specified in subparagraph (iii).

(B) A cost increase which is less than or equal to 20% of the originally approved amount may receive a nonsubstantive review.

(iii) For purposes of this subsection, a full review shall be limited to the criteria specified in section 707(a)(4)—(6), and (8), (b)(1) and (2) and (c)(1) and (5) of the act (35 P. S. § 448.707(a)(4)—(6), and (8), (b)(1) and (2) and (c)(1) and (5)).

(iv) Due to the relatively insignificant consequences of some of the changes that would require a nonsubstantive review, an administrative review can be substituted if the HSA and the Department agree that only an administrative review is necessary. The Department will render its decision on the project within 30 business days of receipt of the required information.

(v) The procedures set forth in this section shall also apply to approvals under 42 U.S.C.A. § 1320a-1 and projects covered under section 901 of the act (35 P. S. § 448.901).

(l) *Changes to certificate of need.*

(1) When an applicant proposes a change to an approved certificate of need, the applicant shall notify the Division of Need Review in writing. The applicant may not proceed with the proposed changes until the appropriate Departmental approvals have been granted. The written notice shall include at least the following:

(i) Name and address of the applicant.

(ii) Name and location of the project.

(iii) The change and reason for the change.

(2) Within 20 days of receipt of the information in paragraph (1)(i), the Department, after consultation with the HSA, will notify the applicant of the type of certificate of need review which will be conducted.

(3) Substantial changes which require a full review include, but are not limited to, the following:

(i) A significant change in site as determined by the Department and the HSA.

(ii) The addition or deletion of a health service.

(iii) A change in an application line item by 20%. Line item is defined as single cost categories as listed in the financial section of the certificate of need application. If the overall cost increase does not meet the full review criteria under paragraph (1)(ii)(A) the Department after consultation with the HSA may elect to do a nonsubstantive review.

(iv) A change of greater than 10 beds or 10%, whichever is less, of affected beds in the application.

(v) A 20% change in renovation or construction square footage. Square footage is defined as allocations as listed in the space exhibit of the certificate of need application.

(4) Changes which do not meet the thresholds set forth in this subsection may receive a nonsubstantive review. A change of less than 10 beds or 10%, whichever is less, is not reviewable if the project has been substantially implemented.

(5) Due to the relatively insignificant consequences of some of the changes that would require a nonsubstantive review, an administrative review can be substituted if the HSA and the Department agree that only an administrative

review is necessary. The Department will render its decision on the project within 30 business days of receipt of the required information.

(6) This subsection shall also apply to approvals under 42 U.S.C.A. § 1320a-1 and projects covered under section 901 of the act (35 P. S. § 448.901).

(m) *Withdrawal of certificates.*

(1) A certificate of need shall remain in effect, providing the facilities and services authorized are in use. In the absence of substantial implementation of an approved project for which a certificate of need was issued, the certificate shall be withdrawn 1 year after issuance, unless the Department extends the time for a definite period, not to exceed 6 months. Notification of a request for an extension shall be made in writing to the Department and appropriate HSA and should be made at least 60 days prior to the expiration of the certificate. Only one such extension may be granted for a project. For projects which are approved to be carried out in phases estimated to require no more than 3 years, the certificate of need shall remain in effect after the first phase is implemented but no longer than 3 years unless the project is substantially implemented. All phased construction must commence within 5 years of approval. All phased construction time frames must be approved as part of the review process.

(2) When it comes to the attention of the Department that the time period in which to substantially implement the project has passed without the project being substantially implemented, the Department will send a notice to the holder of the certificate advising that the certificate shall be withdrawn for failure to implement the project in a timely manner.

(i) A notice of the withdrawal shall be sent to all affected persons, published in a newspaper of general circulation in the area to be served by the project, and published in the *Pennsylvania Bulletin*. The notice shall state the reasons for the withdrawal, and the date by which any affected person may request a hearing on the withdrawal. Objections or comments on the withdrawal may be filed by any persons directly affected.

(ii) If a hearing is requested, the Department will forward the request to the appropriate HSA to hold a hearing in accordance with the procedures established by the HSA for public hearings. Notice of the hearing shall be given in writing to all affected persons, and through a newspaper of general circulation for all others.

(iii) A record of the hearing shall be maintained and forwarded to the Department along with a recommendation by the HSA as to whether the certificate should be withdrawn.

(iv) The Department will consider the recommendation of the HSA, the record of the hearing, and any other pertinent information and render a final decision on the withdrawal within 30 days of receipt of the HSA recommendation.

(3) Substantial implementation of a project occurs when the following requirements are completed relative to, but not limited to, the following types of projects. All of the requirements listed in this paragraph must be completed within 1 year after issuance of the certificate or within 18 months after issuance of the certificate if an extension has been granted.

(i) New construction or renovation projects shall include the following:

(A) The title or long-term lease to the appropriate site has been acquired.

(B) The appropriate State agency has approved the complete set of schematic drawings for the project.

(C) A financial commitment has been obtained, for at least 60% of the total approved capital expenditure. The commitment may be any combination of funds such as the applicant's own funds, grants, gifts, or an enforceable offer and acceptance from a financial institution to provide adequate capital financing for the project.

(D) An enforceable construction contract has been entered into causing the commencement of construction no later than 24 months after issuance of a certificate. Failure to commence construction within this time period shall be considered an abandonment of the project and the certificate issued shall be withdrawn. Erection of the foundation shall constitute commencement of construction.

(ii) Acquisition of equipment. The equipment must either be purchased; the lease agreement must be entered into by the proponent; or if acquired by a comparable arrangement the health care facility or health maintenance organization must have possession of the equipment.

(iii) Addition of new service. A written statement must be submitted to the Department verifying that the service is in operation.

(iv) Donated property. In the case of donated property, the date on which title to the donated property is transferred in accordance with applicable State statutes.

(n) *Reporting requirements.*

(1) During the course of review, the HSA and the Department will, upon request of any person, set forth the status and any findings then made or any other appropriate information regarding an application before them. Other appropriate information includes information regarding the conducting of public hearings, the review cycle, or other information to which the public has access under this chapter.

(2) Each HSA shall prepare and publish, at least annually, reports of certificate of need reviews, including a statement of findings and decisions made in the course of each review since the last report.

(3) The Department will prepare and publish, at least annually, reports of the reviews being conducted, including a statement concerning the status of

each review, and of the reviews completed by the agency since the publication of the last report and a general statement of the findings and decisions made in the course of review.

(4) Persons subject to review under this chapter shall submit periodic progress reports to the HSA and the Department pertaining to the development of projects which have received certificate of need approval. The reports must detail the progress toward the substantial implementation of projects as defined in subsection (m). The time period for submission of the progress reports is the end of the 10th month following certificate of need approval, although in the case of an extension, an additional report is required by the end of the 18th month following project approval.

(5) For information purposes only, at least 30 days prior to termination or substantial reduction of a service or a permanent decrease in the bed complement, a health care provider shall notify in writing the HSA and the Department of its intended action. However, if any such change should involve a capital expenditure in excess of the minimum threshold for review of capital expenditures, as established by Federal law or regulation, the health care provider shall be required to obtain a certificate of need in accordance with this section.

(o) *Penalties.* Penalties shall be imposed in accordance with the act.

Authority

The provisions of this § 401.5 issued under section 2102 (a) and (g) of The Administrative Code of 1929 (71 P. S. § 532 (a) and (g)); and section 201(14) of the Health Care Facilities Act (35 P. S. § 448.201(14)).

Source

The provisions of this § 401.5 amended April 13, 1984, effective April 14, 1984, 14 Pa.B. 1294. Immediately preceding text appears at serial pages (52913) to (52925).

Notes of Decisions

The Department is not required to apply a ''regional approach'' when deciding whether to grant a certificate of need application for a freestanding ambulatory surgical facility. *Jeannette District Memorial Hospital v. Department of Health*, 595 A.2d 677 (Pa. Cmwlth. 1991).

The Department's internal preliminary inquiry of a proposed out-patient therapy program for cancer patients did not confer standing upon the competitors of the center to challenge the Department's ''non-reviewability'' determination that the out-patient program was not required to file an application for a Certificate of Need, because the Health Care Facilities Act (35 P. S. §§ 448.801a—448.820), and the Department's regulations did not require notice of preliminary inquiry to be given to competitors. *Powers v. Department of Health*, 550 A.2d 857 (Pa. Cmwlth. 1988); appeal denied 574 A.2d 75 (Pa. 1989).

Transfer of rights to provide scanner services did not constitute a change in conditions which required written notice to the Department as such written approval is only necessary when a change of costs or conditions in the original Certificate of Need proposal is sought. *Laurel Mobile Health Services, Ltd. v. Department of Health*, 550 A.2d 616 (Pa. Cmwlth. 1988).

Cross References

This section cited in 28 Pa. Code § 401.7 (relating to simultaneous and comparative review); 55 Pa. Code § 1163.453 (relating to allowable and nonallowable costs); 55 Pa. Code § 1181.65 (relating to cost-finding); 55 Pa. Code § 1181.259 (relating to depreciation allowance); and 55 Pa. Code § 1181.260 (relating to interest allowance).

§ 401.6. Certificate of need—statement of policy.

(a) *Statewide goals.*

(1) Sufficient ambulatory surgery capacity shall be available and accessible in this Commonwealth to meet local community needs.

(2) Ambulatory surgery shall be promoted throughout this Commonwealth whenever it represents a cost effective alternative to inpatient surgery.

(3) Until 50% of total surgical procedures in an HSA region—or whatever alternative percentage is consistent with local health systems plans adopted by the Health Systems Agency and approved by the Statewide Health Coordinating Council are performed on an ambulatory basis, as indicated hereafter, no application for CDN approval of an ambulatory surgical facility or service shall be considered by the Department as in appropriately increasing total community health care costs, provided the project represents the least costly and most effective method of providing services and meets the guidelines set forth in this section.

(b) *Definitions.* The following words and terms, when used in this section, have the following meanings, unless the context clearly indicates otherwise:

(1) *Ambulatory surgical facility*—A facility not located upon the premises of a hospital which provides outpatient surgical treatment. The term does not include individual or group practice offices or private physicians or dentists, unless the offices have a distinct part used solely for outpatient surgical treatment on a regular and organized basis. See § 401.2 (relating to definitions).

(2) *Ambulatory surgical service*—The provision of outpatient surgical treatment in a health care facility.

(3) *Independent ambulatory surgical facility*—An ambulatory surgical facility whose majority or controlling interest is not owned or controlled by a hospital, group of hospitals or by corporations owning or controlling hospitals. A hospital or a corporation owning or controlling a hospital desiring to establish an ambulatory surgical facility well outside its current service area shall be considered an independent ambulatory surgical facility for review purposes in the new service area.

(4) *Outpatient surgical treatment*—Surgical treatment to patients who do not require hospitalization, but who require constant medical supervision following the surgical procedure performed. See § 401.2.

(c) *Community need—general.*

(1) The need for an increase in ambulatory surgical services exists if less than 50% of total surgical procedures in an HSA region or whatever alternative

percentage is consistent with local health systems plans are performed on an ambulatory basis. The volume of surgical procedures performed in a physician's office—that is, not a health care facility—shall be excluded.

(2) Additional capacity for ambulatory surgery is needed if each HSA and the Department determine that existing providers of surgery in subregional markets are not making a good faith effort to perform 50% of total surgeries, or whatever alternative percentage is consistent with local health systems plans, on an ambulatory basis.

(3) Once the 50% ambulatory surgical target is met, no additional ambulatory surgery proposals will be considered needed except those which:

(i) Are generated by a facility at full capacity and with a need to expand in order to meet demand.

(ii) Seek to serve underserved populations.

(iii) Are necessary to provide new technology/procedures.

(4) The review of individual ambulatory surgical projects will be based upon a comparative analysis. Comparative analysis of competing proposals will be based upon the criteria for review of CON applications as set forth in the act and this title.

(5) In the interest of fair competition, equal consideration will be given to the following:

(i) Hospitals with no current excess capacity, that is, current operating rooms are utilized for both inpatient and outpatient surgery more than 80% of the time based upon 8 hours per day, 5 days per week.

(ii) Hospitals with excess capacity, but willing to reduce capacity by closing at least one existing operating room for every new ambulatory surgical operating room approved. The closure shall be considered a part of the CON application, and an increase in operating rooms after the implementation of the project shall be considered a change in the scope of the project, and is, therefore subject to CON review.

(iii) Independent freestanding ambulatory surgical facilities.

(6) Hospitals with current excess operating room capacity unwilling to commit to a reduction in inpatient operating rooms will be reviewed on their own merits, but will be given lesser priority than those proposals listed in this section.

(7) Optional preferences—the Department will give additional priority to applications meeting one or more of subparagraphs (i)—(iv). Subparagraphs (i) and (ii) will be used to establish priorities among hospital sponsored or related projects only. The terms shall be considered a part of the CON application and a change shall be considered reviewable.

(i) A proposal which reduces current inpatient operating room capacity by a greater amount than the number of new surgical operating rooms requested.

(ii) A proposal which, in addition to reducing operating rooms, reduces setup and staffed inpatient acute care beds.

(iii) A proposal in which an applicant is willing to guarantee its charges by procedure for at least a 2-year period following initial operation of the approved project. In order to qualify for this preference, the applicant shall include within its application, evidence of binding contractual relationships with major third-party payors guaranteeing charges for the required 2-year period.

(iv) A proposal in which the applicant agrees not to change ownership any sooner than 2 years after the project becomes operational. The ability and expertise of an owner is a critical factor in the issuance of a CON for the development of an ambulatory surgical facility. Thus, all applicants given preference under this subparagraph should be advised that changes in ownership would be considered a substantial change and therefore may be subject to CON review.

(d) *Economic and financial feasibility.*

(1) Proposals to increase ambulatory surgical capacity shall be financially feasible, considering the anticipated volume of care, the reasonableness of service changes and the availability of appropriate financing.

(2) Careful consideration should be given to each project's allocation of costs between a parent corporation and a proposed ambulatory surgical facility to ensure that there is no hidden or unfair subsidization by the parent corporation to make the project appear less costly than it may actually be.

(e) *Quality of care.* Each ambulatory surgery project shall meet the licensure requirements of this title.

(f) *Access to care.* Each ambulatory surgery project shall demonstrate in its application a commitment to serve a fair share of medically underserved patients in its community.

(g) *Project review.* Projects for ambulatory surgical services and facilities shall be reviewed on a batching basis. The effective date for implementation of batching will be the date on which the Department publishes a notice of proposed rulemaking in the *Pennsylvania Bulletin* on batching.

(h) *Research and data.* The Department and the HSAs will collect current information on ambulatory surgical utilization and costs. The Department will require each applicant to report on a timely basis to the Department and the HSAs information on utilization and charges that the Department determines necessary to assure the provisions of this section are implemented.

Source

The provisions of this § 401.6 adopted March 22, 1985, effective March 23, 1985, 15 Pa.B. 1079.

Notes of Decisions

Economic and Financial Feasibility

The Department need not apply a regional approach when considering an application for a Certificate of Need to operate a freestanding ambulatory surgery center nor must the Department compare the applicant's charges to more than other service provider. *Jeannettee District Memorial Hospital v. Department of Health*, 595 A.2d 677 (Pa. Cmwlth. 1991).

The CON Memorandum 85-15, published in 15 Pa.B. 1079, March 23, 1985, and now found in this section, was an interim interpretive policy dealing with the State Health Plan, within the Department's expertise and was therefore beyond the scope of the Regulatory Review Act. *Grandview Surgical Center, Inc. v. Holy Spirit Hospital of the Sisters of Christian Charity*, 533 A.2d 796 (Pa. Cmwlth. 1987).

It was improper for the Board to emphasize statistics of one health care provider as opposed to a regional approach in analyzing investment and utilization patterns. *Grandview Surgical Center, Inc. v. Holy Spirit Hospital of the Sisters of Christian Charity*, 533 A.2d 796 (Pa. Cmwlth. 1987).

"Cost-effectiveness" is an appropriate factor for the Board to consider in a decision. *Grandview Surgical Center, Inc. v. Holy Spirit Hospital of the Sisters of Christian Charity*, 533 A.2d 796 (Pa. Cmwlth. 1987); appeal denied 546 A.2d 623 (Pa. 1988).

§ 401.7. Simultaneous and comparative review.

(a) The following categories of projects will receive simultaneous and comparative review:

(1) Alcohol and other drug treatment and rehabilitation.
(2) Ambulatory surgical services.
(3) Cardiac catheterization.
(4) Cardiac surgery.
(5) Comprehensive medical rehabilitation.
(6) Lithotripters.
(7) Magnetic resonance imaging devices.
(8) Psychiatric services.
(9) Renal dialysis units.
(10) Skilled nursing and intermediate care services.

(b) The Department, after consultation with the HSAs, will establish a schedule for simultaneous and comparative review of the categories of projects identified in this section. The time between the beginning of a period and the beginning of the next succeeding period for submission of applications for a category may not exceed 4 months. This schedule will be submitted for publication as a notice in the *Pennsylvania Bulletin*.

(c) Simultaneous and comparative reviews will follow the procedures in § 401.4 (relating to criteria for Certificate of Need review), with the following modifications:

(1) To qualify for simultaneous and comparative review, an application shall be submitted to the HSA and the Department under § 401.5 (relating to certificate of need) within 5 days of the scheduled beginning date for receipt of applications. An application submitted after the 5th day of the beginning date

will be returned to the applicant for resubmission during a subsequent simultaneous and comparative review period.

(2) An applicant may withdraw an application from a simultaneous and comparative review period by requesting in writing the withdrawal of the application from consideration.

(3) An applicant may request postponement of review until a subsequent simultaneous and comparative review period.

(4) An applicant's request for an extension will be considered a request for postponement of review until a subsequent simultaneous and comparative review period.

(5) An applicant's request for a substantial modification will be considered a request for postponement of review until a subsequent simultaneous and comparative review period.

(6) The HSA and the Department will determine if an application is complete and notify the applicant of its findings by the 15th day of the simultaneous and comparative review period. In determining if an application is complete, the HSA and the Department will examine the application to determine if requested information has been provided. An application which is still incomplete on the 30th day of a review period will be returned to the applicant for resubmission during a subsequent simultaneous and comparative review period.

(7) The HSA shall publish a notice, in at least one newspaper of general circulation serving the localities in which the projects will be developed, within 30 days following the beginning of the simultaneous and comparative review period.

(i) The notice shall contain the following information:

(A) Names and addresses of the applicants.

(B) A brief description and an estimate of the cost of the projects.

(C) The schedule for review.

(D) Notification that the applications are complete.

(E) Notification that the review of the completed applications is beginning.

(F) Notification of the date a public hearing will be held.

(G) Notification of the deadline for submission of objections to the applications and the deadline for submission of intention to attend or testify at the public hearing.

(ii) The Department will provide notice as set forth in this paragraph if one of the following applies:

(A) There is no HSA functioning in an applicant's regional area.

(B) More than one HSA is involved in the review of applications in a particular project category and the Department has determined that one hearing is preferable to a hearing in each regional area.

(8) No additional information will be accepted by the Department after the applications have been deemed complete, except during the public hearing.

Authority

The provisions of this § 401.7 issued under section 702 of the Health Care Facilities Act (35 P. S. § 448.702(j)).

Source

The provisions of this § 401.7 adopted January 9, 1987, effective January 10, 1987, 17 Pa.B. 182.

§ 401.11. Magnetic resonance Certificate of Need—statement of policy.

(a) *Status and trends.* Magnetic resonance (MR) is a category of service that uses the magnetic spin property of certain atomic nuclei to visualize and analyze tissue. Diagnostic techniques include both MR imaging and spectroscopy.

(1) MR imaging has proven to be a useful tool in the diagnosis of the following:

(i) Brain, brain stem, spinal cord disorders and demylenating diseases.

(ii) Diffuse or infiltrating diseases of the liver and kidney.

(iii) Early changes in ischemia and infarction of heart tissue.

(2) Ovarian and uterine tissue can be imaged well through MR. Also, the process can be used to evaluate growth and development of a fetus.

(3) MR spectroscopy has potential application for in vivo analysis of biochemical processes in healthy and diseased tissue. Potential applications include the following:

(i) Determination of early chemical changes in evolving cerebral or myocardial infarctions.

(ii) Determination of the chemical nature and specific diagnosis of tumors throughout the body.

(iii) Analysis of chemical parameters and changes in metabolic diseases of the liver and kidney.

(iv) In vivo analysis of early changes in multiple sclerosis.

(v) In vivo analysis of dementia-producing disorders such as Alzheimer's disease.

(4) The Federal Food and Drug Administration (FDA) has approved MR imaging devices produced by certain manufacturers.

(5) On July 1, 1985, Blue Cross of Western Pennsylvania began coverage for all MR imaging scans performed on FDA-approved equipment provided that a certificate of need has been issued or a project has been deemed nonreviewable. Pennsylvania Blue Shield followed suit in October 1985. In November 1985, The Health Care Finance Administration announced that Medicare will provide reimbursement for MR imaging procedures for a limited number of diagnoses. As of April 1987, third party payers were not reimbursing facilities for spectroscopic services which are regarded as experimental.

(6) MR devices are available with one of three broad categories of magnets. Each type of magnet can be obtained in a variety of field strengths up to 2.5 Telsa. Higher field strength becomes important in MR spectroscopy. The three categories of magnets are:

(i) Resistive.

(ii) Permanent.

(iii) Superconductive.

(7) A recent development is the mobile MR unit. Equipment manufacturers predict that up to 40% of their market will be mobile units.

(8) A type of movable unit is the transportable and relocatable system. These are larger than mobile units and are not intended to be moved more than several times per year.

(9) Tables 1 and 2 show the estimated range of purchase and installation costs, and annual operating costs, respectively, as compiled by the American Hospital Association (AHA). Mobile systems will have the following additional costs:

(i) For the trailer—$500,000.

(ii) For the tractor—$50,000 to $125,000.

Table 1
MR Capital Costs

Item	*Permanent Magnet (Low—High)*	*Superconducting Magnet (Low—High)*
Equipment	$800,000—1,500,000	$1,000,000—2,500,000
Facility Preparation	80,000— 250,000	350,000—1,300,000
Total	$880,000—1,750,000	$1,350,000—3,800,000

Source: AHA Guideline Report, 1985.

Table 2
MR Annual Operating Costs

	Permanent Magnet (Low—High)	*Superconducting Magnet (Low—High)*
Variable Costs		
Maintenance	$40,000— 75,000	$ 75,000— 140,000
Personnel	85,000—138,000	85,000— 135,000
Electrical Power	6,000— 11,000	6,000— 11,000
Cyrogens	-0- -0-	15,000— 65,000
Other Variable	37,500— 75,000	37,500— 75,000
Subtotal	$168,500—299,000	$218,500— 435,000
Fixed Costs		
Depreciation	$176,000—350,000	$270,000— 760,000
Interest @ 10%	88,000—175,000	135,000— 380,000
Total	$432,500—824,000	$623,500—1,575,000

Source: AHA Guideline Report, 1985.

(10) Although MR imaging has distinct advantages over the less expensive computerized axial tomography (CAT) scan, there are important limitations. Seriously ill patients in monitored beds cannot be imaged because the presence of strong magnetic fields will affect electronic monitoring devices. Also, MR is contraindicated for patients with intravenous (IV) needles and ferrous metal implants. The AHA projects that across all disease categories, MR imaging will replace only about 34% of all CAT scans.

(11) Table 4, set forth in subsection (c), shows the present distribution of certificate of need approved MR devices in this Commonwealth.

(b) *Policy.* The following criteria will be used in reviewing certificate of need proposals related to magnetic resonance:

(1) The formula set forth in subsection (c) will be used in certificate of need reviews for MR imaging project proposals.

(2) To the extent feasible, and consistent with other criteria, MR devices should be dispersed throughout a region. Magnetic resonance imaging (MRI) services should be located so that 90% of the population of the region is within 1 hour travel time to a service.

(3) Applicants shall establish and document a policy that MR services will be provided regardless of a patient's ability to pay.

(4) Shared arrangements may be any of the following:

(i) Reciprocal agreements among hospitals with CAT and MRI capability.

(ii) Reciprocal agreements involving use of a device located at a free-standing imaging center.

(iii) Reciprocal agreements involving use of a mobile or a transportable/relocatable unit.

(5) The Department will deem the needs of the population to be best served by hospitals proposing shared arrangements with other health care facilities.

(6) The Department will deem a shared arrangement to be economically more feasible than a single facility use proposal. When comparing two or more shared arrangement proposals, the Department will evaluate the following:

(i) The respective capabilities of the project applicants and associated facilities of each.

(ii) The anticipated volume of care of each.

(iii) The availability of reasonable start-up capital of each.

(iv) Projected marginal revenues of each.

(v) Projected marginal costs, variable costs and fixed costs of each.

(7) An applicant facility shall establish and document a policy that the hospitals in a region to be served by an MR unit will have equal access to the unit. Equal access will be characterized by the following:

(i) A scheduling priority based on patient need. Documented urgent or emergent cases will be given priority access.

(ii) A nondiscriminatory charge schedule.

(iii) Interhospital transport services with appropriate medical supervision established either directly by the applicant or through a mutually agreed upon arrangement with the referring facility.

(8) Charges for MRI services should be reasonably related to service cost. Charges should not exceed the median charge of Commonwealth providers of comparable MRI services by more than 20% without reasonable justification.

(9) Facilities providing MR services shall have a utilization review program that includes MR examinations.

(10) Hospitals offering MR shall be able to directly provide related diagnostic modalities such as the following:

(i) CAT full-body scanning.

(ii) Ultrasound.

(iii) Radionuclide scanning.

(iv) Conventional X-ray, including, but not limited to, arteriography.

(11) A board-certified or board-qualified physician trained in MRI shall be responsible for the operation of the MR facility and interpretation of the MR data. This work shall be the full-time activity of that physician or other physicians delegated by that physician if they have been trained in MRI.

(12) Medical physicist involvement is necessary for quality assurance, computer maintenance and training of staff in magnetic field theory and related issues.

(13) The MR program staff shall include the specialty of radiology and subspecialists appropriate to the applications intended, including experience in computed tomography or nuclear medicine.

(14) Facilities proposing to provide MR services shall also directly provide a variety of medical subspecialty services which include, but are not limited to, oncology, neurology, internal medicine, pathology and radiology.

(15) At least one staff person trained in cardio-pulmonary resuscitation (CPR) shall be on duty in the unit at all times.

(16) The facility shall have a program on image quality control of MR services and a program to calibrate and maintain its diagnostic equipment.

(17) The MR unit shall meet the standards recommended by the FDA.

(18) The area housing the MR unit shall be constructed in accordance with standards established by the manufacturer and Federal or State standards, or both, as may be developed.

(c) *MR need.*

(1) Several methodologies for projection of MRI utilization have been studied.

(i) The methodology used in New York State assumes a ratio of one MR unit per three fully utilized CAT scanners. New York considers 3,000 images per year as full utilization of an MR unit.

(ii) Massachusetts uses the AHA utilization model, at least in part.

(iii) Illinois will approve an MR unit at a hospital which does 4,500 CAT scans per year or more.

(iv) The Health Systems Agency of Southwestern Pennsylvania uses the methodology developed by the AHA.

(v) The AHA methodology is based on the opinions of an expert panel of physicians. The panel determined the percent of patients within discrete ICD-9-CM categories who would require MRI.

(2) The Department adopts the AHA methodology, as set forth in the AHA Hospital Technology Series, Vol. 11, No. 8, ''NMR—Nuclear Magnetic Resonance Guideline Report'' of 1983, to predict the number of initial and followup scans. The Statewide results of this methodology are given in Table 3.

Table 3
Statewide Revised Projections of MRI Procedures
AHA ICD-9-CM Projection Method

HSA REGION	1990 PROJECTED MRI SCAN VOLUME
1	83,372
2	22,294
3	17,747
4	34,336
5	17,246
6	62,775
7	17,352
8	2,516
9	11,024
Total	268,662

(3) Throughput is the number of patients imaged per year. The Health Systems Agency of Southwestern Pennsylvania estimated that a unit is capable of 2,000 procedures per year. By the end of 1986, the 14 test sites in New York State were achieving an average throughput of 2,500 patients per year. Full utilization in New York State is 3,000. A radiological team headed by W. G. Bradley reports in ''MR Installation, 18 Months Clinical Experience'' that patient throughput at the MR operated by the 625-bed Huntington Medical Research Institute averages more than 12 patients per day with as many as 18 patients per day often being examined. By reaching reasonable throughput, the Hun-

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tington Institute has been able to keep average MR charges at about 25% higher than CAT. Twelve patients per day yields a total annual throughput of 3,000 patients.

(4) The following formula is used to predict the number of MRI devices needed in Pennsylvania.

$$\text{MR Units} = \frac{\text{Estimated MR Procedures}}{\text{Throughput}}$$

(5) The Department of Health adopts 2,500 patients per year as a reasonable throughput for a single unit. Therefore, using the formula in paragraph (4), approximately 107 MR units will be adequate to meet the needs of patients in this Commonwealth.

(6) Table 4 shows the projected need for MR units by health service area. Rounding of fractional units next higher integer results in a total State need of 110 units.

Table 4
MR—Projected Need

HSA	Approved* Units	Projected Need	(Shortage) Surplus	MRI Applications Pending Review
I	26	34	(8)	5
II	4	9	(5)	1
III	4	7	(3)	1
IV	7	14	(7)	1
V	4	7	(3)	1
VI	20	26	(6)	7**
VII	5	7	(2)	1
VIII	1	1	0	0
IX	3	5	(2)	0
Total	74	110	(36)	17

*As of August 29, 1989
**One application is requesting 3 MRI units.

Source

The provisions of this § 401.11 adopted July 10, 1987, effective July 11, 1987, 17 Pa.B. 2946; amended August 5, 1988, effective August 6, 1988, 18 Pa.B. 3467; amended December 8, 1989, effective December 19, 1989, 19 Pa.B. 5222. Immediately preceding text appears at serial pages (127049) to (127052) and (129161) to (129163).

§ 401.12. Reviewable clinically related health services—statement of policy.

(a) Section 701(d) of the act (35 P. S. § 448.701(d)), as amended by the act of December 18, 1992 (P. L. ____ , No. 179), requires the Department to publish within 30 days of the effective date of the amendment a list of clinically related health services that require a Certificate of Need.

(b) Clinically related health services which require Certificates of Need are as follows:

Alcohol or other drug rehabilitation—inpatient, limited to hospital or non-hospital, inpatient treatment programs lasting less than 60 days
Ambulatory surgery—single specialty
Ambulatory surgery—general/multiple specialty
Cardiac catheterization—diagnostic
Cardiac catheterization—therapeutic
Comprehensive medical rehabilitation—inpatient
Emergency department
Intermediate care for the mentally retarded (ICF/MR)
Intermediate or skilled nursing care—inpatient
Lithotripsy—biliary
Lithotripsy—renal
Magnetic resonance imaging
Medical surgical—inpatient
Neonatal intensive care—inpatient
Open heart surgery
Organ transplant—heart/lung
Organ transplant—kidney
Organ transplant—liver
Organ transplant—other
Positron Emission Tomography (P.E.T.)
Psychiatric—inpatient adult
Psychiatric—inpatient child and adolescent
Surgery—inpatient

(c) A health care facility as defined under section 103 of the act (35 P. S. § 448.103) is automatically reviewable under section 701(a) of the act.

(d) A person proposing to offer a new, high-cost technology as defined in section 701(g) of the act and which does not appear in subsection (b) shall consult with the Department regarding the reviewability of the proposal.

Source

The provisions of this § 401.12 adopted November 3, 1989, effective November 4, 1989, 19 Pa.B. 4734; amended June 21, 1991, effective June 22, 1991, 21 Pa.B. 2816; amended January 15, 1993, effective January 16, 1993, 23 Pa.B. 290. Immediately preceding text appears at serial pages (157566) to (157567).

Cross References

This section cited in 28 Pa. Code § 401.14 (relating to letters of interest and filing fees—statement of policy).

§ 401.13. Examination of Certificate of Need files—statement of policy.

(a) By prior written request and arrangement only, Certificate of Need (CON) applications and materials will normally be available for examination by the public on Tuesdays, Thursdays and Fridays which are official Commonwealth State government business days from 9 a.m. to 12 p.m. and from 1 p.m. to 4 p.m. in Room 1027, Health and Welfare Building, Commonwealth and Forster Streets, Harrisburg, Pennsylvania. Parties requesting examination of materials shall make requests in writing by designating the name, address and telephone number of the requesting party, project name and description or CON number or both, and the calendar date on which the party would like the materials to be made available for review. Parties shall make sure that written requests reach the Department at least 2 full business days prior to the calendar date requested for review. Requesting parties will be notified by the Division of Need Review staff by telephone of the date on which materials are available. Requesting parties that walk in without prior contact with the Division of Need Review will be given a date for examination of requested documents within 2 full business days, upon providing the information required by this subsection.

(b) CON records maintained by the Central Office in Harrisburg may be reviewed and copied only at the Division of Need Review Office.

(c) CON records will be made available for review by the Division of Need Review staff in the Division conference area only.

(d) A fee of 50¢ per page for all pages copied will be invoiced payable to the Department of Health by check or money order; however, there will be a minimum copy charge of $5. The requesting party or their representatives are responsible to make the copies, using the copy machine in the Division of Need Review Office.

Source

The provisions of this § 401.13 adopted December 21, 1990, effective December 22, 1990, 20 Pa.B. 6301.

§ 401.14. Letters of intent and filing fees—statement of policy.

(a) A person intending to offer, develop, construct, renovate, expand or otherwise establish or undertake to establish either a clinically related health service that is included in the Department's list of reviewable clinically related health services in § 401.12 (relating to addition of a health service subject to Certificate of Need review—statement of policy), or a health care facility as defined in section 103 of the act (35 P. S. § 448.103) shall at the earliest possible time in their planning submit a signed letter of intent to the Department.

(b) Letters of intent shall contain the following information:

(1) The name and address of the applicant.

(2) The name and address of the contact person for the project.

(3) The proposed name and location of the project.

(4) A brief description of the proposed project, including the amount of capital expenditure, the type of health service being proposed or a change in bed capacity involved in the proposed project.

(5) The expected date of project commencement and completion.

(6) The expected capital expenditure, including capital leases or donations as defined in § 401.15 (relating to Certificate of Need application procedures and filing fees—statement of policy), and anticipated source of project financing.

(7) A statement certifying that the data, information and statements are factual to the best of the applicant's knowledge, information and belief.

(c) Every person who submits to the Department a letter of intent shall file a nonrefundable fee of $150 in the form of a certified check made payable to the ''Commonwealth of Pennsylvania.'' The required fee for a letter of intent is due upon filing of the letter of intent. The letter of intent will not be considered until the fee is received.

(d) Within 30 days of receipt of a letter of intent, the Department will assign a project number, determine reviewability of the proposal and notify the applicant if a Certificate of Need is required. If a Certificate of Need is required, the Department will mail to the applicant an application form and appropriate instructions for completion of the application.

(e) Even if the required letter of intent fee is received, the elements of subsection (b) shall be addressed before the time period in subsection (d) commences.

(f) The Department will withdraw from further consideration a letter of intent if a Certificate of Need application is not filed within 1 year of the date of determination of reviewability.

(g) The Department will not accept a facsimile of a letter of intent electronically transmitted to the Department.

Source

The provisions of this § 401.14 adopted February 19, 1993, effective February 20, 1993, 23 Pa.B. 843.

§ 401.15. Certificate of Need application procedures and filing fees.

(a) An application for a Certificate of Need shall be submitted to the Department on application forms provided by the Department. An applicant shall submit an original and one copy of the completed application to the Department of Health, Division of Need Review, and one copy of the completed application to the appropriate district office of the Department. The copy supplied to the district

office is for public review, and copies of the application to persons other than the Department shall be supplied by the applicant in accordance with subsection (o).

(b) An application for a Certificate of Need will be accepted by the Department only on the first 5 business days of each month. Applications received after the fifth day will be returned to the applicant.

(c) Every person who submits to the Department an application for a Certificate of Need shall also file a nonrefundable fee as follows:

(1) For each Certificate of Need application, filed under section 702(b) of the act (35 P. S. § 448.702(b)), $500 plus $3 per $1,000 of proposed capital expenditure. The maximum application fee may not exceed $20,000 for a single proposal.

(2) The letter of intent fee shall be deducted from the required total application fee.

(d) The following formula shall be used in calculation of the required Certificate of Need application fee:

Base fee	$ 500
Add: $3 per $1,000 of proposed capital cost:	
((capital expenditure/$1,000) × $3)	$
Application fee due	$
Subtract: Prepaid letter of intent fee	150
Balance due with application (nonrefundable)	$

(e) The application fee shall be rounded to the nearest dollar.

(f) The following sample calculation demonstrates how the formula in subsection (d) will be applied to determine the amount of the application fee. A proposed capital expenditure of $2,135,700 is assumed.

Base fee	$ 500
Add: $3 per $1,000 of proposed capital cost:	
($2,135,700/$1,000)/ × $3	$ 6,407
Application fee due	$ 6,907
Subtract: Prepaid letter of intent fee	150
Balance due with application (nonrefundable)	$ 6,757

(g) The required fee for a Certificate of Need application, less previously paid letter of intent fee, is due upon filing of the application.

(h) An application shall be mailed to the Division of Need Review, Pennsylvania Department of Health, 1027 Health and Welfare Building, 7th and Forster Streets, Harrisburg, Pennsylvania 17120, accompanied by a certified check made payable to the ''Commonwealth of Pennsylvania'' in the correct amount of the fee. An application submitted without the correct fee in the form of a certified check will be returned immediately to the applicant. The Department will not

begin a preliminary assessment of an application until the appropriate fee is paid in full as determined by the Department.

(i) Consistent with generally accepted accounting principles, a capital lease is a capital expenditure for purposes of Certificates of Need. A lease will be determined to be a capital lease if one or more of the following conditions applies:

(1) Ownership of the leased asset will be conveyed to the lessee at the end of the lease period.

(2) The lease gives the lessee the option to purchase the leased asset at less than fair market value at some point either during the lease period or at the end of the lease period.

(3) The period of the lease is 75% or more of the expected useful life of the leased asset.

(4) The present value of the minimum lease payments is 90% or more of the fair market value of the leased asset.

(j) Acquisition of a donated capital asset will be considered a capital expenditure for purposes of Certificates of Need. Valuation of donated capital assets will be the higher of historic cost or current market value, consistent with generally accepted accounting principles.

(k) Upon receipt of an application for a Certificate of Need and appropriate filing fee, the Department will conduct its preliminary assessment within 60 days, and determine whether additional information is required. If additional information is required, the Department will send notice to the applicant, stating what additional information is required. Upon receipt of the additional information, the Department will complete its preliminary assessment within 45 days of receipt of the same. Timely notice of the beginning of review of the application by the Department will be published after preliminary assessment of the application is completed by the Department.

(l) The Department retains the right to use an expedited review process.

(m) After 1 year from the date of the Department's request for additional information, the Department will withdraw from further consideration a Certificate of Need application for which questions were asked, but no responsive answers have been received.

(n) The ''date of notification'' begins the 90-day time period in which the Department must complete review of the application. The date of notification shall be the date the Department sends notice to the applicant, or publishes a notice of the beginning of a review in the *Pennsylvania Bulletin* or in a newspaper of general circulation, whichever is latest.

(o) Interested persons may request a public meeting within 15 days of publication of the notice. A request for a public meeting shall be in writing and set forth specifically the reasons a public meeting is being requested. The applicant is required to provide a copy of the application to interested persons making a

request for the application. The applicant may charge the interested person the reasonable cost of making the copy.

(p) A cost increase or a change in scope of a previously approved Certificate of Need will be regarded as a new proposal subject to application fees. The fee shall be $500, plus $3 per $1,000 for a proposed capital expenditure over the approved capital expenditure. The total amount of additional fee may not be more than $20,000. Modifications which result in additional capital costs to a proposal during the review process will be subject to additional fees payable at the time of submission of the modification to the Department.

Source

The provisions of this § 401.15 adopted February 19, 1993, effective February 20, 1993, 23 Pa.B. 843.

Cross References

This section cited in 28 Pa. Code § 401.14 (relating to letters of intent and filing fees—statement of policy).

§ 401.16. Positron Emission Tomography (PET) services; interim criteria for Certificate of Need (CON) review—statement of policy.

(a) Acquisition of a PET scanner is subject to review under section 701 of the act (35 P. S. § 448.701).

(b) Certificate of Need review for proposed PET scanners will be conducted using the need methodology in subsection (c), and the review criteria in subsection (h).

(c) The Department will use the following methodology to determine the need for PET scanners in this Commonwealth:

$$\text{PET Units} = \frac{\text{Brain Population} \times (\text{OH} + \text{PTCA} + \text{Epilepsy} + \text{Tumor} + \text{Dementia})}{\text{Optimal use rate}}$$

where:
- OH (Open Heart) = 173/100,000 population
- PTCA = 18/100,000
- Epilepsy = 30/100,000
- Brain Tumor = 18/100,000
- Dementia = 34/100,000
- Optimal Use rate = 2,000 scans per year

(d) The incidence rate for open heart surgery is derived from the formula found at Chapter 26 of the SHP as amended July 16, 1991.

(e) Incidence rates for percutaneous transluminal coronary angioplasty (PTCA), epilepsy, brain tumor and dementia are derived from a methodology developed by the American Hospital Association. This methodology determined which ICD-9 diagnostic codes involve conditions which might require a PET scan, the percentage of patients with the condition who would receive a scan and

the average number of scans each patient would be likely to receive. Incidence data are based on 1989 hospital discharge data reported to the National Center for Health Statistics.

(f) The optimal use rate, expressed as number of scans per unit, is taken from a number of studies as well as from literature supplied to the Department by manufacturers of PET scan devices. This material supports a rate range of six to ten scans per device per day. A midpoint of eight scans per device per day is adopted, and results in a total annual use rate of 2,000 scans per device per year.

(g) Application of the formula in subsection (c) projects the following need by health planning area through the year 1995.

Health Planning Area	*Projected Need*
I	5
II	1
III	1
IV	2
V	1
VI	4
VII	1
VIII	0
IX	1
Total	16

(h) The Department will use the following review criteria in addition to the need projections in subsection (g) to determine the need for a PET service:

(1) A site where PET services are proposed to be offered shall be a site where the following clinical services also are currently offered:

(i) An open heart surgery program that is approved by the Department and where an average of at least 700 open heart cases per year during the most recent 3-year period were performed. In the interest of geographic distribution of PET services, the Department may waive this requirement in its consideration of an application from a hospital where at least 450 open heart cases per year were performed during the most recent 3-year period, if no other hospital in the same health planning area met the 700 case standard. The Department may also waive this requirement in its consideration of an application from a medical college.

(ii) A therapeutic cardiac catheterization service that is approved by the Department and that includes a PTCA program.

(iii) A full range of full-time, onsite related diagnostic modalities including conventional x-ray, full-body computed tomography, ultrasound, magnetic resonance imaging and other radio-nuclide scanning.

(2) The Department will consider applications for shared PET services. The standards in paragraph (1) shall be met by each hospital participating in the shared PET service.

(3) Hospitals in a region served by one or more PET scanners will have equal access to at least one of the units. Equal access will be characterized by the following:

(i) A scheduling priority based on patient need.

(ii) Services provided to patients from referring hospitals will be charged for the PET services at the same rate as patients in the hospital housing the PET scanner.

(iii) Transportation services with appropriate supervision established either directly through the sponsor or through a mutually agreed upon arrangement with the referral facilities.

(4) The equipment shall be certified for clinical use by the Federal Food and Drug Administration (FDA). The facility shall also present evidence of approval by the FDA of its New Drug Application (NDA) for the production of radiopharmaceuticals as part of the CON application.

(5) A PET service shall be under the medical direction of a physician who is board certified in nuclear medicine or nuclear radiology, or trained and licensed in nuclear cardiology and has additional documented experience and training in PET technology, including radiochemistry. The physician shall be licensed by the Nuclear Regulatory Commission to possess radiopharmaceuticals and perform diagnostic procedures employing radiopharmaceuticals in human beings.

(6) Additional staff for a PET service shall include at a minimum the following staff as appropriate:

(i) A radiochemist trained at the master's or Ph.D. level in radiochemistry or radiopharmacy who also has a background in PET physics or radiochemistry and experience in radiopharmaceutical production.

(ii) A nuclear medicine technologist with training onsite or offsite in cyclotron operation and radiopharmaceutical production, and who will work under direction and supervision of the medical director.

(iii) Two radiological technologists with documented training in radiology, nuclear medicine or MRI/CT scanning and who are able to provide support in the areas of PET imaging systems operation, patient preparation for PET studies and image analysis and processing.

(7) The PET service should be available for operation at least 8 hours per day, 5 days per week. Evening and weekend hours are encouraged as an aid to accessibility.

(8) It is the policy of the Department to encourage efficient use of expensive technology through sharing of cyclotron facilities.

(9) Proposals to convert an existing research scanner to clinical use will be subject to CON review.

(10) Additional scanners in a health planning area beyond the need projected in subsection (g) will not be approved until previously approved PET scanners in the health planning area are operating at an average of 2,000 scans per year.

(i) This section shall serve as an interim policy until replaced with standards and criteria in the State Health Services Plan.

Source

The provisions of this § 401.16 adopted May 21, 1993, effective May 22, 1993, 23 Pa.B. 2449.

§ 401.17. Prohibited communications with the Department—statement of policy.

(a) After the conclusion of a public meeting on a Certificate of Need application held under section 704(b) of the act (35 P. S. § 448.104(b)), there may be no ex parte contacts with the Department.

(b) For purposes of this section, an ex parte contact is communication between the following individuals and any member of the Department exercising any responsibility for the applicant:

(1) The applicant for a Certificate of Need.

(2) A person acting on behalf of the applicant.

(3) A person who supports or opposes the granting of a Certificate of Need.

(c) The Department will not accept telephone calls from any of the individuals listed in subsection (b)(1)—(3) after the public meeting, unless that call consists only of a request for a status report. A ''status report'' consists of a statement of the progress of the review of a Certificate of Need application. Communication regarding the substantive elements of a Certificate of Need application is not a status report.

(d) At the conclusion of the public meeting, the meeting officer will announce a schedule during which communications and responses to those communications will be received by the Department and the date upon which the record will be closed. After the public meeting, the Department will not accept written communications from the individuals listed in subsection (b)(1)—(3), unless the document indicates that copies have been sent to those persons who attended the public meeting. If no notation is made on the document, it will be returned by the Department to the sender and will not be considered by the Department in its review of the project nor will it become part of the official file.

(e) If a public meeting is not held, there may be no ex parte contacts with the Department after the time has expired for interested persons to request a public meeting as set forth in section 704(b) of the act. After that date, the individuals listed in subsection (b)(1)—(3) may not contact the Department, except for requests for a status report.

Source

The provisions of this § 401.17 adopted December 2, 1994, effective December 3, 1994, 24 Pa.B. 5993.

§ 401.18. Hospital-based skilled nursing facilities—statement of policy.

(a) The Department will apply the relevant criteria contained in Chapter 14 of the State Health Services Plan (SHSP) in the review of Certificate of Need applications to establish hospital-based skilled nursing facilities.

(b) The criteria to be applied will include the long-term care bed need projections contained in Appendix 14-A to Chapter 14 of the SHSP and any updated revisions to that Appendix. If a proposed hospital-based skilled nursing facility is located in a county for which the number of licensed or approved long-term care beds equals or exceeds the projected bed need, the Department will consider approval of the application only if the applicant is able to demonstrate that the approval is otherwise justified under the criteria contained in Chapter 14 of the SHSP.

(c) This section applies to Certificate of Need applications for which a completion of preliminary assessment has not been published in the *Pennsylvania Bulletin*.

(d) This section will remain in effect unless it is superseded by specific criteria in the SHSP addressing the issue of bed need projections for hospital-based skilled nursing facilities.

Source

The provisions of this § 401.18 adopted November 4, 1994, effective November 5, 1994, 24 Pa.B. 5563.

[Next page is 501-1.]