THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 305

Session of 2007

INTRODUCED BY MUNDY, BELFANTI, BISHOP, BUXTON, CALTAGIRONE, CARROLL, DeLUCA, DePASQUALE, FRANKEL, FREEMAN, GEORGE, GOODMAN, GRUCELA, HESS, JAMES, JOSEPHS, KIRKLAND, KORTZ, MAHONEY, MANDERINO, MANN, MELIO, MUSTIO, OLIVER, PALLONE, ROEBUCK, SANTONI, SCAVELLO, TANGRETTI, J. TAYLOR, THOMAS, WALKO AND YOUNGBLOOD, FEBRUARY 7, 2007

REFERRED TO COMMITTEE ON HEALTH AND HUMAN SERVICES, FEBRUARY 7, 2007

AN ACT

- Amending the act of July 19, 1979 (P.L.130, No.48), entitled "An act relating to health care; prescribing the powers and 3 duties of the Department of Health; establishing and providing the powers and duties of the State Health Coordinating Council, health systems agencies and Health Care Policy Board in the Department of Health, and State Health 7 Facility Hearing Board in the Department of Justice; providing for certification of need of health care providers 9 and prescribing penalties, "further providing for definitions, for powers and duties of Department of Health, 10 for State health services plan, for regulations, for 11 12 certificates of need and for sunset; and prohibiting certain 13 referrals and claims of payment. 14 The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows: 15 16 Section 1. Section 103 of the act of July 19, 1979 (P.L.130, 17 No.48), known as the Health Care Facilities Act, amended 18 December 18, 1992 (P.L.1602, No.179) and October 16, 1998 (P.L.777, No.95), is reenacted and amended to read: 19
- 21 The following words and phrases when used in this act shall

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Section 103. Definitions.

- 1 have, unless the context clearly indicates otherwise, the
- 2 meanings given to them in this section:
- 3 "Act." The comprehensive Health Care Facilities Act.
- 4 "Board." The Health Policy Board established under section
- 5 401.1.
- 6 "Certificate of need." A notice of approval issued by the
- 7 [department] Department of Health under the provisions of this
- 8 act, including those notices of approval issued as an amendment
- 9 to an existing certificate of need.
- 10 "Certification of need (CON) review board." The CON review
- 11 board which consists of technical experts in the fields of
- 12 medicine, health facility administration, health economics,
- 13 <u>health care cost inflation and the like, including experts from</u>
- 14 within the Commonwealth agencies, together with consumers of
- 15 <u>health care</u>, all of whom are appointed by the Secretary of
- 16 Health.
- 17 "Clinically related health service." Certain diagnostic,
- 18 treatment or rehabilitative services as determined in section
- 19 701.
- 20 ["Community-based health services planning committee." A
- 21 committee established in accordance with procedures approved by
- 22 the Department of Health which includes representatives of local
- 23 or regional groups of consumers, business, labor, health care
- 24 providers, payors or other affected interests.]
- 25 "Conflict of interest." [For the purpose of section 501,
- 26 the] The interest of any person, whether financial, by
- 27 association with, or as a contributor of money or time to, any
- 28 nonprofit corporation or other corporation, partnership,
- 29 association, or other organization, and whenever a person is a
- 30 director, officer or employee of such organization, but shall

- 1 not exist whenever the organization in which such person is
- 2 interested is being considered as part of a class or group for
- 3 whom regulations are being considered, if the material facts as
- 4 to the relationship or interest are disclosed or are known to
- 5 the board.
- 6 "Consumer." A natural person who is not involved in the
- 7 provision of health services or health insurance. For the
- 8 purpose of this act, any person who holds a fiduciary position
- 9 in any health care facility, health maintenance organization or
- 10 third party payor shall not be considered a consumer.
- 11 <u>"Council." The Pennsylvania Health Care Cost Containment</u>
- 12 <u>Council.</u>
- "Department." The Department of Health of the Commonwealth.
- 14 "Develop." When used in connection with health services or
- 15 facilities, means to undertake those activities which on their
- 16 completion will result in the offer of a new health service or
- 17 the incurring of a financial obligation in relation to the
- 18 offering of such a service.
- 19 "Health care facility." [For purposes of Chapter 7, any] A
- 20 health care facility providing clinically related health
- 21 services, including, but not limited to, a general or special
- 22 hospital, including psychiatric hospitals, rehabilitation
- 23 hospitals, ambulatory surgical facilities, diagnostic imaging
- 24 centers, MRI facilities, long-term care nursing facilities,
- 25 cancer treatment centers using radiation therapy on an
- 26 ambulatory basis and inpatient drug and alcohol treatment
- 27 facilities, both profit and nonprofit and including those
- 28 operated by an agency or State or local government. The term
- 29 shall also include a hospice. The term shall not include an
- 30 office used primarily for the private or group practice by

- 1 health care practitioners where no reviewable clinically related
- 2 health service is offered, a facility providing treatment solely
- 3 on the basis of prayer or spiritual means in accordance with the
- 4 tenets of any church or religious denomination or a facility
- 5 conducted by a religious organization for the purpose of
- 6 providing health care services exclusively to clergy or other
- 7 persons in a religious profession who are members of the
- 8 religious denominations conducting the facility.
- 9 "Health care practitioner." An individual who is authorized
- 10 to practice some component of the healing arts by a license,
- 11 permit, certificate or registration issued by a Commonwealth
- 12 licensing agency or board.
- "Health care provider" or "provider." An individual, a trust
- 14 or estate, a partnership, a corporation (including associations,
- 15 joint stock companies and insurance companies), the
- 16 Commonwealth, or a political subdivision or instrumentality
- 17 (including a municipal corporation or authority) thereof, that
- 18 operates a health care facility.
- 19 "Health planning area." A geographic area within the
- 20 Commonwealth designated by the Department of Health for purposes
- 21 of health planning.
- 22 "Hearing board." The State Health Facility Hearing Board
- 23 created in the Office of General Counsel under the provisions of
- 24 this act.
- 25 "Interested person" or "person expressing an interest." [For
- 26 the purposes of Chapter 7, a] \underline{A} member of the public who is to
- 27 be served by the proposed new health service in the area to be
- 28 served by the applicant, a health care facility or health
- 29 maintenance organization or any health care provider providing
- 30 similar services in the area to be served by the applicant or

- 1 who has received a certificate of need to provide services in
- 2 the area to be served by the applicant or who has formally filed
- 3 with the [department] Department of Health a letter of intent to
- 4 provide similar services in the area in which the proposed
- 5 service is to be offered or developed and any third party payor
- 6 of health services provided in that area who provides written
- 7 notice to the [department] <u>Department of Health</u> that the person
- 8 is interested in a specific certificate of need application
- 9 before the [department] <u>Department of Health</u>.
- 10 <u>"Local review committee." A committee established in</u>
- 11 accordance with procedures approved by the Department of Health
- 12 which includes representatives of local or regional groups of
- 13 consumers, business, labor, health care providers, payors or
- 14 other affected interests.
- 15 "Offer." Make provision for providing in a regular manner
- 16 and on an organized basis clinically related health services.
- 17 "Patient." A natural person receiving health care in or from
- 18 a health care provider.
- 19 "Person." A natural person, corporation (including
- 20 associations, joint stock companies and insurance companies),
- 21 partnership, trust, estate, association, the Commonwealth, and
- 22 any local governmental unit, authority and agency thereof.
- 23 "Policy board." The Health Policy Board created in the
- 24 Department of Health under the provisions of this act.
- 25 "Public meeting." A meeting open to the public where any
- 26 person has an opportunity to comment on a certificate of need
- 27 application or proposed State health services plan amendment.
- 28 "Secretary." The Secretary of [the Department of] Health of
- 29 the Commonwealth of Pennsylvania.
- 30 ["State health services plan." A document developed by the

- 1 Department of Health, after consultation with the policy board
- 2 and approved by the Governor, that is consistent with section
- 3 401.3, that meets the current and projected needs of the
- 4 Commonwealth's citizens. The State health services plan shall
- 5 contain, in part, the standards and criteria against which
- 6 certificate of need applications are reviewed and upon which
- 7 decisions are based.]
- 8 "Third party payor." A person who makes payments on behalf
- 9 of patients under compulsion of law or contract who does not
- 10 supply care or services as a health care provider or who is
- 11 engaged in issuing any policy or contract of individual or group
- 12 health insurance or hospital or medical service benefits. The
- 13 term shall not include the Federal, State, or any local
- 14 government unit, authority, or agency thereof or a health
- 15 maintenance organization.
- 16 Section 2. Sections 201 and 401.3 of the act, amended or
- 17 added December 18, 1992 (P.L.1602, No.179), are reenacted and
- 18 amended to read:
- 19 Section 201. Powers and duties of the department.
- The Department of Health shall have the power and its duties
- 21 shall be:
- 22 (1) To exercise exclusive jurisdiction over health care
- 23 providers in accordance with the provisions of this act.
- 24 (2) To issue determinations of reviewability or
- 25 nonreviewability of certificate of need proposals.
- 26 (2.1) To develop qualitative and quantitative standards
- 27 and criteria for the review and approval of certificate of
- 28 <u>need applications.</u>
- 29 (3) To issue certificates of need and amended
- 30 certificates of need in accordance with the provisions of

- 1 this act.
- 2 To withdraw expired certificates of need.
- 3 To require, pursuant to regulation, submission of 4 periodic reports by providers of health services and other 5 persons subject to review respecting the development of
- 6 proposals subject to review.
- 7 Upon consultation with the policy board, to research, prepare and, after approval by the Governor, 8 9 publish, no later than 18 months after the effective date of 10 this act and annually thereafter, a revised State health 11 services plan for the Commonwealth as defined under this act. 12 Until the State health services plan as defined in section 13 401.3 is adopted, the department shall apply the State health plan in existence on the effective date of this act, along 14 15 with any subsequent updates to that plan.]
 - (6.1) To develop a certificate of need exceptions process which permits exceptions to be granted to the standards and criteria in order to reflect local experience or ensure access or to respond to circumstances which pose a threat to public health and safety. The exceptions process shall begin only after the department issues a denial of a certificate of need application. All exceptions must be publicly disclosed. This provision creates no right or entitlement to an exception.
 - To collect and disseminate such other information as may be appropriate to determine the appropriate level of facilities and services for the effective implementation of certification of need under this act. Where such information is collected by any other agency of State government, duplication shall be avoided by coordination of data

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- 1 collection activities[.], if such coordination does not
- 2 <u>otherwise unduly burden those State agencies.</u>
- 3 [(8) To furnish such staff support and expertise to the
- 4 policy board as may be needed to perform its
- 5 responsibilities.]
- 6 (9) To receive, log and review all applications for
- 7 certificates of need or amendments thereof and approve or
- 8 disapprove the same.
- 9 (10) To minimize the administrative burden on health
- 10 care providers by eliminating unnecessary duplication of
- financial and operational reports and to the extent possible
- 12 <u>and without undue burden</u> coordinating reviews and inspections
- performed by Federal, State, local and private agencies.
- 14 (11) To adopt and promulgate regulations necessary to
- 15 carry out the purposes and provisions of this act relating to
- 16 certificate of need.
- 17 (12) To enforce the rules and regulations promulgated by
- 18 the department as provided in this act.
- 19 (13) To provide technical assistance to individuals and
- 20 public and private entities in filling out the necessary
- 21 forms for the development of projects and programs.
- 22 (14) To establish and publish in the Pennsylvania
- 23 Bulletin a fee schedule for certificate of need applications
- and letters of intent in accordance with section 902.1.
- 25 (15) To coordinate any data collection activities
- 26 necessary for administration of this act so as not to
- 27 duplicate unnecessarily the data collection activities of
- other Federal and State agencies.
- 29 (16) To modify the list of reviewable clinically related
- 30 health services established under section 701.

- 1 (17) To establish and publish in the Pennsylvania
- 2 <u>Bulletin a detailed schedule of the review process for each</u>
- 3 <u>certificate of need application submitted to the department.</u>
- 4 Section 401.3. State health [services] improvement plan.
- 5 The State health [services] improvement plan shall consist of
- 6 at a minimum:
- 7 (1) An identification of the clinically related health
- 8 services necessary to serve the health needs of the
- 9 population of this Commonwealth, including those medically
- 10 underserved areas in rural and inner-city locations.
- 11 (2) An analysis of the availability, accessibility and
- 12 affordability of the clinically related health services
- 13 necessary to meet the health needs of the population of this
- 14 Commonwealth.
- 15 [(3) Qualitative and quantitative standards and criteria
- for the review of certificate of need applications by the
- department under this act.
- 18 (4) An exceptions process which permits exceptions to be
- 19 granted to the standards and criteria in order to reflect
- 20 local experience or ensure access or to respond to
- 21 circumstances which pose a threat to public health and
- 22 safety.]
- 23 Section 3. Section 602 of the act is reenacted to read:
- 24 Section 602. Regulations.
- 25 The department is hereby authorized and empowered pursuant to
- 26 the provisions of this act to adopt rules and regulations
- 27 establishing procedures required by this act for administration
- 28 of certificate of need.
- Section 4. Sections 603, 701 and 702 of the act, amended
- 30 December 18, 1992 (P.L.1602, No.179), are reenacted and amended

- 1 to read:
- 2 Section 603. Enforcement of orders relating to certificate of
- 3 need.
- 4 (a) (1) No certificate of need shall be granted to any
- 5 person for a health care facility or reviewable clinically
- 6 related health service unless such facility or clinically
- 7 related health service is found by the department and CON
- 8 <u>review board</u> to be needed.
- 9 (2) No person shall offer or develop a health care
- 10 facility or reviewable clinically related health service
- 11 without obtaining a certificate of need as required by this
- 12 act.
- 13 (3) No binding arrangement or commitment for financing
- 14 the offering or development of a health care facility or
- reviewable clinically related health service shall be made by
- any person unless a certificate of need for such clinically
- 17 related health service or facility has been granted in
- 18 accordance with this act.
- 19 (b) Orders for which the time of appeal has expired shall be
- 20 enforced by the department <u>and the CON review board</u> in summary
- 21 proceedings or, when necessary, with the aid of the court.
- 22 (c) No [collateral attack on any order, including] questions
- 23 relating to jurisdiction shall be permitted in the enforcement
- 24 proceeding, but such relief may be sought when such relief has
- 25 not been barred by the failure to take a timely appeal.
- 26 (d) Any person operating a reviewable clinically related
- 27 health service or health care facility within this Commonwealth
- 28 for which no certificate of need has been obtained, after
- 29 service of a cease and desist order of the department, [or after
- 30 expiration of the time for appeal of any final order on appeal,

- 1 upon conviction thereof, shall be [sentenced to pay] subject to
- 2 a fine of not less than [\$100] <u>\$1,000</u> or more than [\$1,000]
- 3 \$10,000 and costs of [prosecution] enforcement. Each day of
- 4 operating a clinically related health service or health care
- 5 facility after issuance of a cease and desist order shall
- 6 constitute a separate offense.
- 7 (e) Any person who violates this act by failing to obtain a
- 8 certificate of need, by deviating from the provisions of the
- 9 certificate, by beginning construction, by providing services,
- 10 or by acquiring equipment after the expiration of a certificate
- 11 of need shall be subject to a penalty of not less than [\$100]
- 12 \$1,000 per day and not more than [\$1,000] \$10,000 per day. Each
- 13 day of each such violation shall be considered a separate
- 14 offense.
- 15 (f) The department may seek injunctive relief to prevent
- 16 continuing violations of this act. In seeking such relief, the
- 17 department need not prove <u>damages or</u> irreparable harm.
- 18 (g) No license to operate a health care facility or
- 19 reviewable clinically related health service by any person in
- 20 this Commonwealth shall be granted and any license issued shall
- 21 be void and of no effect as to any facility, organization,
- 22 service or part thereof for which a certificate of need is
- 23 required by this act and not granted.
- 24 Section 701. Certificate of need required; clinically related
- 25 health services subject to review.
- 26 (a) Any person, including, but not limited to, a health care
- 27 facility, health maintenance organization or health care
- 28 provider who offers, develops, constructs, renovates, expands or
- 29 otherwise establishes or undertakes to establish within the
- 30 State a clinically related health service that is included in

- 1 the department's list of reviewable services developed under
- 2 subsections (d) and (e) or a health care facility as defined in
- 3 section 103 must obtain a certificate of need from the
- 4 department and CON review board if one or more of the following
- 5 factors applies:
- 6 (1) [The proposal requires a capital expenditure in
- 7 excess of \$2,000,000 under] <u>Under</u> generally accepted
- 8 accounting principles, consistently applied[.], the proposal
- 9 requires a capital expenditure in excess of:
- (i) for a new high-cost technology or high-cost
- 11 replacement technology in any health care facility,
- \$500,000;
- (ii) for equipment or other facility improvements in
- an ambulatory surgical facility, or in an office where
- 15 <u>reviewable clinically related health care services are</u>
- 16 <u>offered</u>, whether a free-standing facility or office
- 17 within a hospital, \$1,000,000; or
- 18 (iii) for any other hospital-based improvement,
- 19 \$2,000,000.
- 20 (2) The proposal involves the establishment of a health
- 21 care facility or a reviewable clinically related health
- 22 service.
- 23 (3) The proposal increases the number of licensed beds
- by more than ten beds or 10%, whichever is less, every two
- 25 years.
- 26 (i) If the additional beds are acute care beds and
- are not beds in a distinct-part psychiatric,
- 28 rehabilitation or long-term care unit, all licensed beds
- of the acute-care facility shall be counted in
- determining whether the increased number of beds exceeds

1 10%.

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(ii) If the additional beds are beds in a distinctpart psychiatric, rehabilitation or long-term care unit
of an acute care facility, only the beds within that unit
shall be counted in determining whether the increased
number of beds exceeds 10%.

- (iii) If the additional beds are in a freestanding psychiatric, rehabilitation or long-term care facility, all licensed beds of the freestanding facility shall be counted in determining whether the increased number of beds exceeds 10%.
- 12 (4) The proposal substantially expands an existing
 13 clinically related health service as determined by the
 14 department [in the State health services plan].
- 15 (b) For the purposes of this act, an expenditure for the
- 16 purpose of acquiring an existing health care facility [or
- 17 replacement of equipment where there is no change in service]
- 18 shall not be considered to be a capital expenditure subject to
- 19 review. Expenditures for nonclinical activities or services,
- 20 such as parking garages, computer systems or refinancing of
- 21 debt, and research projects involving premarket approval of new
- 22 equipment shall not be subject to review.
- 23 (c) The capital expenditure threshold identified in
- 24 subsection (a)(1) may be modified periodically by the department
- 25 to reflect any increase in the construction cost or other
- 26 factors influencing health care-related capital expenditures.
- 27 The department shall publish a modification of the expenditure
- 28 threshold through the regulatory review process.
- 29 (d) A list of reviewable clinically related health services
- 30 shall be published by the department and the CON review board

- 1 within 30 days of the effective date of this act and may be
- 2 modified by regulation on an annual basis. Exclusive of new
- 3 high-cost technology, the initial list published by the
- 4 department and the CON review board as required under this
- 5 subsection shall be no more extensive than those services
- 6 reviewable on the effective date of this act. Criteria for
- 7 inclusion of reviewable services shall include, but not be
- 8 limited to:
- 9 (1) the quality of the service to be offered is likely
- 10 to be compromised through insufficient volumes or
- 11 utilization;
- 12 (2) the service is dependent upon the availability of
- scarce natural resources such as human organs;
- 14 (3) the operating costs associated with the service are
- 15 reimbursed by major third party payors on a cost
- 16 reimbursement basis; or
- 17 (4) the service involves the use of new technology.
- 18 (e) Any changes to the list required under subsection (d)
- 19 and proposed by regulation shall be developed by the department
- 20 [after consultation with the policy board.] and the CON review
- 21 board.
- 22 (f) A facility providing treatment solely on the basis of
- 23 prayer or spiritual means in accordance with the tenets of any
- 24 church or religious denomination or a facility conducted by a
- 25 religious organization for the purpose of providing health care
- 26 services exclusively to clergy or other persons in a religious
- 27 profession who are members of the religious denomination
- 28 conducting the facility shall not be considered to constitute a
- 29 health service subject to review under this act.
- 30 (g) As used in this section, "new high-cost technology"

- 1 means new technological equipment with an aggregate purchase
- 2 cost of greater than \$500,000. The department and the CON review
- 3 <u>board</u> shall consult with national medical and surgical
- 4 speciality organizations recognized by the American Board of
- 5 Medical Specialities (ABMS) and other nationally recognized
- 6 scientific resources in the determination of what constitutes
- 7 new technological equipment.
- 8 Section 702. Certificates of need; notice of intent;
- 9 application; issuance.
- 10 (a) Projects requiring a certificate of need shall, at the
- 11 earliest possible time in their planning, but not later than
- 12 April 1 of the calendar year prior to the year of the proposed
- 13 project start date, be submitted to the department and the CON
- 14 <u>review board</u> in a letter of intent in such detail advising of
- 15 the scope and nature of the project as required by regulations.
- 16 Within 30 days after receipt of the letter of intent, the
- 17 department and the CON review board shall inform the applicant
- 18 providing the letter of intent whether the proposed project is
- 19 subject to a certificate of need review or if additional
- 20 information is required to make that determination. If the
- 21 department [determines] and the CON review board determine that
- 22 the project is subject to a certificate of need review, the
- 23 project shall be subject to the remaining provisions of this
- 24 act.
- 25 (b) A person desiring to obtain or amend a certificate of
- 26 need shall apply in writing to the department, supplying such
- 27 information as is required by the department and the CON review
- 28 board, including, but not limited to, a cost impact analysis as
- 29 <u>further defined by the department in regulations implementing</u>
- 30 this act, and certifying that all data, information and

- 1 statements are factual to the best of their knowledge,
- 2 information and belief. The department and the CON review board
- 3 shall have 60 days after receipt of the application within which
- 4 to assess the application and in which to request specific
- 5 further information. If further information is requested, the
- 6 department and the CON review board shall complete its
- 7 preliminary assessment of the application within 45 days of
- 8 receipt of the same. No information shall be required that is
- 9 not specified in the rules and regulations promulgated by the
- 10 department.
- 11 (c) Timely notice of the beginning of review of the
- 12 application by the department shall be published after
- 13 preliminary assessment of the application is completed by the
- 14 department and the CON review board. The "date of notification"
- 15 of the beginning of review shall be the date such notice is
- 16 sent, or the date such notice is published in the Pennsylvania
- 17 Bulletin or in a newspaper of general circulation, whichever is
- 18 latest.
- 19 (d) The department <u>and the CON review board</u> shall approve or
- 20 disapprove the application within 90 days from the date of
- 21 notification of the beginning of the review unless the period
- 22 for review is extended by the applicant in writing.
- 23 (e) (1) Certificates of need shall be granted or refused by
- 24 <u>the department</u>. They shall not be conditioned upon the
- 25 applicant changing other aspects of its facilities or
- services or requiring the applicant to meet other specified
- 27 requirements, and no such condition shall be imposed by the
- department in granting or refusing approval of certificates
- of need.
- 30 (2) A certificate of need shall state the maximum amount

- 1 of expenditures which may be obligated under it and
- 2 applicants proceeding with an approved project may not exceed
- 3 this level of expenditure except as allowed under the
- 4 conditions and procedures established by the department
- 5 through regulation.
- 6 (f) (1) The department and the CON review board shall make
- 7 written findings which state the basis for any final decision
- 8 made by the department. Such findings shall be served upon
- 9 the applicant and provided to all persons expressing an
- interest in the proceedings and shall be made available to
- others upon written request.
- 12 (2) All decisions of the department and the CON review
- board shall be based solely on the record. No ex parte
- contact regarding the application between any employee of the
- department or the CON review board who exercises
- 16 responsibilities respecting the application and the
- 17 applicant, any person acting on behalf of the applicant or
- any person opposed to the issuance of the certificate of need
- 19 shall occur after the commencement of a hearing on the
- application and before a decision is made by the department.
- 21 (g) Modification of the application at any stage of the
- 22 proceeding shall not extend the time limits provided by this act
- 23 unless the department <u>and the CON review board</u> expressly [finds]
- 24 find that the modification represents a substantial change in
- 25 the character of the application.
- 26 (h) The responsibility of performing certificate of need
- 27 review may not be delegated by the department and the CON review
- 28 <u>board</u>. The department <u>and the CON review board</u> shall consider
- 29 recommendations of [one or more community-based health services
- 30 planning committees] the local review committees whose

- 1 localities are affected by specific applications in reviewing
- 2 the applications.
- 3 (i) The department <u>and the CON review board</u> may provide that
- 4 categories of projects shall receive simultaneous and
- 5 comparative review.
- 6 (j) Once the department and the CON review board have
- 7 <u>finished the initial review of an application and determined</u>
- 8 that the application shall be reviewed by a local review
- 9 committee, the department and the CON review board shall notify
- 10 the Pennsylvania Health Care Cost Containment Council in writing
- 11 that a community review is pending and request analyses to
- 12 <u>assist the review process. The council shall offer its analyses</u>
- 13 to the department and the CON review board prior to the
- 14 completion of the review process. The department and the CON
- 15 review board shall share these analyses with the local review
- 16 committee. If the council determines that it does not have the
- 17 requisite data and information to provide analyses to the
- 18 department and the CON review board, the council shall notify
- 19 the department in writing. The department and the CON review
- 20 board shall notify the local review committee about the
- 21 council's determination. In carrying out its responsibilities,
- 22 the council shall have all the powers and duties of the council
- 23 enumerated by the act of July 8, 1986 (P.L.408, No.89), known as
- 24 the "Health Care Cost Containment Act."
- Section 5. Section 703 of the act, amended July 12, 1980
- 26 (P.L.655, No.136), is reenacted and amended to read:
- 27 Section 703. Notice and hearings before [health systems
- 28 agencies] the department and CON review board.
- 29 (a) Notice of completed applications for certificates of
- 30 need or amendment thereto and of the beginning of review shall

- 1 be published by the [health systems agency] department in the
- 2 appropriate news media and by the department in the Pennsylvania
- 3 Bulletin in accordance with 45 Pa.C.S. [Chap. 7B] Ch. 7 Subch. B
- 4 (relating to publication of documents), and the [health systems
- 5 agency] <u>department</u> shall notify all affected persons with notice
- 6 of the schedule for review, the date by which a public hearing
- 7 must be demanded, and of the manner notice will be given of a
- 8 hearing, if one is to be held. Notice to affected persons (other
- 9 than members of the public who are to be served by the proposed
- 10 new institutional health service) shall be by mail (which may be
- 11 part of a newsletter). Members of the public may be notified
- 12 through newspapers of general circulation. Directly affected
- 13 persons may file objections within 15 days of such publication
- 14 with the [local health systems agency] department setting forth
- 15 specifically the reasons such objections were filed. Persons
- 16 filing the objections shall be parties to the proceeding, unless
- 17 and until such objections are withdrawn.
- 18 (b) Affected persons may request a public hearing or the
- 19 [health systems agency] <u>department</u> may require a public hearing
- 20 during the course of such review. Fourteen days written notice
- 21 of the hearing shall be given to affected persons in the same
- 22 manner as a notice of a completed application is provided in
- 23 subsection (a). In the hearing, any person shall have the right
- 24 to be represented by counsel and to present oral or written
- 25 arguments and relevant evidence. Any person directly affected
- 26 may conduct reasonable questioning of persons who make relevant
- 27 factual allegations. A record of the hearing shall be
- 28 maintained.
- 29 Section 6. Sections 704 and 705 of the act, amended December
- 30 18, 1992 (P.L.1602, No.179), are reenacted to read:

- 1 Section 704. Notice of public meetings.
- 2 (a) Notification of the beginning of review of a certificate
- 3 of need application shall be published by the department in the
- 4 appropriate news media and in the Pennsylvania Bulletin in
- 5 accordance with 45 Pa.C.S. Ch. 7 Subch. B (relating to
- 6 publication of documents). The notice shall identify the
- 7 schedule for review, the date by which a public meeting must be
- 8 requested and the manner in which notice will be given of a
- 9 meeting, if one is held.
- 10 (b) Interested persons may request a public meeting within
- 11 15 days of publication, and the department shall hold such a
- 12 meeting or the department may require a public meeting during
- 13 the course of such review. The department shall publish written
- 14 notice of the meeting in the appropriate news media and the
- 15 Pennsylvania Bulletin at least 14 days prior to the public
- 16 meeting date. In the meeting, the applicant and any interested
- 17 person providing prior notice to the department shall have the
- 18 right to present oral or written comments and relevant evidence
- 19 on the application in the manner prescribed by the department.
- 20 The department shall prepare a transcript of the oral testimony
- 21 presented at the meeting. Meetings shall be held in accordance
- 22 with the guidelines and procedures established by the department
- 23 and published in the Pennsylvania Code as a statement of policy.
- 24 The department may require the applicant to provide copies of
- 25 the application to any interested person making a request for
- 26 such application, at the expense of the interested person.
- 27 (c) The applicant may, for good cause shown, request in
- 28 writing a public hearing for the purpose of reconsideration of a
- 29 decision of the department within ten days of service of the
- 30 decision of the department. The department shall treat the

- 1 request in accordance with the provisions of 1 Pa. Code § 35.241
- 2 (relating to application for rehearing or reconsideration). The
- 3 department shall set forth the cause for the hearing and the
- 4 issues to be considered at such hearing. If such hearing is
- 5 granted, it shall be held no sooner than six days and no later
- 6 than 30 days after the notice to grant such a hearing and shall
- 7 be limited to the issues submitted for reconsideration. A
- 8 transcript shall be made of the hearing and a copy of the
- 9 transcript shall be provided at cost to the applicant. The
- 10 department shall affirm or reverse its decision and submit the
- 11 same to the person requesting the hearing within 30 days of the
- 12 conclusion of such hearing. Any change in the decision shall be
- 13 supported by the reasons for the change.
- 14 (d) Where hearings under subsection (b) are held on more
- 15 than two days, consecutive days of hearings and intervening
- 16 weekends and holidays shall be excluded in calculating the time
- 17 permitted for the department to conduct its review, and, if
- 18 briefs are to be filed, ten days subsequent to the adjournment
- 19 of the hearing shall also be excluded.
- 20 Section 705. Good cause.
- 21 Good cause shall be deemed to have been shown if:
- 22 (1) there is significant, relevant information not
- 23 previously considered;
- 24 (2) there is significant change in factors or
- circumstances relied on in making the decision;
- 26 (3) there has been material failure to comply with the
- 27 procedural requirements of this act; or
- 28 (4) good cause is otherwise found to exist.
- Section 7. Sections 706, 707 and 708.1 of the act, amended
- 30 or added December 18, 1992 (P.L.1602, No.179), are reenacted and

- 1 amended to read:
- 2 Section 706. Information during review.
- 3 During the course of review the department and the CON review
- 4 board shall upon request of any person set forth the status, any
- 5 findings made in the proceeding and other appropriate
- 6 information requested. The department and the CON review board
- 7 may require such request in writing.
- 8 Section 707. Criteria for review of applications for
- 9 certificates of need or amendments.
- 10 (a) An application for certificate of need shall be
- 11 considered for approval when the department [determines] and the
- 12 <u>CON review board determine</u> that the application substantially
- 13 meets the requirements listed below:
- 14 (1) There is need by the population served or to be
- served by the proposed service or facility.
- 16 (2) The proposed service or facility will provide care
- 17 consistent with quality standards established by the [State
- 18 health services plan] <u>department</u>.
- 19 (3) The proposed service or facility will meet the
- 20 standards identified [in the State health services plan] by
- 21 <u>the department</u> for access to care by medically underserved
- 22 groups, including individuals eligible for medical assistance
- and persons without health insurance.
- 24 (4) The applicant has submitted a data-based cost
- 25 <u>analysis that includes an analysis demonstrating that:</u>
- 26 (i) There is not a more appropriate, less costly or
- 27 more effective alternative method of providing the
- 28 <u>proposed services.</u>
- 29 <u>(ii) The service or facility is financially and</u>
- 30 economically feasible, considering anticipated volume of

1 care and the availability of reasonable financing based on information from the applicant and other sources 2. 3 during the review process. (iii) The proposed service or facility will not have 4 5 an inappropriate, adverse impact on the overall level of health care expenditures in the area. 6 (iv) The proposed service or facility does not 7 adversely impact the maintenance and development of rural 8 and inner-city health services generally and, in 9 particular, those services provided by health care 10 providers which are based in rural and inner-city 11 locations and which have an established history of 12 13 providing services to medically underserved populations. The department shall issue a certificate of need if the 14 15 project substantially meets the criteria of subsection (a)(1), (2) and (3) and the project is consistent with the State health 16 17 services plan unless the department can demonstrate: 18 There is a more appropriate, less costly or more 19 effective alternative method of providing the proposed 20 services. The service or facility is not financially and 21 economically feasible, considering anticipated volume of care 22 23 and the availability of reasonable financing based on

- information received from the applicant and other sources during the review process.
- 26 (3) The proposed service or facility will have an 27 inappropriate, adverse impact on the overall level of health 28 care expenditures in the area.
- The proposed service or facility adversely impacts 29 30 the maintenance and development of rural and inner-city

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- 1 health services generally and, in particular, those services
- 2 provided by health care providers which are based in rural
- and inner-city locations and which have an established
- 4 history of providing services to medically underserved
- 5 populations.]
- 6 (c) Notwithstanding the provisions of [subsections (a) and
- 7 (b)] <u>subsection (a)</u>, applications for projects described in
- 8 subsection (d) shall be approved unless the department [finds]
- 9 and the CON review board find that the facility or service with
- 10 respect to such expenditure as proposed is not needed [or that
- 11 the project is not consistent with the State health services
- 12 plan]. An application made under this subsection shall be
- 13 approved only to the extent that the department and the CON
- 14 review board [determines] determine it is required to overcome
- 15 the conditions described in subsection (d).
- (d) Subject to the provisions of subsection (c),
- 17 [subsections (a) and (b)] <u>subsection (a)</u> shall not apply to
- 18 capital expenditures required to:
- 19 (1) eliminate or prevent imminent safety hazards as a
- 20 result of violations of safety codes or regulations;
- 21 (2) comply with State licensure standards; or
- 22 (3) comply with accreditation standards, compliance with
- 23 which is required to receive reimbursement or payments under
- 24 Title XVIII or XIX of the Federal Social Security Act.
- 25 Section 708.1. Monitoring certificate of need; expiration of a
- certificate of need.
- 27 A certificate of need or an amendment to it shall expire two
- 28 years from the date issued unless substantially implemented, as
- 29 defined by regulation. The department <u>and the CON review board</u>
- 30 may grant extensions for a specified time upon request of the

- 1 applicant and upon a showing that the applicant has or is making
- 2 a good faith effort to substantially implement the project. An
- 3 expired certificate of need shall be invalid, and no person may
- 4 proceed to undertake any activity pursuant to it for which a
- 5 certificate of need or amendment is required. The applicant
- 6 shall report to the department, on forms prescribed by the
- 7 department, the status of the project until such time as the
- 8 project is licensed or operational, if no license is required.
- 9 Section 8. Section 709 of the act, amended December 18, 1992
- 10 (P.L.1602, No.179), is reenacted to read:
- 11 Section 709. Emergencies.
- 12 Notwithstanding any other provision of this act, in the event
- 13 of an emergency the department may suspend the foregoing
- 14 application process and permit such steps to be taken as may be
- 15 required to meet the emergency including the replacement of
- 16 equipment or facilities.
- 17 Section 9. Section 710 of the act is reenacted to read:
- 18 Section 710. Notice of termination of services.
- 19 For informational purposes only, at least 30 days prior to
- 20 termination or substantial reduction of a service or a permanent
- 21 decrease in the bed complement, the provider shall notify the
- 22 health systems agency and the department of its intended action.
- 23 Section 10. Section 711 of the act, amended December 18,
- 24 1992 (P.L.1602, No.179), is reenacted and amended to read:
- 25 Section 711. Review of activities.
- 26 (a) The department <u>and the CON review board</u> shall prepare
- 27 and publish not less frequently than annually reports of reviews
- 28 conducted under this act, including a statement on the status of
- 29 each such review and of reviews completed by it and statements
- 30 of the decisions made in the course of such reviews since the

- 1 last report. The department and the CON review board shall also
- 2 make available to the general public for examination at
- 3 reasonable times of the business day all applications reviewed
- 4 by it. Such reports and applications shall be considered public
- 5 records.
- 6 (b) The department's <u>and the CON review board's</u> report which
- 7 shall be submitted to the members of the Health and Welfare
- 8 Committees of the Senate and House of Representatives shall
- 9 contain the following information:
- 10 (1) The volume of applications submitted, by project
- 11 type, their dollar value, and the numbers and costs
- associated with those approved and those not approved.
- 13 (2) The assessment of the extent of competition in
- 14 specific service sectors that guided decisions.
- 15 (3) A detailed description of projects involving
- 16 nontraditional or innovative service delivery methods or
- organizational arrangements and the decisions made on each of
- 18 these projects.
- 19 (4) The average time for review, by level of review.
- 20 (5) The fees collected for reviews and the cost of the
- 21 program.
- 22 Section 11. Section 712 of the act, added July 12, 1980
- 23 (P.L.655, No.136) and repealed in part December 20, 1982
- 24 (P.L.1409, No.326), is reenacted and amended to read:
- 25 Section 712. Actions against violations of law and rules and
- regulations[; bonds].
- 27 (a) Whenever any person, regardless of whether such person
- 28 is a licensee, has willfully violated any of the provisions of
- 29 this act or the rules and regulations adopted thereunder, the
- 30 department may maintain any action in the name of the

- 1 Commonwealth for an injunction or other process restraining or
- 2 prohibiting such person from engaging in such activity.
- 3 Section 12. Section 808 of the act, amended December 18,
- 4 1992 (P.L.1602, No.179) and July 7, 2006 (P.L.334, No.69), is
- 5 reenacted and amended to read:
- 6 Section 808. Issuance of license.
- 7 (a) Standards.--The department shall issue a license to a
- 8 health care provider when it is satisfied that the following
- 9 standards have been met:
- 10 (1) that the health care provider is a responsible
- 11 person;
- 12 (2) that the place to be used as a health care facility
- is adequately constructed, equipped, maintained and operated
- to safely and efficiently render the services offered;
- 15 (3) that the health care facility provides safe and
- efficient services which are adequate for the care, treatment
- and comfort of the patients or residents of such facility;
- 18 (4) that there is substantial compliance with the rules
- 19 and regulations adopted by the department pursuant to this
- 20 act; and
- 21 (5) that a certificate of need has been issued if one is
- 22 necessary.
- 23 (b) Separate and limited licenses. -- Separate licenses shall
- 24 not be required for different services within a single health
- 25 care facility except that home health care, home care, hospice
- 26 or long-term nursing care will require separate licenses. A
- 27 limited license, excluding from its terms a particular service
- 28 or portion of a health care facility, may be issued under the
- 29 provisions of this act.
- 30 (c) Addition of services.--When the certificate of need for

- 1 a facility is amended as to services which can be offered, the
- 2 department shall issue an appropriate license for those services
- 3 upon demonstration of compliance with licensure requirements.
- 4 (d) Monitoring.--
- 5 (1) One year after the certificate of need has been
- 6 <u>issued</u>, the department shall monitor quality of the facility
- or service by requesting from the council relevant data,
- 8 which may include mortality rates and the number of
- 9 procedures performed.
- 10 (2) If the department finds that the facility or service
- is not meeting the standards set forth in subsection (a), the
- 12 <u>department shall take disciplinary action pursuant to this</u>
- 13 <u>act and existing regulations.</u>
- 14 Section 13. The act is amended by adding a section to read:
- 15 <u>Section 808.1. Prohibition of referrals and claims of payment.</u>
- 16 <u>(a) Referrals.--A provider may not:</u>
- 17 (1) Refer a person for treatment and services if the
- 18 provider has a financial interest with the person or in the
- 19 entity that receives the referral.
- 20 (2) Enter into an arrangement or scheme, including, but
- 21 not limited to, a cross-referral arrangement, that the
- 22 provider knows or should know has a principal purpose of
- assuring referrals by the provider to a particular entity
- 24 which, if the provider directly made referrals to the entity,
- 25 would be in violation of this act.
- 26 (b) Claim for payment. -- No claim for payment may be
- 27 presented by an entity to any individual, third-party payor or
- 28 other entity for a service furnished pursuant to conduct
- 29 prohibited under subsection (a).
- 30 (c) Refund. -- If an entity collects any amount that was

- 1 billed in violation of this section, the entity shall refund
- 2 that amount on a timely basis to the payor or individual.
- 3 Section 14. Section 901 of the act, amended July 12, 1980
- 4 (P.L.655, No.136), is reenacted and amended to read:
- 5 Section 901. Existing facilities and institutions.
- 6 (a) (1) No certificate of need shall be required for any
- 7 buildings, real property and equipment owned, leased or being
- 8 operated, or under contract for construction, purchase, or lease
- 9 and for all services being rendered by licensed or approved
- 10 providers [on April 1, 1980.] prior to the effective date of
- 11 this paragraph.
- 12 (2) Nor shall a certificate of need be required for any new
- 13 institutional health services for which an approval has been
- 14 granted under section 1122 of the Social Security Act of for
- 15 which an application is found pursuant to such section to be in
- 16 conformity with the standards, criteria or plans to which such
- 17 section refers, or as to which the Federal Secretary of Health
- 18 and Human Services makes a finding that reimbursement shall be
- 19 granted.[: Provided, however, That such approval is in force on
- 20 August 1, 1980 or such application shall have been filed prior
- 21 to August 1, 1980 or the acceptance of applications for reviews
- 22 under this act, whichever shall last occur.]
- 23 (b) However, existing facilities and institutions shall be
- 24 required to obtain a certificate of need for projects outlined
- 25 <u>in section 701.</u>
- 26 Section 15. Section 902.1 of the act, added December 18,
- 27 1992 (P.L.1602, No.179), is reenacted and amended to read:
- 28 Section 902.1. Fees for review of certificate of need
- 29 applications.
- 30 (a) The department shall charge a fee of [\$150] \$500 for

- 1 each letter of intent filed. The letter of intent fee shall be
- 2 deducted from the total application fee required under
- 3 subsection (b) if an application is submitted on the project
- 4 proposed in the letter of intent.
- 5 (b) For each application the department shall charge a fee,
- 6 payable on submission of an application. The fee shall not be
- 7 less than \$500 plus up to [\$3] <u>\$10</u> per \$1,000 of proposed
- 8 capital expenditure and shall not be more than [\$20,000]
- 9 \$50,000.
- 10 (c) The department shall publish a fee schedule in the
- 11 Pennsylvania Bulletin which shall explain the procedure for
- 12 filing fees.
- 13 (d) All fees payable under this section are due upon the
- 14 date of filing a letter of intent or application. If a person
- 15 fails to file the appropriate fee, all time frames required of
- 16 the department under this act, with respect to review of a
- 17 letter of intent or application, are suspended until the
- 18 applicable fee is paid in full.
- 19 (e) Each local review committee may apply for up to \$10,000
- 20 <u>in funding from the department for administrative functions</u>
- 21 <u>associated with reviewing certificate of need proposals. This</u>
- 22 funding is to be allocated from the Patient Safety Authority
- 23 appropriation.
- Section 16. Section 904.1 of the act, added December 18,
- 25 1992 (P.L.1602, No.179), is repealed:
- 26 [Section 904.1. Sunset.
- The authority, obligations and duties arising under Chapter 7
- 28 and all other provisions of this act pertaining to certificates
- 29 of need shall terminate four years after the effective date of
- 30 this section. Twelve months prior to this expiration, the

- Legislative Budget and Finance Committee shall commence a review 1
- 2 of the impact of the certificate of need program on quality,
- 3 access and cost of health care services, including the costs of
- 4 appeals, reviewable under this act.]
- Section 17. This act shall take effect immediately. 5