

CHAPTER 103

(HB 458)

AN ACT relating to ambulatory surgical centers.

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔Section 1. KRS 216B.015 is amended to read as follows:

Except as otherwise provided, for purposes of this chapter, the following definitions shall apply:

- (1) "Abortion facility" means any place in which an abortion is performed;
- (2) "Administrative regulation" means a regulation adopted and promulgated pursuant to the procedures in KRS Chapter 13A;
- (3) "Affected persons" means the applicant; any person residing within the geographic area served or to be served by the applicant; any person who regularly uses health facilities within that geographic area; health facilities located in the health service area in which the project is proposed to be located which provide services similar to the services of the facility under review; health facilities which, prior to receipt by the agency of the proposal being reviewed, have formally indicated an intention to provide similar services in the future; and the cabinet and third-party payors who reimburse health facilities for services in the health service area in which the project is proposed to be located;
- (4) (a) *"Ambulatory surgical center" means a health facility:*
 1. *Licensed pursuant to administrative regulations promulgated by the cabinet;*
 2. *That provides outpatient surgical services, excluding oral or dental procedures; and*
 3. *Seeking recognition and reimbursement as an ambulatory surgical center from any federal, state, or third-party insurer from which payment is sought.*
- (b) *An ambulatory surgical center does not include the private offices of physicians where in-office outpatient surgical procedures are performed as long as the physician office does not seek licensure, certification, reimbursement, or recognition as an ambulatory surgical center from a federal, state, or third-party insurer.*
- (c) *Nothing in this subsection shall preclude a physician from negotiating enhanced payment for outpatient surgical procedures performed in the physician's private office so long as the physician does not seek recognition or reimbursement of his or her office as an ambulatory surgical center without first obtaining a certificate of need or license required under Sections 2 and 3 of this Act.*
- (5)~~(4)~~ "Applicant" means any physician's office requesting a major medical equipment expenditure of one million five hundred thousand dollars (\$1,500,000) or more after July 15, 1996, adjusted annually, or any person, health facility, or health service requesting a certificate of need or license;
- (6)~~(5)~~ "Cabinet" means the Cabinet for Health and Family Services;
- (7)~~(6)~~ "Capital expenditure" means an expenditure made by or on behalf of a health facility which:
 - (a) Under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance or is not for investment purposes only; or
 - (b) Is made to obtain by lease or comparable arrangement any facility or part thereof or any equipment for a facility or part thereof;
- (8)~~(7)~~ "Capital expenditure minimum" means one million five hundred thousand dollars (\$1,500,000) beginning with July 15, 1994, and as adjusted annually thereafter. In determining whether an expenditure exceeds the expenditure minimum, the cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the improvement, expansion, or replacement of any plant or any equipment with respect to which the expenditure is made shall be included. Donations of equipment or facilities to a health facility which if acquired directly by the facility would be subject to review under this chapter shall be considered a capital expenditure, and a transfer of the equipment or facilities for less than fair market value shall be considered a capital expenditure if a transfer of the equipment or facilities at fair market value would be subject to review;

- ~~(9)~~~~(8)~~ "Certificate of need" means an authorization by the cabinet to acquire, to establish, to offer, to substantially change the bed capacity, or to substantially change a health service as covered by this chapter;
- ~~(10)~~~~(9)~~ "Certified surgical assistant" means a certified surgical assistant or certified first assistant who is certified by the National Surgical Assistant Association on the Certification of Surgical Assistants, the Liaison Council on Certification of Surgical Technologists, or the American Board of Surgical Assistants. The certified surgical assistant is an unlicensed health-care provider who is directly accountable to a physician licensed under KRS Chapter 311 or, in the absence of a physician, to a registered nurse licensed under KRS Chapter 314;
- ~~(11)~~~~(10)~~ "Continuing care retirement community" means a community that provides, on the same campus, a continuum of residential living options and support services to persons sixty (60) years of age or older under a written agreement. The residential living options shall include independent living units, nursing home beds, and either assisted living units or personal care beds;
- ~~(12)~~~~(11)~~ "Formal review process" means the ninety (90) day certificate-of-need review conducted by the cabinet;
- ~~(13)~~~~(12)~~ "Health facility" means any institution, place, building, agency, or portion thereof, public or private, whether organized for profit or not, used, operated, or designed to provide medical diagnosis, treatment, nursing, rehabilitative, or preventive care and includes alcohol abuse, drug abuse, and mental health services. This shall include, but shall not be limited to, health facilities and health services commonly referred to as hospitals, psychiatric hospitals, physical rehabilitation hospitals, chemical dependency programs, tuberculosis hospitals, skilled nursing facilities, nursing facilities, nursing homes, personal care homes, intermediate care facilities, family care homes, primary care centers, rural health clinics, outpatient clinics, ambulatory care facilities, ambulatory surgical centers, emergency care centers and services, ambulance providers, hospices, community mental health and mental retardation centers, home health agencies, kidney disease treatment centers and freestanding hemodialysis units, facilities and services owned and operated by health maintenance organizations directly providing health services subject to certificate of need, and others providing similarly organized services regardless of nomenclature;
- ~~(14)~~~~(13)~~ "Health services" means clinically related services provided within the Commonwealth to two (2) or more persons, including, but not limited to, diagnostic, treatment, or rehabilitative services, and includes alcohol, drug abuse, and mental health services;
- ~~(15)~~~~(14)~~ "Independent living" means the provision of living units and supportive services including, but not limited to, laundry, housekeeping, maintenance, activity direction, security, dining options, and transportation;
- ~~(16)~~~~(15)~~ "Intraoperative surgical care" includes the practice of surgical assisting in which the certified surgical assistant or physician assistant is working under the direction of the operating physician as a first or second assist, and which may include the following procedures:
- (a) Positioning the patient;
 - (b) Preparing and draping the patient for the operative procedure;
 - (c) Observing the operative site during the operative procedure;
 - (d) Providing the best possible exposure of the anatomy incident to the operative procedure;
 - (e) Assisting in closure of incisions and wound dressings; and
 - (f) Performing any task, within the role of an unlicensed assistive person, or if the assistant is a physician assistant, performing any task within the role of a physician assistant, as required by the operating physician incident to the particular procedure being performed;
- ~~(17)~~~~(16)~~ "Major medical equipment" means equipment which is used for the provision of medical and other health services and which costs in excess of the medical equipment expenditure minimum. For purposes of this subsection, "medical equipment expenditure minimum" means one million five hundred thousand dollars (\$1,500,000) beginning with July 15, 1994, and as adjusted annually thereafter. In determining whether medical equipment has a value in excess of the medical equipment expenditure minimum, the value of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition of the equipment shall be included;
- ~~(18)~~~~(17)~~ "Nonsubstantive review" means an expedited review conducted by the cabinet of an application for a certificate of need as authorized under KRS 216B.095;
- ~~(19)~~~~(18)~~ "Nonclinically-related expenditures" means expenditures for:

- (a) Repairs, renovations, alterations, and improvements to the physical plant of a health facility which do not result in a substantial change in beds, a substantial change in a health service, or the addition of major medical equipment, and do not constitute the replacement or relocation of a health facility; or
- (b) Projects which do not involve the provision of direct clinical patient care including, but not limited to, the following:
 - 1. Parking facilities;
 - 2. Telecommunications or telephone systems;
 - 3. Management information systems;
 - 4. Ventilation systems;
 - 5. Heating or air conditioning, or both;
 - 6. Energy conservation; or
 - 7. Administrative offices;

~~(20)~~~~(19)~~ "Party to the proceedings" means the applicant for a certificate of need and any affected person who appears at a hearing on the matter under consideration and enters an appearance of record;

~~(21)~~~~(20)~~ "Perioperative nursing" means a practice of nursing in which the nurse provides preoperative, intraoperative, and postoperative nursing care to surgical patients;

~~(22)~~~~(21)~~ "Person" means an individual, a trust or estate, a partnership, a corporation, an association, a group, state, or political subdivision or instrumentality including a municipal corporation of a state;

~~(23)~~~~(22)~~ "Physician assistant" means the same as the definition provided in KRS 311.550;

~~(24)~~~~(23)~~ "Record" means, as applicable in a particular proceeding:

- (a) The application and any information provided by the applicant at the request of the cabinet;
- (b) Any information provided by a holder of a certificate of need or license in response to a notice of revocation of a certificate of need or license;
- (c) Any memoranda or documents prepared by or for the cabinet regarding the matter under review which were introduced at any hearing;
- (d) Any staff reports or recommendations prepared by or for the cabinet;
- (e) Any recommendation or decision of the cabinet;
- (f) Any testimony or documentary evidence adduced at a hearing;
- (g) The findings of fact and opinions of the cabinet or the findings of fact and recommendation of the hearing officer; and
- (h) Any other items required by administrative regulations promulgated by the cabinet;

~~(25)~~~~(24)~~ "Registered nurse first assistant" means one who:

- (a) Holds a current active registered nurse licensure;
- (b) Is certified in perioperative nursing; and
- (c) Has successfully completed and holds a degree or certificate from a recognized program, which shall consist of:
 - 1. The Association of Operating Room Nurses, Inc., Core Curriculum for the registered nurse first assistant; and
 - 2. One (1) year of postbasic nursing study, which shall include at least forty-five (45) hours of didactic instruction and one hundred twenty (120) hours of clinical internship or its equivalent of two (2) college semesters.

A registered nurse who was certified prior to 1995 by the Certification Board of Perioperative Nursing shall not be required to fulfill the requirements of paragraph (c) of this subsection;

~~(26)~~~~(25)~~ "Secretary" means the secretary of the Cabinet for Health and Family Services;

- ~~(27)~~~~(26)~~ "Sexual assault examination facility" means a licensed health facility, emergency medical facility, primary care center, or a children's advocacy center or rape crisis center that is regulated by the Cabinet for Health and Family Services, and that provides sexual assault examinations under KRS 216B.400;
- ~~(28)~~~~(27)~~ "State health plan" means the document prepared triennially, updated annually, and approved by the Governor;
- ~~(29)~~~~(28)~~ "Substantial change in a health service" means:
- (a) The addition of a health service for which there are review criteria and standards in the state health plan;
 - (b) The addition of a health service subject to licensure under this chapter; or
 - (c) The reduction or termination of a health service which had previously been provided in the health facility;
- ~~(30)~~~~(29)~~ "Substantial change in bed capacity" means the addition, reduction, relocation, or redistribution of beds by licensure classification within a health facility;
- ~~(31)~~~~(30)~~ "Substantial change in a project" means a change made to a pending or approved project which results in:
- (a) A substantial change in a health service, except a reduction or termination of a health service;
 - (b) A substantial change in bed capacity, except for reductions;
 - (c) A change of location; or
 - (d) An increase in costs greater than the allowable amount as prescribed by regulation;
- ~~(32)~~~~(31)~~ "To acquire" means to obtain from another by purchase, transfer, lease, or other comparable arrangement of the controlling interest of a capital asset or capital stock, or voting rights of a corporation. An acquisition shall be deemed to occur when more than fifty percent (50%) of an existing capital asset or capital stock or voting rights of a corporation is purchased, transferred, leased, or acquired by comparable arrangement by one (1) person from another person;
- ~~(33)~~~~(32)~~ "To batch" means to review in the same review cycle and, if applicable, give comparative consideration to all filed applications pertaining to similar types of services, facilities, or equipment affecting the same health service area;
- ~~(34)~~~~(33)~~ "To establish" means to construct, develop, or initiate a health facility;
- ~~(35)~~~~(34)~~ "To obligate" means to enter any enforceable contract for the construction, acquisition, lease, or financing of a capital asset. A contract shall be considered enforceable when all contingencies and conditions in the contract have been met. An option to purchase or lease which is not binding shall not be considered an enforceable contract; and
- ~~(36)~~~~(35)~~ "To offer" means, when used in connection with health services, to hold a health facility out as capable of providing, or as having the means of providing, specified health services.

➔Section 2. KRS 216B.020 is amended to read as follows:

- (1) The provisions of this chapter that relate to the issuance of a certificate of need shall not apply to abortion facilities as defined in KRS 216B.015; any hospital which does not charge its patients for hospital services and does not seek or accept Medicare, Medicaid, or other financial support from the federal government or any state government; assisted living residences; family care homes; state veterans' nursing homes; services provided on a contractual basis in a rural primary-care hospital as provided under KRS 216.380; community mental health centers for services as defined in KRS Chapter 210; primary care centers; rural health clinics; private duty nursing services licensed as nursing pools; group homes; end stage renal disease dialysis facilities, freestanding or hospital based; swing beds; special clinics, including, but not limited to, wellness, weight loss, family planning, disability determination, speech and hearing, counseling, pulmonary care, and other clinics which only provide diagnostic services with equipment not exceeding the major medical equipment cost threshold and for which there are no review criteria in the state health plan; nonclinically-related expenditures; nursing home beds that shall be exclusively limited to on-campus residents of a certified continuing care retirement community; the relocation of hospital administrative or outpatient services into medical office buildings which are on or contiguous to the premises of the hospital; residential hospice facilities established by licensed hospice programs; or the following health services provided on site in an existing health facility

when the cost is less than six hundred thousand dollars (\$600,000) and the services are in place by December 30, 1991: psychiatric care where chemical dependency services are provided, level one (1) and level two (2) of neonatal care, cardiac catheterization, and open heart surgery where cardiac catheterization services are in place as of July 15, 1990. The provisions of this section shall not apply to nursing homes, personal care homes, intermediate care facilities, and family care homes; or nonconforming ambulance services as defined by administrative regulation. These listed facilities or services shall be subject to licensure, when applicable.

- (2) Nothing in this chapter shall be construed to authorize the licensure, supervision, regulation, or control in any manner of:
 - (a) Private offices and clinics of physicians, dentists, and other practitioners of the healing arts, except any physician's office that meets the criteria set forth in KRS 216B.015(5) *or that meets the definition of an ambulatory surgical center as set out in Section 1 of this Act*~~{(4)}~~;
 - (b) Office buildings built by or on behalf of a health facility for the exclusive use of physicians, dentists, and other practitioners of the healing arts; unless the physician's office meets the criteria set forth in KRS 216B.015(5)~~{(4)}~~, or unless the physician's office is also an abortion facility as defined in KRS 216B.015, except no capital expenditure or expenses relating to any such building shall be chargeable to or reimbursable as a cost for providing inpatient services offered by a health facility;
 - (c) Dispensaries and first-aid stations located within business or industrial establishments maintained solely for the use of employees, if the facility does not contain inpatient or resident beds for patients or employees who generally remain in the facility for more than twenty-four (24) hours;
 - (d) Establishments, such as motels, hotels, and boarding houses, which provide domiciliary and auxiliary commercial services, but do not provide any health related services and boarding houses which are operated by persons contracting with the United States Veterans Administration for boarding services;
 - (e) The remedial care or treatment of residents or patients in any home or institution conducted only for those who rely solely upon treatment by prayer or spiritual means in accordance with the creed or tenets of any recognized church or religious denomination and recognized by that church or denomination; and
 - (f) On-duty police and fire department personnel assisting in emergency situations by providing first aid or transportation when regular emergency units licensed to provide first aid or transportation are unable to arrive at the scene of an emergency situation within a reasonable time.
- (3) An existing facility licensed as skilled nursing, intermediate care, or nursing home shall notify the cabinet of its intent to change to a nursing facility as defined in Public Law 100-203. A certificate of need shall not be required for conversion of skilled nursing, intermediate care, or nursing home to the nursing facility licensure category.
- (4) Notwithstanding any other provision of law to the contrary, dual-license acute care beds licensed as of December 31, 1995, and those with a licensure application filed and in process prior to February 10, 1996, may be converted to nursing facility beds by December 31, 1996, without applying for a certificate of need. Any dual-license acute care beds not converted to nursing facility beds by December 31, 1996, shall, as of January 1, 1997, be converted to licensed acute care beds.
- (5) Notwithstanding any other provision of law to the contrary, no dual-license acute care beds or acute care nursing home beds that have been converted to nursing facility beds pursuant to the provisions of subsection (3) of this section may be certified as Medicaid eligible after December 31, 1995, without the written authorization of the secretary.
- (6) Notwithstanding any other provision of law to the contrary, total dual-license acute care beds shall be limited to those licensed as of December 31, 1995, and those with a licensure application filed and in process prior to February 10, 1996. No acute care hospital may obtain a new dual license for acute care beds unless the hospital had a licensure application filed and in process prior to February 10, 1996.
- (7) Ambulance services owned and operated by a city government, which propose to provide services in coterminous cities outside of the ambulance service's designated geographic service area, shall not be required to obtain a certificate of need if the governing body of the city in which the ambulance services are to be provided enters into an agreement with the ambulance service to provide services in the city.
- (8) Notwithstanding any other provision of law, a continuing care retirement community's nursing home beds shall not be certified as Medicaid eligible unless a certificate of need has been issued authorizing applications

for Medicaid certification. The provisions of subsection (3) of this section notwithstanding, a continuing care retirement community shall not change the level of care licensure status of its beds without first obtaining a certificate of need.

➔Section 3. KRS 216B.061 is amended to read as follows:

- (1) Unless otherwise provided in this chapter, no person shall do any of the following without first obtaining a certificate of need:
 - (a) Establish a health facility;
 - (b) Obligate a capital expenditure which exceeds the capital expenditure minimum;
 - (c) Make a substantial change in the bed capacity of a health facility;
 - (d) Make a substantial change in a health service;
 - (e) Make a substantial change in a project;
 - (f) Acquire major medical equipment;
 - (g) Alter a geographical area or alter a specific location which has been designated on a certificate of need or license;
 - (h) Transfer an approved certificate of need for the establishment of a new health facility or the replacement of a licensed facility.
- (2) No person shall separate portions of a single project into components in order to evade any expenditure minimum set forth in this chapter. For purposes of this chapter, the acquisition of one (1) or more items of functionally-related diagnostic or therapeutic equipment shall be considered as one (1) project.
- (3) No person shall have ex parte contact with the final decision making authority engaged in certificate of need activities regarding a certificate-of-need application from the commencement of the review cycle to the final decision. If an ex parte contact occurs, it shall be promptly made a part of the record.
- (4) No person shall obligate a capital expenditure in excess of the amount authorized by an existing certificate of need unless the person has received an administrative escalation from the cabinet as prescribed by regulation.
- (5) No person shall proceed to obligate a capital expenditure under an approved certificate of need if there has been a substantial change in the project.
- (6) A certificate of need shall be issued for a specific location and, when applicable, for a designated geographical area.
- (7) ***No person shall establish an ambulatory surgical center as defined in Section 1 of this Act without obtaining a certificate of need. An ambulatory surgical center shall require a certificate of need and license, notwithstanding any exemption contained in KRS 216B.020.***
- (8) ***Nothing in this chapter shall be interpreted to require any ambulatory surgical center licensed as of the effective date of this Act to obtain a certificate of need to continue operations and exercise all of the rights of a licensed health care facility regardless of whether it obtained a certificate of need before being licensed.***

➔Section 4. KRS 216B.095 is amended to read as follows:

- (1) An applicant may waive the procedures for formal review of an application for a certificate of need and request a nonsubstantive review as provided below. The cabinet may grant or deny nonsubstantive review status within ten (10) days of the date the application is deemed completed and shall give notice to all affected persons of the decision to conduct a nonsubstantive review. Any affected person other than the applicant may request a hearing by filing a request with the cabinet within ten (10) days of the notice to conduct a nonsubstantive review. As applicable, hearings shall be conducted as provided in KRS 216B.085. Based solely upon the record established with regard to the matter, the cabinet shall approve or deny a certificate of need on all projects assigned nonsubstantive review status within thirty-five (35) days of the determination of nonsubstantive review status. If the application is denied nonsubstantive review status, it shall automatically be placed in the formal review process.
- (2) If a certificate of need is denied following a nonsubstantive review, the applicant may request that the application be placed in the next cycle of the formal review process. Nothing in this subsection shall require an applicant to pursue a formal review before obtaining judicial review pursuant to KRS 216B.115.

- (3) The cabinet may grant nonsubstantive review status to an application for a certificate of need which is required:
- (a) To change the location of a proposed health facility;
 - (b) To replace or relocate a licensed health facility, if there is no substantial change in health services or substantial change in bed capacity;
 - (c) To replace or repair worn equipment if the worn equipment has been used by the applicant in a health facility for five (5) years or more;
 - (d) For cost escalations;
 - (e) To establish an industrial ambulance service; or
 - (f) In other circumstances the cabinet by administrative regulation may prescribe.
- (4) Notwithstanding any other provision to the contrary in this chapter, the cabinet may approve a certificate of need for a project required for the purposes set out in paragraphs (a) through (f) of subsection (3) of this section, unless it finds the facility or service with respect to which the capital expenditure is proposed to be made is not required; or to the extent the facility or services contemplated by the proposed capital expenditure is addressed in the state health plan, the cabinet finds that the capital expenditure is not consistent with the state health plan.
- (5) The decision of the cabinet approving or denying a certificate of need pursuant to this section shall be final for purposes of judicial appeal, unless the applicant requests the application be placed in the formal review process. An approved certificate shall be issued thirty (30) days after notice of the cabinet's decision, unless a judicial appeal is taken and issuance is enjoined by the court.
- (6) Notwithstanding any other provision of law, the cabinet shall not grant nonsubstantive review status to a certificate of need application that indicates an intent to apply for Medicaid certification of nursing home beds within a continuing care retirement community established under KRS 216B.015, 216B.020, 216B.330, and 216B.332.
- (7) ***Notwithstanding any provision of state law or the state health plan promulgated by administrative regulation in accordance with KRS 216B.040, the cabinet shall grant nonsubstantive review for a certificate of need proposal to establish an ambulatory surgical center if the applicant complies with the following:***
- (a) ***The applicant is an ambulatory surgical center that was organized and in operation as the private office of a physician or physician group prior to October 1, 2006;***
 - (b) ***1. The cabinet's general counsel has submitted a letter to the Accreditation Association for Ambulatory Health Care advising that the cabinet does not object to the applicant's parent company applying for and obtaining Medicare certification; or***
2. The applicant is an ambulatory surgical center that has received from the cabinet a favorable advisory opinion dated June 14, 2005, confirming that the applicant would be exempt from the certificate of need or licensure requirement;
 - (c) ***The applicant's ambulatory surgical center has been inspected and accredited by the Accreditation Association for Ambulatory Health Care since December 31, 2006, and has maintained accreditation with that organization consistently since that time; and***
 - (d) ***The applicant was a party to litigation concerning the ambulatory surgical center and physician office issue and, prior to the effective date of this Act, obtained a Court of Appeals ruling in its favor.***

→Section 5. KRS 304.17A-147 is amended to read as follows:

Notwithstanding any provision of law, a health plan issued or renewed on or after July 15, 2000, that provides coverage for surgical first assisting or intraoperative surgical care benefits or services shall be construed as providing coverage for a certified surgical assistant who performs services as identified in KRS 216B.015(16)~~(15)}~~.

→Section 6. KRS 304.17A-1473 is amended to read as follows:

Notwithstanding any provision of law, a health benefit plan issued or renewed on or after July 15, 2001, that provides coverage for surgical first assisting or intraoperative surgical care benefits or services shall be construed as providing coverage for a certified surgical assistant or physician assistant who performs services as identified in KRS 216B.015(16)~~(15)}~~.

Signed by Governor April 11, 2012.