

**GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2005**

**SESSION LAW 2005-325
SENATE BILL 740**

AN ACT TO AMEND THE CERTIFICATE OF NEED LAWS BY REQUIRING A CERTIFICATE OF NEED BEFORE OFFERING CARDIAC CATHETERIZATION SERVICES, EXCEPT WHEN DOING SO PURSUANT TO A SETTLEMENT AGREEMENT WITH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, REQUIRING HEALTH MAINTENANCE ORGANIZATIONS AND LONG-TERM CARE HOSPITALS TO OBTAIN A CERTIFICATE OF NEED, REQUIRING A CERTIFICATE OF NEED TO PURCHASE CERTAIN EQUIPMENT USED IN CANCER TREATMENT, REQUIRING A CERTIFICATE OF NEED FOR NEW HOSPICE OFFICES AFTER DECEMBER 31, 2005, CHANGING WHO ARE AFFECTED PERSONS ENTITLED TO APPEAL A CERTIFICATE OF NEED DECISION, AUTHORIZING THE FURNISHING OF CARDIAC CATHETERIZATION EQUIPMENT OR SERVICES PURSUANT TO SETTLEMENT AGREEMENTS WITH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, AND MAKING OTHER TECHNICAL CHANGES.

The General Assembly of North Carolina enacts:

SECTION 1. G.S. 131E-176 reads as rewritten:

"§ 131E-176. Definitions.

As used in this Article, unless the context clearly requires otherwise, the following terms have the meanings specified:

- (1) "Adult care home" means a facility with seven or more beds licensed under G.S. 131D-2 or Chapter 131E of the General Statutes that provides residential care for aged or disabled persons whose principal need is a home which provides the supervision and personal care appropriate to their age and disability and for whom medical care is only occasional or incidental.
- (1a) **(See note)** "Air ambulance" means aircraft used to provide air transport of sick or injured persons between destinations within the State.
- (1b) "Ambulatory surgical facility" means a facility designed for the provision of a specialty ambulatory surgical program or a multispecialty ambulatory surgical program. An ambulatory surgical facility serves patients who require local, regional or general anesthesia and a period of post-operative observation. An ambulatory surgical facility may only admit patients for a period of less than 24 hours and must provide at least one designated operating room and at least one designated recovery room, have available the necessary equipment and trained personnel to handle emergencies, provide adequate quality assurance and assessment by an evaluation and review committee, and maintain adequate medical records for each patient. An ambulatory surgical facility may be operated as a part of a physician or dentist's office, provided the facility is licensed under G.S. Chapter 131E, Article 6, Part D, but the performance of incidental, limited ambulatory surgical procedures which do not

- constitute an ambulatory surgical program as defined in subdivision (1b) and which are performed in a physician's or dentist's office does not make that office an ambulatory surgical facility.
- (1c) "Ambulatory surgical program" means a formal program for providing on a same-day basis those surgical procedures which require local, regional or general anesthesia and a period of post-operative observation to patients whose admission for more than 24 hours is determined, prior to surgery, to be medically unnecessary.
 - (2) "Bed capacity" means space used exclusively for inpatient care, including space designed or remodeled for licensed inpatient beds even though temporarily not used for such purposes. The number of beds to be counted in any patient room shall be the maximum number for which adequate square footage is provided as established by rules of the Department except that single beds in single rooms are counted even if the room contains inadequate square footage. The term "bed capacity" also refers to the number of dialysis stations in kidney disease treatment centers, including freestanding dialysis units.
 - (2a) "Bone marrow transplantation services" means the process of infusing bone marrow into persons with diseases to stimulate the production of blood cells.
 - (2b) "Burn intensive care services" means services provided in a unit designed to care for patients who have been severely burned.
 - (2c) "Campus" means the adjacent grounds and buildings, or grounds and buildings not separated by more than a public right-of-way, of a health service facility and related health care entities.
 - (2d) "Capital expenditure" means an expenditure for a project, including but not limited to the cost of construction, engineering, and equipment which under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance. Capital expenditure includes, in addition, the fair market value of an acquisition made by donation, lease, or comparable arrangement by which a person obtains equipment, the expenditure for which would have been considered a capital expenditure under this Article if the person had acquired it by purchase.
 - (2e) ~~"Cardiac angioplasty equipment" means the cardiac catheterization equipment used in surgery for the restoration, repair, or reconstruction of coronary blood vessels.~~
 - (2f) ~~"Cardiac catheterization equipment" means the equipment required to perform diagnostic procedures or therapeutic intervention in which a catheter is introduced into a vein or artery and threaded through the circulatory system to the heart.~~ used to provide cardiac catheterization services.
 - (2g) "Cardiac catheterization services" means those procedures, excluding pulmonary angiography procedures, in which a catheter is introduced into a vein or artery and threaded through the circulatory system into the heart specifically to diagnose abnormalities in the motion, contraction, and blood flow of the moving heart or to perform surgical therapeutic interventions to restore, repair, or reconstruct the coronary blood vessels of the heart.
 - (3) "Certificate of need" means a written order which affords the person so designated as the legal proponent of the proposed project the opportunity to proceed with the development of such project.
 - (4) Repealed by Session Laws 1993, c. 7, s. 2.
 - (5) "Change in bed capacity" means (i) any relocation of health service facility beds, or dialysis stations from one licensed facility or campus

to another, or (ii) any redistribution of health service facility bed capacity among the categories of health service facility bed as defined in G.S. 131E-176(9c), or (iii) any increase in the number of health service facility beds, or dialysis stations in kidney disease treatment centers, including freestanding dialysis units.

- (5a) "Chemical dependency treatment facility" means a public or private facility, or unit in a facility, which is engaged in providing 24-hour a day treatment for chemical dependency or substance abuse. This treatment may include detoxification, administration of a therapeutic regimen for the treatment of chemically dependent or substance abusing persons and related services. The facility or unit may be:
- a. A unit within a general hospital or an attached or freestanding unit of a general hospital licensed under Article 5, Chapter 131E, of the General Statutes,
 - b. A unit within a psychiatric hospital or an attached or freestanding unit of a psychiatric hospital licensed under Article 1A of General Statutes Chapter 122 or Article 2 of General Statutes Chapter 122C,
 - c. A freestanding facility specializing in treatment of persons who are substance abusers or chemically dependent licensed under Article 1A of General Statutes Chapter 122 or Article 2 of General Statutes Chapter 122C; and may be identified as "chemical dependency, substance abuse, alcoholism, or drug abuse treatment units," "residential chemical dependency, substance abuse, alcoholism or drug abuse facilities," or by other names if the purpose is to provide treatment of chemically dependent or substance abusing persons, but shall not include social setting detoxification facilities, medical detoxification facilities, halfway houses or recovery farms.
- (5b) "Chemical dependency treatment beds" means beds that are licensed for the inpatient treatment of chemical dependency. Residential treatment beds for the treatment of chemical dependency or substance abuse are chemical dependency treatment beds. Chemical dependency treatment beds shall not include beds licensed for detoxification.
- (6) "Department" means the North Carolina Department of Health and Human Services.
- (7) To "develop" when used in connection with health services, means to undertake those activities which will result in the offering of institutional health service or the incurring of a financial obligation in relation to the offering of such a service.
- (7a) "Diagnostic center" means a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

- (7b) "Expedited review" means the status given to an application's review process when the applicant petitions for the review and the Department approves the request based on findings that all of the following are met:
- a. The review is not competitive.
 - b. The proposed capital expenditure is less than five million dollars (\$5,000,000).
 - c. A request for a public hearing is not received within the time frame defined in G.S. 131E-185.
 - d. The agency has not determined that a public hearing is in the public interest.
- (7c) "Gamma knife" means equipment which emits photon beams from a stationary radioactive cobalt source to treat lesions deep within the brain and is one type of stereotactic radiosurgery.
- (8), (9) Repealed by Session Laws 1987, c. 511, s. 1.
- (9a) "Health service" means an organized, interrelated medical, diagnostic, therapeutic, and/or rehabilitative activity that is integral to the prevention of disease or the clinical management of a sick, injured, or disabled person. "Health service" does not include administrative and other activities that are not integral to clinical management.
- (9b) "Health service facility" means a hospital; long-term care hospital; psychiatric facility; rehabilitation facility; nursing home facility; adult care home; kidney disease treatment center, including freestanding hemodialysis units; intermediate care facility for the mentally retarded; home health agency office; chemical dependency treatment facility; diagnostic center; ~~oncology treatment center~~; ~~hospice~~, hospice office, hospice inpatient facility, hospice residential care facility; and ambulatory surgical facility.
- (9c) "Health service facility bed" means a bed licensed for use in a health service facility in the categories of (i) acute care beds; (ii) psychiatric beds; (iii) rehabilitation beds; (iv) nursing home beds; (v) intermediate care beds for the mentally retarded; (vi) chemical dependency treatment beds; (vii) hospice inpatient facility beds; (viii) hospice residential care facility beds; ~~and~~ ~~(ix) adult care home beds~~; and (x) long-term care hospital beds.
- (10) "Health maintenance organization (HMO)" means a public or private organization which has received its certificate of authority under Article 67 of Chapter 58 of the General Statutes and which either is a qualified health maintenance organization under Section 1310(d) of the Public Health Service Act or:
- a. Provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual physician services, hospitalization, laboratory, X ray, emergency and preventive services, and out-of-area coverage;
 - b. Is compensated, except for copayments, for the provision of the basic health care services listed above to enrolled participants by a payment which is paid on a periodic basis without regard to the date the health care services are provided and which is fixed without regard to the frequency, extent, or kind of health service actually provided; and
 - c. Provides physicians' services primarily (i) directly through physicians who are either employees or partners of such organizations, or (ii) through arrangements with individual

physicians or one or more groups of physicians organized on a group practice or individual practice basis.

(10a) "Heart-lung bypass machine" means the equipment used to perform extra-corporeal circulation and oxygenation during surgical procedures.

(11) Repealed by Session Laws 1991, c. 692, s. 1.

(12) "Home health agency" means a private organization or public agency, whether owned or operated by one or more persons or legal entities, which furnishes or offers to furnish home health services.

"Home health services" means items and services furnished to an individual by a home health agency, or by others under arrangements with such others made by the agency, on a visiting basis, and except for paragraph e. of this subdivision, in a place of temporary or permanent residence used as the individual's home as follows:

a. Part-time or intermittent nursing care provided by or under the supervision of a registered nurse;

b. Physical, occupational or speech therapy;

c. Medical social services, home health aid services, and other therapeutic services;

d. Medical supplies, other than drugs and biologicals and the use of medical appliances;

e. Any of the foregoing items and services which are provided on an outpatient basis under arrangements made by the home health agency at a hospital or nursing home facility or rehabilitation center and the furnishing of which involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual in his home, or which are furnished at such facility while he is there to receive any such item or service, but not including transportation of the individual in connection with any such item or service.

(13) "Hospital" means a public or private institution which is primarily engaged in providing to inpatients, by or under supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. The term includes all facilities licensed pursuant to G.S. 131E-77 of the General Statutes, except long-term care hospitals.

(13a) "Hospice" means any coordinated program of home care with provision for inpatient care for terminally ill patients and their families. This care is provided by a medically directed interdisciplinary team, directly or through an agreement under the direction of an identifiable hospice administration. A hospice program of care provides palliative and supportive medical and other health services to meet the physical, psychological, social, spiritual and special needs of patients and their families, which are experienced during the final stages of terminal illness and during dying and bereavement.

(13b) "Hospice inpatient facility" means a freestanding licensed hospice facility or a designated inpatient unit in an existing health service facility which provides palliative and supportive medical and other health services to meet the physical, psychological, social, spiritual, and special needs of terminally ill patients and their families in an inpatient setting. For purposes of this Article only, a hospital which

- has a contractual agreement with a licensed hospice to provide inpatient services to a hospice patient as defined in G.S. 131E-201(4) and provides those services in a licensed acute care bed is not a hospice inpatient facility and is not subject to the requirements in G.S. 131E-176(5)(ii) for hospice inpatient beds.
- (13c) "Hospice residential care facility" means a freestanding licensed hospice facility which provides palliative and supportive medical and other health services to meet the physical, psychological, social, spiritual, and special needs of terminally ill patients and their families in a group residential setting.
 - (14) Repealed by Session Laws 1987, c. 511, s. 1.
 - (14a) "Intermediate care facility for the mentally retarded" means facilities licensed pursuant to Article 2 of Chapter 122C of the General Statutes for the purpose of providing health and habilitative services based on the developmental model and principles of normalization for persons with mental retardation, autism, cerebral palsy, epilepsy or related conditions.
 - (14a1) "Kidney disease treatment center" means a facility that is certified as an end-stage renal disease facility by the Centers for Medicare and Medicaid Services, Department of Health and Human Services, pursuant to 42 C.F.R. § 405.
 - (14b) Repealed by Session Laws 1991, c. 692, s. 1.
 - (14b1) "Linear accelerator" means a machine used to produce ionizing radiation in excess of 1,000,000 electron volts in the form of a beam of electrons or photons to treat cancer patients.
 - (14c) "Lithotripter" means extra-corporeal shock wave technology used to treat persons with kidney stones and gallstones.
 - (14c1) "Long-term care hospital" means a hospital that has been classified and designated as a long-term care hospital by the Centers for Medicare and Medicaid Services, Department of Health and Human Services, pursuant to 42 C.F.R. § 412.
 - (14d) Repealed by Session Laws 2001-234, s. 2, effective January 1, 2002.
 - (14e) "Magnetic resonance imaging scanner" means medical imaging equipment that uses nuclear magnetic resonance.
 - (14f) "Major medical equipment" means a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars (\$750,000). In determining whether the major medical equipment costs more than seven hundred fifty thousand dollars (\$750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment as defined in this section.
 - (15) Repealed by Session Laws 1987, c. 511, s. 1.
 - (15a) "Multispecialty ambulatory surgical program" means a formal program for providing on a same-day basis surgical procedures for at least three of the following specialty areas: gynecology, otolaryngology, plastic surgery, general surgery, ophthalmology, orthopedic, or oral surgery.
 - (15b) "Neonatal intensive care services" means those services provided by a health service facility to high-risk newborn infants who require

constant nursing care, including but not limited to continuous cardiopulmonary and other supportive care.

- (16) "New institutional health services" means any of the following:
- a. The construction, development, or other establishment of a new health service facility.
 - b. The obligation by any person of a capital expenditure exceeding two million dollars (\$2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an expenditure is made shall be included in determining if the expenditure exceeds two million dollars (\$2,000,000).
 - c. Any change in bed capacity as defined in G.S. 131E-176(5).
 - d. The offering of dialysis services or home health services by or on behalf of a health service facility if those services were not offered within the previous 12 months by or on behalf of the facility.
 - e. A change in a project that was subject to certificate of need review and for which a certificate of need was issued, if the change is proposed during the development of the project or within one year after the project was completed. For purposes of this subdivision, a change in a project is a change of more than fifteen percent (15%) of the approved capital expenditure amount or the addition of a health service that is to be located in the facility, or portion thereof, that was constructed or developed in the project.
 - f. The development or offering of a health service as listed in this subdivision by or on behalf of any person:
 1. Bone marrow transplantation services.
 2. Burn intensive care services.
 - 2a. Cardiac catheterization services, except cardiac catheterization services provided on equipment furnished by a person authorized to operate such equipment in North Carolina pursuant to either a certificate of need issued for mobile cardiac catheterization equipment or a settlement agreement executed by the Department for provision of cardiac catheterization services.
 3. Neonatal intensive care services.
 4. Open-heart surgery services.
 5. Solid organ transplantation services.
 - f1. The acquisition by purchase, donation, lease, transfer, or comparable arrangement of any of the following equipment by or on behalf of any person:
 1. Air ambulance.
 2. ~~Cardiac angioplasty equipment.~~
 3. Cardiac catheterization equipment.
 4. Gamma knife.
 5. Heart-lung bypass machine.
 - 5a. Linear accelerator.
 6. Lithotripter.
 7. Magnetic resonance imaging scanner.
 8. Positron emission tomography scanner.

9. Simulator.

- g. to k. Repealed by Session Laws 1987, c. 511, s. 1.
 - l. The purchase, lease, or acquisition of any health service facility, or portion thereof, or a controlling interest in the health service facility or portion thereof, if the health service facility was developed under a certificate of need issued pursuant to G.S. 131E-180.
 - m. Any conversion of nonhealth service facility beds to health service facility beds.
 - n. The construction, development or other establishment of a hospice, hospice inpatient facility, or hospice residential care facility;
 - o. The opening of an additional office by an existing home health agency or hospice within its service area as defined by rules adopted by the Department; or the opening of any office by an existing home health agency or hospice outside its service area as defined by rules adopted by the Department.
 - p. The acquisition by purchase, donation, lease, transfer, or comparable arrangement by any person of major medical equipment.
 - q. The relocation of a health service facility from one service area to another.
 - r. The conversion of a specialty ambulatory surgical program to a multispecialty ambulatory surgical program or the addition of a specialty to a specialty ambulatory surgical program.
 - s. The furnishing of mobile medical equipment to any person to provide health services in North Carolina, which was not in use in North Carolina prior to the adoption of this provision, if such equipment would otherwise be subject to review in accordance with G.S. 131E-176(16)(f1.) or G.S. 131E-176(16)(p) if it had been acquired in North Carolina.
 - t. Repealed by Session Laws 2001-242, s. 4, effective June 23, 2001.
 - u. **(See note)** The construction, development, establishment, increase in the number, or relocation of an operating room or operating rooms, other than the relocation of an operating room or operating rooms within the same building or on the same grounds or to grounds not separated by more than a public right-of-way adjacent to the grounds where the operating room is or operating rooms are currently located.
- (17) "North Carolina State Health Coordinating Council" means the Council that prepares, with the Department of Health and Human Services, the State Medical Facilities Plan.
- (17a) "Nursing care" means:
- a. Skilled nursing care and related services for residents who require medical or nursing care;
 - b. Rehabilitation services for the rehabilitation of injured, disabled, or sick persons; or
 - c. Health-related care and services provided on a regular basis to individuals who because of their mental or physical condition require care and services above the level of room and board, which can be made available to them only through institutional facilities.

These are services which are not primarily for the care and treatment of mental diseases.

- (17b) "Nursing home facility" means a health service facility whose bed complement of health service facility beds is composed principally of nursing home facility beds.
- (18) To "offer," when used in connection with health services, means that the person holds himself out as capable of providing, or as having the means for the provision of, specified health services.
- ~~(18a) "Oncology treatment center" means a facility, program, or provider, other than an existing health service facility that provides services for diagnosis, evaluation, or treatment of cancer and its aftereffects or secondary results and for which the total cost of all the medical equipment utilized by the center, exceeds two hundred fifty thousand dollars (\$250,000). In determining whether costs are more than two hundred fifty thousand dollars (\$250,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the facility, program, or provider shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.~~
- (18b) "Open-heart surgery services" means the provision of surgical procedures that utilize a heart-lung bypass machine during surgery to correct cardiac and coronary artery disease or defects.
- (19) "Person" means an individual, a trust or estate, a partnership, a corporation, including associations, joint stock companies, and insurance companies; the State, or a political subdivision or agency or instrumentality of the State.
- (19a) "Positron emission tomography scanner" means equipment that utilizes a computerized radiographic technique that employs radioactive substances to examine the metabolic activity of various body structures.
- (20) "Project" or "capital expenditure project" means a proposal to undertake a capital expenditure that results in the offering of a new institutional health service as defined by this Article. A project, or capital expenditure project, or proposed project may refer to the project from its earliest planning stages up through the point at which the specified new institutional health service may be offered. In the case of facility construction, the point at which the new institutional health service may be offered must take place after the facility is capable of being fully licensed and operated for its intended use, and at that time it shall be considered a health service facility.
- (21) "Psychiatric facility" means a public or private facility licensed pursuant to Article 2 of Chapter 122C of the General Statutes and which is primarily engaged in providing to inpatients, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons.
- (22) "Rehabilitation facility" means a public or private 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.
- (22a) "Replacement equipment" means equipment that costs less than two million dollars (\$2,000,000) and is purchased for the sole purpose of replacing comparable medical equipment currently in use which will be sold or otherwise disposed of when replaced. In determining whether the replacement equipment costs less than two million dollars

(\$2,000,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the replacement equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater.

(23) Repealed by Session Laws 1991, c. 692, s. 1.

(24) Repealed by Session Laws 1993, c. 7, s. 2.

(24a) "Service area" means the area of the State, as defined in the State Medical Facilities Plan or in rules adopted by the Department, which receives services from a health service facility.

(24a1) "Simulator" means a machine that produces high quality diagnostic radiographs and precisely reproduces the geometric relationships of megavoltage radiation therapy equipment to the patient.

(24b) "Solid organ transplantation services" means the provision of surgical procedures and the interrelated medical services that accompany the surgery to remove an organ from a patient and surgically implant an organ from a donor.

(24c) "Specialty ambulatory surgical program" means a formal program for providing on a same-day basis surgical procedures for only the specialty areas identified on the ambulatory surgical facility's 1993 Application for Licensure as an Ambulatory Surgical Center and authorized by its certificate of need.

(25) "State Medical Facilities Plan" means the plan prepared by the Department of Health and Human Services and the North Carolina State Health Coordinating Council, and approved by the Governor. In preparing the Plan, the Department and the State Health Coordinating Council shall maintain a mailing list of persons who have requested notice of public hearings regarding the Plan. Not less than 15 days prior to a scheduled public hearing, the Department shall notify persons on its mailing list of the date, time, and location of the hearing. The Department shall hold at least one public hearing prior to the adoption of the proposed Plan and at least six public hearings after the adoption of the proposed Plan by the State Health Coordinating Council. The Council shall accept oral and written comments from the public concerning the Plan.

(26) Repealed by Session Laws 1983 (Regular Session, 1984), c. 1002, s. 9.

(27) Repealed by Session Laws 1987, c. 511, s. 1."

SECTION 2. G.S. 131E-180 is repealed.

SECTION 3. G.S. 131E-182(a) reads as rewritten:

"(a) The Department in its rules shall establish schedules for submission and review of completed applications. The schedules shall provide that applications for similar proposals in the same ~~health~~-service area will be reviewed together."

SECTION 4. G.S. 131E-185(a1) reads as rewritten:

"(a1) Except as provided in subsection (c) of this section, there shall be a time limit of 90 days for review of the applications, beginning on the day established by rule as the day on which applications for the particular service in the service area shall begin review.

(1) Any person may file written comments and exhibits concerning a proposal under review with the Department, not later than 30 days after the date on which the application begins review. These written comments may include:

a. Facts relating to the service area proposed in the application;

- b. Facts relating to the representations made by the applicant in its application, and its ability to perform or fulfill the representations made;
 - c. Discussion and argument regarding whether, in light of the material contained in the application and other relevant factual material, the application complies with relevant review criteria, plans, and standards.
- (2) No more than 20 days from the conclusion of the written comment period, the Department shall ensure that a public hearing is conducted at a place within the appropriate ~~health~~-service area if one or more of the following circumstances apply; the review to be conducted is competitive; the proponent proposes to spend five million dollars (\$5,000,000) or more; a written request for a public hearing is received before the end of the written comment period from an affected party as defined in G.S. 131E-188(c); or the agency determines that a hearing is in the public interest. At such public hearing oral arguments may be made regarding the application or applications under review; and this public hearing shall include the following:
- a. An opportunity for the proponent of each application under review to respond to the written comments submitted to the Department about its application;
 - b. An opportunity for any ~~affected person as defined in G.S. 131E-188(c),~~ person, except one of the proponents, to ~~present comments regarding comment on~~ the applications under review;
 - c. An opportunity for a representative of the Department, or such other person or persons who are designated by the Department to conduct the hearing, to question each proponent of applications under review with regard to the contents of the application;
- The Department shall maintain a recording of any required public hearing on an application until such time as the Department's final decision is issued, or until a final agency decision is issued pursuant to a contested case hearing, whichever is later; and any person may submit a written synopsis or verbatim statement that contains the oral presentation made at the hearing.
- (3) The Department may contract or make arrangements with a person or persons located within each ~~health~~-service area for the conduct of such public hearings as may be necessary. The Department shall publish, in each ~~health~~-service area, notice of the contracts that it executes for the conduct of those hearings.
 - (4) Within 15 days from the beginning of the review of an application or applications proposing the same service within the same service area, the Department shall publish notice of the deadline for receipt of written comments, of the time and place scheduled for the public hearing regarding the application or applications under review, and of the name and address of the person or agency that will preside.
 - (5) The Department shall maintain all written comments submitted to it during the written comment stage and any written submissions received at the public hearing as part of the Department's file respecting each application or group of applications under review by it. The application, written comments, and public hearing comments, together with all documents that the Department used in arriving at its decision, from whatever source, and any documents that reflect or set out the Department's final analysis of the application or applications

under review, shall constitute the Department's record for the application or applications under review."

SECTION 5. G.S. 131E-188(c) reads as rewritten:

"(c) The term "affected persons" includes: the applicant; any ~~person-individual~~ residing within the ~~service area or the geographic area~~ served or to be served by the applicant; any ~~person-individual~~ who regularly uses health service facilities within that ~~geographic area; area or the service area; health service facilities and health maintenance organizations (HMOs) 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; any person who provides services, similar to the services under review, to individuals residing within the service area or the geographic area proposed to be served by the applicant; health service facilities and HMOs which, any person who, prior to receipt by the agency of the proposal being reviewed, have formally indicated has provided written notice to the agency of an intention to provide similar services in the future; future to individuals residing within the service area or the geographic area to be served by the applicant;~~ third party payers who reimburse health service facilities for services in the ~~health-service area~~ in which the project is proposed to be located; and any agency which establishes rates for health service facilities or HMOs located in the ~~health-service area~~ in which the project is proposed to be located."

SECTION 6. G.S. 131E-176(2f) and (2g), as enacted in this act, shall not preclude the furnishing of cardiac catheterization equipment or the provision of cardiac catheterization services by a person authorized to furnish this equipment or provide these services pursuant to a settlement agreement between the person and the Department of Health and Human Services prior to the effective date of this act.

SECTION 7. G.S. 131E-176, as amended by Section 1 of this act, becomes effective for hospices and hospice offices December 31, 2005. The remainder of this act is effective when it becomes law.

In the General Assembly read three times and ratified this the 16th day of August, 2005.

s/ Marc Basnight
President Pro Tempore of the Senate

s/ James B. Black
Speaker of the House of Representatives

s/ Michael F. Easley
Governor

Approved 11:03 a.m. this 26th day of August, 2005