3

4 5

6 7

8

9

10 11

12

13

14 15

16

17

18 19

20

21

22

23

24

2526

27

28

29

30 31

A bill to be entitled An act relating to health care regulation; amending s. 395.002, F.S.; revising definitions relating to hospital licensing and regulation; amending ss. 395.003 and 400.102, F.S.; restricting persons who may initiate or intervene in an action on an application for licensure of a health care facility, program, or service; creating s. 395.0095, F.S.; providing minimum standards for specified impatient services; specifying requirements for cardiac catheterization and angioplasty, open heart surgery, inpatient comprehensive medical rehabilitation, inpatient general psychiatric services, inpatient substance abuse services, neonatal intensive care services, specialty burn units, heart transplantation, liver transplantation, kidney transplantation, and bone marrow transplantation; amending s. 400.071, F.S.; providing additional requirements for application for a nursing home license; amending s. 400.121, F.S.; restricting persons who may initiate or intervene in an action on an application for licensure of a nursing home facility, program, or service; providing penalties for failure of a nursing home to demonstrate financial feasibility in its application for licensure; amending s. 400.605, F.S.; providing for an expedited licensure process for community-based hospice services; amending s. 400.606, F.S.; providing

additional requirements for application for 1 2 licensure of a hospice; deleting language 3 relating to certificate of need to conform to 4 the act; restricting persons who may initiate 5 or intervene in an action or application for licensure of a hospice; providing penalties for 6 7 failure of a hospice to demonstrate financial 8 feasibility in its application for licensure; repealing ss. 408.031, 408.032(2), (3), (4), 9 (6), and (7), 408.034, 408.035, 408.036, 10 11 408.0361, 408.037, 408.038, 408.039, 408.040, 12 408.041, 408.042, 408.043, 408.044, 408.045, 13 408.0455, and 651.118, F.S., relating to 14 requirements for certificate-of-need review and 15 approval for health care facilities and 16 services; repealing s. 154.245, F.S., relating to certificates of need required as a condition 17 of certain bond validation; amending s. 18 408.033, F.S.; revising provisions relating to 19 20 local and state health planning; amending ss. 20.42, 154.205, 154.213, 154.219, 159.27, 21 22 189.415, 395.0191, 395.1055, 395.603, 395.604, 395.605, 400.23, 400.602, 400.6085, 430.705, 23 24 430.708, and 651.021, F.S., to conform to the repeal of certificate-of-need requirements and 25 26 the process of certificate-of-need review; 27 amending ss. 383.50, 394.4787, 395.602, 28 395.701, 400.051, 409.905, 468.505, and 29 766.316, F.S.; correcting cross references; providing a grandfather clause for specified 30 31

1 inpatient services; providing an effective 2 date. 3 4 Be It Enacted by the Legislature of the State of Florida: 5 6 Section 1. Section 395.002, Florida Statutes, is 7 amended to read: 8 395.002 Definitions.--As used in this chapter: 9 "Accrediting organizations" means the Joint Commission on Accreditation of Healthcare Organizations, the 10 American Osteopathic Association, the Commission on 11 12 Accreditation of Rehabilitation Facilities, and the 13 Accreditation Association for Ambulatory Health Care, Inc. 14 (2) "Acute detoxification services" means hospital inpatient services provided under the direction of a physician 15 16 intended to treat the physiological effects of acute alcohol 17 or drug intoxication during or immediately after the acute 18 intoxication. 19 "Adolescent" means a person who is at least 14 (3) 20 years of age but under 18 years of age. (4)21 "Adult" means a person who is 18 years of age or 22 older. 23 (5) "Agency" means the Agency for Health Care 24 Administration. 25 (6)(3) "Ambulatory surgical center" or "mobile 26 surgical facility" means a facility the primary purpose of 27 which is to provide elective surgical care, in which the 28 patient is admitted to and discharged from such facility 29 within the same working day and is not permitted to stay overnight, and which is not part of a hospital. However, a 30

31 | facility existing for the primary purpose of performing

terminations of pregnancy, an office maintained by a physician for the practice of medicine, or an office maintained for the practice of dentistry shall not be construed to be an ambulatory surgical center, provided that any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003. Any structure or vehicle in which a physician maintains an office and practices surgery, and which can appear to the public to be a mobile office because the structure or vehicle operates at more than one address, shall be construed to be a mobile surgical facility.

(7)(4) "Applicant" means an individual applicant, or any officer, director, or agent, or any partner or shareholder having an ownership interest equal to a 5-percent or greater interest in the corporation, partnership, or other business entity.

(8) (5) "Biomedical waste" means any solid or liquid waste as defined in s. 381.0098(2)(a).

(9) "Bone marrow transplantation" means administration of human blood precursor cells and stem cells to a patient in order to restore normal hematological and immunological functions following ablative therapy with curative intent.

Human blood precursor cells may be obtained from the patient in an autologous transplant or from a medically acceptable related or unrelated donor, and may be derived from bone marrow, circulating blood, or a combination of bone marrow and circulating blood. If chemotherapy is an integral part of the treatment involving bone marrow transplantation, the term "bone marrow transplantation" includes both the

31 transplantation and the chemotherapy.

 (10) "Burn team" means a team consisting of, at a minimum, a burn care physician, nursing staff, and burn care rehabilitation therapy staff.

(11) "Burn unit" means a discrete unit within a hospital that occupies designated physical space separate from other areas of the hospital. A burn unit shall have a minimum of five dedicated burn beds and shall be equipped and staffed to provide specialized care solely for severely burned persons.

cardiac catheterization" means a medical procedure requiring the passage of a catheter into one or more cardiac chambers of the left and right heart, with or without coronary arteriograms, for the purpose of diagnosing congenital or acquired cardiovascular diseases, or for determining measurement of blood pressure flow. Cardiac catheterization also includes the selective catheterization of the coronary ostia with injection of contrast medium into the coronary arteries.

institutional health service that is provided by or on behalf of a health care facility and that consists of one or more laboratories that comprise a room or suite of rooms, and has the equipment and staff required to perform cardiac catheterization serving inpatients and outpatients. A cardiac catheterization program performing angioplasty services, or other types of therapeutic cardiac procedures, shall have the additional necessary equipment and staff to perform angioplasty procedures.

 $\underline{\text{(14)}}_{\text{(6)}}$ "Clinical privileges" means the privileges granted to a physician or other licensed health care

2

3 4

5

6

7

8

9

10

11 12

13

14

15 16

17

18 19

20

21 22

23

24

25

26

27

28

29

30

practitioner to render patient care services in a hospital, but does not include the privilege of admitting patients.

- (15) "Complex neonatal surgery" means any surgical procedure performed upon a neonate by a practitioner with surgical credentials, licensed under chapter 458 or chapter 459, that is associated with entering into or traversing a body cavity, such as the abdomen, thorax, or cranium, with a requirement for either general anesthesia or conscious sedation. Such procedures shall be performed only in hospitals licensed to provide Level III neonatal services.
- (16) "Comprehensive medical rehabilitation inpatient services" means an organized program of integrated intensive care services provided by a coordinated multidisciplinary team to patients with severe physical disabilities, such as stroke; spinal cord injury; congenital deformity; amputation; major multiple trauma; fracture of femur (hip fracture); brain injury; polyarthritis, including rheumatoid arthritis; neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease; and burns.
- (17) "Coronary angioplasty" means a hospital inpatient procedure requiring the dilation of narrowed segments of the coronary vessels, via a balloon-tipped catheter.
 - (18) "Department" means the Department of Health.
- (19)(8) "Director" means any member of the official board of directors as reported in the organization's annual corporate report to the Florida Department of State, or, if no such report is made, any member of the operating board of directors. The term excludes members of separate, restricted boards that serve only in an advisory capacity to the 31 operating board.

(20)(9) "Emergency medical condition" means:

1

7

6

8 9

10

11 12

13

14 15 16

17 18 19

20 21 22

24 25

26

23

27 28 29

- (a) A medical condition manifesting itself by acute symptoms of sufficient severity, which may include severe pain, such that the absence of immediate medical attention could reasonably be expected to result in any of the following:
- 1. Serious jeopardy to patient health, including a pregnant woman or fetus.
 - 2. Serious impairment to bodily functions.
 - 3. Serious dysfunction of any bodily organ or part.
 - (b) With respect to a pregnant woman:
- 1. That there is inadequate time to effect safe transfer to another hospital prior to delivery;
- That a transfer may pose a threat to the health and safety of the patient or fetus; or
- That there is evidence of the onset and persistence of uterine contractions or rupture of the membranes.
- (21)(10) "Emergency services and care" means medical screening, examination, and evaluation by a physician, or, to the extent permitted by applicable law, by other appropriate personnel under the supervision of a physician, to determine if an emergency medical condition exists and, if it does, the care, treatment, or surgery by a physician necessary to relieve or eliminate the emergency medical condition, within the service capability of the facility, available 24 hours a day, 7 days a week.
- (22)(11) "General hospital" means any facility which meets the provisions of subsection(24) $\frac{(13)}{(13)}$ and which regularly makes its facilities and services available to the general population.

(23)(12) "Governmental unit" means the state or any county, municipality, or other political subdivision, or any department, division, board, or other agency of any of the foregoing.

(24)(13) "Hospital" means any establishment that:

- (a) Offers services more intensive than those required for room, board, personal services, and general nursing care, and offers facilities and beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care for illness, injury, deformity, infirmity, abnormality, disease, or pregnancy; and
- (b) Regularly makes available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment of similar extent.

15 16 17

18 19

20

21

22

23

24

25 26

27

28

29

30

1

2

3

4

5

6

7

8

9

10 11

12

13

14

However, the provisions of this chapter do not apply to any institution conducted by or for the adherents of any well-recognized church or religious denomination that depends exclusively upon prayer or spiritual means to heal, care for, or treat any person. For purposes of local zoning matters, the term "hospital" includes a medical office building located on the same premises as a hospital facility, provided the land on which the medical office building is constructed is zoned for use as a hospital; provided the premises were zoned for hospital purposes on January 1, 1992.

(25)(14) "Hospital bed" means a hospital accommodation which is ready for immediate occupancy, or is capable of being made ready for occupancy within 48 hours, excluding provision of staffing, and which conforms to minimum space, equipment, 31 and furnishings standards as specified by rule of the agency

for the provision of services specified in this section to a single patient.

(26) "Inactive license" means a license issued to a hospital that will be temporarily unable to provide a service but is reasonably expected to resume the service. Such designation may be made for a period not to exceed 12 months, but may be renewed by the agency for up to 6 additional months. Requests for an inactive license must be submitted to the agency and approved by the agency prior to any suspension of services.

(27)(15) "Initial denial determination" means a determination by a private review agent that the health care services furnished or proposed to be furnished to a patient are inappropriate, not medically necessary, or not reasonable.

(28)(16) "Intensive residential treatment programs for children and adolescents" means a specialty hospital accredited by the Joint Commission on Accreditation of Healthcare Organizations which provides 24-hour care and which has the primary functions of diagnosis and treatment of patients under the age of 18 having psychiatric disorders in order to restore such patients to an optimal level of functioning.

(29) "Level II neonatal intensive care unit bed" means a patient care station within a neonatal intensive care unit with the capability of providing neonatal intensive care services to ill neonates of 1,000 grams birthweight or over, which is staffed to provide at least 6 hours of nursing care per neonate per day and has the capability of providing ventilator assistance and Level II neonatal intensive care services.

(30) "Level III neonatal intensive care bed" means a patient care station within a neonatal intensive care unit with the capability of providing neonatal intensive care services to severely ill neonates regardless of birthweight, which is staffed to provide 12 or more hours of nursing care per neonate per day and Level III neonatal intensive care services.

 $\underline{(31)}(17)$ "Licensed facility" means a hospital, ambulatory surgical center, or mobile surgical facility licensed in accordance with this chapter.

(32)(18) "Lifesafety" means the control and prevention of fire and other life-threatening conditions on a premises for the purpose of preserving human life.

 $\underline{(33)}$ "Managing employee" means the administrator or other similarly titled individual who is responsible for the daily operation of the facility.

(34) "Maternal-fetal medical specialist" means a board-certified obstetrician who is qualified by training, experience, or special-competence certification in maternal-fetal medicine.

(35)(20) "Medical staff" means physicians licensed under chapter 458 or chapter 459 with privileges in a licensed facility, as well as other licensed health care practitioners with clinical privileges as approved by a licensed facility's governing board.

(36)(21) "Medically necessary transfer" means a transfer made necessary because the patient is in immediate need of treatment for an emergency medical condition for which the facility lacks service capability or is at service capacity.

(37)(22) "Mobile surgical facility" is a mobile facility in which licensed health care professionals provide elective surgical care under contract with the Department of Corrections or a private correctional facility operating pursuant to chapter 957 and in which inmate patients are admitted to and discharged from said facility within the same working day and are not permitted to stay overnight. However, mobile surgical facilities may only provide health care services to the inmate patients of the Department of Corrections, or inmate patients of a private correctional facility operating pursuant to chapter 957, and not to the general public.

- (38) "Neonatal care services" means the aspect of perinatal medicine pertaining to the care of neonates.

 Hospital units providing neonatal care are classified according to the intensity and specialization of the care that can be provided. The agency distinguishes three levels of neonatal care services:
- (a) "Level I neonatal services" means well-baby care services, which include subventilation care, intravenous feedings, and lavage to neonates. Level I neonatal services do not include ventilator assistance except for resuscitation and stabilization. Upon beginning ventilation, the hospital shall implement a patient treatment plan, which shall include the transfer of the neonate to a Level II or Level III neonatal intensive care service at such time that it becomes apparent that ventilation assistance will be required beyond the neonate's resuscitation and stabilization. The hospital shall establish a triage procedure to assess the need for transfer of obstetrical patients to facilities with Level II or Level III neonatal intensive care services prior to their delivery

3

4

5

6

7

8

9

10

11 12

13

14

15

16

17

18 19

20

2122

23

24

2526

27

28

29

30 31 where there is an obstetrical indication that resuscitation will be required for their neonates. Facilities limited to Level I neonatal services may only perform Level I neonatal services.

- (b) "Level II neonatal intensive care services" means services that include the provision of ventilator services and at least 6 hours of nursing care per day. Level II services shall be restricted to neonates of 1,000 grams birthweight and over, with the following exception: ventilation may be provided in a facility with Level II neonatal intensive care services for neonates of less than 1,000 grams birthweight only while waiting to transport the baby to a facility with Level III neonatal intensive care services.
- (c) "Level III neonatal intensive care services" means services that include the provision of continuous cardiopulmonary support services, 12 or more hours of nursing care per day, complex neonatal surgery, neonatal cardiovascular surgery, pediatric neurology and neurosurgery, and pediatric cardiac catheterization. These services may not be performed in a facility with Level II neonatal intensive care services only. Facilities with Level III neonatal intensive care services may perform all neonatal care services. A facility with Level III neonatal intensive care services that does not provide treatment of complex major congenital anomalies that require the services of a pediatric surgeon, or pediatric cardiac catheterization and cardiovascular surgery, shall enter into a written agreement with a facility providing Level III neonatal intensive care services in the same or the nearest service area for the provision of these services. All other services shall be

2

3

4

5

6

7

8

9

10 11

12

13

14

15

16

17

18

19

20

21

22

23

24 25

26

27

28

29

30

provided at each licensed facility with Level III neonatal intensive care services.

- (39) "Neonatologist" means a physician who is certified, or is eligible for certification, by an appropriate board in the area of neonatal-perinatal medicine.
- (40) "Open heart surgery operation" means surgical procedures that treat conditions such as congenital heart defects and heart and coronary artery diseases, including replacement of heart valves, cardiac vascularization, and cardiac trauma. One open heart surgery operation equals one patient admission to the operating room. Open heart surgery operations are classified under the following, Medicare diagnostic-related groups: 104, 105, 106, 107, 108, and 109.
- (41) "Organs" means heart, kidney, liver, bone marrow, lung, heart and lung, pancreas and islet cells, and intestines.
- (42) "Pediatric patient" means a patient under 18 years of age.
- (43)(23) "Person" means any individual, partnership, corporation, association, or governmental unit.
- (44)(24) "Premises" means those buildings, beds, and equipment located at the address of the licensed facility and all other buildings, beds, and equipment for the provision of hospital, ambulatory surgical, or mobile surgical care located in such reasonable proximity to the address of the licensed facility as to appear to the public to be under the dominion and control of the licensee.
- (45)(25) "Private review agent" means any person or entity which performs utilization review services for third-party payors on a contractual basis for outpatient or 31 | inpatient services. However, the term shall not include

full-time employees, personnel, or staff of health insurers, health maintenance organizations, or hospitals, or wholly owned subsidiaries thereof or affiliates under common ownership, when performing utilization review for their respective hospitals, health maintenance organizations, or insureds of the same insurance group. For this purpose, health insurers, health maintenance organizations, and hospitals, or wholly owned subsidiaries thereof or affiliates under common ownership, include such entities engaged as administrators of self-insurance as defined in s. 624.031.

- any subclassification of category 290 or coded in any subclassification of categories 293 through 302 or coded in any subclassification of categories 306 through 316, in Axis I or Axis II, consistent with the diagnostic categories defined in the Diagnostic and Statistical Manual of Mental Disorders; or equivalent codes in the following subclassifications in the International Classification of Disease: category 290, category 293 through 302, or category 306 through 316.
- (47) "Psychiatric inpatient services" means inpatient services provided under the direction of a psychiatrist or clinical psychologist to persons whose sole diagnosis or, in the event of more than one diagnosis, whose principal diagnosis, as defined in the Diagnostic and Statistical Manual of Mental Disorders, is a psychiatric disorder.
- (48) "Research hospital" means a hospital that devotes clearly defined space, staff, equipment, and other resources for research purposes and has documented teaching affiliations with an accredited school of medicine in Florida or another state.

(49) "Research program" means an organized program that conducts clinical trial research, collects treatment data, assesses outcome data, and publishes statistical reports showing research activity and findings.

(50)(26) "Service capability" means all services offered by the facility where identification of services offered is evidenced by the appearance of the service in a patient's medical record or itemized bill.

(51)(27) "At service capacity" means the temporary inability of a hospital to provide a service which is within the service capability of the hospital, due to maximum use of the service at the time of the request for the service.

(52)(28) "Specialty bed" means a bed, other than a general bed, designated on the face of the hospital license for a dedicated use.

(53)(29) "Specialty hospital" means any facility which meets the provisions of subsection (24)(13), and which regularly makes available either:

- (a) The range of medical services offered by general hospitals, but restricted to a defined age or gender group of the population;
- (b) A restricted range of services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical or psychiatric illnesses or disorders; or
- (c) Intensive residential treatment programs for children and adolescents as defined in subsection(28)(16).

(54)(30) "Stabilized" means, with respect to an emergency medical condition, that no material deterioration of the condition is likely, within reasonable medical

probability, to result from the transfer of the patient from a hospital.

- in any subclassification of categories 291, 292, 303, 304, or 305 in Axis I or Axis II consistent with the diagnostic categories defined in the Diagnostic and Statistical Manual of Mental Disorders; or equivalent codes in any subclassification of categories 291, 292, 303, 304, or 305 consistent with the diagnostic categories defined in the International Classification of Diseases.
- services provided under the direction of a professional trained and experienced in substance abuse services, including a psychiatrist, a physician certified by the American Society of Addiction Medicine, a Certified Addictions Professional, a clinical psychologist, a clinical social worker as defined in s. 491.003, or a certified master social worker as defined in s. 491.0145, to persons whose sole diagnosis or, in the event of more than one diagnosis, whose principal diagnosis, as defined in the Diagnostic and Statistical Manual of Mental Disorders, is a substance abuse disorder.
- (57) "Teaching hospital" means any hospital that meets the conditions specified in s. 408.07(44).
- (58) "Temporary license" means a license issued pending the final disposition of a hospital license suspension or revocation proceeding.
- (59) "Tertiary health service" means a health service that, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of

such service. Tertiary health services include organ 1 2 transplantation, specialty burn units, neonatal intensive care units, comprehensive rehabilitation, and medical and surgical 3 procedures considered experimental or developmental in nature. 4 5 (60) "Transplantation program" means surgical services 6 by a hospital through which one or more types of organ 7 transplants are provided to one or more patients, and the 8 offering of some or all phases of bone marrow transplantation. 9 (61)(31) "Utilization review" means a system for reviewing the medical necessity or appropriateness in the 10 11 allocation of health care resources of hospital services given 12 or proposed to be given to a patient or group of patients. 13 (62)(32) "Utilization review plan" means a description of the policies and procedures governing utilization review 14 activities performed by a private review agent. 15 16 (63)(33) "Validation inspection" means an inspection of the premises of a licensed facility by the agency to assess 17 whether a review by an accrediting organization has adequately 18 19 evaluated the licensed facility according to minimum state 20 standards. 21 Section 2. Subsection (9) is added to section 395.003, 22 Florida Statutes, to read: 395.003 Licensure; issuance, renewal, denial, and 23 24 revocation. --(9) In administrative proceedings on an application to 25 26 license any health care facility or program or to provide any 27 service or take any other action requiring health care 28 facility licensure authority, only the applicant is entitled 29 to an administrative hearing on its application. No other

person may initiate or intervene in any action to determine

whether such an application should be approved or denied.

 Section 3. Section 395.0095, Florida Statutes, is created to read:

395.0095 Minimum standards for specified inpatient services.--

- (1) INPATIENT SERVICES.--The following inpatient services when provided by a hospital licensed under this chapter shall be subject to the requirements specified in this section and in s. 395.003 and shall be separately listed on the hospital license:
- (a) Cardiac catheterization and angioplasty. The license shall indicate whether the service is for adults or for children.
- (b) Open heart surgery. The license shall indicate whether the service is for adults or for children.
- (c) Inpatient comprehensive medical rehabilitation.

 The license shall indicate the number of beds dedicated to this service.
- (d) Inpatient general psychiatric services. The license shall indicate whether the service is for adults or for children and adolescents, and the number of beds dedicated to service for adults or for children and adolescents.
- (e) Inpatient substance abuse services. The license shall indicate whether the service is for adults or for children and adolescents, and the number of beds dedicated to service for adults or for children and adolescents.
- (f) Neonatal intensive care services. The license shall indicate whether the services are Level I, Level II, or Level III, and the number of beds dedicated to each level.
- (g) Specialty burn units. The license shall indicate the number of beds dedicated to this service.

| 1 | (h) Heart transplantation. The license shall indicate |
|----|--|
| 2 | whether the service is for adults or for children. |
| 3 | (i) Liver transplantation. The license shall indicate |
| 4 | whether the service is for adults or for children. |
| 5 | (j) Kidney transplantation. The license shall indicate |
| 6 | whether the service is for adults or for children. |
| 7 | (k) Bone marrow transplantation. The license shall |
| 8 | indicate whether the service is for adults or for children. |
| 9 | (2) REQUIREMENTS FOR CARDIAC CATHETERIZATION AND |
| 10 | ANGIOPLASTY |
| 11 | (a) Each cardiac catheterization program shall be |
| 12 | capable of providing immediate endocardiac catheter pacemaking |
| 13 | in cases of cardiac arrest or heart failure, and pressure |
| 14 | recording for monitoring and evaluating valvular disease. |
| 15 | (b) Each cardiac catheterization program shall provide |
| 16 | a range of noninvasive cardiac or circulatory diagnostic |
| 17 | services within the hospital itself, including: |
| 18 | 1. Hematology studies or coagulation studies. |
| 19 | 2. Electrocardiography. |
| 20 | 3. Chest X-ray. |
| 21 | 4. Blood gas studies. |
| 22 | 5. Clinical pathology studies and blood chemistry |
| 23 | analysis. |
| 24 | (c) At a minimum, each cardiac catheterization program |
| 25 | shall include: |
| 26 | 1. A special procedure X-ray room. |
| 27 | 2. A film storage and darkroom for proper processing |
| 28 | of films. |
| 29 | 3. X-ray equipment with the capability in |
| 30 | cineangiocardiography, or equipment with similar capabilities. |
| 31 | 4. An image intensifier. |

| 1 | 5. An automatic injector. |
|----|---|
| 2 | 6. A diagnostic X-ray examination table for special |
| 3 | procedures. |
| 4 | 7. An electrocardiograph. |
| 5 | 8. A blood gas analyzer. |
| 6 | 9. A multichannel polygraph. |
| 7 | 10. Emergency equipment, including, at a minimum, a |
| 8 | temporary pacemaker unit with catheters, ventilitory |
| 9 | assistance devices, and a direct current defibrillator. |
| 10 | (d) Each cardiac catheterization program shall have |
| 11 | the capability of rapid mobilization of the study team within |
| 12 | 30 minutes for emergency procedures, 24 hours a day, 7 days a |
| 13 | week. |
| 14 | (e) Each cardiac catheterization program shall provide |
| 15 | a minimum of 300 catheterizations annually. |
| 16 | (f) Each hospital providing cardiac catheterization |
| 17 | must be fully accredited by the Joint Commission on |
| 18 | Accreditation of Health Care Organizations for special care |
| 19 | units, or be accredited by the American Osteopathic |
| 20 | Association. |
| 21 | (g) Each hospital providing a cardiac catheterization |
| 22 | program shall have the following staff available: |
| 23 | 1. A program director, board-certified or |
| 24 | board-eligible in internal medicine or in radiology with |
| 25 | subspecialty training in cardiology or cardiovascular |
| 26 | radiology. The program director for programs performing |
| 27 | pediatric cardiac catheterization shall be board-eligible or |
| 28 | board-certified by the Sub-Board of Pediatric Cardiology of |
| 29 | the American Board of Pediatrics or the American Osteopathic |

Association in the area of pediatric cardiology.

30

| | 2. | Ар | hysic | ian, | boar | rd-cei | rtified | l or | boa | rd-el | igi | ible | in |
|---------|-------|------|-------|------|------|--------|---------|------|------|-------|------|------|------|
| cardiol | Logy | or | radio | logy | , or | with | specia | aliz | ed t | raini | ng | in | |
| cardiac | c cat | thet | eriza | tion | and | angi | ographi | .c t | echn | iques | 5, V | vho | will |
| perform | n the | e ex | amina | tion | | | | | | | | | |

- 3. Support staff, specially trained in critical care of cardiac patients, with a knowledge of cardiovascular medication and an understanding of catheterization and angiographic equipment.
- 4. Support staff highly skilled in conventional radiographic techniques and angiographic principles, and knowledgeable in every aspect of catheterization and angiographic instrumentation, with a thorough knowledge of the anatomy and physiology of the circulatory system.
- 5. Support staff for patient observation, handling of blood samples, and performing blood gas evaluation calculations.
- 6. Support staff for monitoring physiologic data and alerting the physician of any changes.
- 7. Support staff to perform systematic tests and routine maintenance on cardiac catheterization equipment, who must be available immediately in the event of equipment failure during a procedure.
- 8. Support staff trained in photographic processing and in the operation of automatic processors used for both sheet and cine film.
- 9. A medical review committee that reviews medical invasive procedures such as endoscopy and cardiac catheterization.
- (h) Cardiac catheterization programs licensed in a facility not licensed for open heart surgery must submit, as part of their licensure application, a written protocol for

3

4 5

6

7

8

9

10 11

12

13

14

15

16

17

18

19 20

21

22

2324

2526

2728

31

the transfer of emergency patients to a hospital providing open heart surgery that is within 30 minutes travel time via air or ground emergency transportation vehicle, under average travel conditions.

- (i) Cardiac catheterization programs that include the provision of coronary angioplasty, valvuloplasty, or ablation of intracardiac bypass tracts must be located within a hospital licensed to provide open heart surgery.
- (j) Pediatric cardiac catheterization programs must be located in a hospital in which pediatric open heart surgery is being performed.
 - (3) REQUIREMENTS FOR OPEN HEART SURGERY.--
- (a) Each hospital providing an open heart surgery program must have the capability to provide a full range of open heart surgery operations, including, at a minimum:
 - 1. Repair or replacement of heart valves.
 - 2. Repair of congenital heart defects.
 - 3. Cardiac revascularization.
 - 4. Repair or reconstruction of intrathoracic vessels.
- Treatment of cardiac trauma.
- (b) Each open heart surgery program must document its ability to implement and apply circulatory assist devices such as intra-aortic balloon assist and prolonged cardiopulmonary partial bypass.
- (c) Each hospital with an open heart surgery program shall provide the following services:
- 1. Cardiology, hematology, nephrology, pulmonary medicine, and treatment of infectious diseases.
- 29 <u>2. Pathology, including anatomical, clinical, blood</u> 30 <u>bank, and coagulation laboratory services.</u>
 - 3. Anesthesiology, including respiratory therapy.

| 1 | 4. Radiology, including diagnostic nuclear medicine. |
|----|---|
| 2 | 5. Neurology. |
| 3 | 6. Inpatient cardiac catheterization. |
| 4 | 7. Noninvasive cardiographics, including |
| 5 | electrocardiography, exercise stress testing, and |
| 6 | echocardiography. |
| 7 | 8. Intensive care. |
| 8 | 9. Emergency care available 24 hours per day for |
| 9 | cardiac emergencies. |
| 10 | (d) Each open heart surgery program shall be available |
| 11 | for elective open heart operations 8 hours per day, 5 days a |
| 12 | week. Each open heart surgery program shall possess the |
| 13 | capability for rapid mobilization of the surgical and medical |
| 14 | support teams for emergency cases, 24 hours per day, 7 days a |
| 15 | week. |
| 16 | (e) Open heart surgery shall be available for |
| 17 | emergency open heart surgery operations within a maximum |
| 18 | waiting period of 2 hours. |
| 19 | (f) Open heart surgery shall be available to all |
| 20 | persons in need. A patient's eligibility for open heart |
| 21 | surgery shall be independent of his or her ability to pay. |
| 22 | (g) Each hospital providing an open heart surgery |
| 23 | program must be accredited by the Joint Commission on |
| 24 | Accreditation of Healthcare Organizations for special care |
| 25 | units, or be accredited by the American Osteopathic |
| 26 | Association. |

(h) Each hospital providing open heart surgery must

document that adequate numbers of properly trained personnel shall be available to perform in the following capacities

27

28

2930

31

during open heart surgery:

2

4

5

6

7

8

9

10

11 12

13

14 15

16

17

18 19

20

21

22

23

24

2526

27

28

29

- 1. A cardiovascular surgeon, board-certified by the American Board of Thoracic Surgery, or board-eligible.
 - 2. A physician to assist the operating surgeon.
- 3. A board-certified or board-eligible anesthesiologist trained in open heart surgery.
- 4. A registered nurse or certified operating room technician trained to serve in open heart surgery operations and perform circulating duties.
- 5. A perfusionist to perform extracorporeal perfusion, or a physician or a specially trained nurse, technician, or physician assistant under the supervision of the operating surgeon to operate the heart-lung machine.
- (i) Following an open heart surgery operation, patients shall be cared for in an intensive care unit that provides 24-hour nursing coverage, with at least one registered nurse for every two patients, during the first hours of postoperative care for both adult and pediatric cases. There shall be at least two cardiac surgeons on the staff of a hospital with an adult open heart surgery program, at least one of whom is board-certified and the other at least board-eligible. One of these surgeons must be on call at all times. There shall be at least one board-certified or board-eligible pediatric cardiac surgeon on the staff of a hospital with a pediatric open heart surgery program. A clinical cardiologist must be available for consultation to the surgical team and responsible for the medical management of patients, as well as the selection of suitable candidates for surgery along with the cardiovascular surgical team. Backup personnel in cardiology, anesthesiology, pathology, thoracic surgery, and radiology shall be on call in case of an emergency. Twenty-four hour per day coverage must be arranged

for the operation of the cardiopulmonary bypass pump. All 1 2 members of the team caring for cardiovascular surgical patients must be proficient in cardiopulmonary resuscitation. 3 4 (j) Each open heart surgery program shall provide a 5 minimum of 250 open heart surgeries annually. 6 (4) REQUIREMENTS FOR COMPREHENSIVE MEDICAL 7 REHABILITATION INPATIENT SERVICES .--8 (a) Each specialty hospital providing comprehensive medical rehabilitation inpatient services shall have a minimum 9 10 total capacity of 40 beds. 11 (b) Each general hospital providing comprehensive 12 medical rehabilitation inpatient services shall have a minimum 13 of 20 comprehensive medical rehabilitation beds. 14 (c) Each hospital providing comprehensive medical 15 rehabilitation inpatient beds shall participate in the 16 Medicare and Medicaid programs. (d) Comprehensive medical rehabilitation inpatient 17 services must be provided under a medical director of 18 19 rehabilitation who is a board-certified or board-eligible 20 physiatrist with at least 2 years of experience in the medical management of inpatients requiring rehabilitation services. 21 22 (e) In addition to the required physician services, 23 comprehensive medical rehabilitation inpatient services shall 24 include at least the following provided by qualified personnel: 25 26 1. Rehabilitation nursing. 27 2. Physical therapy. 28 3. Occupational therapy.

Speech therapy.
 Social services.

6. Psychological services.

29

7. Orthotic and prosthetic services. 1 2 (f) Each hospital providing comprehensive medical rehabilitation inpatient services shall be accredited by the 3 4 Commission on Accreditation of Rehabilitation Facilities 5 consistent with the standards applicable to comprehensive 6 inpatient rehabilitation or specialized inpatient 7 rehabilitation, as applicable to the facility. 8 (5) REQUIREMENTS FOR PSYCHIATRIC INPATIENT SERVICES. --9 (a) Admission to hospital units providing psychiatric inpatient services is limited to persons whose sole diagnosis 10 or, in the event of more than one diagnosis, whose principal 11 12 diagnosis, as defined in the Diagnostic and Statistical Manual 13 of Mental Disorders, is a disorder coded in any subclassification of category 290 or coded in any 14 15 subclassification of categories 293 through 302 or coded in 16 any subclassification of categories 306 through 316, in Axis I or Axis II, consistent with the diagnostic categories defined 17 in the Diagnostic and Statistical Manual of Mental Disorders, 18 incorporated herein by reference; or equivalent codes in the 19 20 following subclassifications in the International Classification of Disease, incorporated herein by reference: 21 22 category 290, category 293 through 302, or category 306 through 316. Psychiatric patients in need of medical or 23 surgical care may be treated in acute care medical or surgical 24 beds for their medical or surgical care needs or in a 25 26 psychiatric services unit if the unit is properly staffed and 27 equipped to care for the medical or surgical problem. 28 (b) Each specialty hospital providing psychiatric inpatient services, or each intensive residential treatment 29 30 program for children and adolescents licensed as a specialty hospital, shall have a minimum total capacity of 25 beds.

minimum capacity of a specialty hospital providing psychiatric inpatient services may include beds used for substance abuse inpatient services.

- (c) Psychiatric inpatient services, whether provided directly by the hospital or under contract, shall include, at a minimum, emergency screening services, pharmacology, individual therapy, family therapy, activities therapy, discharge planning, and referral services.
- (d) A separately organized unit for psychiatric inpatient services for adults shall have a minimum of 15 beds.

 A separately organized unit for psychiatric inpatient services for children and adolescents shall have a minimum of 10 beds.
- (e) As required by s. 394.4785(2), facilities providing psychiatric inpatient services to children must have beds and common areas designated for children that cannot be used by adults. Adolescents may be treated in the units designated for children. Adolescents may only be treated in units designated for psychiatric inpatient services for adults if the admitting physician indicates that such placement is medically indicated, or for reasons of safety.
- (f) Each hospital providing psychiatric inpatient services shall be accredited by the Joint Commission on Accreditation of Healthcare Organizations consistent with the standards applicable to psychiatric services provided in inpatient settings for adults or for children and adolescents.
- (g) Each hospital providing psychiatric inpatient services shall also provide outpatient services, either directly or through written agreements with community outpatient mental health programs, such as local psychiatrists, local psychologists, community mental health programs, or other local mental health outpatient programs.

- (h) Each hospital providing psychiatric inpatient services shall have a screening program to assess the most appropriate treatment for the patient. Patients with a dual diagnosis of a psychiatric disorder and a substance abuse disorder shall be evaluated to determine the types of treatment needed, the appropriate treatment setting, and, if necessary, the appropriate sequence of treatment for the psychiatric and substance abuse disorders.
- (6) REQUIREMENTS FOR SUBSTANCE ABUSE INPATIENT SERVICES.--
- (a) Each specialty hospital providing substance abuse inpatient services shall have a minimum total capacity of 25 beds, which may include beds used for psychiatric inpatient services.
- (b) Beds used for acute detoxification services in general hospitals shall be considered a subset of the total number of general acute care beds.
- (c) Substance abuse inpatient services, whether provided directly by the hospital or under contract, shall include, at a minimum, emergency screening services; treatment planning services; pharmacology, if appropriate; individual therapy; family therapy; discharge planning; referral services, including written referral agreements for educational and vocational services; and occupational and recreational therapies.
- (d) A separately organized unit for substance abuse inpatient services for adults shall have a minimum of 10 beds.

 A separately organized unit for substance abuse inpatient services for children and adolescents shall have a minimum of five beds.

2.8

(e) Each hospital providing substance abuse inpatient services to children must have beds and common areas designated for children that cannot be used by adults.

Adolescents may be treated in the units designated for children. Adolescents may only be treated in units designated for substance abuse inpatient services for adults if the admitting physician indicates that such placement is medically indicated, or for reasons of safety.

- (f) Each hospital providing substance abuse inpatient services shall be accredited by the Joint Commission on Accreditation of Healthcare Organizations consistent with the standards applicable to substance abuse services provided in inpatient settings for adults or for children and adolescents.
- (g) Each hospital providing substance abuse inpatient services shall also provide outpatient or referral services, either directly or through written agreements with community outpatient substance abuse programs, such as local psychiatrists, other physicians trained in the treatment of psychiatric or substance abuse disorders, local psychologists, community mental health programs, or other local substance abuse outpatient programs.
- (h) Each hospital providing substance abuse inpatient services shall have a screening program to assess the most appropriate treatment for the patient. Patients with a dual diagnosis of a substance abuse disorder and a psychiatric disorder shall be evaluated to determine the types of treatment needed, the appropriate treatment setting, and, if necessary, the appropriate sequence of treatment for the substance abuse and psychiatric disorders.
- 30 (7) REQUIREMENTS FOR NEONATAL INTENSIVE CARE
 31 SERVICES.--

- (a) No hospital shall be licensed for Level III

 neonatal intensive care services unless the hospital also
 provides Level II neonatal intensive care services. A

 hospital may be licensed for Level II neonatal intensive care
 services without providing Level III services.
- (b) Each hospital providing Level II or Level III

 neonatal intensive care services shall ensure developmental

 followup on patients after discharge to monitor the outcome of

 care and assure necessary referrals to community resources.
- intensive care services shall have a Level III neonatal intensive care unit of at least 15 beds, and shall have 15 or more Level II neonatal intensive care unit beds. A hospital shall not be licensed for Level III neonatal intensive care services only. Each hospital providing only Level II neonatal intensive care services shall have a Level II neonatal intensive care unit with a minimum of 10 beds.
- (d) A hospital shall not be licensed for Level III neonatal intensive care services unless the hospital had a minimum service volume of 1,500 live births for the most recent 12-month period ending 6 months prior to licensure. Specialty children's hospitals are exempt from the requirements of this paragraph.
- (e) A hospital shall not be licensed for Level II

 neonatal intensive care services unless the hospital had a

 minimum service volume of 1,000 live births for the most

 recent 12-month period ending 6 months prior to the licensure.

 Children's specialty hospitals are exempt from the

 requirements of this paragraph.
- 30 (f) Level II neonatal intensive care services shall be 31 directed by a neonatologist or a group of neonatologists who

are on active staff of the hospital with unlimited privileges and provide 24-hour coverage and who are either board-certified or board-eligible in neonatal-perinatal medicine.

- (g) Level III neonatal intensive care services shall be directed by a neonatologist or a group of neonatologists who are on active staff of the hospital with unlimited privileges and provide 24-hour coverage and who are either board-certified or board-eligible in neonatal-perinatal medicine. In addition, hospitals with Level III neonatal intensive care services shall be required to maintain a maternal-fetal medical specialist on active staff of the hospital with unlimited staff privileges. Children's specialty hospitals are exempt from the provisions of this paragraph.
- (h) The nursing staff in Level II and Level III

 neonatal intensive care units shall be under the supervision
 of a head nurse with experience and training in neonatal
 intensive care nursing. The head nurse shall be a registered
 professional nurse. At least one-half of the nursing
 personnel assigned to each work shift in Level II and Level
 III neonatal intensive care units must be registered nurses.
 Nurses in Level II and Level III neonatal intensive care units
 shall be trained to administer cardiorespiratory monitoring,
 assist in ventilation, administer intravenious fluids, provide
 preoperative and postoperative care of newborns requiring
 surgery, manage neonates being transported, and provide
 emergency treatment of conditions such as apnea, seizures, and
 respiratory distress.
- (i) At least one certified respiratory care
 practitioner or respiratory therapist with expertise in the
 care of neonates shall be available at each hospital with

Level II or Level III neonatal intensive care services at all times. There shall be at least one respiratory therapist technician for every four infants receiving assisted ventilation.

- (j) Blood gas determination shall be available and accessible on a 24-hour basis in each hospital with Level II or Level III neonatal intensive care services.
- (k) Each hospital providing Level II or Level III

 neonatal intensive care services shall provide onsite, on a

 24-hour basis, X-ray, obstetric ultrasound, and clinical

 laboratory services. Anesthesia shall be available on an

 on-call basis within 30 minutes. Clinical laboratory services

 shall have the capability to perform microstudies.
- (1) Each hospital providing Level II or Level III

 neonatal intensive care services shall have a dietician or

 nutritionist to provide information on patient dietary needs
 while in the hospital and to provide the patient's family

 instruction or counseling regarding the appropriate

 nutritional and dietary needs of the patient after discharge.
- (m) Each hospital providing Level II or Level III
 neonatal intensive care services shall make available the
 services of the hospital's social services department to
 patients' families, which services shall include, at a
 minimum, family counseling and referral to appropriate
 agencies for services. Children potentially eligible for the
 Medicaid, Children's Medical Services, or developmental
 services programs shall be referred to the appropriate
 eligibility personnel for eligibility determination.
- (n) Each hospital providing Level II or Level III neonatal intensive care services shall provide in-hospital intervention services for infants identified as being at high

 risk for developmental disabilities, which shall include developmental assessment, intervention, and parental support and education.

- (o) Each hospital providing Level II or Level III

 neonatal intensive care services shall have an

 interdisciplinary staff responsible for discharge planning.

 Each hospital shall designate a person responsible for discharge planning.
- (p) Each hospital with a Level II neonatal intensive care unit shall have a nurse-to-neonate ratio of at least 1:4 in that unit at all times. At least 50 percent of the nurses shall be registered nurses.
- (q) Each hospital with a Level III neonatal intensive care unit shall have a pediatric cardiologist who is either board-certified or board-eligible in pediatric cardiology available for consultation at all times.
- (r) Each hospital with a Level III neonatal intensive care unit shall have a nurse-to-neonate ratio of at least 1:2 in that unit at all times. At least 50 percent of the nurses shall be registered nurses.
- intensive care services shall provide documentation of a transfer agreement with a hospital providing Level III neonatal intensive care services in the same or the nearest service district, for patients in need of Level III services. Hospitals providing Level III neonatal intensive care services shall not unreasonably withhold consent to transfer agreements that provide for transfers based upon availability of service in the Level III hospital and that will be applied uniformly to all patients requiring transfer to Level III.

- shall be transferred to a facility with Level III neonatal intensive care services. Neonates weighing more than 1,000 grams requiring one or more Level III services shall also be transferred to a facility with Level III neonatal intensive care services. If a facility with a Level III neonatal intensive care service refuses to accept the transfer patient, the facility with the Level II neonatal intensive care service shall be found in compliance with this paragraph upon a showing of continuous good faith effort to transfer the patient, as documented in the patient's medical record.

 Facilities with Level II neonatal intensive care services may perform only Level I neonatal intensive care services and Level II neonatal intensive care services and
- (u) Each hospital providing Level II or Level III

 neonatal intensive care services shall be accredited by the

 Joint Commission on Accreditation of Health Care Organizations

 consistent with the standards applicable to providing Level II

 or Level III neonatal intensive care services.
 - (8) REQUIREMENTS FOR BURN UNITS. --
- (a) Each hospital with a licensed burn unit shall ensure that appropriate aftercare services are available to the burn care patients in order to ensure a continuum between hospitalization and the rehabilitation phase. These services include, at a minimum, social services consultation, vocational counseling, and physical rehabilitation services.
- (b) Each hospital with a designated burn unit shall provide a public burn prevention program. This requirement may be met by assuring that such programs are made available through other organizations in the service delivery area.

| 1 | (c) Burn unit services shall be available on a |
|----|--|
| 2 | 24-hour, 7-days-a-week, basis. |
| 3 | (d) Each hospital with a licensed burn unit shall have |
| 4 | the following staff available: |
| 5 | 1. A medical director who is board-certified or |
| 6 | board-eligible in general or plastic surgery with at least 2 |
| 7 | years of experience in the management of burn patients. |
| 8 | 2. One full-time registered nurse with 2 years' |
| 9 | intensive care or equivalent experience. |
| 10 | 3. One full-time physical therapist with training in |
| 11 | the management of burn patients. |
| 12 | 4. Surgical support personnel shall be available for |
| 13 | consultation as needed in the following surgical specialities: |
| 14 | a. Cardiothoracic. |
| 15 | b. Neurologic. |
| 16 | c. Obstetrics-gynecologic. |
| 17 | d. Ophthalmic. |
| 18 | e. Oral. |
| 19 | f. Orthopaedic. |
| 20 | g. Otorhinolaryngologic. |
| 21 | h. Pediatric. |
| 22 | <u>i. Plastic.</u> |
| 23 | j. Urologic. |
| 24 | (e) Each hospital with a licensed burn unit shall have |
| 25 | the following nonsurgical support personnel available, as |
| 26 | needed, for consultation in the following specialties: |
| 27 | 1. Anesthesiology. |
| 28 | 2. Cardiology. |
| 29 | 3. Emergency medicine. |
| 30 | 4. Gastroenterology. |
| 31 | 5. Hematology. |

| 1 | 6. Infectious disease. |
|----|--|
| 2 | 7. Internal medicine. |
| 3 | 8. Nephrology. |
| 4 | 9. Neurology. |
| 5 | 10. Nutrition. |
| 6 | 11. Occupational therapy. |
| 7 | 12. Pathology. |
| 8 | 13. Pediatrics. |
| 9 | 14. Psychiatry or psychology. |
| 10 | 15. Pulmonary. |
| 11 | 16. Radiology. |
| 12 | 17. Respiratory therapy. |
| 13 | (f) Each hospital providing burn unit services shall |
| 14 | be accredited by the Joint Commission on Accreditation of |
| 15 | Health Care Organizations consistent with the standards |
| 16 | applicable to providing burn unit services. |
| 17 | (9) REQUIREMENTS FOR ORGAN TRANSPLANTATION PROGRAMS |
| 18 | (a) Each hospital with a licensed transplantation |
| 19 | program, regardless of the type of transplantation program, |
| 20 | shall have: |
| 21 | 1. Staff and other resources necessary to care for the |
| 22 | patient's chronic illness prior to transplantation, during |
| 23 | transplantation, and in the postoperative period. Services |
| 24 | and facilities for inpatient and outpatient care shall be |
| 25 | available on a 24-hour basis. |
| 26 | 2. If cadaveric transplantation will be part of the |
| 27 | transplantation program, a written agreement with an organ |
| 28 | acquisition center for organ procurement is required. A |
| 29 | system by which 24-hour call can be maintained for assessment, |
| 30 | management, and retrieval of all referred donors, cadaver |
| 31 | donors, or organs shared by other transplantation or organ |

procurement agencies is mandatory. Applicants for a bone marrow transplantation program are exempt from the requirements of this subparagraph.

- 3. An age-appropriate, adult or pediatric intensive care unit that includes facilities for prolonged reverse isolation when required.
- 4. A clinical review committee for evaluation and decisionmaking regarding the suitability of a candidate for transplantation.
- 5. Written protocols for patient care for each type of organ transplantation program, including, at a minimum, patient selection criteria for patient management and evaluation during the prehospital, in-hospital, and immediate postdischarge phases of the program.
- 6. Detailed therapeutic and evaluative procedures for the acute and long-term management of each transplantation program patient, including the management of commonly encountered complications.
- 7. Equipment for cooling, flushing, and transporting organs. If cadaveric transplantations are performed, equipment for organ preservation through mechanical perfusion is necessary. This requirement may be met through an agreement with an organ procurement agency. Applicants for a bone marrow transplantation program are exempt from the requirements of this subparagraph.
- 8. An onsite tissue-typing laboratory, or a contractual arrangement with an outside laboratory within the state, that meets the requirements of the American Society of Histocompatibility.
- 9. Pathology services with the capability of studying
 and promptly reporting the patient's response to the organ

 transplantation surgery and analyzing appropriate biopsy material.

- 10. Blood banking facilities.
- 11. A program for the education and training of staff regarding the special care of transplantation patients.
- 12. Education programs for patients and their families, and the patient's primary care physician, regarding aftercare for transplantation patients.
- (b) Each hospital with a licensed transplantation
 program, regardless of the type of transplantation program,
 shall have:
- 1. A staff of physicians with expertise in caring for patients with end-stage disease requiring transplantation.

 The staff shall have medical specialties or subspecialties appropriate for the type of transplantation program to be established. The program shall employ a transplant physician, and a transplant surgeon, if applicable, as defined by the United Network for Organ Sharing. A physician with 1 year of experience in the management of infectious diseases in the transplantation patient shall be a member of the transplant team.
- 2. A program director who shall have a minimum of 1 year of formal training and 1 year of experience at a transplantation program for the same type of organ transplantation program proposed; except that an applicant for a bone marrow transplantation program shall meet the requirements in paragraph (h), paragraph (i), or paragraph (j).
- 3. A staff with experience in the special needs of children, if pediatric transplantations are performed.

| 4. | A | staff | of | nur | ses and n | urse | pra | actitioner | s wi | th |
|------------|----|-------|------|-----|-----------|------|-----|------------|------|-------|
| experience | in | the | care | of | chronica | lly | ill | patients | and | their |
| families. | | | | | | | | | | |

- 5. Contractual agreements with consultants who have expertise in blood banking and are capable of meeting the unique needs of transplant patients on a long-term basis.
- 6. Nutritionists with expertise in the nutritional needs of transplant patients.
- 7. Respiratory therapists with expertise in the needs of transplant patients.
- 8. Social workers, psychologists, psychiatrists, and other individuals skilled in performing comprehensive psychological assessments, counseling patients and families of patients, providing assistance with financial arrangements, and making arrangements for use of community resources.
- (c) Each hospital with a licensed heart transplantation program, in addition to meeting the requirements specified in paragraphs (a) and (b), shall have the following program personnel and services:
- 1. A board-certified or board-eligible adult cardiologist or, in the case of a pediatric heart transplantation program, a board-certified or board-eligible pediatric cardiologist.
- 2. An anesthesiologist experienced in both open heart surgery and heart transplantation.
- 3. A one-bed isolation room in an age-appropriate intensive care unit.
- (d) Each hospital with a licensed liver
 transplantation program, in addition to meeting the
 requirements specified in paragraphs (a) and (b), shall be a
 teaching hospital or research hospital with training programs

relevant to liver transplantation. The following services shall be available in the hospital or through contractual arrangements:

- 1. A department of gastroenterology, including clinics, and adequately equipped procedure rooms.
- 2. Radiology services to provide complex biliary procedures, including transhepathic cholangiography, portal venography, and arteriography.
- 3. A laboratory with the capability of performing and promptly reporting the results of liver function tests, as well as required chemistry, hematology, and virology tests.
- 4. A patient convalescent unit for further monitoring of patient progress for approximately 1 month after hospital discharge following liver transplantation.
- 5. Staff for liver transplantation programs shall be trained in the care of patients with hepatic diseases and liver transplantation.
- (e) Each hospital with a licensed kidney transplantation program shall provide:
- 1. Renal dialysis, and preoperative and postoperative care. Onsite dialysis under the supervision of a board-certified or board-eligible nephrologist shall be available on a 24-hour basis. If pediatric patients are served, a separate pediatric dialysis unit shall be established.
- 2. Outpatient services, including renal dialysis services and ambulatory renal clinic services.
- 3. Ancillary services, including predialysis,
 dialysis, and posttransplantation nutritional services;
 bacteriologic, biochemical, and pathological services;
 radiologic services; and nursing services with the capability

of providing monitoring and support during dialysis and assisting in home care, which shall include vascular access and home dialysis management, when applicable.

- (f) Each licensed adult kidney transplantation program shall be under the direction of a physician with experience in physiology, immunology, and immunosuppressive therapy relevant to kidney transplantation.
- 1. The transplant surgeon shall be board-certified in surgery or a surgical subspecialty and shall have a minimum of 18 months' training in a transplantation center.
- 2. The transplant team performing kidney transplantation shall include physicians who are board-certified or board-eligible in the areas of anesthesiology, nephrology, psychiatry, vascular surgery, and urology.
- 3. Additional support personnel that shall be available include a nephrology nurse with experience in nursing care of patients with permanent kidney failure and a renal dietician.
- 4. A laboratory with the capability of performing and promptly reporting bacteriologic, biochemical, and pathologic analysis.
- $\underline{\text{5.}}$ An anesthesiologist experienced in kidney transplantation.
- (g) Each licensed pediatric kidney transplantation
 program shall have:
- 1. A medical director who is sub-board-certified or sub-board-eligible in pediatric nephrology.
- 2. A dialysis unit head nurse with special training and expertise in pediatric dialysis.

- 3. Nurse staffing at a nurse-to-patient ratio of 1:1 in the pediatric dialysis unit.
- 4. A registered dietician with expertise in nutritional needs of children with chronic renal disease.
- 5. A surgeon with experience in pediatric renal transplantation.
- 6. A radiology service with specialized equipment for obtaining X-rays on pediatric patients.
- 7. Education services, which shall include home and hospital programs to ensure minimal interruption in schooling.
- (h) Each hospital with a licensed pediatric allogeneic or autologous bone marrow transplantation program must be a teaching or research hospital with training programs relevant to pediatric bone marrow transplantation. Each such hospital shall meet the requirements specified in subparagraph 1. Hospitals licensed for allogeneic programs shall meet the additional requirements specified in subparagraph 2.
- 1. Requirements for each hospital with a licensed pediatric allogeneic or autologous transplantation program:
- <u>a. Perform at least 10 pediatric transplants each</u>

 year. If both allogeneic and autologous pediatric transplants

 are performed, at least 10 of each shall be projected.
- b. Have a program director who is a board-certified hematologist or oncologist with experience in the treatment and management of pediatric acute oncological cases involving high-dose chemotherapy or high-dose radiation therapy. The program director must have formal training in pediatric bone marrow transplantation.
- c. Have clinical nurses with experience in the care of critically ill immunosuppressed patients. Nursing staff shall be dedicated to the program full time.

- d. Have an interdisciplinary transplantation team with expertise in hematology, oncology, immunologic diseases, neoplastic diseases including hematopoietic and lymphopoietic malignancies, and nonneoplastic disorders. The team shall direct permanent followup care of the bone marrow transplantation patients, including the maintenance of immunosuppressive therapy and treatment of complications.
- e. Have age-appropriate inpatient transplantation units for posttransplant hospitalization. Posttransplantation care must be provided in a laminar air-flow room; or in a private room with positive pressure, reverse isolation procedures, and terminal high-efficiency particulate aerosol filtration on air blowers. The designated transplant unit shall have a minimum of two beds. The unit may be part of a facility that also manages patients with leukemia or similar disorders.
- f. Have a radiation therapy division onsite that is capable of sublethal X-irradiation, bone marrow ablation, and total lymphoid irradiation. The division shall be under the direction of a board-certified radiation oncologist.
- g. Have an ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation center operated by a teaching hospital.

 The program must include outcome monitoring and long-term patient followup.
- $\underline{\text{h. Have an established research-oriented oncology}}$ program.
- 2. Additional requirements for each hospital with a licensed pediatric allogeneic transplantation program:
- a. A laboratory equipped to handle studies including the use of monoclonal antibodies, if this procedure is

employed by the hospital, or T-cell depletion, separation of lymphocyte and hematological cell subpopulations, and their removal for prevention of graft-versus-host disease. The requirements in this subparagraph may be met through contractual arrangements.

- b. An onsite laboratory equipped for the evaluation and cryopreservation of bone marrow.
- c. An age-appropriate patient convalescent facility to provide a temporary residence setting for transplantation patients during the prolonged convalescence.
- <u>d. An age-appropriate outpatient unit for close</u> supervision of discharged patients.
- (i) Each hospital with a licensed adult allogeneic bone marrow transplantation program must be a teaching or research hospital. Each such hospital shall meet the following requirements:
- $\underline{\text{1. Perform at least 10 adult allogeneic transplants}}$ each year.
- 2. Have a program director who is a board-certified hematologist or oncologist with experience in the treatment and management of adult acute oncological cases involving high-dose chemotherapy or high-dose radiation therapy. The program director must have formal training in bone marrow transplantation.
- 3. Have clinical nurses with experience in the care of critically ill immunosuppressed patients. Nursing staff shall be dedicated to the program full time.
- 4. Have an interdisciplinary transplant team with expertise in hematology, oncology, immunologic diseases, neoplastic diseases including hematopoietic and lymphopoietic malignancies, and nonneoplastic disorders. The team shall

direct permanent followup care of the bone marrow

transplantation patients, including the maintenance of
immunosuppressive therapy and treatment of complications.

- 5. Have inpatient transplantation units for posttransplantation hospitalization. Posttransplantation care must be provided in a laminar air-flow room; or in a private room with positive pressure, reverse isolation procedures, and terminal high-efficiency particulate aerosol filtration on air blowers. The designated transplant unit shall have a minimum of two beds. The unit may be part of a facility that also manages patients with leukemia or similar disorders.
- 6. Have a radiation therapy division onsite that is capable of sublethal X-irradiation, bone marrow ablation, and total lymphoid irradiation. The division shall be under the direction of a board-certified radiation oncologist.
- 7. Have a laboratory equipped to handle studies including the use of monoclonal antibodies, if this procedure is employed by the hospital, or T-cell depletion, separation of lymphocyte and hematological cell subpopulations, and their removal for prevention of graft-versus-host disease. The requirements in this subparagraph may be met through contractual arrangements.
- 8. Have an onsite laboratory equipped for the evaluation and cryopreservation of bone marrow.
- 9. Have an ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation center operated by a teaching hospital.

 The program must include outcome monitoring and long-term patient followup.
- 30 10. Have an established research-oriented oncology program.

- 11. Have a patient convalescent facility to provide a temporary residence setting for transplant patients during the prolonged convalescence.
- 12. Have an outpatient unit for close supervision of discharged patients.
- (j) Each hospital with a licensed adult autologous bone marrow transplantation program must be a teaching hospital, a research hospital, or a community hospital having a research program or affiliated with a research program.

 Each hospital shall meet the following requirements:
- 1. Perform at least 10 adult autologous transplants each year.
- 2. Have a program director who is a board-certified or board-eligible hematologist or oncologist with experience in the treatment and management of adult acute oncological cases involving high-dose chemotherapy or high-dose radiation therapy. The program director must have formal training in bone marrow transplantation or have at least 1 year of documented experience in performing autologous bone marrow transplantation.
- 3. Have clinical nurses with experience in the care of critically ill immunosuppressed patients. Nursing staff shall be dedicated to the program full time.
- 4. Have an interdisciplinary transplantation team with expertise in hematology, oncology, immunologic diseases, neoplastic disease including hematopoietic and lymphopoietic malignancies, and nonneoplastic disorders. The team shall direct permanent followup care of the bone marrow transplantation patients.
- 5. Have inpatient transplantation units for posttransplant hospitalization. Posttransplantation care must

be provided in a laminar air-flow room; or in a private room with positive pressure, reverse isolation procedures, and terminal high-efficiency particulate aerosol filtration on air blowers. The designated transplant unit shall have a minimum of two beds. The unit may be part of a facility that also manages patients with leukemia or similar disorders.

- 6. Have a radiation therapy division onsite that is capable of sublethal X-irradiation and total lymphoid irradiation. The division shall be under the direction of a board-certified radiation oncologist.
- 7. Have an ongoing research program that is integrated either within the hospital or by written agreement with a bone marrow transplantation center operated by a teaching hospital; or the applicant may enter into an agreement with an outpatient provider having a research program. Under the agreement, the outpatient research program may perform specified outpatient phases of adult autologous bone marrow transplantation, including blood screening tests, mobilization of stem cells, stem cell rescue, chemotherapy, and reinfusion of stem cells.
- 8. Have an established research-oriented oncology program.
- (k) Each hospital with a licensed transplantation program for lung, heart and lung, pancreas and islet cells, or intestines shall be a teaching or research hospital with training programs relevant to the type of organ transplantation program proposed to be established. The hospital shall have established interactive programs of basic and applied research in organ failure, transplantation, immunoregulatory responses, and related biology.

 (10)(a) SERVICES FOR LOW-INCOME PATIENTS.--Each hospital providing a service described in this section, or providing a distinct part skilled nursing unit, which hospital has previously received a certificate of need for the service requiring a specified minimum level of service to Medicaid, indigent, or charity care patients, shall continue to provide at least the required minimum level of service. The agency shall monitor annual compliance with this requirement as part of the certification activities described in subsection (13).

- (b) The agency may, for good cause shown, modify the minimum required level of service described in paragraph (a). The agency shall, by rule, define the factors constituting good cause for modification.
 - (11) HOSPITALS APPLYING FOR AN INITIAL LICENSE.--
- (a) Each hospital providing a service described in this section on the effective date of this act, or seeking to establish such a service thereafter, must apply for an initial license for the service. Hospitals with a current license indicating beds dedicated to a service described in this section, or beds dedicated to a distinct part skilled nursing unit, must apply for initial licensure of the service within 3 months after the effective date of this act.
- (b) Each hospital applying for an initial license for comprehensive medical rehabilitation services, psychiatric services, substance abuse services, neonatal intensive care services, or a distinct part skilled nursing unit must, at the time of application, affirm that at least 15 percent of annual patient days in beds dedicated to the service will be Medicaid patient days, and at least 15 percent of annual patient days will be charity care patient days.

```
(c) Each hospital applying for an initial license for cardiac catheterization services, open heart surgery, a burn unit, or an organ transplantation program must, at the time of application, affirm that at least 15 percent of annual admissions to those services will be Medicaid patients, and at least a specified minimum percentage of annual admissions will be charity care patients.
```

- (d) The agency shall, by rule, establish exemptions to the minimum annual percentage of service volumes required for hospital compliance with paragraphs (b) and (c). In establishing such standards, the agency shall give due consideration to any existing commitments described in subsection (10) and to clinical outcome data.
- (e) In the case of a hospital with licensed beds dedicated to comprehensive medical rehabilitation services, psychiatric services, substance abuse services, or neonatal intensive care services, the initial license may grant a variance from the requirements of this section respecting the minimum number of beds required for the service.
- (f) The agency may, for good cause shown, grant a temporary exemption to a hospital seeking an initial license to provide a service described in this section and seeking to comply with the requirements respecting minimum annual service volume and accreditation. The exemption shall be for a specified period of time, not to exceed 1 year from the date of application for an initial or renewal license. Good cause includes the current status of a hospital respecting these services; provided that approval before July 1, 2001, under the certificate-of-need program shall not, of itself, constitute good cause for a temporary exemption.
 - (12) HOSPITALS APPLYING FOR A RENEWAL LICENSE.--

- (a) Each hospital licensed to provide comprehensive medical rehabilitation services, psychiatric services, substance abuse services, or neonatal intensive care services must, at the time of license renewal, reaffirm or modify its commitments regarding the percentage of annual patient days which will be for Medicaid patients and the percentage of annual patient days which will be for charity care patients. The agency shall, by rule, define the factors constituting good cause for modification of previous commitments.
- (b) Each hospital licensed to provide cardiac catheterization services, open heart surgery, a burn unit, or an organ transplantation program must, at the time of license renewal, reaffirm or modify its commitments regarding the percentage of admissions which will be Medicaid patients and percentage of admissions which will be charity care patients. The agency shall, by rule, define the factors constituting good cause for modification of previous commitments.
- (13) CERTIFICATION OF COMPLIANCE.--Each hospital licensed to provide a service described in this section shall thereafter annually certify to the agency that it meets all requirements described herein for that service, except as may be noted by the facility. Misrepresentation of compliance is subject to penalties imposed by the agency as provided in s. 395.003(8).
- (14) NONCOMPLIANCE.--A hospital found to be out of compliance with the requirements of this section is subject to penalties imposed by the agency as provided in s. 395.003(8).

Section 4. Subsections (5) and (9) of section 400.071, Florida Statutes, are amended, and subsections (11) and (12) are added to said section, to read:

400.071 Application for license.--

- (5) The applicant shall furnish satisfactory proof of financial ability to operate and conduct the home in accordance with the requirements of this part and all rules adopted under this part, and the agency shall establish standards for this purpose. The agency also shall establish documentation requirements, to be completed by each applicant, that show anticipated facility revenues and expenditures, the basis for financing the anticipated cash-flow requirements of the facility, and an applicant's access to contingency financing. An application for initial licensure of a nursing home must contain a detailed financial projection including a statement of the projected revenue and expenses for the first 2 years of operation after licensure of the facility.
- home that fails to receive a certificate of need under the provisions of ss. 408.031-408.045. It is the intent of the Legislature that, in reviewing a license application for a certificate-of-need application to add beds to an existing nursing home facility, preference be given to the application of a licensee who has been awarded a Gold Seal as provided for in s. 400.235 or who meets the performance measures for the Gold Seal award process, if the applicant otherwise meets the review criteria specified in s. 408.035.
- (11)(a) Each licensed nursing home that has received a certificate of need before July 1, 2001, requiring a specified minimum level of service to Medicaid, indigent, or charity care patients shall continue to provide at least the required minimum level of service. The agency shall monitor compliance with this requirement as part of the certification activities described in paragraph (d).

(b) The agency may, for good cause shown, modify the minimum required level of service described in paragraph (a).

The agency shall, by rule, define the factors constituting good cause for modification.

- (c)1. Each nursing home applying for an initial license shall, at the time of application, affirm that at least a specified minimum percentage of annual patient days will be Medicaid patient days, and at least a specified minimum percentage of annual patient days will be charity care patient days.
- 2. Each nursing home applying for a renewal license shall, at the time of application, reaffirm or modify its commitments that a specified minimum percentage of annual patient days will be Medicaid patient days, and a specified minimum percentage of annual patient days will be charity care patient days. The agency shall, by rule, define the factors constituting good cause for modification of previous commitments.
- 3. The agency shall, by rule, establish the minimum annual percentage of service volumes required for nursing home compliance with this paragraph. In establishing such standards, the agency shall give due consideration to the existing commitments described in paragraph (a).
- (d) Each nursing home shall annually certify to the agency that it has met the requirements of this subsection except as may be noted by the facility. Misrepresentation of compliance is subject to penalties imposed by the agency as provided in s. 400.121.
- (e) A nursing home found to be out of compliance with the requirements of this subsection is subject to penalties imposed by the agency as provided in s. 400.121.

(12) The applicant for an initial license must certify 1 2 that it will license and operate the nursing home. For an existing nursing home, the applicant must be the current 3 4 licenseholder of the facility. Section 5. Subsection (3) is added to section 400.102, 5 6 Florida Statutes, to read: 7 400.102 Action by agency against licensee; grounds .--8 (3) In administrative proceedings on an application to 9 establish any health care facility or program or to provide any service or take any other action requiring health care 10 11 facility licensure authority, only the applicant is entitled 12 to an administrative hearing on its application. No other 13 person may initiate or intervene in any action to determine 14 whether such an application should be approved or denied. 15 Section 6. Subsections (7) and (8) are added to 16 section 400.121, Florida Statutes, to read: 400.121 Denial, suspension, revocation of license; 17 moratorium on admissions; administrative fines; procedure; 18 19 order to increase staffing .--20 (7) In administrative proceedings on an application to establish any nursing home or program or to provide any 21 22 service or take any other action requiring nursing home facility licensure authority, only the applicant is entitled 23 to an administrative hearing on its application. No other 24 25 person may initiate or intervene in any action to determine 26 whether such an application should be approved or denied. 27 (8) Failure to demonstrate financial feasibility as 28 required by s. 400.071(5) is subject to agency action as 29 provided by this section. Section 7. Paragraph (c) of subsection (2) of section 30

31 400.605, Florida Statutes, is amended to read:

400.605 Administration; forms; fees; rules; inspections; fines.--

(2) The agency shall:

 (c) Issue hospice licenses to all applicants which meet the provisions of this part and applicable rules. The agency shall develop and implement an expedited license application process for community-based hospice services.

Section 8. Subsections (1), (5), and (6) of section 400.606, Florida Statutes, are amended, and new subsections (6), (7), and (8) are added to said section, to read:

400.606 License; application; renewal; conditional license or permit; certificate of need.--

- (1) A license application must be filed on a form provided by the agency and must be accompanied by the appropriate license fee as well as satisfactory proof that the hospice is in compliance with this part and any rules adopted by the department and proof of financial ability to operate and conduct the hospice in accordance with the requirements of this part. An application for initial licensure of a hospice must contain a detailed financial projection, including a statement of the projected revenue and expenses for the first 2 years of operation after licensure of the hospice. The initial application must be accompanied by a plan for the delivery of home, residential, and homelike inpatient hospice services to terminally ill persons and their families. Such plan must contain, but need not be limited to:
- (a) The estimated average number of terminally ill persons to be served monthly.
- (b) The geographic area in which hospice services will be available.

- (c) A listing of services which are or will be provided, either directly by the applicant or through contractual arrangements with existing providers.
- (d) Provisions for the implementation of hospice home care within 3 months after licensure.
- (e) Provisions for the implementation of hospice homelike inpatient care within 12 months after licensure.
- (f) The number and disciplines of professional staff to be employed.
- (g) The name and qualifications of any existing or potential contractee.
 - (h) A plan for attracting and training volunteers.
- (i) The projected annual operating cost of the hospice.
- (j) A statement of financial resources and personnel available to the applicant to deliver hospice care.

If the applicant is an existing health care provider, the application must be accompanied by a copy of the most recent profit-loss statement and, if applicable, the most recent licensure inspection report.

- (5) The agency shall not issue a license to a hospice that fails to receive a certificate of need under the provisions of ss. 408.031-408.045. A licensed hospice is a health care facility as that term is used in s. 408.039(5) and is entitled to initiate or intervene in an administrative hearing.
- (5)(6) A freestanding hospice facility that is primarily engaged in providing inpatient and related services and that is not otherwise licensed as a health care facility shall be required to obtain a certificate of need. However, A

```
freestanding hospice facility with six or fewer beds shall not
2
   be required to comply with institutional standards such as,
3
   but not limited to, standards requiring sprinkler systems,
   emergency electrical systems, or special lavatory devices.
4
5
          (6) In administrative proceedings on an application to
6
   establish a hospice or hospice inpatient facility or program
7
   or to provide any service or take any other action requiring
8
   licensure authority, only the applicant is entitled to an
9
   administrative hearing on its application. No other person may
10
   initiate or intervene in any action to determine whether such
11
   an application should be approved or denied.
12
          (7) The applicant for an initial license must certify
13
   that it will license and operate the hospice or hospice
14
   inpatient facility. For an existing hospice, the applicant
15
   must be the current licenseholder for the program.
16
          (8) Failure to demonstrate financial feasibility as
17
   required by subsection (1) is subject to agency action as
   provided in s. 400.607.
18
           Section 9. Sections 154.245, 408.031, 408.034,
19
20
   408.035, 408.036, 408.0361, 408.037, 408.038, 408.039,
   408.040, 408.041, 408.042, 408.043, 408.044, 408.045,
21
22
   408.0455, and 651.118, Florida Statutes, and subsections (2),
   (3), (4), (6), and (7) of section 408.032, Florida Statutes,
23
24
   are repealed.
25
           Section 10. Paragraphs (b) and (c) of subsection (1),
26
   paragraphs (a) and (f) of subsection (2), and paragraph (b) of
27
   subsection (3) of section 408.033, Florida Statutes, are
28
   amended to read:
29
           408.033 Local and state health planning.--
```

(1) LOCAL HEALTH COUNCILS. --

(b) Each local health council may:

3

4

5

6

7

8

9

10 11

12 13

14

15

16

17

18

19

20

21

22

23

24

25

2627

28

29

30

- Develop a district or regional area health plan that permits each local health council to develop strategies and set priorities for implementation based on its unique local health needs. The district or regional area health plan must contain preferences for the development of health services and facilities, which may be considered by the agency in its review of certificate-of-need applications. The district health plan shall be submitted to the agency and updated periodically. The district health plans shall use a uniform format and be submitted to the agency according to a schedule developed by the agency in conjunction with the local health councils. The schedule must provide for the development of district health plans by major sections over a multiyear period. The elements of a district plan which are necessary to the review of certificate-of-need applications for proposed projects within the district may be adopted by the agency part of its rules.
- 2. Advise the agency on health care issues and resource allocations.
- 3. Promote public awareness of community health needs, emphasizing health promotion and cost-effective health service selection.
- 4. Collect data and conduct analyses and studies related to health care needs of the district, including the needs of medically indigent persons, and assist the agency and other state agencies in carrying out data collection activities that relate to the functions in this subsection.
- 5. Monitor the onsite construction progress, if any, of certificate-of-need approved projects and report council findings to the agency on forms provided by the agency.

 $\underline{5.6}$. Advise and assist any regional planning councils within each district that have elected to address health issues in their strategic regional policy plans with the development of the health element of the plans to address the health goals and policies in the State Comprehensive Plan.

- 6.7. Advise and assist local governments within each district on the development of an optional health plan element of the comprehensive plan provided in chapter 163, to assure compatibility with the health goals and policies in the State Comprehensive Plan and district health plan. To facilitate the implementation of this section, the local health council shall annually provide the local governments in its service area, upon request, with:
- a. A copy and appropriate updates of the district health plan; and
- b. A report of hospital and nursing home utilization statistics for facilities within the local government jurisdiction. 7 and
- c. Applicable agency rules and calculated need methodologies for health facilities and services regulated under s. 408.034 for the district served by the local health council.
- 7.8. Monitor and evaluate the adequacy, appropriateness, and effectiveness, within the district, of local, state, federal, and private funds distributed to meet the needs of the medically indigent and other underserved population groups.
- 8.9. In conjunction with the Agency for Health Care Administration, plan for services at the local level for persons infected with the human immunodeficiency virus.

- <u>9.10</u>. Provide technical assistance to encourage and support activities by providers, purchasers, consumers, and local, regional, and state agencies in meeting the health care goals, objectives, and policies adopted by the local health council.
- 11. Provide the agency with data required by rule for the review of certificate-of-need applications and the projection of need for health services and facilities in the district.
- (c) Local health councils may conduct public hearings pursuant to s. 408.039(3)(b).
 - (2) FUNDING.--

- health councils be borne by application fees for certificates of need and by assessments on selected health care facilities subject to facility licensure by the Agency for Health Care Administration, including abortion clinics, assisted living facilities, ambulatory surgical centers, birthing centers, clinical laboratories except community nonprofit blood banks and clinical laboratories operated by practitioners for exclusive use regulated under s. 483.035, home health agencies, hospices, hospitals, intermediate care facilities for the developmentally disabled, nursing homes, and multiphasic testing centers and by assessments on organizations subject to certification by the agency pursuant to chapter 641, part III, including health maintenance organizations and prepaid health clinics.
- (f) The agency shall deposit in the Health Care Trust Fund all health care facility assessments that are assessed under this subsection and proceeds from the certificate-of-need application fees. The agency shall

3

4 5

6

7

8

9

10 11

12 13

14

15 16

17

18 19

20

21

22

23

24 25

26

27

28

29

30

transfer to the Department of Health an amount sufficient to maintain the aggregate funding level for the local health councils as specified in the General Appropriations Act. The remaining certificate-of-need application fees shall be used only for the purpose of administering the Health Facility and Services Development Act.

- (3) DUTIES AND RESPONSIBILITIES OF THE AGENCY. --
- The agency shall develop and maintain a comprehensive health care database for the purpose of health planning and for certificate-of-need determinations. agency or its contractor is authorized to require the submission of information from health facilities, health service providers, and licensed health professionals which is determined by the agency, through rule, to be necessary for meeting the agency's responsibilities as established in this section.

Section 11. Subsection (3) of section 20.42, Florida Statutes, is amended to read:

- 20.42 Agency for Health Care Administration. --
- (3) The department shall be the chief health policy and planning entity for the state. The department is responsible for health facility licensure, inspection, and regulatory enforcement; investigation of consumer complaints related to health care facilities and managed care plans; the implementation of the certificate of need program; the operation of the State Center for Health Statistics; the administration of the Medicaid program; the administration of the contracts with the Florida Healthy Kids Corporation; the certification of health maintenance organizations and prepaid health clinics as set forth in part III of chapter 641; and 31 any other duties prescribed by statute or agreement.

Section 12. Subsection (4) of section 154.205, Florida Statutes, is amended to read:

154.205 Definitions.--The following terms, whenever used in this part, shall have the following meanings unless a different meaning clearly appears from the context:

(4) "Certificate of need" means a written advisory statement issued by the Agency for Health Care Administration, having as its basis a written advisory statement issued by an areawide council and, where there is no council, by the Agency for Health Care Administration, evidencing community need for a new, converted, expanded, or otherwise significantly modified health facility.

Section 13. Section 154.213, Florida Statutes, is amended to read:

154.213 Agreements of lease.—In undertaking any project pursuant to this part, the authority shall first obtain a valid certificate of need evidencing need for the project and a statement that the project serves a public purpose by advancing the commerce, welfare, and prosperity of the local agency and its people. No project financed under the provisions of this part shall be operated by the authority or any other governmental agency; however, the authority may temporarily operate or cause to be operated all or any part of a project to protect its interest therein pending any leasing of such project in accordance with the provisions of this part. The authority may lease a project or projects to a health facility for operation and maintenance in such manner as to effectuate the purposes of this part under an agreement of lease in form and substance not inconsistent herewith.

(1) Any such agreement of lease may provide, among other provisions, that:

2

3

4

5

6

7

8

9

10

11

12

13

14

15 16

17

18 19

20

21

22

23 24

25

26

27

28

29

- The lessee shall at its own expense operate, repair, and maintain the project or projects leased thereunder.
- (b) The rent payable under the lease shall in the aggregate be not less than an amount sufficient to pay all of the interest, principal, and redemption premiums, if any, on the bonds that shall be issued by the authority to pay the cost of the project or projects leased thereunder.
- (c) The lessee shall pay all costs incurred by the authority in connection with the acquisition, financing, construction, and administration of the project or projects leased, except as may be paid out of the proceeds of bonds or otherwise, including, but without being limited to: Insurance costs, the cost of administering the bond resolution authorizing such bonds and any trust agreement securing the bonds, and the fees and expenses of trustees, paying agents, attorneys, consultants, and others.
- The terms of the lease shall terminate not earlier than the date on which all such bonds and all other obligations incurred by the authority in connection with the project or projects leased thereunder shall be paid in full, including interest, principal, and redemption premiums, if any, or adequate funds for such payment shall be deposited in trust.
- The lessee's obligation to pay rent shall not be subject to cancellation, termination, or abatement by the lessee until such payment of the bonds or provision for such payment shall be made.
- (2) Such lease agreement may contain such additional provisions as in the determination of the authority are 31 necessary or convenient to effectuate the purposes of this

3

4 5

6 7

8

10 11

12 13

14

15 16

17

18

19 20

21 22

23 24

25

26

27

28

29

30

part, including provisions for extensions of the term and renewals of the lease and vesting in the lessee an option to purchase the project leased thereunder pursuant to such terms and conditions consistent with this part as shall be prescribed in the lease. Except as may otherwise be expressly stated in the agreement of lease, to provide for any contingencies involving the damaging, destruction, or condemnation of the project leased or any substantial portion thereof, such option to purchase may not be exercised unless all bonds issued for such project, including all principal, interest, and redemption premiums, if any, and all other obligations incurred by the authority in connection with such project, shall have been paid in full or sufficient funds shall have been deposited in trust for such payment. purchase price of such project shall not be less than an amount sufficient to pay in full all of the bonds, including all principal, interest, and redemption premiums, if any, issued for the project then outstanding and all other obligations incurred by the authority in connection with such project.

Section 14. Subsection (1) of section 154.219, Florida Statutes, is amended to read:

154.219 Revenue bonds.--

(1) The authority is authorized from time to time to issue its negotiable revenue bonds for the purpose of paying all or any part of the cost of any project or projects for which a certificate of need has been obtained, or pursuant to subsections (12) and (13) of s. 154.209 for the purpose of paying all or any part of the cost of acquiring existing or completed health facilities projects. In anticipation of the 31 sale of such revenue bonds, the authority may issue negotiable

4 5

6 7

8

9

10 11

12

13

14

15 16

17 18

19

20

21 22

23

24

25 26

27

28

29

30

bond anticipation notes and may renew the same from time to time, but the maximum maturity of any such note, including renewals thereof, shall not exceed 5 years from the date of issue of the original note. Such notes shall be paid from any revenues of the authority available therefor and not otherwise pledged or from the proceeds of sale of the revenue bonds of the authority in anticipation of which they were issued. The notes shall be issued in the same manner as the revenue bonds. Such notes and the resolution or resolutions authorizing the same may contain any provisions, conditions, or limitation which a bond resolution of the authority may contain.

Section 15. Subsection (16) of section 159.27, Florida Statutes, is amended to read:

159.27 Definitions.--The following words and terms, unless the context clearly indicates a different meaning, shall have the following meanings:

(16) "Health care facility" means property operated in the private sector, whether operated for profit or not, used for or useful in connection with the diagnosis, treatment, therapy, rehabilitation, housing, or care of or for aged, sick, ill, injured, infirm, impaired, disabled, or handicapped persons, without discrimination among such persons due to race, religion, or national origin; or for the prevention, detection, and control of disease, including, without limitation thereto, hospital, clinic, emergency, outpatient, and intermediate care, including, but not limited to, facilities for the elderly such as assisted living facilities, facilities defined in s. 154.205(7)(8), day care and share-a-home facilities, nursing homes, and the following related property when used for or in connection with the 31 | foregoing: laboratory; research; pharmacy; laundry; health

personnel training and lodging; patient, guest, and health personnel food service facilities; and offices and office buildings for persons engaged in health care professions or services; provided, if required by ss. 400.601-400.611 and ss. 408.031-408.045, a certificate of need therefor is obtained prior to the issuance of the bonds.

Section 16. Subsection (3) of section 189.415, Florida Statutes, is amended to read:

189.415 Special district public facilities report.--

(3) A special district proposing to build, improve, or expand a public facility which requires a certificate of need pursuant to chapter 408 shall elect to notify the appropriate local general-purpose government of its plans either in its 5-year plan or at the time the application for license letter of intent is filed with the Agency for Health Care Administration pursuant to s. 408.039.

Section 17. Subsection (4) of section 383.50, Florida Statutes, is amended to read:

383.50 Treatment of abandoned newborn infant.--

(4) Each hospital of this state subject to s. 395.1041 shall, and any other hospital may, admit and provide all necessary emergency services and care, as defined in s. 395.002(21)(10), to any newborn infant left with the hospital in accordance with this section. The hospital or any of its licensed health care professionals shall consider these actions as implied consent for treatment, and a hospital accepting physical custody of a newborn infant has implied consent to perform all necessary emergency services and care. The hospital or any of its licensed health care professionals is immune from criminal or civil liability for acting in good

26

27

28

29

30

standards for ensuring that:

2 subsection limits liability for negligence. 3 Section 18. Subsection (7) of section 394.4787, 4 Florida Statutes, is amended to read: 5 394.4787 Definitions; ss. 394.4786, 394.4787, 6 394.4788, and 394.4789.--As used in this section and ss. 7 394.4786, 394.4788, and 394.4789: 8 "Specialty psychiatric hospital" means a hospital 9 licensed by the agency pursuant to s. $395.002(53)\frac{(29)}{100}$ as a specialty psychiatric hospital. 10 Section 19. Subsection (10) of section 395.0191, 11 Florida Statutes, is amended to read: 12 13 395.0191 Staff membership and clinical privileges.--14 (10) Nothing herein shall be construed by the agency as requiring an applicant for a license certificate of need to 15 16 establish proof of discrimination in the granting of or denial of hospital staff membership or clinical privileges as a 17 precondition to obtaining such license certificate of need 18 19 under the provisions of s. 408.043. 20 Section 20. Paragraph (h) of subsection (1) of section 395.1055, Florida Statutes, is amended to read: 21 395.1055 Rules and enforcement.--22 23 (1) The agency shall adopt rules pursuant to ss. 24 120.536(1) and 120.54 to implement the provisions of this 25 part, which shall include reasonable and fair minimum

faith in accordance with this section. Nothing in this

(h) All hospitals submit such data which as necessary

limited to, patient origin data, hospital utilization data,

31 | type of service reporting, and facility staffing data.

to conduct certificate-of-need reviews required under ss. 408.031-408.045. Such data shall include, but shall not be

3

4 5

6

7

8

9

10 11

12

13

14

15

16

17

18 19

20

21

22

23

24

25 26

27

28

29

30

agency shall not collect data that identifies or could disclose the identity of individual patients. The agency shall utilize existing uniform statewide data sources when available and shall minimize reporting costs to hospitals.

Section 21. Paragraph (c) of subsection (2) of section 395.602, Florida Statutes, is amended to read:

395.602 Rural hospitals.--

- (2) DEFINITIONS.--As used in this part:
- "Inactive rural hospital bed" means a licensed acute care hospital bed, as defined in s. 395.002(23)(12), that is inactive in that it cannot be occupied by acute care inpatients.

Section 22. Subsection (1) of section 395.603, Florida Statutes, is amended to read:

395.603 Rules; rural hospital impact statement.--

(1) The agency shall establish, by rule, a process by which a rural hospital, as defined in s. 395.602, that seeks licensure as a rural primary care hospital or as an emergency care hospital, or becomes a certified rural health clinic as defined in Pub. L. No. 95-210, or becomes a primary care program such as a county health department, community health center, or other similar outpatient program that provides preventive and curative services, may deactivate general hospital beds. Rural primary care hospitals and emergency care hospitals shall maintain the number of actively licensed general hospital beds necessary for the facility to be certified for Medicare reimbursement. Hospitals that discontinue inpatient care to become rural health care clinics or primary care programs shall deactivate all licensed general hospital beds. All hospitals, clinics, and programs with 31 | inactive beds shall provide 24-hour emergency medical care by

staffing an emergency room. Providers with inactive beds shall be subject to the criteria in s. 395.1041. The agency shall specify in rule requirements for making 24-hour emergency care available. Inactive general hospital beds shall be included in the acute care bed inventory, maintained by the agency for certificate-of-need purposes, for 10 years from the date of deactivation of the beds. After 10 years have elapsed, inactive beds shall be excluded from the inventory. The agency shall, at the request of the licensee, reactivate the inactive general beds upon a showing by the licensee that licensure requirements for the inactive general beds are met.

Section 23. Subsection (1) of section 395.604, Florida Statutes, is amended to read:

395.604 Other rural hospital programs.--

(1) The agency may license rural primary care hospitals subject to federal approval for participation in the Medicare and Medicaid programs. Rural primary care hospitals shall be treated in the same manner as emergency care hospitals and rural hospitals with respect to ss. $\underline{395.605(2)-(6)(a)} \ \text{and} \ \underline{395.605(2)-(8)(a)}, 408.033(2)(b)3., \ \text{and} \ \underline{408.038}.$

Section 24. Subsections (5) and (7) of section 395.605, Florida Statutes, are amended to read:

395.605 Emergency care hospitals.--

(5) Rural hospitals that make application under the certificate-of-need program to be licensed as emergency care hospitals shall receive expedited review as defined in s.

408.032. Emergency care hospitals seeking relicensure as acute care general hospitals shall also receive expedited review.

(7) Emergency care hospitals are exempt from certificate-of-need requirements for home health and hospice

2

3

4

5

6

7

8

9

10

11

12

13

14

15 16

17

18 19

20

21

22

23 24

25

26

27

28

29

30

services and for swing beds in a number that does not exceed one-half of the facility's licensed beds.

Section 25. Paragraph (c) of subsection (1) of section 395.701, Florida Statutes, is amended to read:

395.701 Annual assessments on net operating revenues for inpatient services to fund public medical assistance; administrative fines for failure to pay assessments when due; exemption. --

- (1) For the purposes of this section, the term:
- "Hospital" means a health care institution as defined in s. $395.002(24)\frac{(13)}{(13)}$, but does not include any hospital operated by the agency or the Department of Corrections.

Section 26. Paragraph (b) of subsection (1) of section 400.051, Florida Statutes, is amended to read:

400.051 Homes or institutions exempt from the provisions of this part.--

- (1) The following shall be exempt from the provisions of this part:
- (b) Any hospital, as defined in s. $395.002(22)\frac{(11)}{(11)}$, that is licensed under chapter 395.

Section 27. Subsection (5) of section 400.23, Florida Statutes, is amended to read:

400.23 Rules; evaluation and deficiencies; licensure status.--

The agency, in collaboration with the Division of Children's Medical Services of the Department of Health, must, no later than December 31, 1993, adopt rules for minimum standards of care for persons under 21 years of age who reside in nursing home facilities. The rules must include a 31 | methodology for reviewing a nursing home facility under ss.

408.031-408.045 which serves only persons under 21 years of age. A facility may be exempt from these standards for specific persons between 18 and 21 years of age, if the person's physician agrees that minimum standards of care based on age are not necessary.

Section 28. Subsection (6) of section 400.602, Florida Statutes, is amended to read:

400.602 Licensure required; prohibited acts; exemptions; display, transferability of license.--

(6) Notwithstanding s. 400.601(3), at any time after July 1, 1995, any entity entitled to licensure under subsection (5) may obtain a license for up to two additional hospices in accordance with the other requirements of this part and upon receipt of any certificate of need that may be required under the provisions of ss. 408.031-408.045.

Section 29. Paragraph (b) of subsection (2) of section 400.6085, Florida Statutes, is amended to read:

400.6085 Contractual services.—A hospice may contract out for some elements of its services. However, the core services, as set forth in s. 400.609(1), with the exception of physician services, shall be provided directly by the hospice. Any contract entered into between a hospice and a health care facility or service provider must specify that the hospice retains the responsibility for planning, coordinating, and prescribing hospice care and services for the hospice patient and family. A hospice that contracts for any hospice service is prohibited from charging fees for services provided directly by the hospice care team that duplicate contractual services provided to the patient and family.

(2) With respect to contractual arrangements for inpatient hospice care:

2

3

4 5

6

7

8

9

10

11

12 13

14

15 16

17

18

19 20

21

22

23

24

25 26

27

28

29

30

Licensed beds designated for inpatient hospice care through a contract Hospices contracting for inpatient care beds shall not be required to obtain an additional certificate of need for the number of such designated beds. Such beds shall remain licensed to the health care facility and be subject to the appropriate inspections.

Section 30. Subsection (8) of section 409.905, Florida Statutes, is amended to read:

409.905 Mandatory Medicaid services. -- The agency may make payments for the following services, which are required of the state by Title XIX of the Social Security Act, furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any service under this section shall be provided only when medically necessary and in accordance with state and federal law. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, number of services, or any other adjustments necessary to comply with the availability of moneys and any limitations or directions provided for in the General Appropriations Act or chapter 216.

(8) NURSING FACILITY SERVICES. -- The agency shall pay for 24-hour-a-day nursing and rehabilitative services for a recipient in a nursing facility licensed under part II of chapter 400 or in a rural hospital, as defined in s. 395.602, or in a Medicare certified skilled nursing facility operated by a hospital, as defined by s. $395.002(22)\frac{(11)}{(11)}$, that is licensed under part I of chapter 395, and in accordance with provisions set forth in s. 409.908(2)(a), which services are ordered by and provided under the direction of a licensed 31 physician. However, if a nursing facility has been destroyed

or otherwise made uninhabitable by natural disaster or other emergency and another nursing facility is not available, the agency must pay for similar services temporarily in a hospital licensed under part I of chapter 395 provided federal funding is approved and available.

Section 31. Paragraph (b) of subsection (5) of section 430.705, Florida Statutes, is amended to read:

430.705 Implementation of the long-term care community diversion pilot projects.--

- (5) In selecting the pilot project area, the department shall consider the following factors in the area:
- (b) The number of certificates of need awarded for nursing home beds for which renovation, expansion, or construction has not begun.

Section 32. Section 430.708, Florida Statutes, is amended to read:

430.708 Implementation of Medicaid community diversion pilot projects Certificate of need.--To ensure that Medicaid community diversion pilot projects result in a reduction in the projected average monthly nursing home caseload, the agency shall, in accordance with the provisions of s.

408.034(4):

(1) Reduce the projected nursing home bed need in each certificate-of-need batching cycle in the community diversion pilot project areas.

 $\underline{(1)}$ Reduce the conditions imposed on existing nursing homes or those to be constructed, in accordance with the number of projected community diversion slots.

 $\underline{(2)}$ (3) Adopt rules to reduce the number of beds in Medicaid-participating nursing homes eligible for Medicaid,

2

3

4

5

6 7

8

9

10

11

12

13

14

15

16

17

18 19

20

21

22

23

24 25

26

27

28

29

30

through a Medicaid-selective contracting process or some other appropriate method.

(4) Determine the feasibility of increasing the nursing home occupancy threshold used in determining nursing home bed needs under the certificate-of-need process.

Section 33. Paragraph (1) of subsection (1) of section 468.505, Florida Statutes, is amended to read:

468.505 Exemptions; exceptions.--

- (1) Nothing in this part may be construed as prohibiting or restricting the practice, services, or activities of:
- (1) A person employed by a nursing facility exempt from licensing under s. 395.002(24)(13), or a person exempt from licensing under s. 464.022.

Section 34. Paragraph (a) of subsection (2) of section 651.021, Florida Statutes, is amended to read:

651.021 Certificate of authority required.--

(2)(a) Before commencement of construction or marketing for any expansion of a certificated facility equivalent to the addition of at least 20 percent of existing units, written approval must be obtained from the department. This provision does not apply to construction for which a certificate of need from the Agency for Health Care

Administration is required.

Section 35. Section 766.316, Florida Statutes, is amended to read:

766.316 Notice to obstetrical patients of participation in the plan. -- Each hospital with a participating physician on its staff and each participating physician, other than residents, assistant residents, and interns deemed to be 31 participating physicians under s. 766.314(4)(c), under the

Florida Birth-Related Neurological Injury Compensation Plan 1 2 shall provide notice to the obstetrical patients as to the 3 limited no-fault alternative for birth-related neurological injuries. Such notice shall be provided on forms furnished by 4 5 the association and shall include a clear and concise explanation of a patient's rights and limitations under the 6 7 plan. The hospital or the participating physician may elect to 8 have the patient sign a form acknowledging receipt of the notice form. Signature of the patient acknowledging receipt of 9 the notice form raises a rebuttable presumption that the 10 11 notice requirements of this section have been met. Notice need not be given to a patient when the patient has an emergency 12 13 medical condition as defined in s. $395.002\frac{(9)(b)}{(b)}$ or when 14 notice is not practicable. 15 Section 36. Grandfather clause. -- A facility licensed 16 to provide any of the following services pursuant to a valid 17 certificate of need on June 30, 2001, shall continue to be licensed to provide such service on and after the effective 18 19 date of this act: 20 (1) Bone marrow transplantation. (2) Burn unit facilities. 21 22 (3) Cardiac catheterization programs. (4) Level I and Level II neonatology. 23 24 (5) Comprehensive medical rehabilitation outpatient 25 services. 26 (6) Coronary angioplasty. 27 (7) Open heart surgery. 28 (8) Psychiatric inpatient services. 29 (9) Substance abuse inpatient services.

(10) Tertiary health services.

(11) Transplantation programs.

Such facilities shall apply to the Agency for Health Care Administration by October 1, 2001, for relicensure to provide such services pursuant to the provisions of this act. Section 37. This act shall take effect July 1, 2001. HOUSE SUMMARY Revises definitions relating to hospital licensing and regulation. Restricts persons who may initiate or intervene in actions or proceedings on an application for licensure of a health care facility, program, or service. Provides minimum standards and specifies requirements for the following inpatient services: cardiac catheterization and angioplasty, open heart surgery, inpatient comprehensive medical rehabilitation, inpatient general psychiatric services, inpatient substance abuse services, neonatal intensive care services, specialty burn units, and heart, liver, kidney, and bone marrow transplantation. Provides additional licensure application requirements for nursing homes and hospices. Provides penalties for failure of a nursing home or hospice to demonstrate financial feasibility in its license application. Provides for an expedited licensure process for community-based hospices. Repeals requirements for certificate-of-need review and approval for health facilities and services. Conforms provisions relating to certificate-of-need review of proposed and existing health facilities and services. See bill for details.