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HOUSE OF REPRESENTATIVES
COMMITTEE ON
HEALTH REGULATION
ANALYSIS

BILL #: HB 771

RELATING TO: Health Regulation

SPONSOR (S): Representative Rubio

TIED BILL (S): None.

ORIGINATING COMMITTEE (S)/COUNCIL (S)/COMMITTEE (S) OF REFERENCE:

(1) HEALTH REGULATION
(2) COUNCIL FOR HEALTHY COMMUNITIES
(3)
(4)
(5)

I. SUMMARY:

HB 771 effectively repeals the Health Facilities Development Act: the Certificate of Need (CON) review process. This bill eliminates the regulatory process that requires certain health care providers to obtain state approval from the Agency of Health Care Administration before offering new or expanded services or making major capital expenditures. The expected result of the bill is to restrain health care cost by allowing a competitive marketplace to dictate price and force the health care community to compete on price and quality of service to the consumer, as found in other previously regulated industries.

HB 771 codifies existing agency rules for the CON review process as licensure requirements for hospitals without the determination of need potion of such rules for tertiary health services.

In addition, this bill removes the statutory authority for the requirement of a certificate of need for bond validation and construction projects.

By eliminating the CON review process and the associated application fees and facility assessment fees, this bill eliminates current operational funding allocated to health councils.

HB 771 eliminates all statutory cross-references to proposed repealed statutes: the CON review process and local health councils.

The bill's effective date is July 1, 2001.

The fiscal impact of this bill is a decrease in state revenues of $3,307,685 by the loss of CON application fees and a corresponding decrease in expenditures by the same amount in the reduction of staff in the Agency responsible for the CON review process.

II. SUBSTANTIVE ANALYSIS:

A. DOES THE BILL SUPPORT THE FOLLOWING PRINCIPLES:

1.	Less Government	Yes []	No [X]	N/A []
2.	Lower Taxes	Yes []	No []	N/A [x]
3.	Individual Freedom	Yes []	No []	N/A [x]
4.	Personal Responsibility	Yes []	No []	N/A [x]
5.	Family Empowerment	Yes []	No []	N/A [x]

The bill establishes regulatory/licensure requirements for certain health facilities without the determination of need.

B. PRESENT SITUATION:

Hospital Licensure

Section 395, Florida Statutes, provides for the licensing requirements of hospitals and other licensed health facilities. A hospital is defined as offering services more intensive than those required for room, board, personal services and general nursing care. Hospital services include beds offered for use beyond 24 hours by individuals requiring medical, surgical, or psychiatric testing and diagnosis; and treatment for illness, injury, deformity, infirmity, abnormality, disease, or pregnancy. Other recognized hospital services include: clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment of similar extent.

Unaccredited facilities and initial licenses require a certification and/or licensing survey. Currently, **under state and federal regulations, accredited hospitals are "deemed" to meet the requirements and do not receive an annual license and certification survey.** Life-Safety and Risk Management surveys are conducted annually. In addition, each hospital must be surveyed for certification as directed by the Health Care Financing Administration (a federal agency) to receive Medicare reimbursement.

In ordered to be licensed by ACHA, facilities must meet federal and state licensing requirements, submit a completed application, required documentation and have a satisfactory survey completed. **Renewal** applications must be submitted **every two years**, 90 days in advance of expiration of a license. The **initial and renewal fee is $1,500 or $30.00 per bed, whichever is greater**. The survey/inspection fee is $400 or $12 per bed, whichever is greater. The life safety inspection fee is $40 or $1.50 per bed, whichever is greater.

As required by Rule 59A-3.202, Florida Administrative Code, hospitals are licensed by the following classification:

(1) Class I are general hospitals which include; general acute care hospitals with an average length of stay of 25 days or less for all beds; long term care hospitals, which meet the provisions of Rule 59A-3.201(31), Florida Administrative Code; and rural hospitals designated under Chapter 395, Part III, Florida Statutes.

(2) Class II are specialty hospitals offering the same range of medical services offered by general hospitals, but restricted to a defined age or gender group of a population which includes; specialty hospitals for children; and specialty hospitals for women.

(3) Class III are specialty hospitals offering a restricted range of services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical or psychiatric illnesses or disorders. Class III facilities include; specialty medical hospitals; specialty rehabilitation hospitals; specialty psychiatric hospitals, which may include beds licensed to offer intensive residential treatment programs; specialty substance abuse hospitals, which may include beds licensed to offer intensive residential treatment programs.

(4) Class IV is specialty hospitals restricted to offering intensive residential treatment programs for children and adolescents, pursuant to section 395.002(16), Florida Statutes.

According to Rule 59A-3.203, Florida Administrative Code, a person or governmental unit proposing to establish, conduct, or maintain a hospital in this state, must first obtain a license. All persons requesting licensure for the operation of a hospital under the provisions of Chapter 395, Florida Statutes, must make application to the agency and must receive a regular or provisional license prior to the acceptance of patients for care or treatment. The following **documents** must accompany the **initial application**: the hospital's zoning certificate; articles of incorporation; registration of a fictitious name; the name and address of the ultimate owner of the hospital; **a valid certificate of need** or letter of exemption as required by ss. 408.031 through 408.045, Florida Statutes. As well as, approval for licensure from the agency's Office of Plans and Construction; and evidence of medical malpractice insurance through the Patient Compensation Fund or other means of demonstrating financial responsibility as provided for under Chapter 766, Florida Statutes.

An application for **biennial licensure renewa**l must be accompanied by: evidence of medical malpractice insurance through the Patient Compensation Fund or other means of demonstrating financial responsibility as provided for under Chapter 766, Florida Statutes. **In lieu of an agency licensure inspection, a copy of the hospital's most recent accreditation report may be submitted, if the hospital is accredited by an accrediting organization and has evidence of accreditation.** Each license shall specifically state the name of the licensed operator of the hospital, and the class of hospital. A license, unless suspended or revoked, **automatically expires two years from date of issuance,** and is renewable biennially upon application for renewal and payment of the fee prescribed, provided that the applicant and hospital meet the requirements established under the Chapter 395, Part I, F.S., and Rules 59A-3.077–3.093 and 59A-3.200–3.232, F.A.C. Application for renewal of license shall be made not less than 90 days prior to expiration of a license.

AHCA also issues a **provisional license** for any hospital in substantial compliance with the statute and Rules 59A-3.077–3.093 and 59A-3.200–3.232 or 59A-3.100–3.111, F.A.C. Provisional licenses are issued only after the AHCA is satisfied that preparations are being made by the hospital to qualify for regular license, and that the health and safety of patients will not be endangered during the interim. Any new hospital will be issued a provisional license prior to opening date, provided plans, specifications for the building have been approved by the licensing agency, and the hospital has been surveyed and found to meet construction standards and health and safety surveys. A provisional license may be granted for a period of no more than one (1) year and expires automatically at the end of its term. **A provisional license may not be renewed.**

A regular license may be issued after the proposed hospital becomes operational and after the completion of a resurvey to determine compliance with rules. Florida Department of Law Enforcement, FBI fingerprinting, and Abuse Registry screening must be completed on the administrator/chief executive officer prior to the facility being licensed.

Nursing Home Licensure and Certificate of Need Review Process

Section 400.071, Florida Statutes, provides the governing provisions of licensing a nursing home and related facilities. ACHA established rule, 59A-4.103, Florida Administrative Code, implementing the provisions of this section of law. According to rule, the licensee or prospective licensee may make application for an **initial, renewal or change of ownership license** to operate a nursing home facility and must provide all of the information required by Section 400.071, Florida Statutes. The licensure fee must be is included with the application. The annual fee required as calculated to cover the **cost of licensure** is $33.00 per bed, plus the resident protection fee of $.25 per bed and the Health Care Board Assessment of $6.00 per bed. The calculation for this assessment is **a total of $39.25 per bed.** The Health Care Board Assessment is waived for facilities having a certificate of authority under Chapter 651, Florida Statutes.

The licensee of each nursing home must have full legal authority and responsibility for the operation of the facility. The licensee of each facility is responsible for designating one person, who is licensed by the Agency for Health Care Administration, Board of Nursing Home Administrators under Chapter 468, Part II, F.S., as Administrator who oversees the day-to-day administration and operation of the facility. Each nursing home is organized according to a written Table of Organization.

The licensee, for each nursing home it operates, maintains fiscal records in accordance with the requirements of Chapter 400, Part II, and Florida Statutes. An accrual or cash system of accounting is used to reflect transactions of the business. Records and accounts of transactions, such as, general ledgers and disbursement journals, are brought current no less than quarterly and are available for review by authorized representatives of appropriate State and Federal agencies.

CON review covers not only new facility construction but also initiation of increases in the number of inpatient beds in nursing homes, transfers of CONs, and a variety of other projects, which could significantly affect services or costs. Currently, a competitive nursing home provider can challenge the final recommended order of a CON application. Current case law clarifies that the applicant for a CON be the license holder of the facility.

The **CON regulatory process** has arguably been used as a **tool to help control the number of nursing home beds available,** thereby decreasing a demand on service and decreasing the strain on the state's Medicaid budget. According to the Agency for Health Care Administration, the percentage of **Medicaid utilization of nursing home beds has steadily increased: 1990 – 57.77%; 1995 – 63.03%; and 2000 –65.74%.** Medicaid mandatory services include skilled nursing facility services, as specified in s. 409.905(8), Florida Statutes. Paragraph (b) of subsection (2) of s. 409.908, F.S., stipulates that ACHA establish and implement a Florida Title XIX (Medicaid) Long-Term Care Reimbursement Plan. Under the plan, a prospective case mix reimbursement rate is calculated for each nursing home based on the facility's cost of rendering care, with specific accounting for the costs of patient care, operating cost, and property costs. These factors combine to serve as the basis for a facility's per diem rate of reimbursement. These rates are subject to specific regional and county ceilings, and are fixed on the semi-annual semester basis by ACHA using actual audited data reported to ACHA by nursing homes. The only exception to this is an allowance for interim rate adjustments, based on outstanding factors that affect the cost of doing business. These interim rate adjustments have, up to this point, been limited to cost associated

with revisions in federal or state requirements that have a direct impact on the cost of nursing home care to Medicaid recipients.

Hospices Licensure and Certificate of Need Review Process

Section 400.602, Florida Statues, governs the **licensing provision for hospices**. It is unlawful to operate or maintain a hospice without first obtaining a license from the agency. In addition, it is unlawful for any person or legal entity not licensed as a hospice to use the word "hospice" in its name, or to offer or advertise hospice services or hospice-like services in such a way as to mislead a person to believe that the offeror is a licensed hospice.

Services provided by a hospital, nursing home, or other health care facility, health care provider, or caregiver, or under the Community Care for the Elderly Act, do not constitute a hospice unless the facility, provider, or caregiver establishes a separate and distinct administrative program to provide home, residential, and homelike inpatient hospice services.

The license is required to be displayed in a conspicuous place inside the hospice program office. It is **valid only in the possession of the person or public agency to which it is issued; and is not subject to sale, assignment, or other transfer**, voluntary or involuntary; and is not valid for any hospice other than the hospice for which originally issued.

Also section 400.602, Florida Statutes, provides for an exemption to any hospice operating in corporate form exclusively as a hospice, incorporated on or before July 1, 1978, may be transferred to a for-profit or not-for-profit entity, and may transfer the license to that entity. 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 sections 408.031-408.045, Florida Statutes.

Section 400.606, Florida Statues, provides that 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 current law and any rules adopted by the department. In addition, it is required that proof of financial ability to operate and conduct the hospice is present at time of application for licensure. 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. 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.

Each applicant must submit to the agency with its application a description and explanation of any exclusions, permanent suspensions, or terminations from the Medicaid or Medicare programs of the owner, if an individual; of any officer or board member of the hospice, if the owner is a firm, corporation, partnership, or association; or of any person owning 5 percent or more of the hospice. Proof of compliance with disclosure of ownership and control interest requirements of the Medicaid or Medicare programs may be accepted in lieu of this submission.

A **license** issued for the operation of a hospice, unless sooner suspended or revoked, expires **automatically 1 year from the date of issuance**. Sixty days before the expiration date, a hospice wishing to **renew its license** must submit an application for renewal to the agency on forms furnished by the agency. The agency may renew the license if the applicant has first met the requirements established and all applicable rules. However, the application for license renewal is

accompanied by an update of the plan for delivery of hospice care only if information contained in the plan submitted pursuant to subsection (1) is no longer applicable.

A hospice against which a revocation or suspension proceeding is pending at the time of license renewal may be issued a **conditional license** by the agency effective until final disposition of such proceeding. If judicial relief is sought from the final agency action, the court having jurisdiction may issue a **conditional permit for the duration of the judicial proceeding.**

Section 400.607, Florida Statutes, provides that the Agency may deny, revoke, or suspend a license or impose an administrative fine, which may not exceed $5,000.00 per violation.

The provisions of sections 408.034(3), 408.036(1)(d) and (e), and 408.043(2), Florida Statutes, are implemented by Rule 59c-1.0355, Florida Administrative Code. It is the expressed intent of the agency to ensure the availability of hospice programs to all persons requesting and eligible for hospice services, regardless of ability to pay. This rule regulates the establishment of new hospice programs, the construction of freestanding inpatient hospice facilities, and a change in licensed bed capacity of a freestanding inpatient hospice facility. A separate certificate of need application shall be submitted for each service area prior to the issuance of a license from ACHA.

For purposes of the CON review process, need is determined by service area, consisting of a specified county or counties, as follows: **Service Area 1** consists of Escambia, Okaloosa, Santa Rosa, and Walton Counties. **Service Area 2A** consists of Bay, Calhoun, Gulf, Holmes, Jackson, and Washington Counties. **Service Area 2B** consists of Franklin, Gadsden, Jefferson, Leon, Liberty, Madison, Taylor, and Wakulla Counties. **Service Area 3A** consists of Alachua, Bradford, Columbia, Dixie, Gilchrist, Hamilton, Lafayette, Levy, Putnam, Suwanee, and Union Counties. **Service Area 3B** consists of Marion County. **Service Area 3C** consists of Citrus County. **Service Area 3D** consists of Hernando County. **Service Area 3E** consists of Lake and Sumter Counties. **Service Area 4A** consists of Baker, Clay, Duval, Nassau, and St. Johns Counties. **Service Area 4B** consists of Flagler and Volusia Counties. **Service Area 5A** consists of Pasco County. **Service Area 5B** consists of Pinellas County. **Service Area 6A** consists of Hillsborough County. **Service Area 6B** consists of Hardee, Highlands, and Polk Counties. **Service Area 6C** consists of Manatee County. **Service Area 7A** consists of Brevard County. **Service Area 7B** consists of Orange and Osceola Counties. **Service Area 7C** consists of Seminole County. **Service Area 8A** consists of Charlotte and DeSoto Counties. **Service Area 8B** consists of Collier County. **Service Area 8C** consists of Glades, Hendry and Lee Counties. **Service Area 8D** consists of Sarasota County. **Service Area 9A** consists of Indian River County. **Service Area 9B** consists of Martin, Okeechobee, and St. Lucie Counties. **Service Area 9C** consists of Palm Beach County. **Service Area 10** consists of Broward County. **Service Area 11** consists of Dade and Monroe Counties.

Hospice programs must comply with the standards for program licensure described in Chapter 400, Part VI, Florida Statutes, and Chapter 59A-2, Florida Administrative Code. Applicants proposing to establish a new hospice program must demonstrate how they will meet the standards. **A certificate of need** for the establishment of a new hospice program, construction of a freestanding inpatient hospice facility, or change in licensed bed capacity of a freestanding inpatient hospice facility, is not approved unless the applicant meets the applicable review criteria in sections 408.035 and 408.043(2), Florida Statutes, as well as the standards and need determination criteria. Applications to establish a new hospice program are not approved in the absence of a numeric need indicated by the formula unless other criteria outweigh the lack of a numeric need. Numeric need for an additional hospice program may be demonstrated if the projected number of un-served patients who would elect a hospice program is 350 or greater. Three Hundred and Fifty is the targeted minimum 12-month total of patients admitted to a hospice program.

Approval Under Special Circumstances: In the absence of numeric need, the applicant must demonstrate that circumstances exist to justify the approval of a new hospice. Evidence submitted by the applicant must document one or more of the following:

- That a specific terminally ill population is not being served.
- That a county or counties within the service area of a licensed hospice program are not being served.
- That there are persons referred to hospice programs who are not being admitted within 48 hours (excluding cases where a later admission date has been requested). The applicant shall indicate the number of such persons.

Preferences for a new hospice program; the agency shall give preference to an applicant meeting one or more of the criteria as specified:

- Preference shall be given to an applicant who has a commitment to serve populations with unmet needs.
- Preference shall be given to an applicant who proposes to provide the inpatient care component of the hospice program through contractual arrangements with existing health care facilities, unless the applicant demonstrates a more cost-efficient alternative.
- Preference shall be given to an applicant who has a commitment to serve patients who do not have primary caregivers at home; the homeless; and patients with AIDS.
- In the case of proposals for a hospice service area comprised of three or more counties, preference shall be given to an applicant who has a commitment to establish a physical presence in an underserved county or counties.
- Preference shall be given to an applicant who proposes to provide services that are not specifically covered by private insurance, Medicaid, or Medicare.

An applicant for a new hospice program shall provide evidence in the application that the proposal is consistent with the needs of the community and other criteria contained in local health council plans and the State Health Plan. The application for a new hospice program shall include letters from health organizations, social services organizations, and other entities within the proposed service area that endorse the applicant's development of a hospice program.

An applicant for a new hospice program shall provide a detailed program description in its certificate of need application, including:

- Proposed staffing, including use of volunteers.
- Expected sources of patient referrals.
- Projected number of admissions, by payer type, including Medicare, Medicaid, private insurance, self-pay, and indigent care patients for the first 2 years of operation.

- Projected number of admissions, by type of terminal illness, for the first 2 years of operation.
- Projected number of admissions by two age groups, under 65 and 65 or older, for the first 2 years of operation.
- Identification of the services that will be provided directly by hospice staff, volunteers, and those that will be provided through contractual arrangements.
- Proposed arrangements for providing inpatient care (e.g., construction of a freestanding inpatient hospice facility; contractual arrangements for dedicated or renovated space in hospitals or nursing homes).
- Proposed number of inpatient beds that will be located in a freestanding inpatient hospice facility, in hospitals, and in nursing homes.
- Circumstances under which a patient would be admitted to an inpatient bed.
- Provisions for serving persons without primary caregivers at home.
- Arrangements for the provision of bereavement services.
- Proposed community education activities concerning hospice programs.
- Fundraising activities.

The agency will not normally approve a proposal for construction of a freestanding inpatient hospice facility unless the applicant demonstrates that the freestanding facility will be more cost-efficient than contractual arrangements with existing hospitals or nursing homes in the service area. The application shall include the following:

Each hospice program shall report utilization information to the agency or its designee on or before July 20 of each year and January 20 of the following year. The July report shall indicate the number of new patients admitted during the 6-month period composed of the first and second quarters of the current year, the census on the first day of each month included in the report, and the number of patient days of care provided during the reporting period. The January report shall indicate the number of new patients admitted during the 6-month period composed of the third and fourth quarters of the prior year, the census on the first day of each month included in the report, and the number of patient days of care provided during the reporting period.

Certificate of Need

The Certificate of Need program is a regulatory process that requires certain health care providers to obtain state approval from the Agency of Health Care Administration before offering new or expanded services or making major capital expenditures. For example, a certificate of need would be required if a hospital requests to increase its bed capacity or proposes to initiate certain specialized services.

Federal legislation, the National Health Planning and Resource Development Act, primarily dictated state CON laws from 1974-1986. The original intent of the Federal CON laws was to restrain

skyrocketing health care costs, prevent the unnecessary duplication of health resources and achieve equal access to quality health care at a reasonable cost. With the creation of Medicare prospective payment in 1984 and the emergence of managed care, there has been a national trend toward significantly reducing CON or eliminating it altogether. Federal health planning legislation was abolished in 1986 with each state delegated the determination of whether to have a CON program. A report from the American Health Planning Association, published in 2001 shows that currently 15 states have no CON review. Florida ranks 27th in the nation as it pertains to CON regulation, with the number one state being the most restrictive.

The origin of CON in Florida parallels other states' similar laws, originating from local community efforts to allocate philanthropic and federal funding. Florida's first CON laws were part of the Health Facilities and Health Services Planning Act, passed just one year before the effective date of the Congressional mandate. In 1972, Florida was one of the first states to enact Certificate of Need requirements preceding the federal CON mandates of 1974. Florida CON laws were created to bring health care costs under control by preventing certain designated health care facilities from expanding unnecessarily, buying duplicative or unneeded costly equipment, or creating duplicative or unnecessary services. As well, CON laws intended to ensure quality of clinical care by limiting the number of providers performing certain complex medical procedures and thereby assuring clinician proficiency. Additionally, the CON process intended to evaluate impact of new providers on existing providers as well as support more cost-effective ways to provide health services. In short, CON was intended to assure citizens reasonable access to quality health care at a reasonable cost and to ensure that major expenditures and new services proposed by health care providers are needed for quality patient care within a particular region or community.

Sections 408.034 - 408.0455, F.S., designate the Agency for Health Care Administration as the single state agency to issue, revoke, or deny certificates of need. The issuance of the certificate of need predicates licensure requirements as provided under chapters 393, 395, and parts of chapter 400, F.S. It also requires that diagnostic cardiac catheterization service providers be subject to review. This section defines and establishes the application process, establishes fees, provides for conditions and monitoring once the CON is issued and related penalties for non-compliance; limits transfer; provides for special provisions for osteopathic acute care hospital, hospices, rural health networks; defines the certificate of need competitive sealed proposals; and establishes rules for pending proceedings.

The Auditor General's Report, November 2000, The *Certificate of Need and Public Medical Assistance Assessments Programs, Agency for Health Care Administration, Operational Audit* reports: that "ACHA had not diligently pursued the receipt of required reports, thereby limiting management's ability to timely evaluate: (1) whether providers adhered to the service conditions stipulated on issued Certificates of Need and related statutorily mandated fines should be imposed; and (2) whether project costs were within the budgets set forth in the applications for the Certificate of Need."

In 2000, the Florida Legislature established the Florida Commission on Excellence in Health Care to facilitate the development of a comprehensive statewide strategy for improving the health care delivery system through meaningful reporting standards, data collection and review, and quality measurement. As it relates to the CON process, the Commission recommended that: "the legislature should retain certificate of need regulations until after such time as systems for reporting useful clinical outcome data allowing consumers to analyze and choose between existing health care practitioners and providers are implemented".

The CON application files, which contain clinical outcome data, are open to the public and mainly utilized by health care consultants, attorneys and policy decision-making industry representatives. In addition, the office of CON within the Agency for Health Care Administration publishes a report

twice a year with hospital utilization information, one of the only sources of this compilation of this data statewide.

Statutory Revisions to CON 2000

Increases in Licensed Bed Capacity - As of July 2000, an exemption was created so that a proposed increase of up to 10 beds or 10 percent of a hospital's licensed capacity for acute care, mental health services, or hospital based SNU (skilled nursing unit) beds are not subject to review; and conditionally granted exemptions specify the necessity of maintaining a predetermined occupancy level and may require meeting other conditions. Previously, all projects proposing an increase in the licensed bed capacity of a hospital or nursing home were subject to CON review.

Establishment of a Medicare Certified Home Health Agency - As of July 2000, there is no CON review of proposed Medicare certified home health agencies, and no exemption is required. Prior to the implementation of the "Patient Protection Act of 2000", proposed establishment of a Medicare certified home health agency was subject to CON review with exemptions possible for certain types of providers.

Cost Overruns - As of July 2000, there is no CON review of cost overruns, and no exemption is required. Previously, increases in the cost of an approved project were subject to CON review if the increase exceeded specific thresholds.

Statutory Revisions in 1987 – 1997 to CON:

Obstetric services – From October 1987 to present, proposals for OB services are exempt unless the total licensed bed capacity of the hospital increases. Before legislative action in 1987, proposals to initiate or expand obstetric services were reviewable.

Outpatient services -- From October 1987 to present, proposals for exclusively outpatient services were excluded from certificate of need review, regardless of the dollar amount involved. Before legislative action in 1987, there was not any exclusion for outpatient capital expenditures and these expenditures were subject to review.

Tertiary services – From October 1987 to present, specified tertiary services are reviewable. A rule promulgated in 1988 specifies a list of tertiary services, including organ transplantation; specialty burn units; neonatal intensive care units (Level II and Level III); comprehensive medical rehabilitation; adult open heart surgery; neonatal and pediatric cardiac and vascular surgery; and pediatric oncology and hematology.

Capital expenditure threshold - From July 1997 to present, no project is reviewable based solely on the amount of capital expenditure proposed. From October 1987 through June 1997, capital expenditures of $1 million or more for inpatient services were subject to CON review, unless new or expanded beds or services were proposed, and the agency adjusted the $1 million threshold annually for inflation. Prior to October 1987, the threshold for review of a proposed capital expenditure was $600,000.

Major medical equipment - From July 1997 to present, acquisition of medical equipment, regardless of cost, is not reviewable. From October 1987 through June 1997, the amended definition of major medical equipment is that of equipment costing more than $1 million and which the United States Food and Drug Administration (FDA) approve for less than 3 years required review. The agency adjusted the $1 million threshold annually for inflation. Prior to October 1987,

major medical equipment was defined as equipment used to provide health services and costing more than $400,000.

Applicable CON fees required - From 1991 to present, the base fee for a CON application has been $5,000, plus 0.015 of each dollar of proposed capital expenditure, with the total not to exceed $22,000. In 1989, the ceiling amount to the CON application fee was increased from $9,500 to $10,000. While in the previous year, October 1987, a revision to the structure occurred to a base fee of $750, plus 0.006 of each dollar of proposed capital expenditure, with the total not to exceed $9,500. Prior to October 1987, the fee for processing a CON application was calculated with a base fee of $500, plus 0.004 of each dollar of proposed capital expenditure, with the total fee not to exceed $4,000.

The Agency for Health Care Administration Long Range Program Plan for FY 2001-2002 to 2005-2006 proposes that "elimination of unnecessary health facility regulation will play an important role in the Governor's and Legislature's initiatives to improve the business climate in Florida and streamline government operations. Certificates of Need, once considered mandatory for the control of both public and private health care cost in nursing facilities, hospital and home health agencies, have increasingly come to be viewed as overly restrictive deterrents to healthy competition among providers". The agency expresses two major concerns:

- The CON review has been used to give what is perceived as necessary preferences to safety net providers; and
- To control the supply of nursing home beds in order to manage the demand of services from Medicaid Recipients, thereby reducing expenditures to the Medicaid budget.

In May 1998, the Florida Community Hospitals Association published a study to review the history of the CON review process and identified current arguments for the deregulating of CON. The study suggested the consideration of the following:

- Does continued regulation create barriers to the development of managed care?
- Are market forces sufficiently in place to control excess investment, price, and utilization?
- Would market forces sufficiently ensure equitable coverage of indigent care?
- Eliminating the CON process may adversely affect quality of care.
- Would elimination of CON result in excess service capacity?

Various CON **proponents** believe that since government is the number one payer of all health services, it has a right to expect regulatory oversight to focus at a minimum on those services still paid on a fee-for-service basis, lack quality of care standards, are subject to over-utilization, or for quality purposes should be regionalized. A 1996 Dartmouth Atlas on Health Care comprehensive study of our nation's health care system reports that no other competitive industry depends so much on government for its funding and concluded that free enterprise does not exist in the health care industry. The author of the study, Veazey, believes that CON contributes to the preservation of quality services in programs such as open heart surgery, angioplasty, and neonatal intensive care by promoting a concentration of skilled staffs and preventing the proliferation of low volume programs. "Practice makes perfect: higher volumes result in higher quality and lower mortality". Additionally, according to Veazey, CON can help assure financial viability for safety net hospitals by reducing the threat from "cream-skimming" investor owned hospitals and ambulatory care centers.

Opponents of CON most often cite the movement toward a more competitive marketplace as the rationale to dismantle CON. In a recent article from T*he Journal of the James Madison Institute,* Winter 2001, argues that in the 1990s, the manner of paying for medical care is moving rapidly toward prospective market-based capitation payment methods (i.e., managed care). Increasingly,

hospitals and doctors are competing for contracts to provide a full range of services in exchange for a negotiated fixed payment. This payment method makes it less likely that the creation of excess hospitals and services will occur, thereby eliminating the possibility that additional cost to the public is passed on to maintain these services. In citing this theory, proponents of deregulation often recognize that even in a more competitive environment, quality and access to health care services for all citizens is of utmost concern. Thus, even among proponents of deregulation, there is a belief there is a need to strengthen licensure oversight to assure access and quality of health care.

Many local **industry proponents** argue that fees associated with the CON review process are exorbitant and prohibitive in a competitive marketplace. Beginning with the letter of intent required by the Agency for Health Care Administration prior to the submission of an application, health care facilities routinely hire health planners, certified public accounts, and consultants. The CON application is reviewed in a batch cycle process, and once the Agency has made a determination, both competitive health care facilities and the actual applicant can challenge the outcome of the CON review process. Industry representatives argue that the majority of application determinations challenged in the Administrative Hearing process is too lengthy. After the submission of a formal challenge, the case is assigned a hearing officer with a scheduled hearing date, which may be months into the future. After the hearing process, each party involved in the case proposes a recommended order to the Administrative Law Judge. After careful consideration, the Administrative Law Judge then issues a recommended order to the Agency; all parties have a right to file an exception to the recommended order. Subsequently, the Agency issues a final order, and again all parties involved have the right to appeal the final order with the regional District Court of Appeals. The appellate process is lengthy, costly and time consuming to the applicant and the Agency.

Local Health Planning Councils

Section 408.033, F.S., establishes eleven District Local Health Councils to develop strategies and set priorities for implementation of health care services based on each district's unique need. The members of each council are appointed in an equitable manner by the county commission having jurisdiction in the respective district. The local health councils are statutorily responsible for advising the Agency for Health Care Administration on health issues and local resources available, promote public awareness of community health needs, collect data and conduct analyses and studies related to health care needs. Local health planning councils also monitor the health care needs of the medically indigent, the on-site construction progress of certificate of need approved projects, address the health goals and policies of the State Comprehensive Plan, and advise and assist local governments within each district on the development of optional health plan elements. Subsection (2) of section 408.033, F.S., provides that the cost of local health councils be borne by the application fees for certificate of need and by assessments on selected health facilities subject to facility licensure review. Fees and assessments deposited in the Health Care Trust Fund, added with federal funding, create a $13 million current cash balance of fiscal year 2000-2001. For the same fiscal year, approximately $1.58 million in CON application fees have been transferred to the Department of Health for operating the health councils with an additional $677,000 from assessment fees. The remaining CON application fee revenues: $1.858 million, stayed in the Agency for Health Care Administration to administer the Healthy Facilities and Services Development Act (CON review process).

The Agency for Health Care Administration assesses selected health care facilities subject to licensure by the Agency including abortion clinics, assisted living facilities, ambulatory surgical centers, birthing centers, clinical laboratories, home health agencies, hospices, hospitals, Intermediate Care Facilities for the Developmentally Disabled, nursing homes, multiphasic testing centers, including health maintenance organizations and prepaid health clinics. Licensed hospitals

and nursing homes are assessed an annual fee based on number of beds, not to exceed $500; while all other facilities and organizations licensed by the Agency are assess an annual fee of $150. Exemptions from assessment fees include statutorily defined rural hospitals, facilities operated by the Department of Children and Families, Department of Health and the Department of Corrections. All health care facility assessments and proceeds from the application of Certificate of Needs are deposited in the Health Care Trust Fund by the Agency in an amount to maintain aggregate funding for local Health Councils. In addition, Local Health Councils receive grant monies and reimbursed from federal funds provided to the state for specific activities performed by the Health Councils through the Health Care Trust Fund.

Subsection (3) of section 408.033, F.S., provides that the local health planning councils in conjunction with the Agency coordinate planning of health services in the state.

C. EFFECT OF PROPOSED CHANGES

Hospital Licensure

HB 771 substantially increases licensing requirement for hospitals proposing to provide tertiary health care services. Provisions of this bill require specific facility design, service availability, and staffing requirements, much like current requirements for a CON, without the component of need determination. Other provisions of this bill authorize ACHA to develop rules providing for facility modification by facility for service volume requirements.

The bill requires that health facilities must commit to at least 15% of patient days to Medicaid and charity care patient and authorizes the agency to develop rules providing for modification to levels specific to facilities.

This bill provides a Grandfather Clause for facilities with a valid CON to provide tertiary care service, and allows such facilities the opportunity to apply for re-licensure within three months. The grandfather Clause further authorizes such facilities the ability to continue to operate until the agency takes final action on the renewal licensure application.

Nursing Home Licensure

ACHA is statutorily required to allow “any willing provider” to participate in the Medicaid program. This combined with the continually increasing age of the state’s population and the comparatively low rate of nursing home beds available per 1,000 people over sixty-five, raise concerns that by completely repealing CON, there will be a possible increase strain on the Medicaid budget.

The provisions of HB 771 require nursing homes applying for licensure to project financial feasibility and stipulates that a licensed nursing home that has received a CON before July 1, 2001 requiring a specified minimum level of service to Medicaid, indigent, or charity care patients to continue to provide the same level of service. HB 771 requires that the Agency monitor for compliance with all requirements for nursing licensure.

In addition, HB 771 allows the Agency, for good cause; to modify the minimum required service level commitments to Medicaid and Indigent Care patients. As stipulated in HB 771, a nursing home found in non-compliance with the requirements of this bill is subject to penalties imposed by the Agency as provided in section 400.121, Florida Statues, which include either denial, suspension, revocation of license or may include a moratorium on admissions, or administrative fines.

Hospice Licensure

HB 771 requires each Hospice applying for initial licensure and renewal of license to submit financial projection, purporting financial feasibility. In addition, HB 771 stipulates that only the facility applying for licensure has cause for action against final ruling for licensure activity by the Agency; eliminating cost and fees associated with competitive facilities challenging a final order.

In addition, HB 771 removes the requirements that hospices must show proof of a valid certificate of need prior to the issuance of a license. Requires that the applicant hospice must certify it will license and operate the hospice. In addition, the bill requires that the Agency implement an expedited license application process for community-based hospice service.

Certificate of Need

HB 771 effectively eliminates the Certificate of Need regulatory process that requires certain health care providers to obtain state approval from the Agency of Health Care Administration before offering new or expanded services or making major capital expenditures. The expected result of the bill is to restrain health care cost by allowing a competitive marketplace to dictate price and force the health care community to compete on price and quality of service to the consumer, as found in other previously regulated industries.

In addition, this bill removes the statutory authority for the requirement of a certificate of need for bond validation and construction projects. Some opponents of CON deregulation argue that the repeal of the CON review process will destabilize the current bond market.

Health Planning Councils

The Certificate of Need application fees and assessment on facilities provide the state funding for the eleven Health Planning Council Districts in Florida. HB 771 repeals the statutory requirement of the CON review process, thereby eliminating the CON application fees. Although this bill does not diminish the statutory authority of the eleven Health Planning Councils, 95% of their funding is eliminated without consideration given to an alternate funding source. Each of the eleven districts receive $150,000 annually, collectively $1.65 million from the Health Care Trust Fund.

The degree of each council's actual operating budget differs from district to district, greatly depending on the Council's ability to secure local, federal and private funding. Each Health Planning council is charged with providing local community support in the areas of health planning, data collection and the development of cost-effective, innovative medical programs, such as the statewide AIDS Insurance Continuation program administered by District 11: Health Council of South Florida. District 11 estimates that this program alone has saved the State of Florida an estimated $111 million over the past 5 years by providing payment of health care premiums, reducing the need of AIDS patient's need for publicly, state-funded medical assistance.

D. SECTION-BY-SECTION ANALYSIS:

Section 1. Amends subsection (1) of s. 395.022, Florida Statutes, creating statutory **definitions for:** Acute Detoxification Services; Adolescent; Adult; Bone Marrow Transplantation; Burn Team; Burn Unit; Cardiac Catheterization; Cardiac Catheterization Program; Complex Neonatal Surgery; Comprehensive Medical Rehabilitation Inpatient Services; Coronary Angioplasty; Inactive License;

Level II Neonatal Intensive Care Unit (NICU) bed; Level III Neonatal Intensive Care Unit (NICU) bed; Neonatal Care Services: a) Level I neonatal services; b) Level II neonatal intensive care services; c) Level III neonatal intensive care services; Maternal-fetal Medical Specialist; Neonatologist; Open Heart Surgery Operation; Organs; Pediatric Patient; Psychiatric Disorder; Psychiatric Inpatient Services; Research Hospital; Research Program; Substance Abuse Disorder; Substance Abuse Inpatient Services; Teaching Hospital; Temporary License; Tertiary Health Service; and Transplantation Program.

Section 2. Amends section 395.003(9), F.S., preventing any other person from challenging the issuance of a license of a hospital, ambulatory surgical center, or mobile surgical center or any other action requiring licensure authority. Specifies **only the applicant is entitled to an administrative hearing.**

Section 3. Adds section 395.0095, Florida Statues, creating **minimum standards for specialized inpatient services** provided by a hospital in order to be licensed. In addition, specifies that all specialized services shall be separately listed on license which include:

- Cardiac Catheterization / Licenses specifies adults or children
- Open Heart Surgery / Licenses specifies adults or children
- Comprehensive Medical Rehabilitation Services / License specifies number of beds dedicated
- Psychiatric Inpatient Services / License specifies adult or children
- Substance Abuse Inpatient Services / License specifies adults or children, and number of beds dedicated for adults or children
- Neonatal Intensive Care Services:
  - Level I / License specifies number of beds dedicated
  - Level II /License specifies number of beds dedicated
  - Level III / Licenses specifies number of beds dedicated
- Burn Units / Licenses specifies numbers of beds dedicated
- Heart Transplantation / License specifies adult or children
- Liver Transplantation / License specifies adult or children
- Kidney Transplantation / License specifies adults or children
- Bone Marrow Transplantation / License specifies adults or children

Adds subsection (2), 395.0095, Florida Statutes, creating specifications for a **Cardiac Catheterization Program.** Each cardiac catheterization program shall be capable of providing immediate endocardiac catheter pacemaking in cases of cardiac arrest or heart failure, and pressure recording for monitoring and evaluating valvular disease. Each cardiac catheterization program shall provide range of noninvasive cardiac or circulatory diagnostic services within the hospital itself, including: Hematology studies or coagulation studies; Electrocardiography; Chest X-ray; Blood gas studies; Clinical pathology studies and blood chemistry analysis. At a minimum, each cardiac catheterization program shall include: A special procedure X-ray room; film storage and darkroom for proper processing of films; X-ray equipment with the capability in cineangiocardiography, or equipment with similar capabilities. An automatic injector; diagnostic X-ray examination table for special procedures; an electrocardiograph; a blood gas analyzer; a multichannel polygraph. Emergency equipment, including, at a minimum, a temporary pacemaker unit with catheters, ventilitory assistance devices, and a direct current defibrillator.

Each cardiac catheterization program must have the capability of rapid mobilization of the study team within 30 minutes for emergency procedures, 24 hours a day, 7 days a week.

Each cardiac catheterization program shall provide a **minimum of 300 catheterizations annually.**

Each hospital providing cardiac catheterization **must be accredited by the Joint Commission on Accreditation of Health Care Organizations (JCAHO)** for special care units, or be accredited by the **American Osteopathic Association.**

Each hospital providing a cardiac catheterization program shall have the **following staff** available: a program director, board-certified or board-eligible in internal medicine or in radiology with subspecialty training in cardiology or cardiovascular radiology. The program director for programs performing pediatric cardiac catheterization shall be board-eligible or board-certified by the Sub-Board of Pediatric Cardiology of the American Board of Pediatrics or the American Osteopathic Association in the area of pediatric cardiology.

Each cardiac catheterization program must have a physician, board-certified or board-eligible in cardiology or radiology, or with specialized training in cardiac catheterization and angiographic techniques, who will perform the examination. They must also provide support staff, specially trained in critical care of cardiac patients, with knowledge of cardiovascular medication and an understanding of catheterization and angiographic equipment. The program must have support staff 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. Each cardiac catheterization program must have support staff for patient observation, handling of blood samples, and performing blood gas evaluation calculations; support staff for monitoring physiologic data and alerting the physician of any changes. As well as, support staff to perform systematic tests and routine maintenance on cardiac catheterization equipment, which must be available immediately in the event of equipment failure during a procedure; and support staff trained in photographic processing and in the operation of automatic processors used for both sheet and cine film. Each program must have a medical review committee that reviews medical invasive procedures such as endoscopy and cardiac catheterization. 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 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. 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. Pediatric cardiac catheterization programs must be located in a hospital in which pediatric open heart surgery is being performed.

Adds subsection (3), 395.0095, Florida Statutes, creating requirements for **Open Heart Surgery** Program. 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: repair or replacement of heart valves; repair of congenital heart defects; cardiac revascularization; repair or reconstruction of intrathoracic vessels; and treatment of cardiac trauma.

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.

Each hospital with an open heart surgery program shall provide the following services: cardiology, hematology, nephrology, pulmonary medicine, and treatment of infectious diseases.

Each open heart surgery program must have pathology, including anatomical, clinical, blood bank, and coagulation laboratory services; anesthesiology, including respiratory therapy; radiology, including diagnostic nuclear medicine; neurology; inpatient cardiac catheterization; noninvasive cardiographics, including electrocardiography, exercise stress testing, and echocardiography; and intensive care. In addition, each open heart surgery program must have emergency care available

24 hours per day for cardiac emergencies. Each open heart surgery program shall be available for elective open heart operations 8 hours per day, 5 days a 12 week. Each open heart surgery program shall possess the capability for rapid mobilization of the surgical and medical support teams for emergency cases, 24 hours per day, 7 days a week.

Open heart surgery shall be available for emergency open heart surgery operations within a maximum waiting period of 2 hours.

Open heart surgery shall be available to all persons in need. A patient's eligibility for open heart surgery is independent of his or her ability to pay.

Each hospital providing an open heart surgery program must be **accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)** for special care units, or be accredited by the **American Osteopathic Association.**

Each hospital providing open heart surgery must document that adequate numbers of properly trained personnel shall be available to perform in the following capacities during open heart surgery:

- Cardiovascular surgeon, board-certified by the American Board of Thoracic Surgery, or board-eligible;
- Physician to assist the operating surgeon;
- Board-certified or board-eligible anesthesiologist trained in open heart surgery;
- Registered nurse or certified operating room technician trained to serve in open heart surgery operations and perform circulating duties;
- Perfusionist to perform extracorporeal perfusion, or
- Physician or a specially trained nurse, technician, or physician assistant under the supervision of the operating surgeon to operate the heart-lung machine.

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 members of the team caring for cardiovascular surgical patients must be proficient in cardiopulmonary resuscitation. Each open heart surgery program shall provide a minimum of 250 open heart surgeries annually.

Adds **subsection (4), 395.0095, Florida Statutes,** creating requirements for **Comprehensive Medical Rehabilitation Services Program.**

Each specialty hospital providing comprehensive medical rehabilitation inpatient services shall have a **minimum total capacity of 40 beds.** Each general hospital providing comprehensive medical rehabilitation inpatient services shall have a minimum of 20 comprehensive medical rehabilitation beds.

Each hospital providing comprehensive medical rehabilitation inpatient beds shall participate in the Medicare and Medicaid programs.

Comprehensive medical rehabilitation inpatient services must be provided under a medical director of rehabilitation who is a board-certified or board-eligible physiatrist with at least 2 years of experience in the medical management of inpatients requiring rehabilitation services. In addition to the required physician services, comprehensive medical rehabilitation inpatient services shall include at least the following provided by qualified personnel: rehabilitation nursing; physical therapy; occupational therapy; speech therapy; social services; psychological services; orthotic and prosthetic services.

Each hospital providing comprehensive medical rehabilitation inpatient services shall be **accredited by the Commission on Accreditation of Rehabilitation Facilities** consistent with the standards applicable to comprehensive inpatient rehabilitation or specialized inpatient rehabilitation, as applicable to the facility.

Adds subsection (5), 395.0095, Florida Statutes, creating requirements for **Psychiatric Inpatient Service Program.**

Admission to hospital units providing psychiatric inpatient services is limited to persons whose sole diagnosis, in the event of more than one diagnosis, whose principal diagnosis, as defined in the Diagnostic and Statistical Manual of Mental Disorders, is a disorder coded in any sub-classification of category 290 or coded in any sub-classification of categories 293 through 302 or coded in any sub-classification 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, incorporated herein by reference; or equivalent codes in the sub-classifications in the International Classification of Disease, incorporated herein by reference: category 290, category 293 through 302, or category 306 through 316. Psychiatric patients in need of medical or surgical care may be treated in acute care medical or surgical beds for their medical or surgical care needs or in a psychiatric services unit if the unit is properly staffed and equipped to care for the medical or surgical problem.

Each specialty hospital providing psychiatric inpatient services, or each intensive residential treatment program for children and adolescents licensed as a specialty hospital, shall have a **minimum total capacity of 25 beds**. The minimum capacity of a specialty hospital providing psychiatric inpatient services may include beds used for substance abuse inpatient services.

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, and discharge planning, and referral services.

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.**

As required by s. 394.4785(2), F.S., 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.

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.

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.

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.

Adds subsection **(6), 395.0095, Florida Statutes**, creating requirements for **Substance Abuse Inpatient Services Program.**

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. Beds used for acute detoxification services in general hospitals shall be considered a subset of the total number of general acute care beds.

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.

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. 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.

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.

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.

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.

Adds **subsection (7), 395.0095, Florida Statutes**, creating requirements for **Neonatal Intensive Care Services Programs:**

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.

Each hospital providing Level II or Level III neonatal intensive care services shall ensure developmental follow-up on patients after discharge to monitor the outcome of care and assure necessary referrals to community resources.

Each hospital providing Level III neonatal 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.** 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.

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.

Level II neonatal intensive care services must be **directed by a Neonatologist or a group of Neonatologist** 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.

Level III neonatal intensive care services shall be directed by a Neonatologist or a group of Neonatologist 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.

The **nursing staff i**n 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 cardio respiratory monitoring, assist in ventilation, administer intravenous 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. 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.

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.

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 micro studies.

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.

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.

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.

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. 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.** 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. 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**. A hospital providing only Level II neonatal 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 onset 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.

All neonates of 1,000 grams birth weight or less 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.

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.

Adds **subsection (8), 395.0095, Florida Statutes,** creating requirements for **Burn Unit Programs.** 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.

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.

Burn unit services shall be available on a 24-hour, 7-days-a-week, basis.

Each hospital with a licensed burn unit shall have the following **staff available**: A medical director who is board-certified or board-eligible in general or plastic surgery with at least 2 years of experience in the management of burn patients; one full-time registered nurse with 2 years' intensive care or equivalent experience; a full-time physical therapist with training in the management of burn patients. Surgical support personnel shall be available for consultation as needed in the following surgical specialties: Cardiothoracic; Neurologic; Obstetrics-gynecologic; Ophthalmic; Oral; Orthopedic; Otorhinolaryngologic; Pediatric; Plastic; and Urologic.

Each hospital with a licensed burn unit shall have the following nonsurgical **support personnel** available, as needed, for consultation in the following specialties: Anesthesiology; Cardiology.; Emergency medicine; Gastroenterology; Hematology; Infectious disease; Internal medicine; Nephrology; Neurology; Nutrition; Occupational therapy; Pathology; Pediatrics; Psychiatry or psychology; Pulmonary; Radiology; and Respiratory therapy;

Each hospital providing burn unit services shall be accredited by the J**oint Commission on Accreditation of Health Care Organizations** consistent with the standards applicable to providing burn unit services.

Adds **subsection (9), 395.0095, Florida Statutes,** creating requirements for **Organ Transplantation Programs.**

Each hospital with a licensed transplantation program, regardless of the type of transplantation program, shall have: Staff and other resources necessary to care for the patient's chronic illness prior to transplantation, during transplantation, and in the postoperative period. Services and facilities for inpatient and outpatient care shall be **available on a 24-hour basis.**

If cadaveric transplantation will be part of the transplantation program, a written agreement with an organ acquisition center for organ procurement is required. A system by which 24-hour call can be maintained for assessment, management, and retrieval of all referred donors, cadaver 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. An age-appropriate, adult or pediatric intensive care unit that includes facilities for prolonged reverse isolation when required. A clinical review committee for evaluation and decision-making regarding the suitability of a candidate for transplantation. 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 pre-hospital, in-hospital, and immediate post

discharge phases of the program. Detailed therapeutic and evaluative procedures for the acute and long-term management of each transplantation program patient, including the management of commonly encountered complications. 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. 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. Pathology services with the capability of studying and promptly reporting the patient's response to the organ transplantation surgery and analyzing appropriate biopsy material.

Each hospital with a licensed transplantation program, regardless of the type of transplantation program: blood banking facilities. A program for the education and training of staff regarding the special care off transplantation patients. Education programs for patients and their families, and the patient's primary care physician, regarding aftercare for transplantation patients.

Each hospital with a licensed transplantation program, regardless of the type of transplantation program, must have: 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.

Each hospital with a licensed transplantation program must have a program director that has 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.

Each hospital with a licensed for **pediatric transplantations** must have **staff with experience in the special needs of children.** Specialized staff must consist of nurses and nurse practitioners with experience in the care of chronically ill patients and their families. 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. Nutritionists with expertise in the nutritional needs of transplant patients. Respiratory therapists with expertise in the needs of transplant patients. 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.

Each hospital with a licensed heart transplantation program, in addition to meeting the above mentioned requirements, the program must have the following program personnel and services: 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; an anesthesiologist experienced in both open heart surgery and heart transplantation; and one-bed isolation room in an age-appropriate intensive care unit.

Each hospital with a **licensed liver transplantation program, in addition to meeting the prior described requirements must 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: A department of gastroenterology, including clinics, and adequately equipped procedure rooms; radiology services to provide complex biliary

procedures, including transhepathic cholangiography, portal venography, and arteriography; 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.

A patient convalescent unit for further monitoring of patient progress for approximately 1 month after hospital discharge following liver transplantation. Staff for liver transplantation programs shall be trained in the care of patients with hepatic diseases and liver transplantation.

Each hospital with a **licensed kidney transplantation program** shall provide: renal dialysis, and preoperative and postoperative 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. Outpatient services, including renal dialysis services and ambulatory renal clinic services. Ancillary services, including pre-dialysis, dialysis, and post transplantation 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.

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. 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. 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. 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. A laboratory with the capability of performing and promptly reporting bacteriologic, biochemical, and pathologic analysis. An anesthesiologist experienced in kidney transplantation.

Each licensed **pediatric kidney transplantation program** shall have: a medical director who is sub-board-certified or sub-board-eligible in pediatric nephrology. A dialysis unit head nurse with special training and expertise in pediatric dialysis. Nurse staffing at a nurse-to-patient ratio of 1:1 in the pediatric dialysis unit. A registered dietician with expertise in nutritional needs of children with chronic renal disease. A surgeon with experience in pediatric renal transplantation. A radiology service with specialized equipment for obtaining X-rays on pediatric patients. Education services, which shall include home and hospital programs to ensure minimal interruption in schooling.

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 hospital with a licensed **pediatric allogeneic or autologous transplantation program must perform at least 10 pediatric transplants each.** If both allogeneic and autologous pediatric transplants are performed, at least 10 of each shall be projected. Have a program director that 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. Have clinical nurses with experience in the care of critically ill immuno-suppressed patients. Nursing staff shall b e dedicated to the program full time. 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 follow-up care of the bone marrow transplantation patients, including the maintenance of

immunosuppressive therapy and treatment of complications. In addition, the program must have age-appropriate inpatient transplantation units for post transplant hospitalization. Post transplantation care must be provided in a laminar airflow 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. The program must 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.

Each hospital licensed for pediatric allogenic or autologous transplants must 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 follow-up. Have an established research-oriented oncology program. Additional requirements for each hospital with a licensed pediatric allogeneic transplantation program: 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. An onsite laboratory equipped for the evaluation and cryopreservation of bone marrow. An age-appropriate patient convalescent facility to provide a temporary residence setting for transplantation patients during the prolonged convalescence. An age-appropriate outpatient unit for close supervision of discharged patients.

Each hospital with a licensed adult allogeneic bone marrow transplantation program must be a **teaching or research hospital.**

Each such hospital must perform at least **10 adult allogeneic transplants each year.** The licensed hospital must have a program director that 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. Have clinical nurses with experience in the care of critically ill immuno-suppressed patients. Nursing staff shall be dedicated to the program full time. 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 follow-up care of the bone marrow transplantation patients, including the maintenance of immunosuppressive therapy and treatment of complications. Have inpatient transplantation units for post transplantation hospitalization. Post transplantation care must be provided in a laminar airflow 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. 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. 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. Have an onsite laboratory equipped for the evaluation and cryopreservation of bone marrow. 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 follow-up. Have an established research-oriented oncology

program. Have a patient convalescent facility to provide a temporary residence setting for transplant patients during the prolonged convalescence. Have an outpatient unit for close supervision of discharged patients.

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 must perform at least 10 adult autologous transplants each year. Each hospital with a **licensed adult autologous bone marrow transplantation program** have a program director that 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. Have clinical nurses with experience in the care of critically ill immuno-suppressed patients. Nursing staff shall be dedicated to the program full time. 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 follow-up care of the bone marrow transplantation patients. Have inpatient transplantation units for post transplant hospitalization. Post transplantation care must be provided in a laminar airflow 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. 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.

The licensed hospital must 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. Have an established research-oriented oncology program.

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.

Adds **subsection (10), 395.0095, Florida Statutes,** creating **requirements of services for low-income patients,** all facilities that has previously received CON shall continue to provide at least the required minimum levels of service to Medicaid, indigent or charity care. Agency can modify minimum required levels of service by rule.

Adds subsection **(11), 395.0095, Florida Statutes**, creating requirements for hospital applying for initial license. 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.

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.**

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. The agency shall, by rule, establish exemptions to the minimum annual percentage of service volumes required for hospital compliance. In establishing such standards, the agency shall give due consideration to any existing commitments and to clinical outcome data.

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.

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, not to exceed 1 year from the date of application for an initial or renewal license. Good cause includes the status of a hospital respecting these services; if approval before July 1, 2001, under the certificate-of-need program shall not, of itself, constitute good cause for a temporary exemption.

Adds **subsection (12), 395.0095, Florida Statues**, requiring that hospital applying for renewal license: 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, by rule, will define the factors constituting good cause for modification of previous commitments.

Adds **subsection (13), 395.0095, Florida Statutes**, creating Certification of compliance, each hospital licensed to provide services in this section shall **annually certify to the agency that it meets all the requirements. Misrepresentation of compliance is subject to penalties imposed by the agency as subscribed in section 395.003 (8).**

Adds **subsection (14), 395.0095, Florida Statutes**, stipulating that if facility is found in non-compliance, it is subject **to penalties as provided in subsection (8) of section 395.003, Florida Statutes.**

Section 4. Amends subsections (5) and (9) of section 400.017, Florida Statutes, and subsections (11) and (12) are added to said section.

Subsection (5), 400.017, Florida Statutes, requires that an application of **initial license for a nursing home** must contained a detailed **financial projection,** with revenues and expenses for the first 2 years of operation.

Subsection (9), 400.017, Florida Statutes, is amended, removing requirements that a license applicant must have a CON. As well, specifies that the intent of the legislature, that an applicant for license of a nursing home facility be given **preference** to those facilities who meet the performance standards for the '**Gold Seal**" award process as provided for in section 400.235, Florida Statutes.

Subsection (11), 400.017, Florida Statutes, is added, requiring that each licensed nursing home that received a CON before July 1, 2001, requiring a **specific level of service to Medicaid, indigent, or charity care patients** continue to provide at the least the previously required level of service and establishes that the Agency monitor compliance as part of certification activities.

The Agency may modify the minimum required levels of service to Medicaid, indigent, or charity patient days. During the initial licensing application, each **nursing home will affirm** that at least a **minimum percentage of annual patient days will be Medicaid, and charity care**. Each nursing home applying for renewal license must reaffirm or modify its commitments to annual service volume days to Medicaid and charity patient days. The provisions of this section authorize the Agency to establish rules for minimum annual percentages of service volumes. Each Nursing home shall annually certify to the agency that it has met the requirements. **A misrepresentation of compliance is subject to penalties** imposed by the Agency as provided by section 400.121, Florida Statutes. A nursing home found to be out of compliance with the requirements are subject to penalties imposed by the Agency as provided for in section 400.121, Florida Statutes.

The **applicant** for an initial license must certify that it **will license and operate the nursing home**.

Section 5. Adds subsection (3), 400.102, Florida Statutes; l**imiting administrative proceeding** concerning an application to license a **nursing home** to the applicant only. No other person may initiate or intervene in any action to determine license as it relates to the action by the Agency against licensee.

Section 6. Adds subsections (7), 400.121, Florida Statutes; **limiting administrative proceedings** concerning application for licensure of a **nursing home** to the applicant only. No other person may initiate or intervene in any action to determine license as it relates to the denial suspension, revocation of license, moratorium on admission, and administrative.

Subsection (8), 400.121, Florida Statutes, is added, providing that **failure to demonstrate financial** feasibility as required in section 400.071(5), Florida Statutes, is **subject to agency action** provided in this section.

Section 7. Amends paragraphs (c) of subsection (2) of section 400.605, Florida Statutes; requiring the Agency to implement an **expedited license** application process for **community-based hospice** services.

Section 8. Amends subsections (1), (5), (6) (7), and (8) of section 400.606, Florida Statutes; **removing reference to certificate of need;** requiring that an application for initial license of a hospice contained a detailed financial projection, including revenue and expense projections for the first two years of operation.

Deletes section 400.606(5), Florida Statutes, which allows a hospice that fails to receive a certificate of need to an administrative hearing.

Amends section 400.606(6), Florida Statutes, removing the requirement that a freestanding hospice primarily engaged in providing inpatient and related services must obtain a certificate of need and subsequently renumbers the subsection to reflect change in prior subsection.

Adds new section 400.606(6), Florida Statutes, **limiting administrative hearing on licensure for hospice to the applicant only.** No other person may initiate or intervene in any action to determine licensure.

Adds section 400.606(7), Florida Statutes, requiring that the **applicant for license must certify it will license and operate hospice.** For an existing hospice, the applicant must be the current license holder.

Adds section 400.606(8), Florida Statutes, mandating **that failure to demonstrate financial feasibility as required is subject to Agency action.**

Section 9. Repeals sections 154.245, 408.031, 408.034, 408.035, 408.036, 408.0361, 408.037, 408.038, 408.039, 408.040, 408.041, 408.042, 408.043, 408.044, 408.045, 408.0455, and 651.118, Florida Statutes, and subsections (2), (3), (4), (6), and (7) of section 408.032, Florida Statues, repealing the CON review process

Section 10. Amends paragraphs (b) and (c) of subsection (1), paragraphs (a) and (f) of subsection (2), and paragraph (b) of subsection (3) of section 408.033, F.S., removing all cross references to the CON as it relates to local health councils.

Section 11. Amends subsection (3) of section 20.42, Florida Statutes, removing cross-reference to the certificate of need program relating to the organizational structure of the Agency foe Health Care Administration.

Section 12. Amends subsection (4) of section 154.205, Florida Statutes, removing the definition of certificate of need from this section.

Section 13. Amends section 154.213, Florida Statutes, removing the requirement that a health facility needs a certificate of need in agreements of leases with public health facilities.

Section 14. Amends subsection (1) of section 154.219, Florida Statutes, removing the cross-reference for a health facility to have a certificate of need to issue revenue bonds to fund cost of projects for which a certificate of need has been obtained.

Section 15. Amends subsection (16) of section 159.27, Florida Statutes, removing cross references to statutes as it relates licensure of a nursing home and related health facilities when a certificate of need is obtained prior to the issuance of bonds.

Section 16. Amends subsection (3) of section 189.415, Florida Statutes, deleting the reference of a “certificate of need” and inserting “application for license” relating to a special district proposing to build, improve or expand a public facility which requires notification of such action to the local general purpose government entity for purposes of the special district public facilities report.

Section 17. Amends subsection (4) of section 383.50, Florida Statutes, by correcting statutory cross-references, reflecting the subsection additions to this act.

Section 18. Amends subsection (7) of section 394.48787, Florida Statutes, correcting changes in statutory cross-references amended by this act.

Section 19. Amends subsection (10) of section 395.0191, Florida Statutes, inserting "licenses" deleting "certificate of need" as it pertains to establishing proof of discrimination in the granting of or a denial of hospital staff membership or clinical privileges as a precondition to obtaining such license.

Section 20. Amends paragraph (h) of subsection (1) of section 395.1055, Florida Statutes, removing the requirement of hospitals to provided the agency for health care administration data required to conduct the certificate of need review.

Section 21. Amends paragraph © of subsection (2) of section 395.602, Florida Statutes, correcting the numbering of statutory cross references amended by this act.

Section 22. Amends subsection (1) of section 395.603, Florida Statutes, removing the requirement of rural hospital to maintain an inactive acute care bed inventory for the purposes of the ACHA's ability to determine need as it relates to the certificate of need review process.

Section 23. Amends subsection (1) of section 395.604, Florida Statutes, correcting the numbering of cross references amended by this act.

Section 24. Amends subsection (5) and (7) of section 395.605, Florida Statutes, removing all references of a rural hospital's ability to have an expedited certificate of need review when such facility proposes to provide emergency care. In addition, removes the exemption of an emergency care hospital seeking re-licensure expedited review. As well, it removes exemptions for emergency care hospital from the CON review process as it relates to home health and hospices services and for swing beds.

Section 25. Amends paragraph (c) of subsection (1) of section 395.701, Florida Statutes, correcting the numbering of statutory cross references amended by this act.

Section 26. Amends paragraph (b) of subsection (1) of section 400.051, Florida Statutes, correcting the numbering of statutory cross references amended by this act.

Section 27. Amends subsection (5) of section 400.23, Florida Statutes, removing the requirement the agency adopt rules which include a methodology for reviewing a nursing home facility governed under ss. 408.031-408.045, F.S., which are repealed by this act.

Section 28. Amends subsection (6), of section 400.602, Florida Statutes, eliminating the statutory requirement that an exempted for-profit hospice from obtaining a certificate of need for the allowed addition two hospices.

Section 29. Amends paragraph (b) of subsection (2) of section 400.6085, Florida Statutes, eliminating the clarifying language that a hospital contracting for hospice services does not need to obtain a certificate of need for hospices services, since CON is repealed by this act.

Section 30. Amends subsection (8) of section 409.905, Florida Statutes, by correcting the numbering of statutory cross-references amended by this act.

Section 31. Amends paragraph (b) of subsection (5) of section 430.705, Florida Statutes, by eliminating the reference to certificate of need as it relates the implementation of a of a long-term care community diversion project.

Section 32. Amends section 430.708, Florida Statutes, by eliminating the reference of certificate of need as it relates to the implementation of Medicaid community diversion pilot project.

Section 33. Amends paragraph (l) of subsection (1) of section 468.505, Florida Statutes, by correcting the numbering of statutory cross-references that are amended by this act.

Section 34. Amends paragraph (a) of subsection (2) of section 651.021, Florida Statutes, eliminating reference to certificate of need as it relates to the issuance of a certificate of authority in continuing care contracts.

Section 35. Amends section 766.316, Florida Statutes, by correcting the numbering of statutory cross-references amended by this act.

Section 36. Amends, the Laws of Florida, creating a **grandfather clause for health facilities that are currently licensed and have a valid CON prior to June 30, 2001.** Facilities that provide specialty services, i.e., bone marrow transplantation; burn units; cardiac catheterization programs, Level I, II, III, neonatology; comprehensive medical rehabilitation outpatient services; coronary angioplasty; open heart surgery; psychiatric inpatient services; substance abuse inpatient services; tertiary health services; and transplantation programs; will continued to be licensed after the effective date of this act. Such facilities shall apply to the Agency for health Care Administration by October 1, 2001 for re-licensure pursuant to the provisions of this act.

Section 37. Provides for an effective date of July 1, 2001.

III. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT:

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Department of Health

According to the Department of Health, elimination of the certificate of need program would result in an enormous funding shortfall for local health councils and the department. This analysis assumes that all health care facility assessment fees ($731,071) would be transferred to the department.

Agency for Health Care Administration /Repeal of CON

	Amount (FY 01-02)	**Amount (FY 02-03)**
Non-Recurring Impact		
Licenses	$0	$0
Fees	$(1,174,619)	$(1,174,619)
Grants	$0	$0

Transfers in / Another Agency	$0	$0
Subtotal Non-Recurring Revenues	**$(1,174,619)**	**$(1,174,619)**
Recurring Impact		
Licenses	$0	$0
Fees (loss of CON fee revenue)	$(1,401,995)	$(1,401,995)
Fees (loss of health Facility Assessment Fee)	$ (731,071)	$ (731,071)
Grants	$0	$0
Transfer In / Another Agency	$0	$0
Subtotal Recurring Revenues	**$(2,133,066)**	**$(2,133,066)**
Total Revenues	**$(3,307,685)**	**$(3,307,685)**

2. Expenditures:

Department of Health

Information provided by the Department of Health indicates that the three full time equivalent positions in the department that are funded from fees generated by certificate of need application fees and health care facility assessment fees would be impacted as well as the local health councils. Furthermore, the department analysis assumes that the assessment fees would continue to be transferred to the Department of Health.

Agency for Health Care Administration /Repeal of CON

	Amount (FY 01-02)	**Amount (FY 02-03)**
Non-Recurring Impact		
Licenses	$0	$0
Fees	$(1,174,619)	$(1,174,619)
Grants	$0	$0
Transfers in / Another Agency	$0	$0
Subtotal Non-Recurring Revenues	**$(1,174,619)**	**$(1,174,619)**
Recurring Impact		
Licenses	$0	$0
Fees (loss of CON fee revenue)	$(1,401,995)	$(1,401,995)
Fees (loss of health Facility Assessment Fee)	$ (731,071)	$ (731,071)
Grants	$0	$0
Transfer In / Another Agency	$0	$0
Subtotal Recurring Revenues	**$(2,133,066)**	**$(2,133,066)**
Total Revenues	**$(3,307,685)**	**$(3,307,685)**

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health Care Facilities

HB 771 eliminates up to $22,000 per health care facility of CON application fees. The bill will significantly reduce the cost of consulting fees and any attorney fees associated with the approval of an application for Certificate of Need. The actual dollar amount that will potential be saved by health care facilities cannot be determined at this time.

D. FISCAL COMMENTS:

The Agency's recommendations within their long range program plan, cites an estimated reduction in staff associated with the CON review to be as much as 18 position with a total reduction in expenditures of approximately $836,525 by FY 2005-06.

IV. CONSEQUENCES OF ARTICLE VII, SECTION 18 OF THE FLORIDA CONSTITUTION:

A. APPLICABILITY OF THE MANDATES PROVISION:

This bill does not require a city or county to expend funds or to take any action requiring the expenditures of funds.

B. REDUCTION OF REVENUE RAISING AUTHORITY:

This bill does not reduce the authority that municipalities or counties have to raise revenues in the aggregate.

C. REDUCTION OF STATE TAX SHARED WITH COUNTIES AND MUNICIPALITIES:

This bill does not reduce the percentage of a state tax shared with counties or municipalities.

V. COMMENTS:

A. CONSTITUTIONAL ISSUES:

None.

B. RULE-MAKING AUTHORITY:

This bill authorizes the Agency for Health Care Administration to adopt rules to implement provisions of this bill.

C. OTHER COMMENTS:

The current Florida legislative climate is toward minimizing unnecessary regulations and supporting market forces designed to gain operating efficiencies achieved in other previously regulated industries.

VI. AMENDMENTS OR COMMITTEE SUBSTITUTE CHANGES:

None.

VII. SIGNATURES:

COMMITTEE ON HEALTH REGULATION:

Prepared by:	Staff Director:
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