CHAMBER ACTION

The Committee on Health Care recommends the following:

Committee Substitute

Remove the entire bill and insert:

A bill to be entitled

An act relating to certificates of need; amending s. 395.003, F.S.; providing certain restrictions on the licensure of hospitals; providing exceptions; authorizing rulemaking; amending s. 408.032, F.S.; revising definitions; amending s. 408.033, F.S.; revising provisions relating to local health councils; deleting provisions relating to regional areas; revising funding provisions; making the Agency for Health Care Administration solely responsible for coordinated planning of health care services; transferring certain duties from the agency to the Department of Health; amending ss. 408.034 and 408.035, F.S., to conform; amending s. 408.036, F.S.; revising the list of projects subject to review; including beds in community nursing homes and intermediate care facilities for the developmentally disabled in project review requirements; including conversion from a general hospital to another form of hospital in project review requirements; revising the list

of projects subject to expedited review; revising the list of projects subject to exemption from review; specifying certain facility or provider notice requirements; amending s. 408.0361, F.S.; requiring the agency to adopt rules to develop licensing standards for cardiology services and burn units; providing criteria for such rules; requiring certain providers to comply with such rules; requiring the agency to include certain provisions in establishing the rules; requiring the agency to establish a technical advisory panel and adopt rules based on the panel's recommendations; requiring the secretary of the agency to appoint an advisory group; providing membership criteria for such group; requiring the group to make certain recommendations; requiring the secretary to appoint a workgroup; providing the components of such workgroup's assessment; requiring a report; amending s. 408.038, F.S.; providing for a higher application fee; amending s. 408.039, F.S.; specifying an annual review cycle; amending s. 408.040, F.S.; providing that failure to report compliance constitutes noncompliance; amending s. 408.043, F.S.; deleting special provisions relating to sole acute care hospitals in high-growth counties; amending s. 408.0455, F.S.; deleting an obsolete judicial or administrative abatement provision; providing an effective date.

WHEREAS, the Legislature finds that it is essential for the public health and safety of this state that general hospitals

providing emergency services be available in our communities, and

WHEREAS, the Legislature finds that a substantial number of hospitals have closed in this state and is concerned that more hospitals may close, and

WHEREAS, the Legislature finds the creation of hospitals with limited services will serve only paying patients and may cause harm to the existence of general hospitals serving broad populations, including the medically indigent of this state, and

WHEREAS, the Legislature finds that the creation of hospitals with limited services may limit or eliminate competitive alternatives in the health care service market, may result in overutilization of certain high-cost health care services such as cardiac, orthopedic, surgical, and oncology services, may increase costs to the health care system, and may adversely affect the quality of health care, NOW, THEREFORE,

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsections (9), (10), and (11) are added to section 395.003, Florida Statutes, to read:

395.003 Licensure; issuance, renewal, denial, modification, suspension, and revocation.--

(9) A hospital shall not be licensed or relicensed if:

(a) The diagnostic-related groups for 65 percent or more of the discharges from the hospital, in the most recent year for which data is available to the Agency for Health Care

Administration pursuant to s. 408.061, are for diagnosis, care, and treatment of patients with:

1. Cardiac-related diseases and disorders classified as diagnostic-related groups 103-145, 478-479, 514-518, or 525-527;

2. Orthopedic-related diseases and disorders classified as diagnostic-related groups 209-256, 471, 491, 496-503, or 519-520;

3. Cancer-related diseases and disorders classified as diagnostic-related groups 64, 82, 172, 173, 199, 200, 203, 257-260, 274, 275, 303, 306, 307, 318, 319, 338, 344, 346, 347, 363, 366, 367, 400-414, 473, or 492; or

4. Any combination of the above discharges.

(b) The hospital restricts its medical and surgical services to primarily or exclusively cardiac, orthopedic, surgical, or oncology specialties.

(10) A hospital licensed as of June 1, 2004, shall be exempt from the requirements in subsection (9) so long as the hospital maintains the same ownership, facility street address, and range of services that were in existence on June 1, 2004. Any transfer of beds, or other agreements that result in the establishment of a hospital or hospital services within the intent of this section, shall be subject to these provisions. Unless otherwise exempt under subsection (9), the agency shall deny or revoke a license if a hospital violates any of the criteria under subsection (9).

(11) The agency may adopt rules implementing the licensure requirements set forth in subsection (9). Within 14 days after rendering its decision on a license application or revocation,

the agency shall publish its proposed decision in the Florida Administrative Weekly. Within 21 days after publication of the agency's decision, any authorized person may file a request for an administrative hearing. In administrative proceedings challenging the approval, denial, or revocation of a license pursuant to subsection (9), the hearing will be based on the facts and law existing at the time of the agency's proposed agency action. Existing hospitals may initiate or intervene in an administrative hearing to approve, deny, or revoke licensure under subsection (9) based upon a showing that an established program will be substantially affected by the issuance or renewal of a license to a hospital within the same district or service area.

Section 2. Subsections (9), (13), (17), and (18) of section 408.032, Florida Statutes, are amended to read:

408.032 Definitions relating to Health Facility and Services Development Act.--As used in ss. 408.031-408.045, the term:

(9) "Health services" means inpatient diagnostic, curative, or comprehensive medical rehabilitative services and includes mental health services. Obstetric services are not health services for purposes of ss. 408.031-408.045.

(13) "Long-term care hospital" means a hospital licensed under chapter 395 which meets the requirements of 42 C.F.R. s. 412.23(e) and seeks exclusion from the acute care Medicare prospective payment system for inpatient hospital services.

(17) "Tertiary health service" means a health service which, due to its high level of intensity, complexity,

specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service. Examples of such service include, but are not limited to, pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, ~~specialty burn units,~~ neonatal intensive care units, ~~comprehensive rehabilitation,~~ and medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service. The agency shall establish by rule a list of all tertiary health services.

~~(18) "Regional area" means any of those regional health planning areas established by the agency to which local and district health planning funds are directed to local health councils through the General Appropriations Act.~~

Section 3. Section 408.033, Florida Statutes, is amended to read:

408.033 Local and state health planning.--

(1) LOCAL HEALTH COUNCILS.--

(a) Local health councils are hereby established as public or private nonprofit agencies serving the counties of a district ~~or regional area of the agency~~. The members of each council shall be appointed in an equitable manner by the county commissions having jurisdiction in the respective district. Each council shall be composed of a number of persons equal to $1^{1}/_{2}$ times the number of counties which compose the district or 12

members, whichever is greater. Each county in a district shall be entitled to at least one member on the council. The balance of the membership of the council shall be allocated among the counties of the district on the basis of population rounded to the nearest whole number; except that in a district composed of only two counties, no county shall have fewer than four members. The appointees shall be representatives of health care providers, health care purchasers, and nongovernmental health care consumers, but not excluding elected government officials. The members of the consumer group shall include a representative number of persons over 60 years of age. A majority of council members shall consist of health care purchasers and health care consumers. The local health council shall provide each county commission a schedule for appointing council members to ensure that council membership complies with the requirements of this paragraph. The members of the local health council shall elect a chair. Members shall serve for terms of 2 years and may be eligible for reappointment.

(b) Each local health council may:

1. Develop a district ~~or regional area~~ health plan that permits each local health council to develop strategies and set priorities for implementation based on its unique local health needs. ~~The district or regional area health plan must contain preferences for the development of health services and facilities, which may be considered by the agency in its review of certificate-of-need applications. The district health plan shall be submitted to the agency and updated periodically. The district health plans shall use a uniform format and be~~

~~submitted to the agency according to a schedule developed by the agency in conjunction with the local health councils. The schedule must provide for the development of district health plans by major sections over a multiyear period. The elements of a district plan which are necessary to the review of certificate-of-need applications for proposed projects within the district may be adopted by the agency as a part of its rules.~~

2. Advise the agency on health care issues and resource allocations.

3. Promote public awareness of community health needs, emphasizing health promotion and cost-effective health service selection.

4. Collect data and conduct analyses and studies related to health care needs of the district, including the needs of medically indigent persons, and assist the agency and other state agencies in carrying out data collection activities that relate to the functions in this subsection.

5. Monitor the onsite construction progress, if any, of certificate-of-need approved projects and report council findings to the agency on forms provided by the agency.

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

7. Advise and assist local governments within each district on the development of an optional health plan element

of the comprehensive plan provided in chapter 163, to assure compatibility with the health goals and policies in the State Comprehensive Plan and district health plan. To facilitate the implementation of this section, the local health council shall annually provide the local governments in its service area, upon request, with:

a. A copy and appropriate updates of the district health plan;

b. A report of hospital and nursing home utilization statistics for facilities within the local government jurisdiction; and

c. Applicable agency rules and calculated need methodologies for health facilities and services regulated under s. 408.034 for the district served by the local health council.

8. Monitor and evaluate the adequacy, appropriateness, and effectiveness, within the district, of local, state, federal, and private funds distributed to meet the needs of the medically indigent and other underserved population groups.

9. In conjunction with the Department of Health ~~Agency for Health Care Administration~~, plan for services at the local level for persons infected with the human immunodeficiency virus.

10. Provide technical assistance to encourage and support activities by providers, purchasers, consumers, and local, regional, and state agencies in meeting the health care goals, objectives, and policies adopted by the local health council.

11. Provide the agency with data required by rule for the review of certificate-of-need applications and the projection of need for health services and facilities in the district.

(c) Local health councils may conduct public hearings pursuant to s. 408.039(3)(b).

(d) Each local health council shall enter into a memorandum of agreement with each regional planning council in its district that elects to address health issues in its strategic regional policy plan. In addition, each local health council shall enter into a memorandum of agreement with each local government that includes an optional health element in its comprehensive plan. Each memorandum of agreement must specify the manner in which each local government, regional planning council, and local health council will coordinate its activities to ensure a unified approach to health planning and implementation efforts.

(e) Local health councils may employ personnel or contract for staffing services with persons who possess appropriate qualifications to carry out the councils' purposes. However, such personnel are not state employees.

(f) Personnel of the local health councils shall provide an annual orientation to council members about council member responsibilities. ~~The orientation shall include presentations and participation by agency staff.~~

(g) Each local health council is authorized to accept and receive, in furtherance of its health planning functions, funds, grants, and services from governmental agencies and from private or civic sources and to perform studies related to local health planning in exchange for such funds, grants, or services. Each local health council shall, no later than January 30 of each year, render an accounting of the receipt and disbursement of

such funds received by it to the Department of Health ~~agency~~. The department ~~agency~~ shall consolidate all such reports and submit such consolidated report to the Legislature no later than March 1 of each year. ~~Funds received by a local health council pursuant to this paragraph shall not be deemed to be a substitute for, or an offset against, any funding provided pursuant to subsection (2).~~

(2) FUNDING.--

(a) The Legislature intends that the cost of local health councils be borne by ~~application fees for certificates of need and by~~ assessments on selected health care facilities subject to facility licensure by the Agency for Health Care Administration, including abortion clinics, assisted living facilities, ambulatory surgical centers, birthing centers, clinical laboratories except community nonprofit blood banks and clinical laboratories operated by practitioners for exclusive use regulated under s. 483.035, home health agencies, hospices, hospitals, intermediate care facilities for the developmentally disabled, nursing homes, and multiphasic testing centers and by assessments on organizations subject to certification by the agency pursuant to chapter 641, part III, including health maintenance organizations and prepaid health clinics.

(b)1. A hospital licensed under chapter 395, a nursing home licensed under chapter 400, and an assisted living facility licensed under chapter 400 shall be assessed an annual fee based on number of beds.

2. All other facilities and organizations listed in paragraph (a) shall each be assessed an annual fee of $150.

3. Facilities operated by the Department of Children and Family Services, the Department of Health, or the Department of Corrections and any hospital which meets the definition of rural hospital pursuant to s. 395.602 are exempt from the assessment required in this subsection.

(c)1. The agency shall, by rule, establish fees for hospitals and nursing homes based on an assessment of $2 per bed. However, no such facility shall be assessed more than a total of $500 under this subsection.

2. The agency shall, by rule, establish fees for assisted living facilities based on an assessment of $1 per bed. However, no such facility shall be assessed more than a total of $150 under this subsection.

3. The agency shall, by rule, establish an annual fee of $150 for all other facilities and organizations listed in paragraph (a).

(d) The agency shall, by rule, establish a facility billing and collection process for the billing and collection of the health facility fees authorized by this subsection.

(e) A health facility which is assessed a fee under this subsection is subject to a fine of $100 per day for each day in which the facility is late in submitting its annual fee up to maximum of the annual fee owed by the facility. A facility which refuses to pay the fee or fine is subject to the forfeiture of its license.

(f) The agency shall deposit in the Health Care Trust Fund all health care facility assessments that are assessed under this subsection and ~~proceeds from the certificate-of-need~~

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

(3) DUTIES AND RESPONSIBILITIES OF THE AGENCY.--

(a) The agency~~, in conjunction with the local health councils,~~ is responsible for the coordinated planning of health care services in the state.

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

~~(c) The agency shall assist personnel of the local health councils in providing an annual orientation to council members about council member responsibilities.~~

(c)~~(d)~~ The Department of Health ~~agency~~ shall contract with the local health councils for the services specified in subsection (1). All contract funds shall be distributed according to an allocation plan developed by the department ~~agency that provides for a minimum and equal funding base for each local health council. Any remaining funds shall be~~

~~distributed based on adjustments for workload. The agency may also make grants to or reimburse local health councils from federal funds provided to the state for activities related to those functions set forth in this section~~. The department ~~agency~~ may withhold funds from a local health council or cancel its contract with a local health council which does not meet performance standards agreed upon by the department ~~agency~~ and local health councils.

Section 4. Subsections (1) and (2) of section 408.034, Florida Statutes, are amended to read:

408.034 Duties and responsibilities of agency; rules.--

(1) The agency is designated as the single state agency to issue, revoke, or deny certificates of need and to issue, revoke, or deny exemptions from certificate-of-need review in accordance with ~~the district plans and~~ present and future federal and state statutes. The agency is designated as the state health planning agency for purposes of federal law.

(2) In the exercise of its authority to issue licenses to health care facilities and health service providers, as provided under chapters 393, 395, and parts II and VI of chapter 400, the agency may not issue a license to any health care facility or~~,~~ health service provider~~, hospice, or part of a health care facility~~ which fails to receive a certificate of need or an exemption for the licensed facility or service.

Section 5. Section 408.035, Florida Statutes, is amended to read:

408.035 Review criteria.--The agency shall determine the reviewability of applications and shall review applications for

certificate-of-need determinations for health care facilities and health services in context with the following criteria:

(1) The need for the health care facilities and health services being proposed ~~in relation to the applicable district health plan~~.

(2) The availability, quality of care, accessibility, and extent of utilization of existing health care facilities and health services in the service district of the applicant.

(3) The ability of the applicant to provide quality of care and the applicant's record of providing quality of care.

~~(4) The need in the service district of the applicant for special health care services that are not reasonably and economically accessible in adjoining areas.~~

~~(5) The needs of research and educational facilities, including, but not limited to, facilities with institutional training programs and community training programs for health care practitioners and for doctors of osteopathic medicine and medicine at the student, internship, and residency training levels.~~

(4)~~(6)~~ The availability of resources, including health personnel, management personnel, and funds for capital and operating expenditures, for project accomplishment and operation.

(5)~~(7)~~ The extent to which the proposed services will enhance access to health care for residents of the service district.

(6)~~(8)~~ The immediate and long-term financial feasibility of the proposal.

(7)~~(9)~~ The extent to which the proposal will foster competition that promotes quality and cost-effectiveness.

(8)~~(10)~~ The costs and methods of the proposed construction, including the costs and methods of energy provision and the availability of alternative, less costly, or more effective methods of construction.

(9)~~(11)~~ The applicant's past and proposed provision of health care services to Medicaid patients and the medically indigent.

(10)~~(12)~~ The applicant's designation as a Gold Seal Program nursing facility pursuant to s. 400.235, when the applicant is requesting additional nursing home beds at that facility.

Section 6. Section 408.036, Florida Statutes, is amended to read:

408.036 Projects subject to review; exemptions.--

(1) APPLICABILITY.--Unless exempt under subsection (3), all health-care-related projects, as described in paragraphs (a)-(e) ~~(a)-(h)~~, are subject to review and must file an application for a certificate of need with the agency. The agency is exclusively responsible for determining whether a health-care-related project is subject to review under ss. 408.031-408.045.

(a) The addition of beds in community nursing homes or intermediate care facilities for the developmentally disabled by new construction or alteration.

(b) The new construction or establishment of additional health care facilities, including a replacement health care

facility when the proposed project site is not located on the same site as or within 1 mile of the existing health care facility provided that the number of beds in each licensed bed category will not increase.

(c) The conversion from one type of health care facility to another, including the conversion from a general hospital, a specialty hospital, or a long-term care hospital.

~~(d) An increase in the total licensed bed capacity of a health care facility.~~

(d)~~(e)~~ The establishment of a hospice or hospice inpatient facility, except as provided in s. 408.043.

~~(f) The establishment of inpatient health services by a health care facility, or a substantial change in such services.~~

~~(g) An increase in the number of beds for acute care, nursing home care beds, specialty burn units, neonatal intensive care units, comprehensive rehabilitation, mental health services, or hospital-based distinct part skilled nursing units, or at a long-term care hospital.~~

(e)~~(h)~~ The establishment of tertiary health services.

(2) PROJECTS SUBJECT TO EXPEDITED REVIEW.--Unless exempt pursuant to subsection (3), projects subject to an expedited review shall include, but not be limited to:

~~(a) Research, education, and training programs.~~

~~(b) Shared services contracts or projects.~~

(a)~~(c)~~ A transfer of a certificate of need, except that when an existing hospital is acquired by a purchaser, all certificates of need issued to the hospital which are not yet

operational shall be acquired by the purchaser, without need for a transfer.

(b) Replacement of a community nursing home or intermediate care facility for the developmentally disabled when the proposed project site is located within the same district and within the same planning area of the replaced health care facility provided the number of licensed beds is the same as that of the facility being replaced.

~~(d) A 50-percent increase in nursing home beds for a facility incorporated and operating in this state for at least 60 years on or before July 1, 1988, which has a licensed nursing home facility located on a campus providing a variety of residential settings and supportive services. The increased nursing home beds shall be for the exclusive use of the campus residents. Any application on behalf of an applicant meeting this requirement shall be subject to the base fee of $5,000 provided in s. 408.038.~~

~~(e) Replacement of a health care facility when the proposed project site is located in the same district and within a 1-mile radius of the replaced health care facility.~~

~~(f) The conversion of mental health services beds licensed under chapter 395 or hospital-based distinct part skilled nursing unit beds to general acute care beds; the conversion of mental health services beds between or among the licensed bed categories defined as beds for mental health services; or the conversion of general acute care beds to beds for mental health services.~~

~~1. Conversion under this paragraph shall not establish a new licensed bed category at the hospital but shall apply only to categories of beds licensed at that hospital.~~

~~2. Beds converted under this paragraph must be licensed and operational for at least 12 months before the hospital may apply for additional conversion affecting beds of the same type.~~

The agency shall develop rules to implement the provisions for expedited review, including time schedule, application content which may be reduced from the full requirements of s. 408.037(1), and application processing.

(3) EXEMPTIONS.--Upon request, the following projects are subject to exemption from the provisions of subsection (1):

~~(a) For replacement of a licensed health care facility on the same site, provided that the number of beds in each licensed bed category will not increase.~~

(a)~~(b)~~ For hospice services or for swing beds in a rural hospital, as defined in s. 395.602, in a number that does not exceed one-half of its licensed beds.

(b)~~(c)~~ For the conversion of licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital, as defined in s. 395.602, so long as the conversion of the beds does not involve the construction of new facilities. The total number of skilled nursing beds, including swing beds, may not exceed one-half of the total number of licensed beds in the rural hospital as of July 1, 1993. Certified skilled nursing beds designated under this paragraph, excluding swing beds, shall be included in the community nursing

home bed inventory. A rural hospital which subsequently decertifies any acute care beds exempted under this paragraph shall notify the agency of the decertification, and the agency shall adjust the community nursing home bed inventory accordingly.

(c)~~(d)~~ For the addition of nursing home beds at a skilled nursing facility that is part of a retirement community that provides a variety of residential settings and supportive services and that has been incorporated and operated in this state for at least 65 years on or before July 1, 1994. All nursing home beds must not be available to the public but must be for the exclusive use of the community residents.

~~(e) For an increase in the bed capacity of a nursing facility licensed for at least 50 beds as of January 1, 1994, under part II of chapter 400 which is not part of a continuing care facility if, after the increase, the total licensed bed capacity of that facility is not more than 60 beds and if the facility has been continuously licensed since 1950 and has received a superior rating on each of its two most recent licensure surveys.~~

(d)~~(f)~~ For an inmate health care facility built by or for the exclusive use of the Department of Corrections as provided in chapter 945. This exemption expires when such facility is converted to other uses.

~~(g) For the termination of an inpatient health care service, upon 30 days' written notice to the agency.~~

~~(h) For the delicensure of beds, upon 30 days' written notice to the agency. A request for exemption submitted under~~

~~this paragraph must identify the number, the category of beds, and the name of the facility in which the beds to be delicensed are located.~~

~~(i) For the provision of adult inpatient diagnostic cardiac catheterization services in a hospital.~~

~~1. In addition to any other documentation otherwise required by the agency, a request for an exemption submitted under this paragraph must comply with the following criteria:~~

~~a. The applicant must certify it will not provide therapeutic cardiac catheterization pursuant to the grant of the exemption.~~

~~b. The applicant must certify it will meet and continuously maintain the minimum licensure requirements adopted by the agency governing such programs pursuant to subparagraph 2.~~

~~c. The applicant must certify it will provide a minimum of 2 percent of its services to charity and Medicaid patients.~~

~~2. The agency shall adopt licensure requirements by rule which govern the operation of adult inpatient diagnostic cardiac catheterization programs established pursuant to the exemption provided in this paragraph. The rules shall ensure that such programs:~~

~~a. Perform only adult inpatient diagnostic cardiac catheterization services authorized by the exemption and will not provide therapeutic cardiac catheterization or any other services not authorized by the exemption.~~

~~b. Maintain sufficient appropriate equipment and health personnel to ensure quality and safety.~~

~~c. Maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.~~

~~d. Maintain appropriate program volumes to ensure quality and safety.~~

~~e. Provide a minimum of 2 percent of its services to charity and Medicaid patients each year.~~

~~3.a. The exemption provided by this paragraph shall not apply unless the agency determines that the program is in compliance with the requirements of subparagraph 1. and that the program will, after beginning operation, continuously comply with the rules adopted pursuant to subparagraph 2. The agency shall monitor such programs to ensure compliance with the requirements of subparagraph 2.~~

~~b.(I) The exemption for a program shall expire immediately when the program fails to comply with the rules adopted pursuant to sub-subparagraphs 2.a., b., and c.~~

~~(II) Beginning 18 months after a program first begins treating patients, the exemption for a program shall expire when the program fails to comply with the rules adopted pursuant to sub-subparagraphs 2.d. and e.~~

~~(III) If the exemption for a program expires pursuant to sub-sub-subparagraph (I) or sub-sub-subparagraph (II), the agency shall not grant an exemption pursuant to this paragraph for an adult inpatient diagnostic cardiac catheterization program located at the same hospital until 2 years following the date of the determination by the agency that the program failed to comply with the rules adopted pursuant to subparagraph 2.~~

(e)~~(j)~~ For mobile surgical facilities and related health care services provided under contract with the Department of Corrections or a private correctional facility operating pursuant to chapter 957.

(f)~~(k)~~ For state veterans' nursing homes operated by or on behalf of the Florida Department of Veterans' Affairs in accordance with part II of chapter 296 for which at least 50 percent of the construction cost is federally funded and for which the Federal Government pays a per diem rate not to exceed one-half of the cost of the veterans' care in such state nursing homes. These beds shall not be included in the nursing home bed inventory.

(g)~~(l)~~ For combination within one nursing home facility of the beds or services authorized by two or more certificates of need issued in the same planning subdistrict. An exemption granted under this paragraph shall extend the validity period of the certificates of need to be consolidated by the length of the period beginning upon submission of the exemption request and ending with issuance of the exemption. The longest validity period among the certificates shall be applicable to each of the combined certificates.

(h)~~(m)~~ For division into two or more nursing home facilities of beds or services authorized by one certificate of need issued in the same planning subdistrict. An exemption granted under this paragraph shall extend the validity period of the certificate of need to be divided by the length of the period beginning upon submission of the exemption request and ending with issuance of the exemption.

~~(n) For the addition of hospital beds licensed under chapter 395 for acute care, mental health services, or a hospital-based distinct part skilled nursing unit in a number that may not exceed 10 total beds or 10 percent of the licensed capacity of the bed category being expanded, whichever is greater. Beds for specialty burn units, neonatal intensive care units, or comprehensive rehabilitation, or at a long-term care hospital, may not be increased under this paragraph.~~

~~1. In addition to any other documentation otherwise required by the agency, a request for exemption submitted under this paragraph must:~~

~~a. Certify that the prior 12-month average occupancy rate for the category of licensed beds being expanded at the facility meets or exceeds 80 percent or, for a hospital-based distinct part skilled nursing unit, the prior 12-month average occupancy rate meets or exceeds 96 percent.~~

~~b. Certify that any beds of the same type authorized for the facility under this paragraph before the date of the current request for an exemption have been licensed and operational for at least 12 months.~~

~~2. The timeframes and monitoring process specified in s. 408.040(2)(a)-(c) apply to any exemption issued under this paragraph.~~

~~3. The agency shall count beds authorized under this paragraph as approved beds in the published inventory of hospital beds until the beds are licensed.~~

~~(o) For the addition of acute care beds, as authorized by rule consistent with s. 395.003(4), in a number that may not~~

~~exceed 10 total beds or 10 percent of licensed bed capacity, whichever is greater, for temporary beds in a hospital that has experienced high seasonal occupancy within the prior 12-month period or in a hospital that must respond to emergency circumstances.~~

(i)~~(p)~~ For the addition of nursing home beds licensed under chapter 400 in a number not exceeding 10 total beds or 10 percent of the number of beds licensed in the facility being expanded, whichever is greater.

1. In addition to any other documentation required by the agency, a request for exemption submitted under this paragraph must:

a. Effective until June 30, 2001, certify that the facility has not had any class I or class II deficiencies within the 30 months preceding the request for addition.

b. Effective on July 1, 2001, certify that the facility has been designated as a Gold Seal nursing home under s. 400.235.

c. Certify that the prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 96 percent.

d. Certify that any beds authorized for the facility under this paragraph before the date of the current request for an exemption have been licensed and operational for at least 12 months.

2. The timeframes and monitoring process specified in s. 408.040(2)(a)-(c) apply to any exemption issued under this paragraph.

3. The agency shall count beds authorized under this paragraph as approved beds in the published inventory of nursing home beds until the beds are licensed.

(j) For the establishment of a Level II neonatal intensive care unit with at least 10 beds, upon documentation to the agency that the applicant hospital had a minimum of 1,500 births during the previous 12 months; or the establishment of a Level III neonatal intensive care unit with at least 15 beds, upon documentation to the agency that the applicant hospital has a Level II neonatal intensive care unit of at least 10 beds and had a minimum of 3,500 births during the previous 12 months; provided the applicant demonstrates that it meets the quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency transportation, and data reporting requirements as found in agency certificate-of-need rules for Level II and Level III neonatal intensive care units and that the applicant commits to the provision of services to Medicaid and charity care patients at a level equal to or greater than the district average. Such commitment shall be subject to the provisions of s. 408.040.

~~(q) For establishment of a specialty hospital offering a range of medical service restricted to a defined age or gender group of the population or a restricted range of services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical illnesses or disorders, through the transfer of beds and services from an existing hospital in the same county.~~

~~(r) For the conversion of hospital-based Medicare and Medicaid certified skilled nursing beds to acute care beds, if the conversion does not involve the construction of new facilities.~~

~~(s)1. For an adult open-heart-surgery program to be located in a new hospital provided the new hospital is being established in the location of an existing hospital with an adult open-heart-surgery program, the existing hospital and the existing adult open-heart-surgery program are being relocated to a replacement hospital, and the replacement hospital will utilize a closed-staff model. A hospital is exempt from the certificate-of-need review for the establishment of an open-heart-surgery program if the application for exemption submitted under this paragraph complies with the following criteria:~~

~~a. The applicant must certify that it will meet and continuously maintain the minimum Florida Administrative Code and any future licensure requirements governing adult open-heart programs adopted by the agency, including the most current guidelines of the American College of Cardiology and American Heart Association Guidelines for Adult Open Heart Programs.~~

~~b. The applicant must certify that it will maintain sufficient appropriate equipment and health personnel to ensure quality and safety.~~

~~c. The applicant must certify that it will maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.~~

~~d. The applicant is a newly licensed hospital in a physical location previously owned and licensed to a hospital performing more than 300 open-heart procedures each year, including heart transplants.~~

~~e. The applicant must certify that it can perform more than 300 diagnostic cardiac catheterization procedures per year, combined inpatient and outpatient, by the end of the third year of its operation.~~

~~f. The applicant's payor mix at a minimum reflects the community average for Medicaid, charity care, and self-pay patients or the applicant must certify that it will provide a minimum of 5 percent of Medicaid, charity care, and self-pay to open-heart-surgery patients.~~

~~g. If the applicant fails to meet the established criteria for open-heart programs or fails to reach 300 surgeries per year by the end of its third year of operation, it must show cause why its exemption should not be revoked.~~

~~h. In order to ensure continuity of available services, the applicant of the newly licensed hospital may apply for this certificate-of-need before taking possession of the physical facilities. The effective date of the certificate-of-need will be concurrent with the effective date of the newly issued hospital license.~~

~~2. By December 31, 2004, and annually thereafter, the agency shall submit a report to the Legislature providing information concerning the number of requests for exemption received under this paragraph and the number of exemptions granted or denied.~~

~~3. This paragraph is repealed effective January 1, 2008.~~

~~(t)1. For the provision of adult open-heart services in a hospital located within the boundaries of Palm Beach, Polk, Martin, St. Lucie, and Indian River Counties if the following conditions are met: The exemption must be based upon objective criteria and address and solve the twin problems of geographic and temporal access. A hospital shall be exempt from the certificate-of-need review for the establishment of an open-heart-surgery program when the application for exemption submitted under this paragraph complies with the following criteria:~~

~~a. The applicant must certify that it will meet and continuously maintain the minimum licensure requirements adopted by the agency governing adult open-heart programs, including the most current guidelines of the American College of Cardiology and American Heart Association Guidelines for Adult Open Heart Programs.~~

~~b. The applicant must certify that it will maintain sufficient appropriate equipment and health personnel to ensure quality and safety.~~

~~c. The applicant must certify that it will maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.~~

~~d. The applicant can demonstrate that it is referring 300 or more patients per year from the hospital, including the emergency room, for cardiac services at a hospital with cardiac~~

~~services, or that the average wait for transfer for 50 percent or more of the cardiac patients exceeds 4 hours.~~

~~e. The applicant is a general acute care hospital that is in operation for 3 years or more.~~

~~f. The applicant is performing more than 300 diagnostic cardiac catheterization procedures per year, combined inpatient and outpatient.~~

~~g. The applicant's payor mix at a minimum reflects the community average for Medicaid, charity care, and self-pay patients or the applicant must certify that it will provide a minimum of 5 percent of Medicaid, charity care, and self-pay to open-heart-surgery patients.~~

~~h. If the applicant fails to meet the established criteria for open-heart programs or fails to reach 300 surgeries per year by the end of its third year of operation, it must show cause why its exemption should not be revoked.~~

~~2. By December 31, 2004, and annually thereafter, the Agency for Health Care Administration shall submit a report to the Legislature providing information concerning the number of requests for exemption received under this paragraph and the number of exemptions granted or denied.~~

(k) For the addition of comprehensive medical rehabilitation or mental health services or beds provided the applicant commits to the provision of services to Medicaid or charity care patients at a level equal to or greater than the district average. Such commitment shall be subject to the provisions of s. 408.040.

(4) REQUESTS FOR EXEMPTIONS.--A request for exemption under subsection (3) may be made at any time and is not subject to the batching requirements of this section. The request shall be supported by such documentation as the agency requires by rule. The agency shall assess a fee of $250 for each request for exemption submitted under subsection (3).

(5) NOTIFICATION.--Health care facilities and providers must provide notification to the agency of the following:

(a) Replacement of a health care facility when the proposed project site is located in the same district and on the existing site or within a 1-mile radius of the replaced health care facility, provided that the number and type of beds do not increase.

(b) For the termination of a health care service, upon 30 days' written notice to the agency.

(c) For the addition or delicensure of beds.

Notification under this subsection may be made at any time, prior to the action described, by electronic, facsimile, or written means.

Section 7. Section 408.0361, Florida Statutes, is amended to read:

408.0361 Cardiology services and burn unit licensure ~~Diagnostic cardiac catheterization services providers; compliance with guidelines and requirements~~.--

(1) Each provider of diagnostic cardiac catheterization services shall comply with ~~the requirements of s. 408.036(3)(i)2.a.-d., and~~ rules adopted by ~~of~~ the agency that

establish licensure standards ~~for Health Care Administration~~ governing the operation of adult inpatient diagnostic cardiac catheterization programs. The rules shall ensure that such programs:

(a) Comply with~~, including~~ the most recent guidelines of the American College of Cardiology and American Heart Association Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories.

(b) Perform only adult inpatient diagnostic cardiac catheterization services and will not provide therapeutic cardiac catheterization or any other cardiology services.

(c) Maintain sufficient appropriate equipment and health care personnel to ensure quality and safety.

(d) Maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.

(e) Demonstrate a plan to provide services to Medicaid and charity care patients.

(2) Each provider of adult interventional cardiology services or operator of a burn unit shall comply with rules adopted by the agency that establish licensure standards that govern the provision of adult interventional cardiology services or the operation of a burn unit. Such rules shall consider, at a minimum, staffing, equipment, physical plant, operating protocols, the provision of services to Medicaid and charity care patients, accreditation, licensure period and fees, and enforcement of minimum standards. The certificate-of-need rules for adult interventional cardiology services and burn units in

effect on June 30, 2004, are authorized pursuant to this subsection and shall remain in effect and shall be enforceable by the agency until the licensure rules are adopted. Existing providers and any provider with a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for adult interventional cardiology services or burn units shall be considered grandfathered and receive a license for their programs effective on the effective date of this act. The grandfathered licensure shall be for at least 2 years or a period specified in the rule, whichever is longer, but shall be required to meet licensure standards applicable to existing programs for every subsequent licensure period.

(3) In establishing rules for adult interventional cardiology services, the agency shall include provisions that allow for:

(a) Establishment of two hospital program licensure levels: a Level I program authorizing the performance of adult percutaneous cardiac intervention without onsite cardiac surgery and a Level II program authorizing the performance of percutaneous cardiac intervention with onsite cardiac surgery.

(b) For a hospital seeking a Level I program, demonstration that, for the most recent 12-month period as reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations or transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease and that it has a formalized, written transfer agreement with a hospital that has a Level II program,

including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes.

(c) For a hospital seeking a Level II program, demonstration that, for the most recent 12-month period as reported to the agency, it has performed a minimum of 1,100 adult inpatient and outpatient diagnostic cardiac catheterizations, of which at least 400 must be therapeutic catheterizations, or has discharged at least 800 patients with the principal diagnosis of ischemic heart disease.

(d) Compliance with the most recent guidelines of the American College of Cardiology and American Heart Association guidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and patient selection criteria to ensure patient quality and safety.

(e) Establishment of appropriate hours of operation and protocols to ensure availability and timely referral in the event of emergencies.

(f) Demonstration of a plan to provide services to Medicaid and charity care patients.

(4) The agency shall establish a technical advisory panel to develop procedures and standards for measuring outcomes of interventional cardiac programs. Members of the panel shall include representatives of the Florida Hospital Association, the Florida Society of Thoracic and Cardiovascular Surgeons, the Florida Chapter of the American College of Cardiology, and the Florida Chapter of the American Heart Association and others with experience in statistics and outcome measurement. Based on recommendations from the panel, the agency shall develop and

adopt rules for the interventional cardiac programs that include at least the following:

(a) A standard data set consisting primarily of data elements reported to the agency in accordance with s. 408.061.

(b) A risk adjustment procedure that accounts for the variations in severity and case mix found in hospitals in this state.

(c) Outcome standards specifying expected levels of performance in Level I and Level II adult interventional cardiology services. Such standards may include, but shall not be limited to, in-hospital mortality, infection rates, nonfatal myocardial infarctions, length of stay, postoperative bleeds, and returns to surgery.

(d) Specific steps to be taken by the agency and licensed hospitals that do not meet the outcome standards within specified time periods, including time periods for detailed case reviews and development and implementation of corrective action plans.

(5) The Secretary of Health Care Administration shall appoint an advisory group to study the issue of replacing certificate-of-need review of organ transplant programs under this chapter with licensure regulation of organ transplant programs under chapter 395. The advisory group shall include three representatives of organ transplant providers, one representative of an organ procurement organization, one representative of the Division of Health Quality Assurance, one representative of Medicaid, and one organ transplant patient advocate. The advisory group shall, at minimum, make

recommendations regarding access to organs, delivery of services to Medicaid and charity care patients, staff training, and resource requirements for organ transplant programs in a report due to the secretary and the Legislature by July 1, 2005.

(6) The Secretary of Health Care Administration shall appoint a workgroup to study certificate-of-need regulations and changing market conditions related to the supply and distribution of hospital beds. The assessment by the workgroup shall include, but not be limited to, the following:

(a) The appropriateness of current certificate-of-need methodologies and other criteria for evaluating proposals for new hospitals and transfer of beds to new sites.

(b) Additional factors that should be considered, including the viability of safety net services, the extent of market competition, and the accessibility of hospital services.

The workgroup shall submit a report by January 1, 2005, to the secretary and the Legislature identifying specific problem areas and recommending needed changes in statutes or rules.

Section 8. Section 408.038, Florida Statutes, is amended to read:

408.038 Fees.--The agency shall assess fees on certificate-of-need applications. Such fees shall be for the purpose of funding ~~the functions of the local health councils and~~ the activities of the agency and shall be allocated as provided in s. 408.033. The fee shall be determined as follows:

(1) A minimum base fee of $10,000 ~~$5,000~~.

(2) In addition to the base fee of $10,000 ~~$5,000~~, 0.015 of each dollar of proposed expenditure, except that a fee may not exceed $50,000 ~~$22,000~~.

Section 9. Subsection (1), paragraph (a) of subsection (3), and paragraphs (a) and (b) of subsection (4) of section 408.039, Florida Statutes, are amended to read:

408.039 Review process.--The review process for certificates of need shall be as follows:

(1) REVIEW CYCLES.--The agency by rule shall provide for applications to be submitted on a timetable or cycle basis; provide for review on a timely basis; and provide for all completed applications pertaining to similar types of services or facilities affecting the same service district to be considered in relation to each other no less often than annually ~~two times a year~~.

(3) APPLICATION PROCESSING.--

(a) An applicant shall file an application with the agency, and shall furnish a copy of the application to ~~the local health council and~~ the agency. Within 15 days after the applicable application filing deadline established by agency rule, the staff of the agency shall determine if the application is complete. If the application is incomplete, the staff shall request specific information from the applicant necessary for the application to be complete; however, the staff may make only one such request. If the requested information is not filed with the agency within 21 days after ~~of~~ the receipt of the staff's request, the application shall be deemed incomplete and deemed withdrawn from consideration.

(4) STAFF RECOMMENDATIONS.--

(a) The agency's review of and final agency action on applications shall be in accordance with ~~the district health plan, and~~ statutory criteria~~,~~ and the implementing administrative rules. In the application review process, the agency shall give a preference, as defined by rule of the agency, to an applicant which proposes to develop a nursing home in a nursing home geographically underserved area.

(b) Within 60 days after all the applications in a review cycle are determined to be complete, the agency shall issue its State Agency Action Report and Notice of Intent to grant a certificate of need for the project in its entirety, to grant a certificate of need for identifiable portions of the project, or to deny a certificate of need. The State Agency Action Report shall set forth in writing its findings of fact and determinations upon which its decision is based. ~~If a finding of fact or determination by the agency is counter to the district health plan of the local health council, the agency shall provide in writing its reason for its findings, item by item, to the local health council.~~ If the agency intends to grant a certificate of need, the State Agency Action Report or the Notice of Intent shall also include any conditions which the agency intends to attach to the certificate of need. The agency shall designate by rule a senior staff person, other than the person who issues the final order, to issue State Agency Action Reports and Notices of Intent.

Section 10. Section 408.040, Florida Statutes, is amended to read:

408.040 Conditions and monitoring.--

(1)(a) The agency may issue a certificate of need or an exemption predicated upon statements of intent expressed by an applicant in the application for a certificate of need or exemption. Any conditions imposed on a certificate of need or an exemption based on such statements of intent shall be stated on the face of the certificate of need or in the exemption approval.

(b) The agency may consider, in addition to the other criteria specified in s. 408.035, a statement of intent by the applicant that a specified percentage of the annual patient days at the facility will be utilized by patients eligible for care under Title XIX of the Social Security Act. Any certificate of need issued to a nursing home in reliance upon an applicant's statements that a specified percentage of annual patient days will be utilized by residents eligible for care under Title XIX of the Social Security Act must include a statement that such certification is a condition of issuance of the certificate of need. The certificate-of-need program shall notify the Medicaid program office and the Department of Elderly Affairs when it imposes conditions as authorized in this paragraph in an area in which a community diversion pilot project is implemented.

(c) A certificateholder or exemption holder may apply to the agency for a modification of conditions imposed under paragraph (a) or paragraph (b). If the holder of a certificate of need or exemption demonstrates good cause why the certificate or exemption should be modified, the agency shall reissue the certificate of need or exemption with such modifications as may

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

(d) If the holder of a certificate of need or exemption fails to comply with a condition upon which the issuance of the certificate or exemption was predicated, the agency shall ~~may~~ assess an administrative fine against the certificate or exemption holder ~~certificateholder~~ in an amount not to exceed $1,000 per failure per day. Failure to annually report compliance with any condition upon which the issuance of the certificate or exemption was predicated constitutes noncompliance. In assessing the penalty, the agency shall take into account as mitigation the degree of noncompliance ~~relative lack of severity of a particular failure~~. Proceeds of such penalties shall be deposited in the Public Medical Assistance Trust Fund.

(2)(a) Unless the applicant has commenced construction, if the project provides for construction, unless the applicant has incurred an enforceable capital expenditure commitment for a project, if the project does not provide for construction, or unless subject to paragraph (b), a certificate of need shall terminate 18 months after the date of issuance. The agency shall monitor the progress of the holder of the certificate of need in meeting the timetable for project development specified in the application ~~with the assistance of the local health council as specified in s. 408.033(1)(b)5.,~~ and may revoke the certificate of need~~,~~ if the holder of the certificate is not meeting such timetable and is not making a good-faith effort, as defined by rule, to meet it.

(b) A certificate of need issued to an applicant holding a provisional certificate of authority under chapter 651 shall terminate 1 year after the applicant receives a valid certificate of authority from the Office of Insurance Regulation of the Financial Services Commission.

(c) The certificate-of-need validity period for a project shall be extended by the agency, to the extent that the applicant demonstrates to the satisfaction of the agency that good-faith commencement of the project is being delayed by litigation or by governmental action or inaction with respect to regulations or permitting precluding commencement of the project.

(3) The agency shall require the submission of an executed architect's certification of final payment for each certificate-of-need project approved by the agency. Each project that involves construction shall submit such certification to the agency within 30 days following completion of construction.

Section 11. Section 408.043, Florida Statutes, is amended to read:

408.043 Special provisions.--

(1) OSTEOPATHIC ACUTE CARE HOSPITALS.--When an application is made for a certificate of need to construct or to expand an osteopathic acute care hospital, the need for such hospital shall be determined on the basis of the need for and availability of osteopathic services and osteopathic acute care hospitals in the district. When a prior certificate of need to establish an osteopathic acute care hospital has been issued in a district, and the facility is no longer used for that purpose,

the agency may continue to count such facility and beds as an existing osteopathic facility in any subsequent application for construction of an osteopathic acute care hospital.

(2) HOSPICES.--When an application is made for a certificate of need to establish or to expand a hospice, the need for such hospice shall be determined on the basis of the need for and availability of hospice services in the community. The formula on which the certificate of need is based shall discourage regional monopolies and promote competition. The inpatient hospice care component of a hospice which is a freestanding facility, or a part of a facility, which is primarily engaged in providing inpatient care and related services and is not licensed as a health care facility shall also be required to obtain a certificate of need. Provision of hospice care by any current provider of health care is a significant change in service and therefore requires a certificate of need for such services.

(3) RURAL HEALTH NETWORKS.--Preference shall be given in the award of a certificate of need to members of certified rural health networks, as provided for in s. 381.0406, subject to the following conditions:

(a) Need must be shown pursuant to s. 408.035.

(b) The proposed project must:

1. Strengthen health care services in rural areas through partnerships between rural care providers; or

2. Increase access to inpatient health care services for Medicaid recipients or other low-income persons who live in rural areas.

(c) No preference shall be given under this section for the establishment of skilled nursing facility services by a hospital.

(4) PRIVATE ACCREDITATION NOT REQUIRED.--Accreditation by any private organization may not be a requirement for the issuance or maintenance of a certificate of need under ss. 408.031-408.045.

~~(5) SOLE ACUTE CARE HOSPITALS IN HIGH GROWTH COUNTIES.--Notwithstanding any other provision of law, an acute care hospital licensed under chapter 395 may add up to 180 additional beds without agency review if such hospital is located in a county that has experienced at least a 60-percent growth rate for the most recent 10-year period for which data are available as determined by using the population statistics published in the most recent edition of the Florida Statistical Abstract, is the sole acute care hospital in the county, and is the only acute care hospital within a 10-mile radius of another hospital. A hospital shall provide written notice to the agency that it qualifies under this subsection prior to the addition of beds. Such projects shall not be subject to challenge under s. 408.039 or chapter 120. Acute care beds added under this subsection shall not be included in the inventory of hospital beds used by the agency in the calculation of the fixed-bed-need pool for acute care hospitals.~~

Section 12. Section 408.0455, Florida Statutes, is amended to read:

408.0455 Rules; pending proceedings.--The rules of the agency in effect on June 30, 2004 ~~1997~~, shall remain in effect

and shall be enforceable by the agency with respect to ss. 408.031-408.045 until such rules are repealed or amended by the agency~~, and no judicial or administrative proceeding pending on July 1, 1997, shall be abated as a result of the provisions of ss. 408.031-408.043(1) and (2); s. 408.044; or s. 408.045~~.

Section 13. This act shall take effect July 1, 2004.