Amendment No. ____ Barcode 394000

CHAMBER ACTION

| İ | Senate House |
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| 1 | 1/RE/3R . |
| 2 | 04/07/2004 11:39 AM . |
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| 11 | Senator Pruitt moved the following amendment: |
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| 13 | Senate Amendment (with title amendment) |
| 14 | Delete everything after the enacting clause |
| 15 | |
| 16 | and insert: |
| 17 | Section 1. Subsections (9), (10), and (11) are added |
| 18 | to section 395.003, Florida Statutes, to read: |
| 19 | 395.003 Licensure; issuance, renewal, denial, |
| 20 | modification, suspension, and revocation |
| 21 | (9) A hospital may not be licensed or relicensed if: |
| 22 | (a) The diagnosis-related groups for 65 percent or |
| 23 | more of the discharges from the hospital, in the most recent |
| 24 | year for which data is available to the Agency for Health Care |
| 25 | Administration pursuant to s. 408.061, are for diagnosis, |
| 26 | care, and treatment of patients who have: |
| 27 | 1. Cardiac-related diseases and disorders classified |
| 28 | as diagnosis-related groups 103-145, 478-479, 514-518, or |
| 29 | <u>525-527;</u> |
| 30 | 2. Orthopedic-related diseases and disorders |
| 31 | classified as diagnosis-related groups 209-256, 471, 491, |
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496-503, or 519-520;

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3. Cancer-related diseases and disorders classified as diagnosis-related groups 64, 82, 172, 173, 199, 200, 203.

4 257-260, 274, 275, 303, 306, 307, 318, 319, 338, 344, 346,

5 | 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 subsection (9) as 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 subsection (9). Unless the hospital is otherwise exempt under subsection (9), the agency shall deny or revoke the license of a hospital that violates any of the criteria set forth in that subsection.

(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 must be based on the facts and law existing at the time of the agency's proposed agency action. Existing

31 hospitals may initiate or intervene in an administrative

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hearing to approve, deny, or revoke licensure under subsection (9) based upon a showing that an established program will be 3 substantially affected by the issuance or renewal of a license to a hospital within the same district or service area. 5 Section 2. Subsections (9), (13), and (17) of section 408.032, Florida Statutes, are amended, and subsection (18) of 6 7 that section is repealed, to read: 408.032 Definitions relating to Health Facility and 8 Services Development Act.--As used in ss. 408.031-408.045, the 9 10 term: 11 (9) "Health services" means <u>inpatient</u> diagnostic, curative, or comprehensive medical rehabilitative services and 12 13 includes mental health services. Obstetric services are not health services for purposes of ss. 408.031-408.045. 14 15 (13) "Long-term care hospital" means a hospital 16 licensed under chapter 395 which meets the requirements of 42 17 C.F.R. s. 412.23(e) and seeks exclusion from the acute care Medicare prospective payment system for inpatient hospital 18 19 services. 20 (17) "Tertiary health service" means a health service which, due to its high level of intensity, complexity, 21 specialized or limited applicability, and cost, should be 22 23 limited to, and concentrated in, a limited number of hospitals 24 to ensure the quality, availability, and cost-effectiveness of 25 such service. Examples of such service include, but are not limited to, pediatric cardiac catheterization, pediatric 26 27 open-heart surgery, organ transplantation, specialty burn units, neonatal intensive care units, comprehensive 28 rehabilitation, and medical or surgical services which are 29

31 | provision of such services is not yet contemplated within the

experimental or developmental in nature to the extent that the

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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 $1 \frac{1}{2}$ 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 31 | shall consist of health care purchasers and health care

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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.
- 27 3. Promote public awareness of community health needs, 28 emphasizing health promotion and cost-effective health service 29 selection.
- 4. Collect data and conduct analyses and studies 31 | related to health care needs of the district, including the

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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, 31 | federal, and private funds distributed to meet the needs of

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the medically indigent and other underserved population groups.

- 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 31 | appropriate qualifications to carry out the councils'

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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.
- (q) 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 31 agencies, hospices, hospitals, intermediate care facilities

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- for the developmentally disabled, nursing homes, health care clinics, and multiphasic testing centers and by assessments on 3 organizations subject to certification by the agency pursuant to chapter 641, part III, including health maintenance 4 5 organizations and prepaid health clinics.
- (b)1. A hospital licensed under chapter 395, a nursing 6 7 home licensed under chapter 400, and an assisted living facility licensed under chapter 400 shall be assessed an 8 annual fee based on number of beds. 9
 - 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 22 23 bed. However, no such facility shall be assessed more than a 24 total of \$150 under this subsection.
- 25 3. The agency shall, by rule, establish an annual fee 26 of \$150 for all other facilities and organizations listed in paragraph (a). 27
 - (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 31

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- 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 3 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 6 Fund all health care facility assessments that are assessed under this subsection and proceeds from the 8 9 certificate-of-need application fees. The agency shall transfer <u>such funds</u> to the Department of Health <u>for</u> an amount 10 11 sufficient to maintain the aggregate funding of level for the local health councils as specified in the General 12 Appropriations Act. The remaining certificate-of-need 13 application fees shall be used only for the purpose of 14 15 administering the certificate-of-need program Health Facility 16 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. 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 31 | health councils in providing an annual orientation to council

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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), (2), and (5) 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 31 care facility or, health service provider that, hospice, or

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part of a health care facility which fails to receive a certificate of need or an exemption for the licensed facility or service.

- (5) The agency shall establish by rule a nursing-home-bed-need methodology that has a goal of maintaining a subdistrict average occupancy rate of 94 percent and that reduces the community nursing home bed need for the areas of the state where the agency establishes pilot community diversion programs through the Title XIX aging waiver program.
- 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.
- 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 31 | training programs and community training programs for health

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care practitioners and for doctors of osteopathic medicine and medicine at the student, internship, and residency training 3 levels. (4)(6) The availability of resources, including health 4 5 personnel, management personnel, and funds for capital and operating expenditures, for project accomplishment and 6 7 operation. 8 (5) (7) The extent to which the proposed services will enhance access to health care for residents of the service 9 district. 10 11 (6) The immediate and long-term financial 12 feasibility of the proposal. 13 (7) The extent to which the proposal will foster 14 competition that promotes quality and cost-effectiveness. 15 (8) (10) The costs and methods of the proposed 16 construction, including the costs and methods of energy provision and the availability of alternative, less costly, or 17 more effective methods of construction. 18 19 (9)(11) The applicant's past and proposed provision of health care services to Medicaid patients and the medically 21 indigent. (10) (12) The applicant's designation as a Gold Seal 22 23 Program nursing facility pursuant to s. 400.235, when the 24 applicant is requesting additional nursing home beds at that 25 facility. 26 Section 6. Section 408.036, Florida Statutes, is 27 amended to read: 28 408.036 Projects subject to review; exemptions .--29 (1) APPLICABILITY. -- Unless exempt under subsection (3), all health-care-related projects, as described in 30 31 | paragraphs(a)-(e)(a)-(h), are subject to review and must

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- 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.
- 4 | 408.031-408.045.

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- (a) The addition of beds <u>in community nursing homes or</u> <u>intermediate care facilities for the developmentally disabled</u> 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 <u>or within 1 mile of</u> the existing health care facility, if 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.
 - (e)(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.
- 29 <u>(f)(h)</u> The establishment of tertiary health services.
 30 <u>including inpatient comprehensive rehabilitation services</u>.
 - (q) An increase in the number of beds for acute care

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in a hospital that is located in a low-growth county. A low-growth county is defined as a county that has: 3 1. A hospital with an occupancy rate for licensed acute care which has been below 60 percent for the previous 5 4 5 <u>years;</u> 2. Experienced a growth rate of 4 percent or less for 6 the most recent 3-year period for which data are available, as 8 determined using the population statistics published in the most recent edition of the Florida Statistical Abstract; 9 3. A population of 400,000 or fewer according to the 10 11 most recent edition of the Florida Statistical Abstract; and 12 4. A hospital that has combined gross revenue from 13 Medicaid and charity patients which exceeds \$60 million per year for the previous 2 years. 14 15 16 This paragraph is repealed effective July 1, 2009. 17 (2) PROJECTS SUBJECT TO EXPEDITED REVIEW.--Unless 18 exempt pursuant to subsection (3), projects subject to an 19 expedited review shall include, but not be limited to: 20 (a) Research, education, and training programs. (b) Shared services contracts or projects. 21 2.2 (a) (c) A transfer of a certificate of need, except 23 that when an existing hospital is acquired by a purchaser, all certificates of need issued to the hospital which are not yet 24 operational shall be acquired by the purchaser, without need 25 26 for a transfer. 27 (b) Replacement of a nursing home within the same 28 district, if the proposed project site is located within a 29 geographic area that contains at least 65 percent of the 30 facility's current residents and is within a 30-mile radius of

31 the replaced nursing home.

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| 1 | (c) Relocation of a portion of a nursing home's |
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| 2 | licensed beds to a facility within the same district, if the |
| 3 | relocation is within a 30-mile radius of the existing facility |
| 4 | and the total number of nursing home beds in the district does |
| 5 | not increase. |
| 6 | (d) A 50-percent increase in nursing home beds for a |
| 7 | facility incorporated and operating in this state for at least |
| 8 | 60 years on or before July 1, 1988, which has a licensed |
| 9 | nursing home facility located on a campus providing a variety |
| 10 | of residential settings and supportive services. The |
| 11 | increased nursing home beds shall be for the exclusive use of |
| 12 | the campus residents. Any application on behalf of an |
| 13 | applicant meeting this requirement shall be subject to the |
| 14 | base fee of \$5,000 provided in s. 408.038. |
| 15 | (e) Replacement of a health care facility when the |
| 16 | proposed project site is located in the same district and |
| 17 | within a 1-mile radius of the replaced health care facility. |
| 18 | (f) The conversion of mental health services beds |
| 19 | licensed under chapter 395 or hospital-based distinct part |
| 20 | skilled nursing unit beds to general acute care beds; the |
| 21 | conversion of mental health services beds between or among the |
| 22 | licensed bed categories defined as beds for mental health |
| 23 | services; or the conversion of general acute care beds to beds |
| 24 | for mental health services. |
| 25 | 1. Conversion under this paragraph shall not establish |
| 26 | a new licensed bed category at the hospital but shall apply |
| 27 | only to categories of beds licensed at that hospital. |
| 28 | 2. Beds converted under this paragraph must be |
| 29 | licensed and operational for at least 12 months before the |
| 30 | hospital may apply for additional conversion affecting beds of |
| 31 | the same type. |

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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.

5 408.037(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 that 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 31 | community that provides a variety of residential settings and

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- 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 31 therapeutic cardiac catheterization pursuant to the grant of

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| the | exemption. |

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- 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 31 comply with the rules adopted pursuant to subparagraph 2. The

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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-subparagraph (I) or 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) (i) 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.

(q)(1) For combination within one nursing home 31 | facility of the beds or services authorized by two or more

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- certificates of need issued in the same planning subdistrict.
- An exemption granted under this paragraph shall extend the
- 3 validity period of the certificates of need to be consolidated
- by the length of the period beginning upon submission of the 4
- 5 exemption request and ending with issuance of the exemption.
- The longest validity period among the certificates shall be 6
- 7 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.
 - $\underline{\text{(i)}}$ For the addition of hospital beds licensed under chapter 395 for comprehensive rehabilitation 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 31 | occupancy rate meets or exceeds 96 percent.

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- b. Certify that the 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.
- (j)(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; or, for the addition of nursing home beds licensed under chapter 400 at a facility that has been designated as a Gold Seal nursing home under s. 400.235 in a number not exceeding 20 total beds or 10 percent of the number of licensed beds 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 31 | facility has not had any class I or class II deficiencies

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. | 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.

 $\underline{\text{b.e.}}$ Certify that the prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 96 percent.

c.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.

(k) For the establishment of:

- 1. 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
- 2. 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,

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- 29 if the applicant demonstrates that it meets the requirements
 30 for quality of care, nurse staffing, physician staffing,
- 31 physical plant, equipment, emergency transportation, and data

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reporting found in agency certificate-of-need rules for Level II and Level III neonatal intensive care units and if the applicant commits to the provision of services to Medicaid and 3 charity patients at a level equal to or greater than the district average. Such a commitment is subject to s. 408.040. (q) For establishment of a specialty hospital offering 6 a range of medical service restricted to a defined age or 8 gender group of the population or a restricted range of 9 services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical illnesses or 10 11 disorders, through the transfer of beds and services from an existing hospital in the same county. 12 13 (r) For the conversion of hospital-based Medicare and Medicaid certified skilled nursing beds to acute care beds, if 14 15 the conversion does not involve the construction of new 16 facilities. 17 (s)1. For an adult open-heart-surgery program to be located in a new hospital provided the new hospital is being 18 19 established in the location of an existing hospital with an 20 adult open-heart-surgery program, the existing hospital and 21 the existing adult open-heart-surgery program are being 22 relocated to a replacement hospital, and the replacement 23 hospital will utilize a closed-staff model. A hospital is exempt from the certificate-of-need review for the 24 25 establishment of an open-heart-surgery program if the 26 application for exemption submitted under this paragraph 27 complies with the following criteria: a. The applicant must certify that it will meet and 2.8 continuously maintain the minimum Florida Administrative Code 29 and any future licensure requirements governing adult 30

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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 31 | the physical facilities. The effective date of the

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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.

(1)(t)1. For the provision of adult open-heart services in a hospital located within the boundaries of a health service planning district, as defined in s. 408.032(5), which has experienced an annual net out-migration of at least 600 open-heart-surgery cases for 3 consecutive years according to the most recent data reported to the agency, and the district's population per licensed and operational open-heart programs exceeds the state average of population per licensed and operational open-heart programs by at least 25 percent 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. All hospitals within a health service planning district which meet the criteria reference in sub-subparagraphs 2.a.-h. shall be eligible for this exemption on July 1, 2004, and shall receive the exemption upon filing for it and subject to the following:

a. A hospital that has received a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for the establishment of an open-heart-surgery program is entitled to receive a letter of 31 exemption for the establishment of an adult open-heart-surgery

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- program upon filing a request for exemption and complying with
 the criteria enumerated in sub-subparagraphs 2.a.-h., and is
 entitled to immediately commence operation of the program.
- b. An otherwise eligible hospital that has not 4 5 received a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for 6 7 the establishment of an open-heart-surgery program is entitled to immediately receive a letter of exemption for the 8 establishment of an adult open-heart-surgery program upon 9 filing a request for exemption and complying with the criteria 10 enumerated in sub-subparagraphs 2.a.-h., but is not entitled 11 to commence operation of its program until December 31, 2006. 12
 - 2. 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.
- 31 d. The applicant can demonstrate that it <u>has</u>

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- discharged at least 300 inpatients with a principal diagnosis of ischemic heart disease for the most recent 12-month period 3 as reported to the agency is referring 300 or more patients per year from the hospital, including the emergency room, for 4 5 cardiac services at a hospital with cardiac services, or that the average wait for transfer for 50 percent or more of the 6 7 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.
 - q. 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.
 - 3.2. 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 it has received under this paragraph during the calendar year and the number of exemptions it has granted or denied during the calendar year.
- (m) For the provision of percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital without an approved adult 31 open-heart-surgery program. In addition to any other

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documentation required by the agency, a request for an exemption submitted under this paragraph must comply with the 3 following: 4 1. The applicant must certify that it will meet and 5 continuously maintain the requirements adopted by the agency for the provisions of these services. These licensure 6 requirements must be adopted by rule pursuant to ss. 8 120.536(1) and 120.54 and must be consistent with the quidelines published by the American College of Cardiology and 9 the American Heart Association for the provision of 10 11 percutaneuos coronary interventions in hospitals without adult open-heart services. At a minimum, the rules shall require 12 13 that: a. Cardiologists be experienced interventionalists who 14 have performed a mimimum of 75 interventions within the 15 16 previous 12 months. b. The hospital provide a minimum of 36 emergency 17 18 interventions annually in order to continue to provide the 19 <u>service.</u> 20 c. The hospital offer sufficient physician, nursing, 21 and laboratory staff to provide the services 24 hours a day, 7 2.2 days a week. d. Nursing and technical staff have demonstrated 23 experience in handling acutely ill patients requiring 24 25 intervention based on previous experience in dedicated interventional laboratories or surgical centers. 26 27 e. Cardiac care nursing staff be adept in hemodynamic 28 monitoring and Intra-aortic Balloon Pump management. 29 f. Formalized written transfer agreements be developed with a hospital with an adult open-heart-surgery program and 30

31 written transport protocols be in place to ensure safe and

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- efficient transfer of a patient within 60 minutes. Transfer
 and transport agreements must be received and tested, with
 appropriate documentation maintained at least every 3 months.
 - g. Hospitals implementing the service first undertake a training program of 3 to 6 months' duration, which includes establishing standard and testing logistics, creating quality assessment and error management practices, and formalizing patient-selection criteria.
 - 2. The applicant must certify that it will at all times use the patient-selection criteria for the performance of primary angioplasty at hospitals without adult open-heart-surgery programs issued by the American College of Cardiology and the American Heart Association. At a minimum, these criteria must provide for:
 - a. Avoidance of interventions in hemodynamically stable patients who have identified symptoms or medical histories.
 - b. Transfer of patients who have a history of coronary disease and clinical presentation of hemodynamic instability.
 - 3. The applicant must agree to submit to the agency a quarterly report detailing patient characteristics, treatment, and outcomes for all patients receiving emergency percutaneous coronary interventions pursuant to this paragraph. This report must be submitted within 15 days after the close of each calendar quarter.
 - 4. The exemption provided by this paragraph does not apply unless the agency determines that the hospital has taken all necessary steps to be in compliance with all requirements of this paragraph, including the training program required under sub-subparagraph 1.q.
- 5. If the hospital fails to continuously comply with

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- the requirements of sub-subparagraphs 1.c.-f. and subparagraphs 2. and 3., this exemption immediately expires.
- 6. If the hospital fails to meet the volume
 requirements of sub-subparagraphs 1.a. and b. within 18 months
 after the program begins offering the service, this exemption
 immediately expires.

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- 8 If the exemption for this service expires under subparagraph
- 9 5. or subparagraph 6., the agency may not grant another
- 10 exemption for this service to the same hospital for 2 years
- 11 and then only upon a showing that the hospital will remain in
- 12 compliance with the requirements of this paragraph through a
- 13 demonstration of corrections to the deficiencies that caused
- 14 the exemption to expire. Compliance with this paragraph
- 15 <u>includes compliance with the rules adopted pursuant to this</u>

16 <u>paragrap</u>h.

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- (n) For the addition of mental health services or beds if the applicant commits to providing services to Medicaid or charity care patients at a level equal to or greater than the district average. Such a commitment is subject to s. 408.040.
- (o) For replacement of a licensed nursing home on the same site, or within 3 miles of the same site, if the number of licensed beds does not increase.
- (p) For consolidation or combination of licensed
 nursing homes or transfer of beds between licensed nursing
 homes within the same planning subdistrict, by providers that
 operate multiple nursing homes within that planning
 subdistrict, if there is no increase in the planning
 subdistrict total number of nursing home beds and the site of
 the relocation is not more than 30 miles from the original
- the relocation is not more than 30 miles from the original

31 <u>location.</u>

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| 1 | (q) For beds in state mental health treatment |
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| 2 | facilities operated under s. 394.455(30) and state mental |
| 3 | health forensic facilities operated under s. 916.106(8). |
| 4 | (r) For beds in state developmental services |
| 5 | institutions as defined in s. 393.063. |
| 6 | (4) <u>REQUESTS FOR EXEMPTION</u> A request for exemption |
| 7 | under subsection (3) may be made at any time and is not |
| 8 | subject to the batching requirements of this section. The |
| 9 | request shall be supported by such documentation as the agency |
| 10 | requires by rule. The agency shall assess a fee of \$250 for |
| 11 | each request for exemption submitted under subsection (3). |
| 12 | (5) NOTIFICATION Health care facilities and |
| 13 | providers must provide to the agency notification of: |
| 14 | (a) Replacement of a health care facility when the |
| 15 | proposed project site is located in the same district and on |
| 16 | the existing site or within a 1-mile radius of the replaced |
| 17 | health care facility, if the number and type of beds do not |
| 18 | increase. |
| 19 | (b) The termination of a health care service, upon 30 |
| 20 | days' written notice to the agency. |
| 21 | (c) The addition or delicensure of beds. |
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| 23 | Notification under this subsection may be made by electronic, |
| 24 | facsimile, or written means at any time before the described |
| 25 | action has been taken. |
| 26 | Section 7. Section 408.0361, Florida Statutes, is |
| 27 | amended to read: |
| 28 | 408.0361 Cardiology services and burn unit licensure |
| 29 | Diagnostic cardiac catheterization services providers; |
| 30 | compliance with guidelines and requirements |
| 31 | (1) Each provider of diagnostic cardiac |

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- catheterization services shall comply with the requirements of

 s. 408.036(3)(i)2.a.-d., and rules adopted by of the agency

 which establish licensure standards for Health Care

 Administration governing the operation of adult inpatient

 diagnostic cardiac catheterization programs. The rules must

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

31 units in effect on June 30, 2004, are ratified pursuant to

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- this subsection and shall remain in effect and be enforceable by the agency until the licensure rules are adopted. Existing 3 providers and any provider with a notice of intent to grant a certificate of need or a final order of the agency granting a 4 a certificate of need for adult interventional cardiology services or burn units shall be considered grandfathered-in 6 and shall receive a license for their programs effective on July 1, 2004. That licensure shall remain valid for at least 3 8 years or a period specified in the rule, whichever is longer, 9 but such programs must meet licensure standards applicable to 10 11 existing programs for every subsequent licensure period. (3) In establishing rules for adult interventional 12 cardiology services, the agency shall include provisions that 13 14 allow for: 15 (a) Establishment of two hospital program licensure 16 levels: a Level I program authorizing the performance of adult primary percutaneous cardiac intervention for emergent 17 18 patients without onsite cardiac surgery and a Level II program 19 authorizing the performance of percutaneous cardiac intervention with onsite cardiac surgery. (b) For a hospital seeking a Level I program, 2.1 demonstration that, for the most recent 12-month period as 23 reported to the agency, it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations 24 25 or has transferred at least 300 inpatients with the principal diagnosis of ischemic heart disease and that it has a 26 27 formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols 2.8 to ensure safe and efficient transfer of a patient within 60 30 minutes.
 - (c) For a hospital seeking a Level II program,

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- demonstration that it has discharged at least 800 patients with the principal diagnosis of ischemic heart disease.
- 3 (d) Compliance with the most recent quidelines of the American College of Cardiology and American Heart Association 4 quidelines for staffing, physician training and experience, operating procedures, equipment, physical plant, and 6
- patient-selection criteria to ensure patient quality and 8 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 12 13 Medicaid and charity patients.
- (4) The agency shall establish a technical advisory 14 panel to develop procedures and standards for measuring
- outcomes of interventional cardiac programs. Members of the 16
- 17 panel shall include representatives of the Florida Hospital
- Association, the Florida Society of Thoracic and 18
- 19 Cardiovascular Surgeons, the Florida Chapter of the American
- 20 College of Cardiology, and the Florida Chapter of the American
- 21 Heart Association and others who have experience in statistics
- 2.2 and outcome measurement. Based upon recommendations from the
- panel, the agency shall develop and adopt for the 23
- interventional cardiac programs rules that include at least 24
- the following: 25
- (a) A standard data set consisting primarily of data 26 27 elements reported to the agency in accordance with s. 408.061.
- 28 (b) A risk-adjustment procedure that accounts for the 29 variations in severity and case mix found in hospitals in this 30 state.
- 31 (c) Outcome standards specifying expected levels of

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performance in Level I and Level II adult interventional cardiology services. Such standards may include, but are not limited to, inhospital mortality, infection rates, nonfatal 3 myocardial infarctions, length of stay, postoperative bleeds, 4 and returns to surgery. (d) Specific steps to be taken by the agency and 6 licensing hospitals that do not meet the outcome standards 8 within specified time periods, including time periods for detailed case reviews and development and implementation of 9 corrective action plans. 10 11 (9) The Secretary of Health Care Administration shall appoint an advisory group to study the issue of replacing 12 13 certificate-of-need review of organ transplant programs under this chapter with licensure regulation of organ transplant 14 programs under chapter 395. The advisory group shall include 15 16 three representatives of organ transplant providers, one representative of an organ procurement organization, one 17 representative of the Division of Health Quality Assurance, 18 19 one representative of Medicaid, and one advocate for organ transplant patients. The advisory group shall, at a minimum, 21 make recommendations regarding access to organs, delivery of 2.2 services to Medicaid and charity patients, staff training, and 23 resource requirements for organ transplant programs in a 24 report due to the secretary and the Legislature by July 1, 25 2005. (10) The Secretary of Health Care Administration shall 26 27 appoint a work group to study certificate-of-need regulations 28 and changing market conditions related to the supply and distribution of hospital beds. The assessment by the work 29 group shall include, but need not be limited to: 30

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- 1 methodologies and other criteria for evaluating proposals for 2 new hospitals and transfers 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

6 <u>services.</u>

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- 8 The workgroup shall, by January 1, 2005, submit to the
 9 secretary and the Legislature a report identifying specific
 10 program areas and recommending needed changes in statutes and
- 11 rules.
- 12 Section 8. Section 408.038, Florida Statutes, is 13 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:
- 20 (1) A minimum base fee of \$10,000\$, \$5,000.
- 21 (2) In addition to the base fee of \$10,000\$\\$5,000\$,
 22 0.015 of each dollar of proposed expenditure, except that a
 23 fee may not exceed \$50,000\$\\$22,000\$.
- Section 9. Subsections (1), paragraph (a) of subsection (3), and paragraph (a) and (b) of subsection (4) of section 408.039, are amended to read:
- 408.039 Review process.—The review process for certificates of need shall be as follows:
- 29 (1) REVIEW CYCLES.--The agency by rule shall provide 30 for applications to be submitted on a timetable or cycle 31 basis; provide for review on a timely basis; and provide for

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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 6 7 agency, and shall furnish a copy of the application to the 8 local health council and the agency. Within 15 days after the applicable application filing deadline established by agency 9 rule, the staff of the agency shall determine if the 10 11 application is complete. If the application is incomplete, the staff shall request specific information from the 12 applicant necessary for the application to be complete; 13 14 however, the staff may make only one such request. If the 15 requested information is not filed with the agency within 21 16 days after of the receipt of the staff's request, the application shall be deemed incomplete and deemed withdrawn 17 from consideration. 18
 - (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, 31 to grant a certificate of need for identifiable portions of

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- the project, or to deny a certificate of need. The State Agency Action Report shall set forth in writing its findings 3 of fact and determinations upon which its decision is based. If a finding of fact or determination by the agency is counter 5 to the district health plan of the local health council, the 6 agency shall provide in writing its reason for its findings, 7 item by item, to the local health council. If the agency intends to grant a certificate of need, the State Agency 8 Action Report or the Notice of Intent shall also include any 9 conditions which the agency intends to attach to the 10 11 certificate of need. The agency shall designate by rule a senior staff person, other than the person who issues the 12 final order, to issue State Agency Action Reports and Notices 13 of Intent. 14
- 15 Section 10. Section 408.040, Florida Statutes, is 16 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 an 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 31 | an applicant's statements that a specified percentage of

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- 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.
 - 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 an 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.
 - exemption fails to comply with a condition upon which the issuance of the certificate or exemption was predicated, the agency may assess an administrative fine against the certificateholder or exemption holder 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

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- construction, if the project provides for construction, unless the applicant has incurred an enforceable capital expenditure 3 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 6 holder of the certificate of need in meeting the timetable for project development specified in the application with the 8 9 assistance of the local health council as specified in s. 408.033(1)(b)5., and may revoke the certificate of need, if 10 11 the holder of the certificate is not meeting such timetable and is not making a good-faith effort, as defined by rule, to 12 13 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 31 | completion of construction.

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| 1 | Section 11. <u>Subsection (5) of section 408.043, Florida</u> |
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| 2 | Statutes, is repealed. |
| 3 | Section 12. Section 408.0455, Florida Statutes, is |
| 4 | amended to read: |
| 5 | 408.0455 Rules; pending proceedingsThe rules of the |
| 6 | agency in effect on June 30, $\underline{2004}$ $\underline{1997}$, shall remain in effect |
| 7 | and shall be enforceable by the agency with respect to ss. |
| 8 | 408.031-408.045 until such rules are repealed or amended by |
| 9 | the agency , and no judicial or administrative proceeding |
| 10 | pending on July 1, 1997, shall be abated as a result of the |
| 11 | provisions of ss. 408.031-408.043(1) and (2); s. 408.044; or |
| 12 | s. 408.045 . |
| 13 | Section 13. This act shall take effect July 1, 2004. |
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| 16 | ======== T I T L E A M E N D M E N T ========= |
| 17 | And the title is amended as follows: |
| 18 | Delete everything before the enacting clause |
| 19 | |
| 20 | and insert: |
| 21 | A bill to be entitled |
| 22 | An act relating to certificate of need; |
| 23 | amending s. 395.003, F.S.; providing additional |
| 24 | conditions for the licensure or relicensure of |
| 25 | hospitals; exempting currently licensed |
| 26 | hospitals; amending s. 408.032, F.S.; |
| 27 | redefining terms relating to the Health |
| 28 | Facility and Services Development Act; deleting |
| 29 | the term "regional area"; amending s. 408.033, |
| 30 | F.S.; deleting provisions relating to regional |
| 31 | area health plans; transferring certain duties |

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| from the Agency for Health Care Administration |
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| to the Department of Health; deleting an agency |
| responsibility relating to orientation of local |
| health council members; deleting a requirement |
| that local health councils be partly funded by |
| application fees for certificates of need; |
| adding sources of funding for local health |
| councils; amending s. 408.034, F.S.; revising |
| criteria for certificate-of-need review and for |
| issuing licenses to health care facilities and |
| health service providers; revising criteria for |
| the nursing-home-bed-need methodology; amending |
| s. 408.035, F.S.; revising the criteria for |
| reviewing applications for certificate-of-need |
| determinations; amending s. 408.036, F.S.; |
| revising criteria for determining whether a |
| health-care-related project is subject to |
| review; providing that the replacement or |
| relocation of a nursing home is subject to |
| expedited review under specified conditions; |
| revising the criteria for determining whether a |
| project is subject to exemption from review |
| upon request; repealing the exemption for |
| specified services; adding an optional |
| exemption for neonatal intensive care units |
| that meet certain requirements; providing |
| exemptions for adding beds for comprehensive |
| rehabilitation, for beds in state mental health |
| treatment facilities, for beds in state mental |
| health treatment facilities and state mental |
| health forensic facilities, and for beds in 43 |

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| state developmental services institutions; |
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| revising the criteria for optional exemption of |
| adult open-heart services; requiring the agency |
| to report annually to the Legislature specified |
| information concerning exemptions requested and |
| granted during the preceding calendar year; |
| adding an optional exemption for the provision |
| of percutaneous coronary intervention under |
| certain conditions; requiring health care |
| facilities and providers to provide to the |
| agency notice of the replacement of a health |
| care facility or a nursing home, in specified |
| circumstances, consolidation of nursing homes, |
| the termination of a health care service, and |
| the addition or delicensure of beds; amending |
| s. 408.0361, F.S., relating to compliance with |
| requirements imposed on diagnostic cardiac |
| catheterization services providers; revising |
| the scope of application, to include the |
| compliance required of cardiology services and |
| the licensure of burn units; requiring the |
| Secretary of Health Care Administration to |
| appoint an advisory group to study replacing |
| certificate-of-need review of organ transplant |
| programs with licensure regulation of organ |
| transplant providers; requiring a report to the |
| secretary and the Legislature; requiring the |
| secretary to appoint a work group to study |
| certificate-of-need regulation and changing |
| market conditions related to the supply and |
| distribution of hospital beds; requiring a 44 |

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| report to the secretary and the Legislature; |
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| amending s. 408.038, F.S.; revising fees |
| assessed on certificate-of-need applications; |
| amending s. 408.039, F.S.; revising the review |
| process for certificates of need; requiring |
| shorter review cycles; deleting a requirement |
| to file a copy of the application with the |
| local health council; deleting a requirement to |
| consider the district health plan in reviewing |
| and taking action on the applications; amending |
| s. 408.040, F.S.; applying the conditions to |
| the issuance of a certificate of need to the |
| issuance of an exemption; providing that |
| certain failures to annually report compliance |
| with certain conditions to receiving a |
| certificate of need or an exemption constitute |
| noncompliance; repealing s. 408.043(5), F.S., |
| relating to the authority of a sole acute care |
| hospital in a high growth county to add beds |
| without agency review; amending s. 408.0455, |
| F.S.; providing for the rules of the agency |
| which are in effect on June 30, 2004, rather |
| than those in effect on June 30, 1997, to |
| remain in effect; providing an effective date. |
| |
| WHEREAS, appropriate access to adult cardiac care is an |
| issue of critical state importance to all residents of the |
| state and to all health service planning districts of the |
| state, and |
| |

WHEREAS, the certificate-of-need process, for most

31 geographic areas in the state, has provided adequate access to 45 2:09 PM 03/30/04

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adult open-heart-surgery services to Floridians as well as tourists, business travelers, indigents, and migrant workers who receive such services, and

WHEREAS, the number of adult open-heart-surgery programs in certain health service planning districts has not kept pace with the dramatic increase in population in those areas, and

WHEREAS, there have been numerous technological advances in the area of primary angioplasty and stent procedures known collectively as percutaneous coronary interventions, and these advanced interventional treatments provide the highest standard of care for people suffering acute myocardial infarctions, and

WHEREAS, the success of these interventional treatments requires immediate access (within 1 hour) to hospitals having interventional technology and a backup open-heart-surgery program, and

WHEREAS, hospitals that cannot perform percutaneous coronary interventions must resort to the use of thrombolytics, a less effective treatment in many instances, and therefore adults in need of percutaneous coronary interventions are being denied these procedures due to lack of access, and

WHEREAS, diagnosis; discharge from the transferring hospital; transfer arrangements, including, but not limited to, insurance and administrative approval; transportation availability; admission to the receiving hospital; staff availability at the receiving hospital; and, most importantly, bed availability at the receiving hospital as well as travel delays to the receiving hospital contribute to the time taken 31 to effectuate a transfer of a cardiac patient, and

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| 1 | WHEREAS, the Legislature finds that timely access and |
|----|---|
| 2 | availability for every adult in this state, regardless of |
| 3 | socioeconomic class or geographic location, to these |
| 4 | interventional treatments and open-heart surgery is of |
| 5 | critical state concern, especially because myocardial |
| 6 | infarctions and related coronary disease are no respecters of |
| 7 | location or time, and |
| 8 | WHEREAS, to ensure that it provides the quality of care |
| 9 | desired, each hospital that qualifies for the exemption |
| 10 | provided by this act will be subject to more stringent |
| 11 | criteria and will also be subject to continual monitoring by |
| 12 | the Agency for Health Care Administration, and |
| 13 | WHEREAS, the Legislature intends to ensure that |
| 14 | standards of quality are maintained while promoting |
| 15 | competition in the provision of adult cardiac care, NOW, |
| 16 | THEREFORE, |
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