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A bill to be entitled An act relating to certificates of need; amending s. 408.032, F.S.; redefining the term "tertiary health service," as used in the Health Facility and Services Development Act, to include open-heart surgery; amending s. 408.036, F.S.; amending provisions specifying which health-care-related projects are subject to review and must file an application for a certificate of need; exempting certain projects from review, including the provision of percutaneous coronary intervention, in specified circumstances; providing for the expiration of such an exemption and for postponement of the renewal of the exemption, as specified; providing additional exemptions; amending s. 408.038, F.S.; providing increases in fees for certificate-of-need applications; providing for uses of the increased revenues; amending s. 408.039, F.S.; amending the review process for certificates of need; providing for automatic approval if the Agency for Health Care Administration does not issue a final order within a specified time; providing that a court must require the losing party to pay attorney's fees and costs of the prevailing party in certain circumstances; creating the Hospital Statutory and Regulatory Reform Council; providing legislative intent; providing for membership and duties of the council; providing an effective date.

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Be It Enacted by the Legislature of the State of Florida: 2 3 Section 1. Subsection (17) of section 408.032, Florida 4 Statutes, is amended to read: 5 408.032 Definitions relating to Health Facility and 6 Services Development Act. -- As used in ss. 408.031-408.045, the 7 term: 8 "Tertiary health service" means a health service 9 which, due to its high level of intensity, complexity, 10 specialized or limited applicability, and cost, should be 11 limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of 12 13 such service. Examples of such service include, but are not limited to, organ transplantation, adult and pediatric 14 open-heart surgery, specialty burn units, neonatal intensive 15 care units, comprehensive rehabilitation, and medical or 16 17 surgical services which are experimental or developmental in 18 nature to the extent that the provision of such services is 19 not yet contemplated within the commonly accepted course of 20 diagnosis or treatment for the condition addressed by a given The agency shall establish by rule a list of all 21 service. tertiary health services. 22 Section 2. Subsections (2) and (3) of section 408.036, 23 24 Florida Statutes, are amended to read: 408.036 Projects subject to review; exemptions.--25 (2) PROJECTS SUBJECT TO EXPEDITED REVIEW. -- Unless 26 27 exempt pursuant to subsection (3), projects subject to an 28 expedited review shall include, but are not be limited to: 29 (a) Research, education, and training programs.

(b) Shared services contracts or projects.

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(b) (c) A transfer of a certificate of need, except that a purchaser who acquires an existing hospital also acquires all pending certificates of need filed by the existing hospital and all approved certificates of need owned by that hospital.

(c) (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. 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.

(d) (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 31 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.

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408.037(1), and application processing.

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(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.
- (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.
- (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.
- (d) For the addition of nursing home beds at a skilled nursing facility that is part of a retirement community that 31 provides a variety of residential settings and supportive

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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.
- (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.

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- 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.
- The applicant must certify it will provide a minimum of 2 percent of its services to charity and Medicaid patients.
- 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:
- 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.
- Maintain sufficient appropriate equipment and health personnel to ensure quality and safety.
- Maintain appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.
- 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.
- (j) For the provision of percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital that does not have an approved adult open-heart surgery program. In addition to any other documentation otherwise required by the agency, the prerequisites to a request for an exemption which is submitted under this paragraph include:
- 1. The applicant must certify that it will meet and continuously maintain the requirements adopted by the agency for the provision of these services. These licensure requirements must be adopted by rule and must be consistent with the guidelines for the provision of emergency percutaneous coronary interventions in hospitals that do not have adult open-heart services which are published by the

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American College of Cardiology and the American Heart
Association. At a minimum, the rules must provide that:

- <u>a. Cardiologists must be experienced</u> <u>interventionalists who have performed a minimum of 75</u> interventions within the previous 12 months.
- b. The hospital must provide a minimum of 36 emergency interventions annually, in order to continue to provide the service.
- c. The hospital must offer sufficient physician, nursing, and laboratory staff to provide the services 24 hours a day, 7 days a week.
- d. Nursing and technical staff must have demonstrated experience in handling acutely ill patients who require intervention, which is based on previous experience in dedicated interventional laboratories or surgical centers.
- <u>e. Cardiac care nursing staff must be adept in</u>
 hemodynamic monitoring and IABP (Intra-Aortic Balloon Pump)
 management.
- f. Formalized written transfer agreements must be developed with a hospital that has an adult open-heart surgery program, and written transport protocols must be in place to ensure safe and efficient transfer of a patient within 60 minutes. Transfer and transport agreements must be reviewed and tested at least every 3 months and appropriate documentation must be maintained.
- g. Hospitals that implement the service must first undertake a 3 to 6-month training program that includes establishing standards, testing logistics, creating quality-assessment and error-management practices, and formalizing patient-selection criteria.

1 2. The applicant must certify that it will at all times use the patient-selection criteria for the performance 2 3 of primary angioplasty at hospitals that do not have open-heart surgery programs which are issued by the American 4 5 College of Cardiology and the American Heart Association. 6 3. The applicant must agree to submit to the agency a 7 quarterly report that details patient characteristics and 8 treatment and outcomes for all patients who receive emergency 9 percutaneous coronary interventions pursuant to this exemption. The report must be submitted within 15 days after 10 11 the close of each calendar quarter. The agency must have determined that the hospital 12 has taken all necessary steps to be in compliance with this 13 paragraph. 14 15 An exemption provided under this paragraph expires immediately 16 17 if the hospital fails to meet the requirements of sub-subparagraphs 1.a. and b. within 18 months after the 18 19 program begins offering the service or to comply continuously with the rules adopted under sub-subparagraphs 1.c., d., e., 20 21 and f. or with subparagraphs 2. and 3. If the exemption provided under this paragraph expires because of such 22 deficiencies, the agency may not grant another exemption under 23 24 this paragraph to the same hospital for 2 years and, after the 2-year period has expired, may grant such an exemption only if 25 the hospital demonstrates its willingness to remain in 26 27 compliance with the adopted rules by correcting the deficiencies that caused the exemption to expire. 28 29 (k) (†) For mobile surgical facilities and related 30 health care services provided under contract with the

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Department of Corrections or a private correctional facility operating pursuant to chapter 957.

(1)(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.

(m)(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.

(n) (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.

(o) (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 30 10 total beds or 10 percent of the 31 licensed capacity of the bed category being expanded,

whichever is greater; for the addition of medical rehabilitation beds licensed under chapter 395 in a number that may not exceed 8 total beds or 10 percent of capacity, whichever is greater; or for the addition of mental health services beds licensed under chapter 395 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 or, 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 75 80 percent or, for a hospital-based distinct part skilled nursing unit, the prior 12-month average occupancy rate meets or exceeds 96 percent or, for medical rehabilitation beds, meets or exceeds 80 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.

 $\underline{(p)}$ (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 $\underline{30}$ $\underline{10}$ 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.

 $\underline{(q)}(p)$ 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.

- CODING: Words stricken are deletions; words underlined are additions.

- 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.
- (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.
- the proposed site of which is in the same district and within 10 miles of the existing facility and within the current primary service area, defined as the fewest number of zip codes comprising 75 percent of the hospital's inpatient admissions. For fiscal year 2001-2002 only, for transfer by a health care system of existing services and not more than 100 licensed and approved beds from a hospital in district 1, subdistrict 1, to another location within the same subdistrict in order to establish a satellite facility that will improve access to outpatient and inpatient care for residents of the district and subdistrict and that will use new medical technologies, including advanced diagnostics, computer assisted imaging, and telemedicine to improve care. This paragraph is repealed on July 1, 2002.
- (t) For 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 does not establish a new licensed bed category at the hospital but applies 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.
- (u) For the creation of at least a 10-bed Level II neonatal intensive care unit in an applicant hospital that has demonstrated to the agency that the hospital had at least 1,500 births during the previous 12 months.
- (v) For the addition of Level II or Level III neonatal intensive care beds in a number not to exceed 6 beds or 10 percent of licensed capacity in that category, whichever is greater, if the hospital certifies that the average occupancy rate for the category of licensed neonatal intensive care beds during the immediately preceding 12 months is at least 75 percent.

Section 3. 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. Except for the increased amount of funds received under subsection (3), the fees must

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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 $\frac{$5,000}{}$, 0.015 of each dollar of proposed expenditure, except that a fee may not exceed \$50,000 $\frac{$22,000}{}$.
- (3) Any increase in fee revenues which is generated by increases in the minimum base fee or increases in the fee limit, as authorized by the 2003 Legislature, must be used only to fund activities of the certificate-of-need program.

Section 4. Paragraph (e) of subsection (5) and paragraph (c) of subsection (6) 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:

- (5) ADMINISTRATIVE HEARINGS.--
- The agency shall issue its final order within 45 days after receipt of the recommended order. If the agency fails to take action within 45 days, the Division of Administrative Hearing's recommended order is considered approved such time, or as otherwise agreed to by the applicant and the agency, the applicant may take appropriate legal action to compel the agency to act. When making a determination on an application for a certificate of need, the agency is specifically exempt from the time limitations provided in s. 120.60(1).
 - (6) JUDICIAL REVIEW. --
- (c) The court, in its discretion, may award reasonable attorney's fees and costs to the prevailing party if the court finds that there was a complete absence of a justiciable issue 31 of law or fact raised by the losing party. If the losing party

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is a hospital, the court shall order it to pay the reasonable attorney's fees and costs of the hospital that is the 2 3 prevailing party, including fees and costs incurred as a result of the administrative hearing and the judicial appeal. 4 5 Section 5. Hospital Statutory and Regulatory Reform 6 Council; legislative intent; creation; membership; duties.--7 (1) It is the intent of the Legislature to provide for 8 the protection of the public health and safety in the 9 establishment, construction, maintenance, and operation of hospitals. However, the Legislature further intends that the 10 11 police power of the state be exercised toward that purpose only to the extent necessary and that regulation remain 12 current with the ever-changing standard of care and not 13 restrict the introduction and use of new medical technologies 14 and procedures. 15 In order to achieve the purposes expressed in 16 17 subsection (1), it is necessary that the state establish a mechanism for the ongoing review and updating of laws 18 19 regulating hospitals. The Hospital Statutory and Regulatory Reform Council is created and located, for administrative 20 21 purposes only, within the Agency for Health Care 22 Administration. The council shall consist of no more than 15 members, including: 23 24 (a) Nine members appointed by the Florida Hospital 25 Association who represent acute care, teaching, specialty, 26 rural, government-owned, for-profit, and not-for-profit 27 hospitals; 28 (b) Two members appointed by the Governor who 29 represent patients;

(c) Two members appointed by the President of the

Senate who represent private businesses that provide health

insurance coverage for their employees, one of whom represents

small private businesses and one of whom represents large

private businesses. As used in this paragraph, the term

"private business" does not include an entity licensed under

chapter 627, Florida Statutes, or chapter 641, Florida

Statutes, or otherwise licensed or authorized to provide

health insurance services, either directly or indirectly, in

this state; and

- (d) Two members appointed by the Speaker of the House of Representatives who represent physicians.
- terms and may be reappointed. A member shall serve until his or her successor is appointed. The council shall annually elect from among its members a chair and a vice chair. The council shall meet at least twice a year and shall hold additional meetings as it considers necessary. Members appointed by the Florida Hospital Association may not receive compensation or reimbursement of expenses for their services. Members appointed by the Governor, the President of the Senate, or the Speaker of the House of Representatives may be reimbursed for travel expenses by the agency.
- (4) The council, as its first priority, shall review chapters 395 and 408, Florida Statutes, and shall make recommendations to the Legislature for the repeal of regulatory provisions that are no longer necessary or that fail to promote cost-efficient, high-quality medicine.
- (5) The council, as its second priority, shall recommend to the Secretary of Health and the Secretary of Health Care Administration regulatory changes relating to hospital licensure and regulation to assist the Department of Health and the Agency for Health Care Administration in

1	carrying out their duties and to ensure that the intent of the
2	Legislature as expressed in this subsection is carried out.
3	(6) In determining whether a statute or rule is
4	appropriate or necessary, the council shall consider whether:
5	(a) The statute or rule is necessary to prevent
6	substantial harm, which is recognizable and not remote, to the
7	<pre>public health, safety, or welfare;</pre>
8	(b) The statute or rule restricts the use of new
9	medical technologies or encourages the implementation of more
10	cost-effective medical procedures;
11	(c) The statute or rule has an unreasonable effect on
12	job creation or job retention in the state;
13	(d) The public is or can be effectively protected by
14	other means;
15	(e) The overall cost-effectiveness and economic effect
16	of the proposed statute or rule, including the indirect costs
17	to consumers, will be favorable; and
18	(f) A lower-cost regulatory alternative to the statute
19	or rule could be adopted.
20	Section 6. This act shall take effect July 1, 2003.
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SENATE SUMMARY Relates to certificates of need. Redefines the term "tertiary health service" as used in the Health Facility and Services Development Act, to include adult and pediatric open-heart surgery. Amends provisions specifying which health-care-related projects are subject to the service of the services of th to review and must file an application for a certificate of need. Exempts certain projects from review, including the provision of percutaneous coronary intervention, in specified circumstances. Provides for the expiration of specified circumstances. Provides for the expiration of such an exemption and for postponing the renewal of the exemption, as specified. Provides additional exemptions. Provides for increases in fees for certificate-of-need applications. Provides that such increased revenues must be used only to fund the certificate-of-need program. Provides for automatic approval of a certificate-of-need application if the Agency for Health Care Administration does not issue its final order within 45 days after receipt of the recommended order. Provides that a court receipt of the recommended order. Provides that a court must order a hospital that is a losing party to pay reasonable attorney's fees and costs of a hospital that is the prevailing party. Creates the Hospital Statutory and Regulatory Reform Council. Provides legislative intent. Provides membership and duties of the council.