Florida Senate - 2004

By Senator Pruitt

28-1694-04

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1	A bill to be entitled
2	An act relating to certificates of need;
3	amending s. 395.003, F.S.; prohibiting the
4	Agency for Health Care Administration from
5	issuing or renewing a hospital's license if
6	more than a specified percentage of the
7	hospital's patients receive care and treatment
8	classified in specified diagnostic-related
9	groups; providing an exemption; authorizing the
10	agency to adopt rules; amending s. 408.032,
11	F.S.; revising definitions relating to health
12	facilities and services; amending s. 408.033,
13	F.S.; requiring that local health councils
14	serve counties in a health service planning
15	district; directing the local health council to
16	develop a plan for services at the local level
17	with the Department of Health; providing for
18	the costs of operating a local health council
19	to come from assessments imposed on selected
20	health care facilities; directing the
21	department to enter into contracts with the
22	local health councils for certain services;
23	amending s. 408.034, F.S.; conforming
24	provisions to changes made by the act; amending
25	s. 408.035, F.S.; revising criteria for
26	reviewing an application for a
27	certificate-of-need; amending s. 408.036, F.S.;
28	revising health-care-related projects that are
29	subject to the certificate-of-need process;
30	revising health-care-related projects that are
31	subject to an expedited certificate-of-need
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1	process; revising the list of projects exempt
2	from the certificate-of-need process; requiring
3	health care facilities and providers to notify
4	the agency of certain specified activities;
5	amending s. 408.0361, F.S.; requiring the
6	agency to adopt rules for licensure standards
7	for adult interventional cardiology services
8	and burn units; providing minimum criteria for
9	inclusion in the rules; providing that certain
10	health care providers of adult interventional
11	cardiology services are exempt from complying
12	with the rules for 2 years following the date
13	of their next license renewal, but must meet
14	the licensure standards thereafter; requiring
15	the agency to license two levels of treatment
16	for adult interventional cardiology services;
17	providing criteria for the two levels of
18	licensure; directing the Secretary of Health
19	Care Administration to appoint an advisory
20	group to study the issue of replacing
21	certificate-of-need review of organ transplant
22	programs operating under ch. 408, F.S., with
23	licensure regulation of organ transplant
24	programs under ch. 395, F.S.; providing for
25	membership; requiring the advisory group to
26	make certain recommendations; directing the
27	advisory group to submit a report to the
28	Governor, the secretary, and the Legislature by
29	a specific date; amending s. 408.038, F.S.;
30	increasing fees for certificate-of-need
31	applications; amending s. 408.039, F.S.;

1	providing for an annual review cycle for
2	certificate-of-need applications; revising the
3	review procedures; amending s. 408.040, F.S.;
4	providing for conditions and monitoring for
5	holders of a certificate of need or an
6	exemption certificate; providing that failure
7	to report to the agency constitutes
8	noncompliance with conditions of the
9	certificate; amending s. 408.0455, F.S.;
10	providing that rules of the agency in effect on
11	June 30, 2004, shall remain in effect until
12	amended or repealed; repealing s. 408.043(2),
13	F.S., relating to special provisions for
14	hospice facilities; repealing s. 408.045, F.S.,
15	relating to the use of a competitive sealed
16	proposal to obtain a certificate of need for an
17	intermediate care facility for the
18	developmentally disabled; providing an
19	effective date.
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21	WHEREAS, the Legislature finds that it is essential for
22	the public health and safety of this state that general
23	hospitals be available to serve the residents of this state,
24	and
25	WHEREAS, the Legislature finds that over 60 general
26	hospitals have closed in this state and the Legislature is
27	concerned that more hospitals may close, and
28	WHEREAS, the Legislature finds that creating hospitals
29	that provide limited services will serve only paying patients
30	and may cause harm to the continued existence of general
31	hospitals serving broad populations of this state, and
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           WHEREAS, the Legislature finds that creating hospitals
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    that provide limited services may limit or eliminate
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    competitive alternatives in the health care service market;
   may result in over-utilization of certain high-cost health
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    care services, such as cardiac, orthopedic, and cancer
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    services; may increase costs to the health care system; and
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   may adversely affect the quality of health care, NOW,
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    THEREFORE,
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    Be It Enacted by the Legislature of the State of Florida:
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           Section 1. Subsection (9) is added to section 395.003,
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    Florida Statutes, to read:
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           395.003 Licensure; issuance, renewal, denial,
   modification, suspension, and revocation .--
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          (9)(a) A hospital may not be licensed under this part,
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    or have its license renewed, if 65 percent or more of its
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    discharged patients, as reported to the Agency for Health Care
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    Administration under s. 408.061, received diagnosis, care, and
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    treatment within the following diagnostic-related groups:
           1. Cardiac-related diseases and disorders classified
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    as DRGs 103-145, 478-479, 514-518, 525-527;
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           2. Orthopedic-related diseases and disorders
    classified as DRGs 209-256, 471, 491, 496-503, 519-520;
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           3. Cancer-related diseases and disorders classified as
    DRGs 64, 82, 172, 173, 199, 200, 203, 257-260, 274, 275, 303,
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    306, 307, 318, 319, 338, 344, 346, 347, 363, 366, 367,
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    400-414, 473, 492; or
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              Any combination of the above discharges.
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The agency may not issue or renew a hospital's license if the 1 hospital's actual discharges in the most recent year for which 2 3 data is available, or the projected discharges over the next 12 months, meet the criteria of this subsection. The agency 4 5 shall revoke a hospital's license if the hospital fails to б meet these criteria during any year of operation. 7 (b) Hospitals licensed on or before June 1, 2004, 8 shall be exempt from the requirements in this subsection if the hospital maintains the same ownership, facility street 9 10 address, and range of services provided on June 1, 2004. 11 (c) The agency may adopt rules to administer this subsection. However, the statutory requirements are applicable 12 on July 1, 2004. In any administrative proceeding challenging 13 14 the denial or revocation of a hospital's license under this subsection, the hearing shall be based on the facts and law in 15 effect at the time of the agency's proposed agency action. Any 16 17 hospital may initiate or intervene in an administrative hearing to deny or revoke the license of a competing hospital 18 19 located within the same district or service area on a showing 20 that one of the hospital's established programs will be substantially affected if a license is issued to the competing 21 22 hospital. Section 2. Section 408.032, Florida Statutes, is 23 24 amended to read: 25 408.032 Definitions relating to Health Facility and Services Development Act .-- As used in ss. 408.031-408.045, the 26 27 term: 28 "Agency" means the Agency for Health Care (1)29 Administration. "Capital expenditure" means an expenditure, 30 (2) 31 including an expenditure for a construction project undertaken 5

1 by a health care facility as its own contractor, which, under 2 generally accepted accounting principles, is not properly 3 chargeable as an expense of operation and maintenance, which 4 is made to change the bed capacity of the facility, or 5 substantially change the services or service area of the 6 health care facility, health service provider, or hospice, and 7 which includes the cost of the studies, surveys, designs, plans, working drawings, specifications, initial financing 8 9 costs, and other activities essential to acquisition, 10 improvement, expansion, or replacement of the plant and 11 equipment. "Certificate of need" means a written statement 12 (3) 13 issued by the agency evidencing community need for a new, converted, expanded, or otherwise significantly modified 14 health care facility, health service, or hospice. 15 (4) "Commenced construction" means initiation of and 16 17 continuous activities beyond site preparation associated with erecting or modifying a health care facility, including 18 19 procurement of a building permit applying the use of 20 agency-approved construction documents, proof of an executed owner/contractor agreement or an irrevocable or binding forced 21 account, and actual undertaking of foundation forming with 22 23 steel installation and concrete placing. 24 (5) "District" means a health service planning district composed of the following counties: 25 District 1.--Escambia, Santa Rosa, Okaloosa, and Walton 26 27 Counties. 28 District 2.--Holmes, Washington, Bay, Jackson, 29 Franklin, Gulf, Gadsden, Liberty, Calhoun, Leon, Wakulla, Jefferson, Madison, and Taylor Counties. 30 31

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1 District 3.--Hamilton, Suwannee, Lafayette, Dixie, 2 Columbia, Gilchrist, Levy, Union, Bradford, Putnam, Alachua, 3 Marion, Citrus, Hernando, Sumter, and Lake Counties. 4 District 4.--Baker, Nassau, Duval, Clay, St. Johns, 5 Flagler, and Volusia Counties. б District 5.--Pasco and Pinellas Counties. 7 District 6.--Hillsborough, Manatee, Polk, Hardee, and 8 Highlands Counties. 9 District 7.--Seminole, Orange, Osceola, and Brevard 10 Counties. 11 District 8.--Sarasota, DeSoto, Charlotte, Lee, Glades, Hendry, and Collier Counties. 12 District 9.--Indian River, Okeechobee, St. Lucie, 13 Martin, and Palm Beach Counties. 14 15 District 10.--Broward County. District 11.--Dade and Monroe Counties. 16 17 "Exemption" means the process by which a proposal (6) 18 that would otherwise require a certificate of need may proceed 19 without a certificate of need. (7) "Expedited review" means the process by which 20 certain types of applications are not subject to the review 21 cycle requirements contained in s. 408.039(1), and the letter 22 of intent requirements contained in s. 408.039(2). 23 24 (8) "Health care facility" means a hospital, long-term 25 care hospital, skilled nursing facility, hospice, or intermediate care facility for the developmentally disabled. A 26 facility relying solely on spiritual means through prayer for 27 28 healing is not included as a health care facility. 29 "Health services" means inpatient diagnostic, (9) curative, or comprehensive medical rehabilitative services and 30 31

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1 includes mental health services. Obstetric services are not 2 health services for purposes of ss. 408.031-408.045. 3 (10) "Hospice" or "hospice program" means a hospice as defined in part VI of chapter 400. 4 5 (11) "Hospital" means a health care facility licensed б under chapter 395. 7 (12) "Intermediate care facility for the 8 developmentally disabled means a residential facility 9 licensed under chapter 393 and certified by the Federal 10 Government under pursuant to the Social Security Act as a 11 provider of Medicaid services to persons who are mentally retarded or who have a related condition. 12 (13) "Long-term care hospital" means a hospital 13 14 licensed under chapter 395 which meets the requirements of 42 15 C.F.R. s. 412.23(e) and seeks exclusion from the acute care 16 Medicare prospective payment system for inpatient hospital 17 services. (14) "Mental health services" means inpatient services 18 19 provided in a hospital licensed under chapter 395 and listed 20 on the hospital license as psychiatric beds for adults; psychiatric beds for children and adolescents; intensive 21 residential treatment beds for children and adolescents; 22 substance abuse beds for adults; or substance abuse beds for 23 24 children and adolescents. 25 (15) "Nursing home geographically underserved area" 26 means: 27 (a) A county in which there is no existing or approved 28 nursing home; 29 (b) An area with a radius of at least 20 miles in which there is no existing or approved nursing home; or 30 31 8

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1	(a) In ence with a medius of at least 20 miles in
1	(c) An area with a radius of at least 20 miles in
2	which all existing nursing homes have maintained at least a 95
3	percent occupancy rate for the most recent 6 months or a 90
4	percent occupancy rate for the most recent 12 months.
5	(16) "Skilled nursing facility" means an institution,
6	or a distinct part of an institution, which is primarily
7	engaged in providing, to inpatients, skilled nursing care and
8	related services for patients who require medical or nursing
9	care, or rehabilitation services for the rehabilitation of
10	injured, disabled, or sick persons.
11	(17) "Tertiary health service" means a health service
12	which, due to its high level of intensity, complexity,
13	specialized or limited applicability, and cost, should be
14	limited to, and concentrated in, a limited number of hospitals
15	to ensure the quality, availability, and cost-effectiveness of
16	<u>the</u> such service. Examples of <u>this</u> such service include, but
17	are not limited to, pediatric cardiac catheterization,
18	pediatric open-heart surgery,organ transplantation, specialty
19	burn units, neonatal intensive care units, comprehensive
20	rehabilitation, and medical or surgical services that which
21	are experimental or developmental in nature to the extent that
22	providing the the provision of such services is not yet
23	contemplated within the commonly accepted course of diagnosis
24	or treatment for the condition addressed by a given service.
25	The agency shall establish by rule a list of all tertiary
26	health services.
27	(18) "Regional area" means any of those regional
28	health planning areas established by the agency to which local
29	and district health planning funds are directed to local
30	health councils through the General Appropriations Act.
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1 Section 3. Section 408.033, Florida Statutes, is 2 amended to read: 3 408.033 Local and state health planning .--(1) LOCAL HEALTH COUNCILS.--4 5 (a) Local health councils are hereby established as б public or private nonprofit agencies serving the counties of a district or regional area of the agency. The members of each 7 8 council shall be appointed in an equitable manner by the 9 county commissions having jurisdiction in the respective 10 district. Each council shall be composed of a number of 11 persons equal to $1 \ 1/2$ times the number of counties that which compose the district or 12 members, whichever is 12 greater. Each county in a district shall be entitled to at 13 least one member on the council. The balance of the 14 membership of the council shall be allocated among the 15 counties of the district on the basis of population rounded to 16 17 the nearest whole number; except that in a district composed 18 of only two counties, no county shall have fewer than four 19 members. The appointees shall be representatives of health 20 care providers, health care purchasers, and nongovernmental 21 health care consumers, but not excluding elected government officials. The members of the consumer group shall include a 22 representative number of persons over 60 years of age. A 23 24 majority of council members shall consist of health care 25 purchasers and health care consumers. The local health council shall provide each county commission a schedule for 26 appointing council members to ensure that council membership 27 28 complies with the requirements of this paragraph. The members 29 of the local health council shall elect a chair. Members shall 30 serve for terms of 2 years and may be eligible for 31 reappointment.

1 (b) Each local health council may: 2 1. Develop a district or regional area health plan 3 that permits each local health council to develop strategies and set priorities for implementation based on its unique 4 5 local health needs. The district or regional area health plan б must contain preferences for the development of health 7 services and facilities, which may be considered by the agency 8 in its review of certificate-of-need applications. The district health plan shall be submitted to the agency and 9 10 updated periodically. The district health plans shall use a 11 uniform format and be submitted to the agency according to a schedule developed by the agency in conjunction with the local 12 health councils. The schedule must provide for the development 13 of district health plans by major sections over a multiyear 14 period. The elements of a district plan which are necessary 15 16 to the review of certificate-of-need applications for proposed 17 projects within the district may be adopted by the agency as 18 part of its rules. 19 2. Advise the agency on health care issues and 20 resource allocations. 21 Promote public awareness of community health needs, 3. emphasizing health promotion and cost-effective health service 22 23 selection. 24 4. Collect data and conduct analyses and studies related to health care needs of the district, including the 25 needs of medically indigent persons, and assist the agency and 26 27 other state agencies in carrying out data collection activities that relate to the functions in this subsection. 28 29 5. Monitor the onsite construction progress, if any, 30 of certificate-of-need approved projects and report council 31 findings to the agency on forms provided by the agency. 11

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1	6. Advise and assist any regional planning councils
2	within each district that have elected to address health
3	issues in their strategic regional policy plans with the
4	development of the health element of the plans to address the
5	health goals and policies in the State Comprehensive Plan.
6	7. Advise and assist local governments within each
7	district on the development of an optional health plan element
8	of the comprehensive plan provided in chapter 163, to assure
9	compatibility with the health goals and policies in the State
10	Comprehensive Plan and district health plan. To facilitate
11	the implementation of this section, the local health council
12	shall annually provide the local governments in its service
13	area, upon request, with:
14	a. A copy and appropriate updates of the district
15	health plan;
16	b. A report of hospital and nursing home utilization
17	statistics for facilities within the local government
18	jurisdiction; and
19	c. Applicable agency rules and calculated need
20	methodologies for health facilities and services regulated
21	under s. 408.034 for the district served by the local health
22	council.
23	8. Monitor and evaluate the adequacy, appropriateness,
24	and effectiveness, within the district, of local, state,
25	federal, and private funds distributed to meet the needs of
26	the medically indigent and other underserved population
27	groups.
28	9. In conjunction with the Department of Health Agency
29	for Health Care Administration, plan for services at the local
30	level for persons infected with the human immunodeficiency
31	virus.
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1 10. Provide technical assistance to encourage and support activities by providers, purchasers, consumers, and 3 local, regional, and state agencies in meeting the health care goals, objectives, and policies adopted by the local health council.

б 11. Provide the agency with data required by rule for 7 the review of certificate-of-need applications and the 8 projection of need for health services and facilities in the district. 9

10 (c) Local health councils may conduct public hearings 11 under pursuant to s. 408.039(3)(b).

Each local health council shall enter into a 12 (d) memorandum of agreement with each regional planning council in 13 its district that elects to address health issues in its 14 strategic regional policy plan. In addition, each local 15 health council shall enter into a memorandum of agreement with 16 17 each local government that includes an optional health element in its comprehensive plan. Each memorandum of agreement must 18 19 specify the manner in which each local government, regional 20 planning council, and local health council will coordinate its 21 activities to ensure a unified approach to health planning and 22 implementation efforts.

(e) Local health councils may employ personnel or 23 24 contract for staffing services with persons who possess 25 appropriate qualifications to carry out the councils' purposes. However, these such personnel are not state 26 27 employees.

28 (f) Personnel of the local health councils shall 29 provide an annual orientation to council members about council 30 member responsibilities. The orientation shall include

31 presentations and participation by agency staff.

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1 (g) Each local health council is authorized to accept 2 and receive, in furtherance of its health planning functions, 3 funds, grants, and services from governmental agencies and from private or civic sources and to perform studies related 4 5 to local health planning in exchange for such funds, grants, б or services. Each local health council shall, no later than January 30 of each year, render an accounting of the receipt 7 8 and disbursement of such funds received by it to the 9 Department of Health agency. The Department of Health agency 10 shall consolidate all such reports and submit such 11 consolidated report to the Legislature no later than March 1 of each year. Funds received by a local health council 12 13 pursuant to this paragraph shall not be deemed to be a 14 substitute for, or an offset against, any funding provided 15 pursuant to subsection (2). 16 (2) FUNDING.--17 The Legislature intends that the cost of local (a) health councils be borne by application fees for certificates 18 19 of need and by assessments on selected health care facilities 20 subject to facility licensure by the Agency for Health Care Administration, including abortion clinics, assisted living 21 facilities, ambulatory surgical centers, birthing centers, 22 clinical laboratories except community nonprofit blood banks 23 24 and clinical laboratories operated by practitioners for exclusive use regulated under s. 483.035, home health 25 agencies, hospices, hospitals, intermediate care facilities 26 for the developmentally disabled, nursing homes, and 27 28 multiphasic testing centers and by assessments on 29 organizations subject to certification by the agency under pursuant to chapter 641, part III, including health 30 31 maintenance organizations and prepaid health clinics.

1 (b)1. A hospital licensed under chapter 395, a nursing home licensed under chapter 400, and an assisted living 2 3 facility licensed under chapter 400 shall be assessed an annual fee based on number of beds. 4 5 2. All other facilities and organizations listed in б paragraph (a) shall each be assessed an annual fee of \$150. Facilities operated by the Department of Children 7 3. 8 and Family Services, the Department of Health, or the 9 Department of Corrections and any hospital that which meets 10 the definition of rural hospital under pursuant to s. 395.602 11 are exempt from the assessment required in this subsection. 12 (c)1. The agency shall, by rule, establish fees for 13 hospitals and nursing homes based on an assessment of \$2 per 14 bed. However, no such facility shall be assessed more than a total of \$500 under this subsection. 15 The agency shall, by rule, establish fees for 16 2. 17 assisted living facilities based on an assessment of \$1 per 18 bed. However, no such facility shall be assessed more than a 19 total of \$150 under this subsection. 20 The agency shall, by rule, establish an annual fee 3. 21 of \$150 for all other facilities and organizations listed in 22 paragraph (a). The agency shall, by rule, establish a facility 23 (d) 24 billing and collection process for the billing and collection of the health facility fees authorized by this subsection. 25 (e) A health facility which is assessed a fee under 26 27 this subsection is subject to a fine of \$100 per day for each 28 day in which the facility is late in submitting its annual fee 29 up to maximum of the annual fee owed by the facility. A facility which refuses to pay the fee or fine is subject to 30 31 the forfeiture of its license.

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1	(f) The agency shall deposit in the Health Care Trust
2	Fund all health care facility assessments that are assessed
3	under this subsection and proceeds from the
4	certificate-of-need application fees. The agency shall
5	transfer <u>these funds</u> to the Department of Health <u>for</u> an amount
6	sufficient to maintain the aggregate funding <u>of</u> level for the
7	local health councils as specified in the General
8	Appropriations Act. The remaining certificate-of-need
9	application fees shall be used only for the purpose of
10	administering the <u>certificate-of-need program</u> Health Facility
11	and Services Development Act.
12	(3) DUTIES AND RESPONSIBILITIES OF THE AGENCY
13	(a) The agency , in conjunction with the local health
14	councils, is responsible for the coordinated planning of
15	health care services in the state.
16	(b) The agency shall develop and maintain a
17	comprehensive health care database for the purpose of health
18	planning and for certificate-of-need determinations. The
19	agency or its contractor is authorized to require the
20	submission of information from health facilities, health
21	service providers, and licensed health professionals which is
22	determined by the agency, through rule, to be necessary for
23	meeting the agency's responsibilities as established in this
24	section.
25	(c) The agency shall assist personnel of the local
26	health councils in providing an annual orientation to council
27	members about council member responsibilities.
28	<u>(c)</u> The <u>Department of Health</u> agency shall contract
29	with the local health councils for the services specified in
30	subsection (1). All contract funds shall be distributed
31	according to an allocation plan developed by the Department of
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1 2 <u>Health</u> agency that provides for a minimum and equal funding base for each local health council. Any remaining funds shall

3 be distributed based on adjustments for workload. The agency 4 may also make grants to or reimburse local health councils 5 from federal funds provided to the state for activities б related to those functions set forth in this section. The 7 Department of Health agency may withhold funds from a local 8 health council or cancel its contract with a local health council which does not meet performance standards agreed upon 9 10 by the Department of Health agency and local health councils. 11 Section 4. Subsections (1) and (2) of section 408.034,

12 Florida Statutes, are amended to read:

13 408.034 Duties and responsibilities of agency; 14 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 22 to health care facilities and health service providers, as 23 24 provided under chapters 393, 395, and parts II and VI of 25 chapter 400, the agency may not issue a license to any health 26 care facility or, health service provider that, hospice, or part of a health care facility which fails to receive a 27 28 certificate of need or an exemption for the licensed facility 29 or service. 30 Section 5. Section 408.035, Florida Statutes, is

31 amended to read:

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1	408.035 Review criteriaThe agency shall determine
2	the reviewability of applications and shall review
3	applications for certificate-of-need determinations for health
4	care facilities and health services in context with the
5	following criteria:
б	(1) The need for the health care facilities and health
7	services being proposed in relation to the applicable district
8	health plan.
9	(2) The availability, quality of care, accessibility,
10	and extent of utilization of existing health care facilities
11	and health services in the service district of the applicant.
12	(3) The ability of the applicant to provide quality of
13	care and the applicant's record of providing quality of care.
14	(4) The need in the service district of the applicant
15	for special health care services that are not reasonably and
16	economically accessible in adjoining areas.
17	(5) The needs of research and educational facilities,
18	including, but not limited to, facilities with institutional
19	training programs and community training programs for health
20	care practitioners and for doctors of osteopathic medicine and
21	medicine at the student, internship, and residency training
22	levels.
23	(4) (6) The availability of resources, including health
24	personnel, management personnel, and funds for capital and
25	operating expenditures, for project accomplishment and
26	operation.
27	(5) (7) The extent to which the proposed services will
28	enhance access to health care for residents of the service
29	district.
30	(6) (8) The immediate and long-term financial
31	feasibility of the proposal.
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1	(7) (9) The extent to which the proposal will foster
2	competition that promotes quality and cost-effectiveness.
3	(8) (10) The costs and methods of the proposed
4	construction, including the costs and methods of energy
5	provision and the availability of alternative, less costly, or
б	more effective methods of construction.
7	(9) (11) The applicant's past and proposed provision of
8	health care services to Medicaid patients and the medically
9	indigent.
10	(10) (12) The applicant's designation as a Gold Seal
11	Program nursing facility <u>under</u> pursuant to s. 400.235, when
12	the applicant is requesting additional nursing home beds at
13	that facility.
14	Section 6. Section 408.036, Florida Statutes, is
15	amended to read:
16	408.036 Projects subject to review; exemptions
17	(1) APPLICABILITYUnless exempt under subsection
18	(3), all health-care-related projects, as described in
19	paragraphs <u>(a)-(e)(a)-(h), are subject to review and must</u>
20	file an application for a certificate of need with the agency.
21	The agency is exclusively responsible for determining whether
22	a health-care-related project is subject to review under ss.
23	408.031-408.045.
24	(a) The addition of <u>community nursing home or ICF/DD</u>
25	beds by new construction or alteration.
26	(b) The new construction or establishment of
27	additional health care facilities, including a replacement
28	health care facility when the proposed project site is not
29	located on the same site as, or within 1 mile of, the existing
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30 health care facility, if the number of beds in each licensed

31 bed category will not increase.

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1 (c) The conversion from one type of health care facility to another, including the conversion from a general 2 3 hospital, a specialty hospital, or long-term care hospital. (d) An increase in the total licensed bed capacity of 4 5 a health care facility. 6 (d) (d) (e) The establishment of a hospice or hospice 7 inpatient facility, except as provided in s. 408.043. 8 (f) The establishment of inpatient health services by 9 a health care facility, or a substantial change in such 10 services. 11 (q) An increase in the number of beds for acute care, nursing home care beds, specialty burn units, neonatal 12 intensive care units, comprehensive rehabilitation, mental 13 14 health services, or hospital-based distinct part skilled nursing units, or at a long-term care hospital. 15 (e)(h) The establishment of tertiary health services. 16 17 (2) PROJECTS SUBJECT TO EXPEDITED REVIEW.--Unless exempt under pursuant to subsection (3), projects subject to 18 19 an expedited review shall include, but not be limited to: 20 (a) Research, education, and training programs. (b) Shared services contracts or projects. 21 (a) (c) A transfer of a certificate of need, except 22 that, when an existing hospital is acquired by a purchaser, 23 24 all certificates of need issued to the hospital which are not 25 yet operational are acquired by the purchaser without need for a transfer. 26 27 (b) Replacement of a community nursing home or ICF/DD 28 when the proposed project site is located within the same 29 district and the same planning area of the health care 30 facility being replaced, if the number of licensed beds in the 31

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

1 which may be reduced from the full requirements of s. 2 408.037(1), and application processing. 3 (3) EXEMPTIONS.--Upon request, the following projects 4 are subject to exemption from the provisions of subsection 5 (1): б (a) For replacement of a licensed health care facility 7 on the same site, provided that the number of beds in each 8 licensed bed category will not increase. 9 (a)(b) For hospice services or for swing beds in a 10 rural hospital, as defined in s. 395.602, in a number that 11 does not exceed one-half of its licensed beds. (b)(c) For the conversion of licensed acute care 12 13 hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital, as defined in s. 395.602, so 14 long as the conversion of the beds does not involve the 15 construction of new facilities. The total number of skilled 16 17 nursing beds, including swing beds, may not exceed one-half of the total number of licensed beds in the rural hospital as of 18 19 July 1, 1993. Certified skilled nursing beds designated under this paragraph, excluding swing beds, shall be included in the 20 21 community nursing home bed inventory. A rural hospital which subsequently decertifies any acute care beds exempted under 22 this paragraph shall notify the agency of the decertification, 23 24 and the agency shall adjust the community nursing home bed 25 inventory accordingly.

26 <u>(c)(d)</u> For the addition of nursing home beds at a 27 skilled nursing facility that is part of a retirement 28 community that provides a variety of residential settings and 29 supportive services and that has been incorporated and 30 operated in this state for at least 65 years on or before July 31 1, 1994. All nursing home beds must not be available to the

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1 public but must be for the exclusive use of the community 2 residents. 3 (e) For an increase in the bed capacity of a nursing 4 facility licensed for at least 50 beds as of January 1, 1994, 5 under part II of chapter 400 which is not part of a continuing б care facility if, after the increase, the total licensed bed 7 capacity of that facility is not more than 60 beds and if the 8 facility has been continuously licensed since 1950 and has 9 received a superior rating on each of its two most recent licensure surveys. 10 11 (d)(f) For an inmate health care facility built by or for the exclusive use of the Department of Corrections as 12 provided in chapter 945. This exemption expires when the such 13 facility is converted to other uses. 14 (g) For the termination of an inpatient health care 15 16 service, upon 30 days' written notice to the agency. 17 (h) For the delicensure of beds, upon 30 days' written notice to the agency. A request for exemption submitted under 18 19 this paragraph must identify the number, the category of beds, 20 and the name of the facility in which the beds to be 21 delicensed are located. (e)(i) For the provision of adult inpatient diagnostic 22 cardiac catheterization services in a hospital. 23 24 1. In addition to any other documentation otherwise 25 required by the agency, a request for an exemption submitted under this paragraph must comply with the following criteria: 26 27 The applicant must certify it will not provide a. 28 therapeutic cardiac catheterization pursuant to the grant of 29 the exemption. 30 The applicant must certify it will meet and b. 31 continuously maintain the minimum licensure requirements 23 **CODING:**Words stricken are deletions; words underlined are additions.

1 adopted by the agency governing such programs under pursuant 2 to subparagraph 2. 3 The applicant must certify it will provide a c. 4 minimum of 2 percent of its services to charity and Medicaid 5 patients. б 2. The agency shall adopt licensure requirements by 7 rule which govern the operation of adult inpatient diagnostic 8 cardiac catheterization programs established under pursuant to the exemption provided in this paragraph. The rules shall 9 10 ensure that the such programs: 11 Perform only adult inpatient diagnostic cardiac a. catheterization services authorized by the exemption and will 12 13 not provide therapeutic cardiac catheterization or any other services not authorized by the exemption. 14 15 b. Maintain sufficient appropriate equipment and health personnel to ensure quality and safety. 16 17 Maintain appropriate times of operation and c. 18 protocols to ensure availability and appropriate referrals in 19 the event of emergencies. 20 Maintain appropriate program volumes to ensure d. quality and safety. 21 e. Provide a minimum of 2 percent of its services to 22 charity and Medicaid patients each year. 23 24 3.a. The exemption provided by this paragraph shall 25 not apply unless the agency determines that the program is in compliance with the requirements of subparagraph 1. and that 26 the program will, after beginning operation, continuously 27 28 comply with the rules adopted under pursuant to subparagraph 29 2. The agency shall monitor the such programs to ensure compliance with the requirements of subparagraph 2. 30 31

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1 b.(I) The exemption for a program expires shall expire 2 immediately when the program fails to comply with the rules 3 adopted under pursuant to sub-subparagraphs 2.a., b., and c. (II) Beginning 18 months after a program first begins 4 5 treating patients, the exemption for a program expires shall б expire when the program fails to comply with the rules adopted 7 under pursuant to sub-subparagraphs 2.d. and e. 8 (III) If the exemption for a program expires under 9 pursuant to sub-sub-subparagraph (I) or sub-subparagraph 10 (II), the agency may shall not grant an exemption under 11 pursuant to this paragraph for an adult inpatient diagnostic cardiac catheterization program located at the same hospital 12 until 2 years following the date of the determination by the 13 agency that the program failed to comply with the rules 14 adopted under pursuant to subparagraph 2. 15 (f) (f) (f) For mobile surgical facilities and related 16 17 health care services provided under contract with the 18 Department of Corrections or a private correctional facility 19 operating under pursuant to chapter 957. 20 (g) (k) For state veterans' nursing homes operated by 21 or on behalf of the Florida Department of Veterans' Affairs in accordance with part II of chapter 296 for which at least 50 22 percent of the construction cost is federally funded and for 23 24 which the Federal Government pays a per diem rate not to exceed one-half of the cost of the veterans' care in the such 25 state nursing homes. These beds shall not be included in the 26 27 nursing home bed inventory. 28 (h) (1) For combination within one nursing home 29 facility of the beds or services authorized by two or more 30 certificates of need issued in the same planning subdistrict. 31 An exemption granted under this paragraph shall extend the 25

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.

6 (i)(m) For division into two or more nursing home 7 facilities of beds or services authorized by one certificate 8 of need issued in the same planning subdistrict. An exemption 9 granted under this paragraph shall extend the validity period 10 of the certificate of need to be divided by the length of the 11 period beginning upon submission of the exemption request and 12 ending with issuance of the exemption.

(n) For the addition of hospital beds licensed under 13 14 chapter 395 for acute care, mental health services, or a hospital-based distinct part skilled nursing unit in a number 15 that may not exceed 10 total beds or 10 percent of the 16 17 licensed capacity of the bed category being expanded, whichever is greater. Beds for specialty burn units, neonatal 18 19 intensive care units, or comprehensive rehabilitation, or at a 20 long-term care hospital, may not be increased under this 21 paragraph. 22 1. In addition to any other documentation otherwise

23 required by the agency, a request for exemption submitted 24 under this paragraph must:

25 a. Certify that the prior 12-month average occupancy 26 rate for the category of licensed beds being expanded at the 27 facility meets or exceeds 80 percent or, for a hospital-based 28 distinct part skilled nursing unit, the prior 12-month average 29 occupancy rate meets or exceeds 96 percent.

30 b. Certify that any beds of the same type authorized
31 for the facility under this paragraph before the date of the

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1 current request for an exemption have been licensed and 2 operational for at least 12 months. 3 2. The timeframes and monitoring process specified in 4 s. 408.040(2)(a)-(c) apply to any exemption issued under this 5 paragraph. 6 3. The agency shall count beds authorized under this 7 paragraph as approved beds in the published inventory of 8 hospital beds until the beds are licensed. 9 (o) For the addition of acute care beds, as authorized by rule consistent with s. 395.003(4), in a number that may 10 11 not exceed 10 total beds or 10 percent of licensed bed capacity, whichever is greater, for temporary beds in a 12 13 hospital that has experienced high seasonal occupancy within the prior 12-month period or in a hospital that must respond 14 to emergency circumstances. 15 (j)(p) For the addition of nursing home beds licensed 16 17 under chapter 400 in a number not exceeding 10 total beds or 10 percent of the number of beds licensed in the facility 18 19 being expanded, whichever is greater. 20 1. In addition to any other documentation required by 21 the agency, a request for exemption submitted under this 22 paragraph must: 23 Effective until June 30, 2001, certify that the a 24 facility has not had any class I or class II deficiencies within the 30 months preceding the request for addition. 25 b. Effective on July 1, 2001, certify that the 26 27 facility has been designated as a Gold Seal nursing home under s. 400.235. 28 29 c. Certify that the prior 12-month average occupancy 30 rate for the nursing home beds at the facility meets or 31 exceeds 96 percent.

1 d. Certify that any beds authorized for the facility 2 under this paragraph before the date of the current request 3 for an exemption have been licensed and operational for at least 12 months. 4 5 2. The timeframes and monitoring process specified in б s. 408.040(2)(a)-(c) apply to any exemption issued under this 7 paragraph. 8 3. The agency shall count beds authorized under this 9 paragraph as approved beds in the published inventory of 10 nursing home beds until the beds are licensed. 11 (k) For establishing a Level II neonatal intensive care unit with at least 10 beds, upon documentation to the 12 agency that the applicant hospital had a minimum of 1,500 13 14 births during the previous 12 months, or establishing a Level III neonatal intensive care unit with at least 15 beds, upon 15 documentation to the agency that the applicant hospital has a 16 17 Level II neonatal intensive care unit of at least 10 beds and had a minimum of 3,500 births during the previous 12 months, 18 19 if the applicant commits to providing services to Medicaid and charity care patients at a level equal to or greater than the 20 district average. This commitment is subject to s. 408.040. 21 (1) For adding comprehensive medical rehabilitation or 22 mental health services or beds, if the applicant commits to 23 24 providing services to Medicaid or charity care patients at a 25 level equal to or greater than the district average. This commitment is subject to s. 408.040. 26 27 (q) For establishment of a specialty hospital offering 28 a range of medical service restricted to a defined age or 29 gender group of the population or a restricted range of 30 services appropriate to the diagnosis, care, and treatment of

31 | patients with specific categories of medical illnesses or

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1 disorders, through the transfer of beds and services from an 2 existing hospital in the same county. 3 (r) For the conversion of hospital-based Medicare and 4 Medicaid certified skilled nursing beds to acute care beds, if 5 the conversion does not involve the construction of new 6 facilities. 7 (s)1. For an adult open-heart-surgery program to be 8 located in a new hospital provided the new hospital is being established in the location of an existing hospital with an 9 10 adult open-heart-surgery program, the existing hospital and 11 the existing adult open-heart-surgery program are being relocated to a replacement hospital, and the replacement 12 hospital will utilize a closed-staff model. A hospital is 13 exempt from the certificate-of-need review for the 14 establishment of an open-heart-surgery program if the 15 application for exemption submitted under this paragraph 16 17 complies with the following criteria: 18 a. The applicant must certify that it will meet and 19 continuously maintain the minimum Florida Administrative Code 20 and any future licensure requirements governing adult open-heart programs adopted by the agency, including the most 21 current guidelines of the American College of Cardiology and 22 American Heart Association Guidelines for Adult Open Heart 23 24 Programs. 25 b. The applicant must certify that it will maintain 26 sufficient appropriate equipment and health personnel to 27 ensure quality and safety. 28 c. The applicant must certify that it will maintain 29 appropriate times of operation and protocols to ensure 30 availability and appropriate referrals in the event of 31 emergencies.

1d. The applicant is a newly licensed hospital in a2physical location previously owned and licensed to a hospital3performing more than 300 open-heart procedures each year,4including heart transplants.5e. The applicant must certify that it can perform more6than 300 diagnostic cardiac catheterization procedures per7year, combined inpatient and outpatient, by the end of the8third year of its operation.9f. The applicant's payor mix at a minimum reflects the10community average for Medicaid, charity care, and self-pay11patients or the applicant must certify that it will provide a12minimum of 5 percent of Medicaid, charity care, and self-pay13to open-heart-surgery patients.14g. If the applicant fails to meet the established15criteria for open-heart programs or fails to reach 30016surgeries per year by the end of its third year of operation,17it must show cause why its exemption should not be revoked.18h. In order to ensure continuity of available19services, the applicant of the newly licensed hospital may20apply for this certificate-of-need before taking possession of21the newly issued hospital license.22. By December 31, 2004, and annually thereafter, the20agency shall submit a report to the Legislature providing20information concerning the number of requests for exemption20received under this paragraph and the number of exemptions20<		
3 performing more than 300 open-heart procedures each year, including heart transplants. 5 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. 9 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. 1 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. 1 h. In order to ensure continuity of available services, the applicant of the newly licensed hospital may apply for this certificate-of-need before taking possession of the physical facilities. The effective date of the certificate-of-need will be concurrent with the effective date of the newly issued hospital license. 2. By December 31, 2004, and annually thereafter, the agency shall submit a report to the Legislature providing information concerning the number of requests for exemption received under this paragraph and the number of exemptions granted or denied. 3. This paragraph is repealed effective January 1, 2008.	1	d. The applicant is a newly licensed hospital in a
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<pre>10 community average for Medicaid, charity care, and self-pay 11 patients or the applicant must certify that it will provide a 12 minimum of 5 percent of Medicaid, charity care, and self-pay 13 to open-heart-surgery patients. 14 g. If the applicant fails to meet the established 15 criteria for open-heart programs or fails to reach 300 16 surgeries per year by the end of its third year of operation, 17 it must show cause why its exemption should not be revoked. 18 h. In order to ensure continuity of available 19 services, the applicant of the newly licensed hospital may 20 apply for this certificate-of-need before taking possession of 21 the physical facilities. The effective date of the 22 certificate-of-need will be concurrent with the effective date 23 of the newly issued hospital license. 24 2. By December 31, 2004, and annually thereafter, the 25 agency shall submit a report to the Legislature providing 26 information concerning the number of requests for exemption 27 received under this paragraph and the number of exemptions 28 granted or denied. 29 3. This paragraph is repealed effective January 1, 2008.</pre>	8	third year of its operation.
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28 granted or denied. 29 3. This paragraph is repealed effective January 1, 30 2008.	26	information concerning the number of requests for exemption
 3. This paragraph is repealed effective January 1, 2008. 	27	received under this paragraph and the number of exemptions
30 2008.	28	granted or denied.
	29	3. This paragraph is repealed effective January 1,
31	30	2008.
	31	

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1	(t)1. For the provision of adult open-heart services
2	in a hospital located within the boundaries of Palm Beach,
3	Polk, Martin, St. Lucie, and Indian River Counties if the
4	following conditions are met: The exemption must be based upon
5	objective criteria and address and solve the twin problems of
6	geographic and temporal access. A hospital shall be exempt
7	from the certificate-of-need review for the establishment of
8	an open-heart-surgery program when the application for
9	exemption submitted under this paragraph complies with the
10	following criteria:
11	a. The applicant must certify that it will meet and
12	continuously maintain the minimum licensure requirements
13	adopted by the agency governing adult open-heart programs,
14	including the most current guidelines of the American College
15	of Cardiology and American Heart Association Guidelines for
16	Adult Open Heart Programs.
17	b. The applicant must certify that it will maintain
18	sufficient appropriate equipment and health personnel to
19	ensure quality and safety.
20	c. The applicant must certify that it will maintain
21	appropriate times of operation and protocols to ensure
22	availability and appropriate referrals in the event of
23	emergencies.
24	d. The applicant can demonstrate that it is referring
25	300 or more patients per year from the hospital, including the
26	emergency room, for cardiac services at a hospital with
27	cardiac services, or that the average wait for transfer for 50
28	percent or more of the cardiac patients exceeds 4 hours.
29	e. The applicant is a general acute care hospital that
30	is in operation for 3 years or more.
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1	f. The applicant is performing more than 300
2	diagnostic cardiac catheterization procedures per year,
3	combined inpatient and outpatient.
4	g. The applicant's payor mix at a minimum reflects the
5	community average for Medicaid, charity care, and self-pay
6	patients or the applicant must certify that it will provide a
7	minimum of 5 percent of Medicaid, charity care, and self-pay
8	to open-heart-surgery patients.
9	h. If the applicant fails to meet the established
10	criteria for open-heart programs or fails to reach 300
11	surgeries per year by the end of its third year of operation,
12	it must show cause why its exemption should not be revoked.
13	2. By December 31, 2004, and annually thereafter, the
14	Agency for Health Care Administration shall submit a report to
15	the Legislature providing information concerning the number of
16	requests for exemption received under this paragraph and the
17	number of exemptions granted or denied.
18	(4) A request for exemption under subsection (3) may
19	be made at any time and is not subject to the batching
20	requirements of this section. The request shall be supported
21	by such documentation as the agency requires by rule. The
22	agency shall assess a fee of \$250 for each request for
23	exemption submitted under subsection (3).
24	(5) NOTIFICATIONHealth care facilities and
25	providers must notify the agency of the following:
26	(a) Replacement of a health care facility when the
27	proposed project site is located in the same district and on
28	the existing health care facility site or within a 1-mile
29	radius of the replaced health care facility, if the number and
30	type of beds do not increase.
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1 (b) The termination of a health care service, upon 30 2 days' written notice to the agency. 3 (c) The addition or delicensure of beds. 4 Notification under this subsection may be made at any time 5 б before the action described, by electronic, facsimile, or 7 written means. 8 Section 7. Section 408.0361, Florida Statutes, is amended to read: 9 10 408.0361 Diagnostic cardiac catheterization services 11 providers; compliance with guidelines and requirements .--(1) Each provider of diagnostic cardiac 12 13 catheterization services shall comply with the requirements of s. 408.036(3)(e)2.a.-d.s. 408.036(3)(i)2.a.-d., and rules of 14 the agency for Health Care Administration governing the 15 operation of adult inpatient diagnostic cardiac 16 17 catheterization programs, including the most recent guidelines of the American College of Cardiology and American Heart 18 Association Guidelines for Cardiac Catheterization and Cardiac 19 Catheterization Laboratories. 20 (2) The agency shall adopt rules for licensure 21 standards for adult interventional cardiology services and 22 burn units licensed under chapter 395. The rules shall 23 24 consider at a minimum: 25 (a) Staffing; 26 (b) Equipment; 27 (c) Physical plant; 28 Operating protocols; (d) 29 Provision of services to Medicaid and charity care (e) 30 patients; 31 (f) Accreditation;

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1 (g) Licensure period; 2 (h) Fees; and 3 (i) Enforcement of minimum standards. 4 5 Any provider holding a certificate of need on July 1, 2004, б and any provider in receipt of a notice of intent to grant a 7 certificate of need or a final order of the agency granting a 8 certificate of need for an adult interventional cardiology service or burn unit shall be exempt from complying with the 9 10 rules for 2 years following the date of its next license 11 renewal. Thereafter, each provider must meet the licensure standards for each license renewal. 12 (3) When adopting rules for adult interventional 13 14 cardiology services, the agency shall include rules that allow 15 for: (a) The establishment of two hospital program 16 17 licensure levels: a Level I program authorizing the 18 performance of adult percutaneous cardiac intervention without 19 on-site cardiac surgery and a Level II program authorizing the 20 performance of percutaneous cardiac intervention with on-site cardiac surgery. 21 (b) A hospital seeking a Level I program, 22 demonstration that for the most recent 12-month period as 23 24 reported to the agency it has provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations 25 and that it has a formalized, written transfer agreement with 26 27 a hospital that has a Level II program, including written 28 transport protocols to ensure safe and efficient transfer of a 29 patient within 60 minutes. 30 (c) A hospital seeking a Level II program, 31 demonstration that for the most recent 12-month period as

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1 reported to the agency that it has performed a minimum of 1,100 adult inpatient and outpatient diagnostic cardiac 2 3 catheterizations, or has discharged at least 800 patients with the primary diagnosis of ischemic heart disease. 4 5 (d) A demonstration of sufficient trained staff, б equipment, and operating procedures to assure patient quality 7 and safety. 8 (e) The establishment of appropriate hours of 9 operation and protocols to ensure availability and timely 10 referral in the event of emergencies. 11 (f) A demonstration of a plan to provide services to Medicaid and charity care patients. 12 (4) After a hospital's cardiac interventional program 13 has been operational for 12 consecutive months, and the 14 risk-adjusted mortality for coronary bypass surgery for any 15 successive 12-month period exceeds, by more than 1.75 times, 16 17 the national risk-adjusted mortality rate for coronary bypass surgery, as reported to the American Society of Thoracic 18 19 Surgeons, in the first 2 years of operation of the hospital's Level II program, or by more than 1.25 times the national risk 20 21 adjusted mortality rate for coronary bypass surgery, as 22 reported by the American Society of Thoracic Surgeons, in any successive 12-month period after the second year of operation, 23 24 the hospital shall perform a 30-day focused review of its Level II program with the intention of reducing the 25 risk-adjusted mortality rate to reasonably acceptable levels. 26 27 If mortality levels do not return to reasonably acceptable 28 levels, the agency may initiate action up to and including 29 suspension or revocation of licensure of the Level II program. 30 Section 8. The Secretary of Health Care Administration 31 shall appoint an advisory group to study the issue of

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1 replacing certificate-of-need review of organ transplant programs operating under chapter 408, Florida Statutes, with 2 3 licensure regulation of organ transplant programs under chapter 395, Florida Statutes. The advisory group must include 4 5 three representatives of organ transplant providers, one б representative of an organ procurement organization, one 7 representative of the Division of Health Quality Assurance, 8 one representative of the Medicaid program, and one organ transplant patient advocate. The advisory group shall, at a 9 10 minimum, make recommendations regarding access to organs, 11 delivery of services to Medicaid and charity care patients, staff training, and resource requirements for organ transplant 12 programs in a report submitted to the Governor, the Secretary 13 14 of Health Care Administration, and the Legislature by July 1, 2005. 15 Section 9. Section 408.038, Florida Statutes, is 16 17 amended to read: 408.038 Fees.--The agency shall assess fees on 18 19 certificate-of-need applications. The Such fees shall be for 20 the purpose of funding the functions of the local health 21 councils and the activities of the agency and shall be allocated as provided in s. 408.033. The fee shall be 22 determined as follows: 23 24 (1) A minimum base fee of 10,000; 5,000. 25 (2) In addition to the base fee of 10,000, 0.015 of each dollar of proposed expenditure, except that a 26 27 fee may not exceed\$50,000\$22,000. 28 Section 10. Section 408.039, Florida Statutes, is 29 amended to read: 30 408.039 Review process. -- The review process for 31 certificates of need shall be as follows:

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(1) REVIEW CYCLES. -- The agency by rule shall provide for applications to be submitted on a timetable or cycle basis; provide for review on a timely basis; and provide for all completed applications pertaining to similar types of services or facilities affecting the same service district to be considered in relation to each other no less often than annually two times a year. (2) LETTERS OF INTENT.--(a) At least 30 days before prior to filing an application, a letter of intent shall be filed by the applicant with the agency, respecting the development of a proposal subject to review. No letter of intent is required for expedited projects as defined by rule by the agency. (b) The agency shall provide a mechanism by which in filed letters of intent. (c) Letters of intent must describe the proposal; specify the number of beds sought, if any; identify the and identify the applicant. (d) Within 21 days after filing a letter of intent, the agency shall publish notice of the filing of letters of intent in the Florida Administrative Weekly and notice that, if requested, a public hearing shall be held at the local level within 21 days after the application is deemed complete. Notices under this paragraph must contain due dates applicable to the cycle for filing applications and for requesting a hearing.

30 (a) An applicant shall file an application with the 31 agency, and shall furnish a copy of the application to the

(3) APPLICATION PROCESSING.--

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14 applications may be filed to compete with proposals described 15 16

17 18 19 services to be provided and the specific subdistrict location; 20

local health council and the agency. Within 15 days after the 2 applicable application filing deadline established by agency 3 rule, the staff of the agency shall determine if the application is complete. If the application is incomplete, 5 the staff shall request specific information from the applicant necessary for the application to be complete; however, the staff may make only one such request. If the requested information is not filed with the agency within 21 days of the receipt of the staff's request, the application shall be deemed incomplete and deemed withdrawn from

11 consideration. (b) Upon the request of any applicant or substantially 12

affected person within 14 days after notice that an 13 application has been filed, a public hearing may be held at 14 the agency's discretion if the agency determines that a 15 proposed project involves issues of great local public 16 17 interest. The public hearing shall allow applicants and other 18 interested parties reasonable time to present their positions 19 and to present rebuttal information. A recorded verbatim record of the hearing shall be maintained. The public hearing 20 21 shall be held at the local level within 21 days after the application is deemed complete. 22

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STAFF RECOMMENDATIONS. --(4)

24 (a) The agency's review of and final agency action on applications shall be in accordance with the district health 25 plan, and statutory criteria, and the implementing 26 27 administrative rules. In the application review process, the agency shall give a preference, as defined by rule of the 28 29 agency, to an applicant that which proposes to develop a 30 nursing home in a nursing home geographically underserved 31 area.

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1 (b) Within 60 days after all the applications in a 2 review cycle are determined to be complete, the agency shall 3 issue its State Agency Action Report and Notice of Intent to 4 grant a certificate of need for the project in its entirety, 5 to grant a certificate of need for identifiable portions of б the project, or to deny a certificate of need. The State Agency Action Report shall set forth in writing its findings 7 of fact and determinations upon which its decision is based. 8 9 If a finding of fact or determination by the agency is counter 10 to the district health plan of the local health council, the 11 agency shall provide in writing its reason for its findings, item by item, to the local health council. If the agency 12 13 intends to grant a certificate of need, the State Agency 14 Action Report or the Notice of Intent shall also include any conditions which the agency intends to attach to the 15 certificate of need. The agency shall designate by rule a 16 17 senior staff person, other than the person who issues the final order, to issue State Agency Action Reports and Notices 18 19 of Intent. 20 The agency shall publish its proposed decision set (C) forth in the Notice of Intent in the Florida Administrative 21 Weekly within 14 days after the Notice of Intent is issued. 22 (d) If no administrative hearing is requested under 23 24 pursuant to subsection (5), the State Agency Action Report and the Notice of Intent shall become the final order of the 25 agency. The agency shall provide a copy of the final order to 26 the appropriate local health council. 27 28 (5) ADMINISTRATIVE HEARINGS.--29 Within 21 days after publication of notice of the (a) State Agency Action Report and Notice of Intent, any person 30 31 authorized under paragraph (c) to participate in a hearing may

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1 file a request for an administrative hearing; failure to file 2 a request for hearing within 21 days of publication of notice 3 shall constitute a waiver of any right to a hearing and a 4 waiver of the right to contest the final decision of the 5 agency. A copy of the request for hearing shall be served on 6 the applicant.

7 (b) Hearings shall be held in Tallahassee unless the 8 administrative law judge determines that changing the location 9 will facilitate the proceedings. The agency shall assign 10 proceedings requiring hearings to the Division of 11 Administrative Hearings of the Department of Management Services within 10 days after the time has expired for 12 13 requesting a hearing. Except upon unanimous consent of the parties or upon the granting by the administrative law judge 14 of a motion of continuance, hearings shall commence within 60 15 days after the administrative law judge has been assigned. All 16 17 parties, except the agency, shall bear their own expense of preparing a transcript. In any application for a certificate 18 19 of need which is referred to the Division of Administrative 20 Hearings for hearing, the administrative law judge shall 21 complete and submit to the parties a recommended order as provided in ss. 120.569 and 120.57. The recommended order 22 shall be issued within 30 days after the receipt of the 23 24 proposed recommended orders or the deadline for submission of the such proposed recommended orders, whichever is earlier. 25 The division shall adopt procedures for administrative 26 hearings which shall maximize the use of stipulated facts and 27 28 shall provide for the admission of prepared testimony. 29 (c) In administrative proceedings challenging the 30 issuance or denial of a certificate of need, only applicants 31 considered by the agency in the same batching cycle are

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1 entitled to a comparative hearing on their applications. 2 Existing health care facilities may initiate or intervene in 3 an administrative hearing upon a showing that an established 4 program will be substantially affected by the issuance of any 5 certificate of need, whether reviewed under s. 408.036(1) or 6 (2), to a competing proposed facility or program within the 7 same district.

8 (d) The applicant's failure to strictly comply with 9 the requirements of s. 408.037(1) or paragraph (2)(c) is not 10 cause for dismissal of the application, unless the failure to 11 comply impairs the fairness of the proceeding or affects the 12 correctness of the action taken by the agency.

13 (e) The agency shall issue its final order within 45 14 days after receipt of the recommended order. If the agency 15 fails to take action within this such time, or as otherwise agreed to by the applicant and the agency, the applicant may 16 17 take appropriate legal action to compel the agency to act. When making a determination on an application for a 18 19 certificate of need, the agency is specifically exempt from the time limitations provided in s. 120.60(1). 20

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(6) JUDICIAL REVIEW.--

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(a) A party to an administrative hearing for an application for a certificate of need has the right, within not more than 30 days after the date of the final order, to seek judicial review in the District Court of Appeal <u>under</u> pursuant to s. 120.68. The agency shall be a party <u>to this</u> in any such proceeding.

(b) In <u>the such</u> judicial review, the court shall affirm the final order of the agency, unless the decision is arbitrary, capricious, or not in compliance with ss. 408.031-408.045.

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(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
 of law or fact raised by the losing party.

5 Section 11. Section 408.040, Florida Statutes, is 6 amended to read:

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408.040 Conditions and monitoring.--

8 (1)(a) The agency may issue a certificate of need <u>or</u> 9 <u>an exemption</u> predicated upon statements of intent expressed by 10 an applicant in the application for a certificate of need <u>or</u> 11 <u>exemption</u>. Any conditions imposed on a certificate of need <u>or</u> 12 <u>an exemption</u> based on such statements of intent shall be 13 stated on the face of the certificate of need <u>or in the</u> 14 exemption approval.

(b) The agency may consider, in addition to the other 15 criteria specified in s. 408.035, a statement of intent by the 16 17 applicant that a specified percentage of the annual patient 18 days at the facility will be utilized by patients eligible for 19 care under Title XIX of the Social Security Act. Any certificate of need issued to a nursing home in reliance upon 20 21 an applicant's statements that a specified percentage of annual patient days will be utilized by residents eligible for 22 care under Title XIX of the Social Security Act must include a 23 24 statement that this such certification is a condition of 25 issuance of the certificate of need. The certificate-of-need program shall notify the Medicaid program office and the 26 Department of Elderly Affairs when it imposes conditions as 27 28 authorized in this paragraph in an area in which a community 29 diversion pilot project is implemented.

30 (c) A certificateholder or exemption holder may apply
31 to the agency for a modification of conditions imposed under

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1 paragraph (a) or paragraph (b). If the holder of a certificate 2 of need or exemption demonstrates good cause why the 3 certificate or exemption should be modified, the agency shall reissue the certificate of need or exemption with such 4 5 modifications as may be appropriate. The agency shall by rule б define the factors constituting good cause for modification. 7 (d) If the holder of a certificate of need or 8 certificate-of-need exemption fails to comply with a condition 9 upon which the issuance of the certificate or exemption was 10 predicated, the agency shall may assess an administrative fine 11 against the certificateholder or exemption holder in an amount not to exceed \$1,000 per failure per day. Failure to annually 12 13 report compliance with any condition upon which the issuance of the certificate or exemption was predicated constitutes 14 noncompliance. In assessing the penalty, the agency shall take 15 into account as mitigation the degree of noncompliance 16 17 relative lack of severity of a particular failure. Proceeds 18 of such penalties shall be deposited in the Public Medical 19 Assistance Trust Fund. 20 (2)(a) Unless the applicant has commenced 21 construction, if the project provides for construction, unless the applicant has incurred an enforceable capital expenditure 22 commitment for a project, if the project does not provide for 23 construction, or unless subject to paragraph (b), a 24 certificate of need shall terminate 18 months after the date 25 of issuance. The agency shall monitor the progress of the 26 holder of the certificate of need in meeting the timetable for 27 28 project development specified in the application with the 29 assistance of the local health council as specified in s. 408.033(1)(b)5., and may revoke the certificate of need, if 30 31 the holder of the certificate is not meeting such timetable

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1 and is not making a good-faith effort, as defined by rule, to
2 meet it.

3 (b) A certificate of need issued to an applicant
4 holding a provisional certificate of authority under chapter
5 651 shall terminate 1 year after the applicant receives a
6 valid certificate of authority from the Office of Insurance
7 Regulation of the Financial Services Commission.

8 (c) The certificate-of-need validity period for a 9 project shall be extended by the agency, to the extent that 10 the applicant demonstrates to the satisfaction of the agency 11 that good-faith commencement of the project is being delayed 12 by litigation or by governmental action or inaction with 13 respect to regulations or permitting precluding commencement 14 of the project.

15 (3) The agency shall require the submission of an 16 executed architect's certification of final payment for each 17 certificate-of-need project approved by the agency. Each 18 project that involves construction shall submit such 19 certification to the agency within 30 days following 20 completion of construction.

21 Section 12. Section 408.0455, Florida Statutes, is 22 amended to read:

408.0455 Rules; pending proceedings. -- The rules of the 23 24 agency in effect on June 30, 2004 1997, shall remain in effect 25 and shall be enforceable by the agency with respect to ss. 408.031-408.045 until the such rules are repealed or amended 26 by the agency, and no judicial or administrative proceeding 27 28 pending on July 1, 1997, shall be abated as a result of the 29 provisions of ss. 408.031-408.043(1) and (2); s. 408.044; or 30 s. 408.045.

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Section 13. Subsection (2) of section 408.043, and section 408.045, Florida Statutes, are repealed. Section 14. This act shall take effect July 1, 2004. б SENATE SUMMARY Directs the Agency for Health Care Administration not to issue or renew a license of a hospital if more than a specified percentage of the hospital's patients receive care and treatment classified in certain specified diagnostic-related groups. Provides exemptions. Authorizes the agency to adopt rules. Directs the local health council to develop a plan for services at the local level with the Department of Health. Provides that the costs to operate a local health council come from assessments imposed on selected health care facilities. Revises criteria for reviewing an application for a certificate of need. Requires the agency to adopt rules for licensure standards for adult interventional cardiology services and burn units. Provides that certain health care providers of adult interventional cardiology service are event from complying with the rules for 2 health care providers of adult interventional cardiology service are exempt from complying with the rules for 2 years following the date of their next license renewal, but must meet the licensure standards thereafter. Requires the agency to license two levels of treatment for adult interventional cardiology services. Directs the agency to appoint an advisory group to study the specified issues. Requires the advisory group to make certain recommendations. Directs the advisory group to submit a report to the Governor, the secretary, and the Legislature by a specific date. Provides for conditions and monitoring for holders of a certificate of need or an exemption certificate. (See bill for details.)