

Bill No. HB 329

Amendment No. ____ Barcode 430190

CHAMBER ACTION

SenateHouse

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11 Senator Pruitt moved the following amendment:

13 **Senate Amendment (with title amendment)**

14 Delete everything after the enacting clause

16 and insert:

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

19 395.003 Licensure; issuance, renewal, denial,
 20 modification, suspension, and revocation.--

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

22 (a) The diagnosis-related groups for 65 percent or
 23 more of the discharges from the hospital, in the most recent
 24 year for which data is available to the Agency for Health Care
 25 Administration pursuant to s. 408.061, are for diagnosis,
 26 care, and treatment of patients who have:

27 1. Cardiac-related diseases and disorders classified
 28 as diagnosis-related groups 103-145, 478-479, 514-518, or
 29 525-527;

30 2. Orthopedic-related diseases and disorders
 31 classified as diagnosis-related groups 209-256, 471, 491,

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 496-503, or 519-520;

2 3. Cancer-related diseases and disorders classified as
3 diagnosis-related groups 64, 82, 172, 173, 199, 200, 203,
4 257-260, 274, 275, 303, 306, 307, 318, 319, 338, 344, 346,
5 347, 363, 366, 367, 400-414, 473, or 492; or

6 4. Any combination of the above discharges.

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

10 (10) A hospital licensed as of June 1, 2004, shall be
11 exempt from subsection (9) as long as the hospital maintains
12 the same ownership, facility street address, and range of
13 services that were in existence on June 1, 2004. Any transfer
14 of beds, or other agreements that result in the establishment
15 of a hospital or hospital services within the intent of this
16 section, shall be subject to subsection (9). Unless the
17 hospital is otherwise exempt under subsection (9), the agency
18 shall deny or revoke the license of a hospital that violates
19 any of the criteria set forth in that subsection.

20 (11) The agency may adopt rules implementing the
21 licensure requirements set forth in subsection (9). Within 14
22 days after rendering its decision on a license application or
23 revocation, the agency shall publish its proposed decision in
24 the Florida Administrative Weekly. Within 21 days after
25 publication of the agency's decision, any authorized person
26 may file a request for an administrative hearing. In
27 administrative proceedings challenging the approval, denial,
28 or revocation of a license pursuant to subsection (9), the
29 hearing must be based on the facts and law existing at the
30 time of the agency's proposed agency action. Existing
31 hospitals may initiate or intervene in an administrative

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 hearing to approve, deny, or revoke licensure under subsection
2 (9) based upon a showing that an established program will be
3 substantially affected by the issuance or renewal of a license
4 to a hospital within the same district or service area.

5 Section 2. Subsections (9), (13), and (17) of section
6 408.032, Florida Statutes, are amended, and subsection (18) of
7 that section is repealed, to read:

8 408.032 Definitions relating to Health Facility and
9 Services Development Act.--As used in ss. 408.031-408.045, the
10 term:

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

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

20 (17) "Tertiary health service" means a health service
21 which, due to its high level of intensity, complexity,
22 specialized or limited applicability, and cost, should be
23 limited to, and concentrated in, a limited number of hospitals
24 to ensure the quality, availability, and cost-effectiveness of
25 such service. Examples of such service include, but are not
26 limited to, pediatric cardiac catheterization, pediatric
27 open-heart surgery, organ transplantation, ~~specialty burn~~
28 ~~units,~~ neonatal intensive care units, comprehensive
29 rehabilitation, and medical or surgical services which are
30 experimental or developmental in nature to the extent that the
31 provision of such services is not yet contemplated within the

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 commonly accepted course of diagnosis or treatment for the
2 condition addressed by a given service. The agency shall
3 establish by rule a list of all tertiary health services.

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

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

10 408.033 Local and state health planning.--

11 (1) LOCAL HEALTH COUNCILS.--

12 (a) Local health councils are hereby established as
13 public or private nonprofit agencies serving the counties of a
14 district ~~or regional area of the agency~~. The members of each
15 council shall be appointed in an equitable manner by the
16 county commissions having jurisdiction in the respective
17 district. Each council shall be composed of a number of
18 persons equal to 1 1/2 times the number of counties which
19 compose the district or 12 members, whichever is greater. Each
20 county in a district shall be entitled to at least one member
21 on the council. The balance of the membership of the council
22 shall be allocated among the counties of the district on the
23 basis of population rounded to the nearest whole number;
24 except that in a district composed of only two counties, no
25 county shall have fewer than four members. The appointees
26 shall be representatives of health care providers, health care
27 purchasers, and nongovernmental health care consumers, but not
28 excluding elected government officials. The members of the
29 consumer group shall include a representative number of
30 persons over 60 years of age. A majority of council members
31 shall consist of health care purchasers and health care

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 consumers. The local health council shall provide each county
2 commission a schedule for appointing council members to ensure
3 that council membership complies with the requirements of this
4 paragraph. The members of the local health council shall
5 elect a chair. Members shall serve for terms of 2 years and
6 may be eligible for reappointment.

7 (b) Each local health council may:

8 1. Develop a district ~~or regional~~ area health plan
9 that permits each local health council to develop strategies
10 and set priorities for implementation based on its unique
11 local health needs. ~~The district or regional area health plan~~
12 ~~must contain preferences for the development of health~~
13 ~~services and facilities, which may be considered by the agency~~
14 ~~in its review of certificate-of-need applications. The~~
15 ~~district health plan shall be submitted to the agency and~~
16 ~~updated periodically. The district health plans shall use a~~
17 ~~uniform format and be submitted to the agency according to a~~
18 ~~schedule developed by the agency in conjunction with the local~~
19 ~~health councils. The schedule must provide for the development~~
20 ~~of district health plans by major sections over a multiyear~~
21 ~~period. The elements of a district plan which are necessary~~
22 ~~to the review of certificate-of-need applications for proposed~~
23 ~~projects within the district may be adopted by the agency as a~~
24 ~~part of its rules.~~

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

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

30 4. Collect data and conduct analyses and studies
31 related to health care needs of the district, including the

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 needs of medically indigent persons, and assist the agency and
2 other state agencies in carrying out data collection
3 activities that relate to the functions in this subsection.

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

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

12 7. Advise and assist local governments within each
13 district on the development of an optional health plan element
14 of the comprehensive plan provided in chapter 163, to assure
15 compatibility with the health goals and policies in the State
16 Comprehensive Plan and district health plan. To facilitate
17 the implementation of this section, the local health council
18 shall annually provide the local governments in its service
19 area, upon request, with:

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

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

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

29 8. Monitor and evaluate the adequacy, appropriateness,
30 and effectiveness, within the district, of local, state,
31 federal, and private funds distributed to meet the needs of

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 the medically indigent and other underserved population
2 groups.

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

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

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

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

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

29 (e) Local health councils may employ personnel or
30 contract for staffing services with persons who possess
31 appropriate qualifications to carry out the councils'

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 purposes. However, such personnel are not state employees.

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

6 (g) Each local health council is authorized to accept
7 and receive, in furtherance of its health planning functions,
8 funds, grants, and services from governmental agencies and
9 from private or civic sources and to perform studies related
10 to local health planning in exchange for such funds, grants,
11 or services. Each local health council shall, no later than
12 January 30 of each year, render an accounting of the receipt
13 and disbursement of such funds received by it to the
14 Department of Health ~~agency~~. The department ~~agency~~ shall
15 consolidate all such reports and submit such consolidated
16 report to the Legislature no later than March 1 of each year.
17 ~~Funds received by a local health council pursuant to this~~
18 ~~paragraph shall not be deemed to be a substitute for, or an~~
19 ~~offset against, any funding provided pursuant to subsection~~
20 ~~(2).~~

21 (2) FUNDING.--

22 (a) The Legislature intends that the cost of local
23 health councils be borne by ~~application fees for certificates~~
24 ~~of need and by~~ assessments on selected health care facilities
25 subject to facility licensure by the Agency for Health Care
26 Administration, including abortion clinics, assisted living
27 facilities, ambulatory surgical centers, birthing centers,
28 clinical laboratories except community nonprofit blood banks
29 and clinical laboratories operated by practitioners for
30 exclusive use regulated under s. 483.035, home health
31 agencies, hospices, hospitals, intermediate care facilities

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 for the developmentally disabled, nursing homes, health care
2 clinics, and multiphasic testing centers and by assessments on
3 organizations subject to certification by the agency pursuant
4 to chapter 641, part III, including health maintenance
5 organizations and prepaid health clinics.

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

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

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

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

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

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

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

31 (e) A health facility which is assessed a fee under

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 this subsection is subject to a fine of \$100 per day for each
2 day in which the facility is late in submitting its annual fee
3 up to maximum of the annual fee owed by the facility. A
4 facility which refuses to pay the fee or fine is subject to
5 the forfeiture of its license.

6 (f) The agency shall deposit in the Health Care Trust
7 Fund all health care facility assessments that are assessed
8 under this subsection and ~~proceeds from the~~
9 ~~certificate-of-need application fees. The agency shall~~
10 transfer such funds to the Department of Health for an amount
11 ~~sufficient to maintain the aggregate funding of level for the~~
12 local health councils ~~as specified in the General~~
13 ~~Appropriations Act. The remaining certificate-of-need~~
14 application fees shall be used only for the purpose of
15 administering the certificate-of-need program ~~Health Facility~~
16 ~~and Services Development Act.~~

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

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

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

30 ~~(c) The agency shall assist personnel of the local~~
31 ~~health councils in providing an annual orientation to council~~

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 ~~members about council member responsibilities.~~
2 (c)(d) The Department of Health ~~agency~~ shall contract
3 with the local health councils for the services specified in
4 subsection (1). All contract funds shall be distributed
5 according to an allocation plan developed by the department
6 ~~agency that provides for a minimum and equal funding base for~~
7 ~~each local health council. Any remaining funds shall be~~
8 ~~distributed based on adjustments for workload. The agency may~~
9 ~~also make grants to or reimburse local health councils from~~
10 ~~federal funds provided to the state for activities related to~~
11 ~~those functions set forth in this section. The department~~
12 ~~agency~~ may withhold funds from a local health council or
13 cancel its contract with a local health council which does not
14 meet performance standards agreed upon by the department
15 ~~agency~~ and local health councils.

16 Section 4. Subsections (1), (2), and (5) of section
17 408.034, Florida Statutes, are amended to read:

18 408.034 Duties and responsibilities of agency;
19 rules.--

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

27 (2) In the exercise of its authority to issue licenses
28 to health care facilities and health service providers, as
29 provided under chapters 393, 395, and parts II and VI of
30 chapter 400, the agency may not issue a license to any health
31 care facility or, health service provider that, ~~hospice, or~~

Bill No. HB 329

Amendment No. ____ Barcode 430190

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

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

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

13 408.035 Review criteria.--The agency shall determine
14 the reviewability of applications and shall review
15 applications for certificate-of-need determinations for health
16 care facilities and health services in context with the
17 following criteria:

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

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

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

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

29 ~~(5) The needs of research and educational facilities,~~
30 ~~including, but not limited to, facilities with institutional~~
31 ~~training programs and community training programs for health~~

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 ~~care practitioners and for doctors of osteopathic medicine and~~
2 ~~medicine at the student, internship, and residency training~~
3 ~~levels.~~

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

8 (5)~~(7)~~ The extent to which the proposed services will
9 enhance access to health care for residents of the service
10 district.

11 (6)~~(8)~~ The immediate and long-term financial
12 feasibility of the proposal.

13 (7)~~(9)~~ The extent to which the proposal will foster
14 competition that promotes quality and cost-effectiveness.

15 (8)~~(10)~~ The costs and methods of the proposed
16 construction, including the costs and methods of energy
17 provision and the availability of alternative, less costly, or
18 more effective methods of construction.

19 (9)~~(11)~~ The applicant's past and proposed provision of
20 health care services to Medicaid patients and the medically
21 indigent.

22 (10)~~(12)~~ The applicant's designation as a Gold Seal
23 Program nursing facility pursuant to s. 400.235, when the
24 applicant is requesting additional nursing home beds at that
25 facility.

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

28 408.036 Projects subject to review; exemptions.--

29 (1) APPLICABILITY.--Unless exempt under subsection
30 (3), all health-care-related projects, as described in
31 paragraphs (a)-(g)~~(a)-(h)~~, are subject to review and must

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 file an application for a certificate of need with the agency.
2 The agency is exclusively responsible for determining whether
3 a health-care-related project is subject to review under ss.
4 408.031-408.045.

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

8 (b) The new construction or establishment of
9 additional health care facilities, including a replacement
10 health care facility when the proposed project site is not
11 located on the same site as or within 1 mile of the existing
12 health care facility, if the number of beds in each licensed
13 bed category will not increase.

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

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

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

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

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

29 ~~(f)(h)~~ The establishment of tertiary health services,
30 including inpatient comprehensive rehabilitation services.

31 (g) An increase in the number of beds for acute care

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 in a hospital that is located in a low-growth county. A

2 low-growth county is defined as a county that has:

3 1. A hospital with an occupancy rate for licensed
4 acute care which has been below 60 percent for the previous 5
5 years;

6 2. Experienced a growth rate of 4 percent or less for
7 the most recent 3-year period for which data are available, as
8 determined using the population statistics published in the
9 most recent edition of the Florida Statistical Abstract;

10 3. A population of 400,000 or fewer according to the
11 most recent edition of the Florida Statistical Abstract; and

12 4. A hospital that has combined gross revenue from
13 Medicaid and charity patients which exceeds \$60 million per
14 year for the previous 2 years.

15
16 This paragraph is repealed effective July 1, 2009.

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

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

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

22 (a)(c) A transfer of a certificate of need, except
23 that when an existing hospital is acquired by a purchaser, all
24 certificates of need issued to the hospital which are not yet
25 operational shall be acquired by the purchaser, without need
26 for a transfer.

27 (b) Replacement of a nursing home within the same
28 district, if the proposed project site is located within a
29 geographic area that contains at least 65 percent of the
30 facility's current residents and is within a 30-mile radius of
31 the replaced nursing home.

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 (c) Relocation of a portion of a nursing home's
2 licensed beds to a facility within the same district, if the
3 relocation is within a 30-mile radius of the existing facility
4 and the total number of nursing home beds in the district does
5 not increase.

6 ~~(d) A 50-percent increase in nursing home beds for a~~
7 ~~facility incorporated and operating in this state for at least~~
8 ~~60 years on or before July 1, 1988, which has a licensed~~
9 ~~nursing home facility located on a campus providing a variety~~
10 ~~of residential settings and supportive services. The~~
11 ~~increased nursing home beds shall be for the exclusive use of~~
12 ~~the campus residents. Any application on behalf of an~~
13 ~~applicant meeting this requirement shall be subject to the~~
14 ~~base fee of \$5,000 provided in s. 408.038.~~

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

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

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

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

Bill No. HB 329

Amendment No. ____ Barcode 430190

1
2 The agency shall develop rules to implement the provisions for
3 expedited review, including time schedule, application content
4 which may be reduced from the full requirements of s.
5 408.037(1), and application processing.

6 (3) EXEMPTIONS.--Upon request, the following projects
7 are subject to exemption from the provisions of subsection
8 (1):

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

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

15 ~~(b)(c)~~ For the conversion of licensed acute care
16 hospital beds to Medicare and Medicaid certified skilled
17 nursing beds in a rural hospital, as defined in s. 395.602, so
18 long as the conversion of the beds does not involve the
19 construction of new facilities. The total number of skilled
20 nursing beds, including swing beds, may not exceed one-half of
21 the total number of licensed beds in the rural hospital as of
22 July 1, 1993. Certified skilled nursing beds designated under
23 this paragraph, excluding swing beds, shall be included in the
24 community nursing home bed inventory. A rural hospital that
25 ~~which~~ subsequently decertifies any acute care beds exempted
26 under this paragraph shall notify the agency of the
27 decertification, and the agency shall adjust the community
28 nursing home bed inventory accordingly.

29 ~~(c)(d)~~ For the addition of nursing home beds at a
30 skilled nursing facility that is part of a retirement
31 community that provides a variety of residential settings and

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 supportive services and that has been incorporated and
2 operated in this state for at least 65 years on or before July
3 1, 1994. All nursing home beds must not be available to the
4 public but must be for the exclusive use of the community
5 residents.

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

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

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

20 ~~(h) For the delicensure of beds, upon 30 days' written~~
21 ~~notice to the agency. A request for exemption submitted under~~
22 ~~this paragraph must identify the number, the category of beds,~~
23 ~~and the name of the facility in which the beds to be~~
24 ~~delicensed are located.~~

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

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

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

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 ~~the exemption.~~

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

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

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

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

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

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

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

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

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

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 ~~agency shall monitor such programs to ensure compliance with~~
2 ~~the requirements of subparagraph 2.~~

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

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

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

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

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

30 ~~(g)(l)~~ For combination within one nursing home
31 facility of the beds or services authorized by two or more

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 certificates of need issued in the same planning subdistrict.
2 An exemption granted under this paragraph shall extend the
3 validity period of the certificates of need to be consolidated
4 by the length of the period beginning upon submission of the
5 exemption request and ending with issuance of the exemption.
6 The longest validity period among the certificates shall be
7 applicable to each of the combined certificates.

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

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

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

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

Bill No. HB 329

Amendment No. ____ Barcode 430190

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

5 2. The timeframes and monitoring process specified in
6 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 hospital beds until the beds are licensed.

11 ~~(o) For the addition of acute care beds, as authorized~~
12 ~~by rule consistent with s. 395.003(4), in a number that may~~
13 ~~not exceed 10 total beds or 10 percent of licensed bed~~
14 ~~capacity, whichever is greater, for temporary beds in a~~
15 ~~hospital that has experienced high seasonal occupancy within~~
16 ~~the prior 12-month period or in a hospital that must respond~~
17 ~~to emergency circumstances.~~

18 ~~(j)(p)~~ For the addition of nursing home beds licensed
19 under chapter 400 in a number not exceeding 10 total beds or
20 10 percent of the number of beds licensed in the facility
21 being expanded, whichever is greater; or, for the addition of
22 nursing home beds licensed under chapter 400 at a facility
23 that has been designated as a Gold Seal nursing home under s.
24 400.235 in a number not exceeding 20 total beds or 10 percent
25 of the number of licensed beds in the facility being expanded,
26 whichever is greater.

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

30 a. ~~Effective until June 30, 2001,~~ Certify that the
31 facility has not had any class I or class II deficiencies

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 within the 30 months preceding the request for addition.

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

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

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

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

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

18 (k) For the establishment of:

19 1. A Level II neonatal intensive care unit with at
20 least 10 beds, upon documentation to the agency that the
21 applicant hospital had a minimum of 1,500 births during the
22 previous 12 months; or

23 2. A Level III neonatal intensive care unit with at
24 least 15 beds, upon documentation to the agency that the
25 applicant hospital has a Level II neonatal intensive care unit
26 of at least 10 beds and had a minimum of 3,500 births during
27 the previous 12 months,

28
29 if the applicant demonstrates that it meets the requirements
30 for quality of care, nurse staffing, physician staffing,
31 physical plant, equipment, emergency transportation, and data

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 reporting found in agency certificate-of-need rules for Level
2 II and Level III neonatal intensive care units and if the
3 applicant commits to the provision of services to Medicaid and
4 charity patients at a level equal to or greater than the
5 district average. Such a commitment is subject to s. 408.040.

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

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

17 (l) Notwithstanding any other provisions of this
18 chapter to the contrary:(s)

19 1. For an adult open-heart-surgery program to be
20 located in a new hospital provided the new hospital is being
21 established in the location of an existing hospital with an
22 adult open-heart-surgery program, the existing hospital and
23 the existing adult open-heart-surgery program are being
24 relocated to a replacement hospital, and the replacement
25 hospital will utilize a closed-staff model. A hospital is
26 exempt from the certificate-of-need review for the
27 establishment of an open-heart-surgery program if the
28 application for exemption submitted under this paragraph
29 complies with the following criteria:

30 a. The applicant must certify that it will meet and
31 continuously maintain the minimum Florida Administrative Code

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 and any future licensure requirements governing adult
2 open-heart programs adopted by the agency, including the most
3 current guidelines of the American College of Cardiology and
4 American Heart Association Guidelines for Adult Open Heart
5 Programs.

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

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

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

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

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

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

30 h. In order to ensure continuity of available
31 services, the applicant of the newly licensed hospital may

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 apply for this certificate-of-need before taking possession of
2 the physical facilities. The effective date of the
3 certificate-of-need will be concurrent with the effective date
4 of the newly issued hospital license.

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

10 3. This paragraph is repealed effective January 1,
11 2008.

12 ~~(m)(t)~~1. For the provision of adult open-heart
13 services in a hospital located within the boundaries of a
14 health service planning district, as defined in s. 408.032(5),
15 which has experienced an annual net out-migration of at least
16 600 open-heart-surgery cases for 3 consecutive years according
17 to the most recent data reported to the agency, and the
18 district's population per licensed and operational open-heart
19 programs exceeds the state average of population per licensed
20 and operational open-heart programs by at least 25 percent
21 ~~Palm Beach, Polk, Martin, St. Lucie, and Indian River Counties~~
22 ~~if the following conditions are met: The exemption must be~~
23 ~~based upon objective criteria and address and solve the twin~~
24 ~~problems of geographic and temporal access. All hospitals~~
25 within a health service planning district which meet the
26 criteria reference in sub-subparagraphs 2.a.-h. shall be
27 eligible for this exemption on July 1, 2004, and shall receive
28 the exemption upon filing for it and subject to the following:

29 a. A hospital that has received a notice of intent to
30 grant a certificate of need or a final order of the agency
31 granting a certificate of need for the establishment of an

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 open-heart-surgery program is entitled to receive a letter of
2 exemption for the establishment of an adult open-heart-surgery
3 program upon filing a request for exemption and complying with
4 the criteria enumerated in sub-subparagraphs 2.a.-h., and is
5 entitled to immediately commence operation of the program.

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

15 2. A hospital shall be exempt from the
16 certificate-of-need review for the establishment of an
17 open-heart-surgery program when the application for exemption
18 submitted under this paragraph complies with the following
19 criteria:

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

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

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

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 emergencies.

2 d. The applicant can demonstrate that it has
3 discharged at least 300 inpatients with a principal diagnosis
4 of ischemic heart disease for the most recent 12-month period
5 as reported to the agency is referring 300 or more patients
6 per year from the hospital, including the emergency room, for
7 cardiac services at a hospital with cardiac services, or that
8 the average wait for transfer for 50 percent or more of the
9 cardiac patients exceeds 4 hours.

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

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

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

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

24 ~~3.2.~~ By December 31, 2004, and annually thereafter,
25 the agency ~~for Health Care Administration~~ shall submit a
26 report to the Legislature providing information concerning the
27 number of requests for exemption it has received under this
28 paragraph during the calendar year and the number of
29 exemptions it has granted or denied during the calendar year.

30 (n) For the provision of percutaneous coronary
31 intervention for patients presenting with emergency myocardial

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 infarctions in a hospital without an approved adult
2 open-heart-surgery program. In addition to any other
3 documentation required by the agency, a request for an
4 exemption submitted under this paragraph must comply with the
5 following:

6 1. The applicant must certify that it will meet and
7 continuously maintain the requirements adopted by the agency
8 for the provisions of these services. These licensure
9 requirements must be adopted by rule pursuant to ss.
10 120.536(1) and 120.54 and must be consistent with the
11 guidelines published by the American College of Cardiology and
12 the American Heart Association for the provision of
13 percutaneous coronary interventions in hospitals without adult
14 open-heart services. At a minimum, the rules shall require
15 that:

16 a. Cardiologists be experienced interventionalists who
17 have performed a minimum of 75 interventions within the
18 previous 12 months.

19 b. The hospital provide a minimum of 36 emergency
20 interventions annually in order to continue to provide the
21 service.

22 c. The hospital offer sufficient physician, nursing,
23 and laboratory staff to provide the services 24 hours a day, 7
24 days a week.

25 d. Nursing and technical staff have demonstrated
26 experience in handling acutely ill patients requiring
27 intervention based on previous experience in dedicated
28 interventional laboratories or surgical centers.

29 e. Cardiac care nursing staff be adept in hemodynamic
30 monitoring and Intra-aortic Balloon Pump management.

31 f. Formalized written transfer agreements be developed

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 with a hospital with an adult open-heart-surgery program and
2 written transport protocols be in place to ensure safe and
3 efficient transfer of a patient within 60 minutes. Transfer
4 and transport agreements must be received and tested, with
5 appropriate documentation maintained at least every 3 months.

6 g. Hospitals implementing the service first undertake
7 a training program of 3 to 6 months' duration, which includes
8 establishing standard and testing logistics, creating quality
9 assessment and error management practices, and formalizing
10 patient-selection criteria.

11 2. The applicant must certify that it will at all
12 times use the patient-selection criteria for the performance
13 of primary angioplasty at hospitals without adult
14 open-heart-surgery programs issued by the American College of
15 Cardiology and the American Heart Association. At a minimum,
16 these criteria must provide for:

17 a. Avoidance of interventions in hemodynamically
18 stable patients who have identified symptoms or medical
19 histories.

20 b. Transfer of patients who have a history of coronary
21 disease and clinical presentation of hemodynamic instability.

22 3. The applicant must agree to submit to the agency a
23 quarterly report detailing patient characteristics, treatment,
24 and outcomes for all patients receiving emergency percutaneous
25 coronary interventions pursuant to this paragraph. This report
26 must be submitted within 15 days after the close of each
27 calendar quarter.

28 4. The exemption provided by this paragraph does not
29 apply unless the agency determines that the hospital has taken
30 all necessary steps to be in compliance with all requirements
31 of this paragraph, including the training program required

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 under sub-subparagraph 1.g.

2 5. If the hospital fails to continuously comply with
3 the requirements of sub-subparagraphs 1.c.-f. and
4 subparagraphs 2. and 3., this exemption immediately expires.

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

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

19 (o) For the addition of mental health services or beds
20 if the applicant commits to providing services to Medicaid or
21 charity care patients at a level equal to or greater than the
22 district average. Such a commitment is subject to s. 408.040.

23 (p) For replacement of a licensed nursing home on the
24 same site, or within 3 miles of the same site, if the number
25 of licensed beds does not increase.

26 (q) For consolidation or combination of licensed
27 nursing homes or transfer of beds between licensed nursing
28 homes within the same planning subdistrict, by providers that
29 operate multiple nursing homes within that planning
30 subdistrict, if there is no increase in the planning
31 subdistrict total number of nursing home beds and the site of

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 the relocation is not more than 30 miles from the original
2 location.

3 (r) For beds in state mental health treatment
4 facilities operated under s. 394.455(30) and state mental
5 health forensic facilities operated under s. 916.106(8).

6 (s) For beds in state developmental services
7 institutions as defined in s. 393.063.

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

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

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

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

23 (c) The addition or delicensure of beds.

24
25 Notification under this subsection may be made by electronic,
26 facsimile, or written means at any time before the described
27 action has been taken.

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

30 408.0361 Cardiology services and burn unit licensure
31 ~~Diagnostic cardiac catheterization services providers;~~

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 ~~compliance with guidelines and requirements.--~~

2 (1) Each provider of diagnostic cardiac
3 catheterization services shall comply with ~~the requirements of~~
4 ~~s. 408.036(3)(i)2.a.-d., and rules adopted by~~ of the agency
5 which establish licensure standards for Health Care
6 Administration governing the operation of adult inpatient
7 diagnostic cardiac catheterization programs. The rules must
8 ensure that the programs:

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

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

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

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

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

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

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 rules for adult interventional cardiology services and burn
2 units in effect on June 30, 2004, are ratified pursuant to
3 this subsection and shall remain in effect and be enforceable
4 by the agency until the licensure rules are adopted. Existing
5 providers, any provider with an exemption for open heart
6 surgery, and any provider with 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 adult interventional cardiology
9 services or burn units shall be considered grandfathered-in
10 and shall receive a license for their programs effective on
11 July 1, 2004, or the date their program becomes operational,
12 whichever is later. That licensure shall remain valid for at
13 least 3 years or a period specified in the rule, whichever is
14 longer, but the programs must meet licensure standards
15 applicable to existing programs for every subsequent licensure
16 period.

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

20 (a) Establishment of two hospital program licensure
21 levels: a Level I program authorizing the performance of adult
22 primary percutaneous cardiac intervention for emergent
23 patients without onsite cardiac surgery and a Level II program
24 authorizing the performance of percutaneous cardiac
25 intervention with onsite cardiac surgery.

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

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 formalized, written transfer agreement with a hospital that
2 has a Level II program, including written transport protocols
3 to ensure safe and efficient transfer of a patient within 60
4 minutes.

5 (c) For a hospital seeking a Level II program,
6 demonstration that for the most recent 12-month period as
7 reported to the agency it has discharged at least 800 patients
8 with the principal diagnosis of ischemic heart disease.

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

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

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

20 (4) The agency shall establish a technical advisory
21 panel to develop procedures and standards for measuring
22 outcomes of interventional cardiac programs. Members of the
23 panel shall include representatives of the Florida Hospital
24 Association, the Florida Society of Thoracic and
25 Cardiovascular Surgeons, the Florida Chapter of the American
26 College of Cardiology, and the Florida Chapter of the American
27 Heart Association and others who have experience in statistics
28 and outcome measurement. Based upon recommendations from the
29 panel, the agency shall develop and adopt for the
30 interventional cardiac programs rules that include at least
31 the following:

Bill No. HB 329

Amendment No. ____ Barcode 430190

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

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

6 (c) Outcome standards specifying expected levels of
7 performance in Level I and Level II adult interventional
8 cardiology services. Such standards may include, but are not
9 limited to, inhospital mortality, infection rates, nonfatal
10 myocardial infarctions, length of stay, postoperative bleeds,
11 and returns to surgery.

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

17 (9) The Secretary of Health Care Administration shall
18 appoint an advisory group to study the issue of replacing
19 certificate-of-need review of organ transplant programs under
20 this chapter with licensure regulation of organ transplant
21 programs under chapter 395. The advisory group shall include
22 three representatives of organ transplant providers, one
23 representative of an organ procurement organization, one
24 representative of the Division of Health Quality Assurance,
25 one representative of Medicaid, and one advocate for organ
26 transplant patients. The advisory group shall, at a minimum,
27 make recommendations regarding access to organs, delivery of
28 services to Medicaid and charity patients, staff training, and
29 resource requirements for organ transplant programs in a
30 report due to the secretary and the Legislature by July 1,
31 2005.

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 (10) The Secretary of Health Care Administration shall
2 appoint a work group to study certificate-of-need regulations
3 and changing market conditions related to the supply and
4 distribution of hospital beds. The assessment by the work
5 group shall include, but need not be limited to:

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

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

13
14 The workgroup shall, by January 1, 2005, submit to the
15 secretary and the Legislature a report identifying specific
16 program areas and recommending needed changes in statutes and
17 rules.

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

20 408.038 Fees.--The agency shall assess fees on
21 certificate-of-need applications. Such fees shall be for the
22 purpose of funding the ~~functions of the local health councils~~
23 ~~and the~~ activities of the agency and shall be allocated as
24 provided in s. 408.033. The fee shall be determined as
25 follows:

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

27 (2) In addition to the base fee of ~~\$10,000~~\$5,000,
28 0.015 of each dollar of proposed expenditure, except that a
29 fee may not exceed ~~\$50,000~~\$22,000.

30 Section 9. Subsections (1), paragraph (a) of
31 subsection (3), and paragraph (a) and (b) of subsection (4) of

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 section 408.039, are amended to read:

2 408.039 Review process.--The review process for
3 certificates of need shall be as follows:

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

11 (3) APPLICATION PROCESSING.--

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

25 (4) STAFF RECOMMENDATIONS.--

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

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 home in a nursing home geographically underserved area.

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

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

23 408.040 Conditions and monitoring.--

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

31 (b) The agency may consider, in addition to the other

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 criteria specified in s. 408.035, a statement of intent by the
2 applicant that a specified percentage of the annual patient
3 days at the facility will be utilized by patients eligible for
4 care under Title XIX of the Social Security Act. Any
5 certificate of need issued to a nursing home in reliance upon
6 an applicant's statements that a specified percentage of
7 annual patient days will be utilized by residents eligible for
8 care under Title XIX of the Social Security Act must include a
9 statement that such certification is a condition of issuance
10 of the certificate of need. The certificate-of-need program
11 shall notify the Medicaid program office and the Department of
12 Elderly Affairs when it imposes conditions as authorized in
13 this paragraph in an area in which a community diversion pilot
14 project is implemented.

15 (c) A certificateholder or an exemption holder may
16 apply to the agency for a modification of conditions imposed
17 under paragraph (a) or paragraph (b). If the holder of a
18 certificate of need or an exemption demonstrates good cause
19 why the certificate or exemption should be modified, the
20 agency shall reissue the certificate of need or exemption with
21 such modifications as may be appropriate. The agency shall by
22 rule define the factors constituting good cause for
23 modification.

24 (d) If the holder of a certificate of need or an
25 exemption fails to comply with a condition upon which the
26 issuance of the certificate or exemption was predicated, the
27 agency may assess an administrative fine against the
28 certificateholder or exemption holder in an amount not to
29 exceed \$1,000 per failure per day. Failure to annually report
30 compliance with any condition upon which the issuance of the
31 certificate or exemption was predicated constitutes

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 ~~noncompliance.~~ In assessing the penalty, the agency shall take
2 into account as mitigation the degree of noncompliance
3 ~~relative lack of severity of a particular failure.~~ Proceeds
4 of such penalties shall be deposited in the Public Medical
5 Assistance Trust Fund.

6 (2)(a) Unless the applicant has commenced
7 construction, if the project provides for construction, unless
8 the applicant has incurred an enforceable capital expenditure
9 commitment for a project, if the project does not provide for
10 construction, or unless subject to paragraph (b), a
11 certificate of need shall terminate 18 months after the date
12 of issuance. The agency shall monitor the progress of the
13 holder of the certificate of need in meeting the timetable for
14 project development specified in the application ~~with the~~
15 ~~assistance of the local health council as specified in s.~~
16 ~~408.033(1)(b)5.~~, and may revoke the certificate of need, if
17 the holder of the certificate is not meeting such timetable
18 and is not making a good-faith effort, as defined by rule, to
19 meet it.

20 (b) A certificate of need issued to an applicant
21 holding a provisional certificate of authority under chapter
22 651 shall terminate 1 year after the applicant receives a
23 valid certificate of authority from the Office of Insurance
24 Regulation of the Financial Services Commission.

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

Bill No. HB 329

Amendment No. ____ Barcode 430190

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

7 Section 11. Subsection (5) of section 408.043, Florida
8 Statutes, is repealed.

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

11 408.0455 Rules; pending proceedings.--The rules of the
12 agency in effect on June 30, 2004 ~~1997~~, shall remain in effect
13 and shall be enforceable by the agency with respect to ss.
14 408.031-408.045 until such rules are repealed or amended by
15 the agency, ~~and no judicial or administrative proceeding~~
16 ~~pending on July 1, 1997, shall be abated as a result of the~~
17 ~~provisions of ss. 408.031-408.043(1) and (2); s. 408.044; or~~
18 ~~s. 408.045.~~

19 Section 13. If any provision of this act or the
20 application thereof to any person or circumstance is held
21 invalid, the invalidity does not affect other provisions or
22 applications of the act which can be given effect without the
23 invalid provision or application, and to this end the
24 provisions of this act are declared severable.

25 Section 14. Section 52 of chapter 2001-45, Laws of
26 Florida, as amended by section 1693 of chapter 2003-261, Laws
27 of Florida, is amended to read:

28 Section 52. (1) Notwithstanding the establishment of
29 need as provided for in chapter 408, Florida Statutes, no
30 certificate of need for additional community nursing home beds
31 shall be approved by the agency until July 1, 2006.

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 (2) The Legislature finds that the continued growth in
2 the Medicaid budget for nursing home care has constrained the
3 ability of the state to meet the needs of its elderly
4 residents through the use of less restrictive and less
5 institutional methods of long-term care. It is therefore the
6 intent of the Legislature to limit the increase in Medicaid
7 nursing home expenditures in order to provide funds to invest
8 in long-term care that is community-based and provides
9 supportive services in a manner that is both more
10 cost-effective and more in keeping with the wishes of the
11 elderly residents of this state.

12 (3) This moratorium on certificates of need shall not
13 apply to sheltered nursing home beds in a continuing care
14 retirement community certified by the former Department of
15 Insurance or by the Office of Insurance Regulation pursuant to
16 chapter 651, Florida Statutes.

17 (4)(a) This moratorium on certificates of need shall
18 not apply, and a certificate of need for additional community
19 nursing home beds may be approved, for a county that meets the
20 following circumstances:

21 1. The county has no community nursing home beds; and

22 2. The lack of community nursing home beds occurs
23 because all nursing home beds in the county which were
24 licensed on July 1, 2001, have subsequently closed.

25 (b) The certificate-of-need review for such
26 circumstances shall be subject to the comparative review
27 process consistent with the provisions of section 408.039,
28 Florida Statutes, and the number of beds may not exceed the
29 number of beds lost by the county after July 1, 2001.

30
31 This subsection shall be repealed upon the expiration of the

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 moratorium established in subsection (1).

2 (5) This moratorium on certificates of need shall not
3 apply for the addition of nursing home beds licensed under
4 chapter 400 to a nursing home located in a county having up to
5 50,000 residents, in a number not exceeding 10 total beds or
6 10 percent of the number of beds licensed in the facility
7 being expanded, whichever is greater. In addition to any other
8 documentation required by the agency, a request submitted
9 under this paragraph must:

10 (a) Certify that the facility has not had any class I
11 or class II deficiencies within the 30 months preceding the
12 request for addition.

13 (b) Certify that the prior 12-month average occupancy
14 rate for the nursing home beds at the facility meets or
15 exceeds 94 percent and the facility had not had any class I or
16 class II deficiencies since its initial licensure.

17 (c) For a facility that has been licensed for less
18 than 24 months, certify that the prior 6-month average
19 occupancy rate for the nursing home beds at the facility meets
20 or exceeds 94 percent and that the facility has not had any
21 class I or class II deficiencies since its initial licensure.

22
23 This subsection shall be repealed upon the expiration of the
24 moratorium established in subsection (1).

25 Section 15. This act shall take effect July 1, 2004.

26
27
28 ===== T I T L E A M E N D M E N T =====

29 And the title is amended as follows:

30 Delete everything before the enacting clause

31

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 and insert:

2 A bill to be entitled

3 An act relating to certificate of need;

4 amending s. 395.003, F.S.; providing additional

5 conditions for the licensure or relicensure of

6 hospitals; exempting currently licensed

7 hospitals; amending s. 408.032, F.S.;

8 redefining terms relating to the Health

9 Facility and Services Development Act; deleting

10 the term "regional area"; amending s. 408.033,

11 F.S.; deleting provisions relating to regional

12 area health plans; transferring certain duties

13 from the Agency for Health Care Administration

14 to the Department of Health; deleting an agency

15 responsibility relating to orientation of local

16 health council members; deleting a requirement

17 that local health councils be partly funded by

18 application fees for certificates of need;

19 adding sources of funding for local health

20 councils; amending s. 408.034, F.S.; revising

21 criteria for certificate-of-need review and for

22 issuing licenses to health care facilities and

23 health service providers; revising criteria for

24 the nursing-home-bed-need methodology; amending

25 s. 408.035, F.S.; revising the criteria for

26 reviewing applications for certificate-of-need

27 determinations; amending s. 408.036, F.S.;

28 revising criteria for determining whether a

29 health-care-related project is subject to

30 review; providing that the replacement or

31 relocation of a nursing home is subject to

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 expedited review under specified conditions;
2 revising the criteria for determining whether a
3 project is subject to exemption from review
4 upon request; repealing the exemption for
5 specified services; adding an optional
6 exemption for neonatal intensive care units
7 that meet certain requirements; providing
8 exemptions for adding beds for comprehensive
9 rehabilitation, for beds in state mental health
10 treatment facilities, for beds in state mental
11 health treatment facilities and state mental
12 health forensic facilities, and for beds in
13 state developmental services institutions;
14 revising the criteria for optional exemption of
15 adult open-heart services; requiring the agency
16 to report annually to the Legislature specified
17 information concerning exemptions requested and
18 granted during the preceding calendar year;
19 adding an optional exemption for the provision
20 of percutaneous coronary intervention under
21 certain conditions; requiring health care
22 facilities and providers to provide to the
23 agency notice of the replacement of a health
24 care facility or a nursing home, in specified
25 circumstances, consolidation of nursing homes,
26 the termination of a health care service, and
27 the addition or delicensure of beds; amending
28 s. 408.0361, F.S., relating to compliance with
29 requirements imposed on diagnostic cardiac
30 catheterization services providers; revising
31 the scope of application, to include the

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 compliance required of cardiology services and
2 the licensure of burn units; requiring the
3 Secretary of Health Care Administration to
4 appoint an advisory group to study replacing
5 certificate-of-need review of organ transplant
6 programs with licensure regulation of organ
7 transplant providers; requiring a report to the
8 secretary and the Legislature; requiring the
9 secretary to appoint a work group to study
10 certificate-of-need regulation and changing
11 market conditions related to the supply and
12 distribution of hospital beds; requiring a
13 report to the secretary and the Legislature;
14 amending s. 408.038, F.S.; revising fees
15 assessed on certificate-of-need applications;
16 amending s. 408.039, F.S.; revising the review
17 process for certificates of need; requiring
18 shorter review cycles; deleting a requirement
19 to file a copy of the application with the
20 local health council; deleting a requirement to
21 consider the district health plan in reviewing
22 and taking action on the applications; amending
23 s. 408.040, F.S.; applying the conditions to
24 the issuance of a certificate of need to the
25 issuance of an exemption; providing that
26 certain failures to annually report compliance
27 with certain conditions to receiving a
28 certificate of need or an exemption constitute
29 noncompliance; repealing s. 408.043(5), F.S.,
30 relating to the authority of a sole acute care
31 hospital in a high growth county to add beds

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 without agency review; amending s. 408.0455,
2 F.S.; providing for the rules of the agency
3 which are in effect on June 30, 2004, rather
4 than those in effect on June 30, 1997, to
5 remain in effect; providing for severability;
6 amending s. 52, ch. 2001-45, Laws of Florida,
7 as amended; specifying nonapplication of
8 moratoriums on certificates of need and
9 authorizing approval of certain certificates of
10 need for certain counties under certain
11 circumstances; providing review requirements
12 and bed limitations; providing for future
13 expiration of the moratoriums; providing an
14 effective date.

15
16 WHEREAS, appropriate access to adult cardiac care is an
17 issue of critical state importance to all residents of the
18 state and to all health service planning districts of the
19 state, and

20 WHEREAS, the certificate-of-need process, for most
21 geographic areas in the state, has provided adequate access to
22 adult open-heart-surgery services to Floridians as well as
23 tourists, business travelers, indigents, and migrant workers
24 who receive such services, and

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

29 WHEREAS, there have been numerous technological
30 advances in the area of primary angioplasty and stent
31 procedures known collectively as percutaneous coronary

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 interventions, and these advanced interventional treatments
2 provide the highest standard of care for people suffering
3 acute myocardial infarctions, and

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

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

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

22 WHEREAS, the Legislature finds that timely access and
23 availability for every adult in this state, regardless of
24 socioeconomic class or geographic location, to these
25 interventional treatments and open-heart surgery is of
26 critical state concern, especially because myocardial
27 infarctions and related coronary disease are no respecters of
28 location or time, and

29 WHEREAS, to ensure that it provides the quality of care
30 desired, each hospital that qualifies for the exemption
31 provided by this act will be subject to more stringent

Bill No. HB 329

Amendment No. ____ Barcode 430190

1 criteria and will also be subject to continual monitoring by
2 the Agency for Health Care Administration, and

3 WHEREAS, the Legislature intends to ensure that
4 standards of quality are maintained while promoting
5 competition in the provision of adult cardiac care, NOW,
6 THEREFORE,

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