

1 A bill to be entitled

2 An act relating to certificate of need; amending s.
3 395.003, F.S.; providing additional conditions for the
4 licensure or relicensure of hospitals; exempting currently
5 licensed hospitals; amending s. 408.032, F.S.; redefining
6 terms relating to the Health Facility and Services
7 Development Act; deleting the term "regional area";
8 amending s. 408.033, F.S.; deleting provisions relating to
9 regional area health plans; transferring certain duties
10 from the Agency for Health Care Administration to the
11 Department of Health; deleting an agency responsibility
12 relating to orientation of local health council members;
13 deleting a requirement that local health councils be
14 partly funded by application fees for certificates of
15 need; adding sources of funding for local health councils;
16 amending s. 408.034, F.S.; revising criteria for
17 certificate-of-need review and for issuing licenses to
18 health care facilities and health service providers;
19 revising criteria for the nursing-home-bed-need
20 methodology; amending s. 408.035, F.S.; revising the
21 criteria for reviewing applications for certificate-of-
22 need determinations; amending s. 408.036, F.S.; revising
23 criteria for determining whether a health-care-related
24 project is subject to review; providing that the
25 replacement or relocation of a nursing home is subject to
26 expedited review under specified conditions; revising the
27 criteria for determining whether a project is subject to
28 exemption from review upon request; repealing the
29 exemption for specified services; adding an optional

30 exemption for neonatal intensive care units that meet
 31 certain requirements; providing exemptions for adding beds
 32 for comprehensive rehabilitation, for beds in state mental
 33 health treatment facilities, for beds in state mental
 34 health treatment facilities and state mental health
 35 forensic facilities, and for beds in state developmental
 36 services institutions; revising the criteria for optional
 37 exemption of adult open-heart services; requiring the
 38 agency to report annually to the Legislature specified
 39 information concerning exemptions requested and granted
 40 during the preceding calendar year; adding an optional
 41 exemption for the provision of percutaneous coronary
 42 intervention under certain conditions; requiring health
 43 care facilities and providers to provide to the agency
 44 notice of the replacement of a health care facility or a
 45 nursing home, in specified circumstances, consolidation of
 46 nursing homes, the termination of a health care service,
 47 and the addition or delicensure of beds; amending s.
 48 408.0361, F.S., relating to compliance with requirements
 49 imposed on diagnostic cardiac catheterization services
 50 providers; revising the scope of application, to include
 51 the compliance required of cardiology services and the
 52 licensure of burn units; requiring the Secretary of Health
 53 Care Administration to appoint an advisory group to study
 54 replacing certificate-of-need review of organ transplant
 55 programs with licensure regulation of organ transplant
 56 providers; requiring a report to the secretary and the
 57 Legislature; requiring the secretary to appoint a work
 58 group to study certificate-of-need regulation and changing

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59 market conditions related to the supply and distribution
60 of hospital beds; requiring a report to the secretary and
61 the Legislature; amending s. 408.038, F.S.; revising fees
62 assessed on certificate-of-need applications; amending s.
63 408.039, F.S.; revising the review process for
64 certificates of need; requiring shorter review cycles;
65 deleting a requirement to file a copy of the application
66 with the local health council; deleting a requirement to
67 consider the district health plan in reviewing and taking
68 action on the applications; amending s. 408.040, F.S.;
69 applying the conditions to the issuance of a certificate
70 of need to the issuance of an exemption; providing that
71 certain failures to annually report compliance with
72 certain conditions to receiving a certificate of need or
73 an exemption constitute noncompliance; repealing s.
74 408.043(5), F.S., relating to the authority of a sole
75 acute care hospital in a high growth county to add beds
76 without agency review; amending s. 408.0455, F.S.;
77 providing for the rules of the agency which are in effect
78 on June 30, 2004, rather than those in effect on June 30,
79 1997, to remain in effect; providing for severability;
80 amending s. 52, ch. 2001-45, Laws of Florida, as amended;
81 specifying nonapplication of moratoriums on certificates
82 of need and authorizing approval of certain certificates
83 of need for certain counties under certain circumstances;
84 providing review requirements and bed limitations;
85 providing for future expiration of the moratoriums;
86 providing an effective date.

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88 WHEREAS, appropriate access to adult cardiac care is an
 89 issue of critical state importance to all residents of the state
 90 and to all health service planning districts of the state, and

91 WHEREAS, the certificate-of-need process, for most
 92 geographic areas in the state, has provided adequate access to
 93 adult open-heart-surgery services to Floridians as well as
 94 tourists, business travelers, indigents, and migrant workers who
 95 receive such services, and

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

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

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

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

113 WHEREAS, diagnosis; discharge from the transferring
 114 hospital; transfer arrangements, including, but not limited to,
 115 insurance and administrative approval; transportation
 116 availability; admission to the receiving hospital; staff

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117 availability at the receiving hospital; and, most importantly,
 118 bed availability at the receiving hospital as well as travel
 119 delays to the receiving hospital contribute to the time taken to
 120 effectuate a transfer of a cardiac patient, and

121 WHEREAS, the Legislature finds that timely access and
 122 availability for every adult in this state, regardless of
 123 socioeconomic class or geographic location, to these
 124 interventional treatments and open-heart surgery is of critical
 125 state concern, especially because myocardial infarctions and
 126 related coronary disease are no respecters of location or time,
 127 and

128 WHEREAS, to ensure that it provides the quality of care
 129 desired, each hospital that qualifies for the exemption provided
 130 by this act will be subject to more stringent criteria and will
 131 also be subject to continual monitoring by the Agency for Health
 132 Care Administration, and

133 WHEREAS, the Legislature intends to ensure that standards
 134 of quality are maintained while promoting competition in the
 135 provision of adult cardiac care, NOW, THEREFORE,

136
 137 Be It Enacted by the Legislature of the State of Florida:

138
 139 Section 1. Subsections (9), (10), and (11) are added to
 140 section 395.003, Florida Statutes, to read:

141 395.003 Licensure; issuance, renewal, denial,
 142 modification, suspension, and revocation.--

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

144 (a) The diagnosis-related groups for 65 percent or more of
 145 the discharges from the hospital, in the most recent year for

146 which data is available to the Agency for Health Care
 147 Administration pursuant to s. 408.061, are for diagnosis, care,
 148 and treatment of patients who have:

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

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

153 3. Cancer-related diseases and disorders classified as
 154 diagnosis-related groups 64, 82, 172, 173, 199, 200, 203, 257-
 155 260, 274, 275, 303, 306, 307, 318, 319, 338, 344, 346, 347, 363,
 156 366, 367, 400-414, 473, or 492; or

157 4. Any combination of the above discharges.

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

161 (10) A hospital licensed as of June 1, 2004, shall be
 162 exempt from subsection (9) as long as the hospital maintains the
 163 same ownership, facility street address, and range of services
 164 that were in existence on June 1, 2004. Any transfer of beds, or
 165 other agreements that result in the establishment of a hospital
 166 or hospital services within the intent of this section, shall be
 167 subject to subsection (9). Unless the hospital is otherwise
 168 exempt under subsection (9), the agency shall deny or revoke the
 169 license of a hospital that violates any of the criteria set
 170 forth in that subsection.

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

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

187 Section 2. Subsections (9), (13), and (17) of section
 188 408.032, Florida Statutes, are amended, and subsection (18) of
 189 that section is repealed, to read:

190 408.032 Definitions relating to Health Facility and
 191 Services Development Act.--As used in ss. 408.031-408.045, the
 192 term:

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

197 (13) "Long-term care hospital" means a hospital licensed
 198 under chapter 395 which meets the requirements of 42 C.F.R. s.
 199 412.23(e) and seeks exclusion from the acute care Medicare
 200 prospective payment system for inpatient hospital services.

201 (17) "Tertiary health service" means a health service
 202 which, due to its high level of intensity, complexity,
 203 specialized or limited applicability, and cost, should be

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

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

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

222 408.033 Local and state health planning.--

223 (1) LOCAL HEALTH COUNCILS.--

224 (a) Local health councils are hereby established as public
 225 or private nonprofit agencies serving the counties of a district
 226 ~~or regional area of the agency.~~ The members of each council
 227 shall be appointed in an equitable manner by the county
 228 commissions having jurisdiction in the respective district. Each
 229 council shall be composed of a number of persons equal to 1 1/2
 230 times the number of counties which compose the district or 12
 231 members, whichever is greater. Each county in a district shall
 232 be entitled to at least one member on the council. The balance

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233 of the membership of the council shall be allocated among the
 234 counties of the district on the basis of population rounded to
 235 the nearest whole number; except that in a district composed of
 236 only two counties, no county shall have fewer than four members.
 237 The appointees shall be representatives of health care
 238 providers, health care purchasers, and nongovernmental health
 239 care consumers, but not excluding elected government officials.
 240 The members of the consumer group shall include a representative
 241 number of persons over 60 years of age. A majority of council
 242 members shall consist of health care purchasers and health care
 243 consumers. The local health council shall provide each county
 244 commission a schedule for appointing council members to ensure
 245 that council membership complies with the requirements of this
 246 paragraph. The members of the local health council shall elect
 247 a chair. Members shall serve for terms of 2 years and may be
 248 eligible for reappointment.

249 (b) Each local health council may:

250 1. Develop a district ~~or regional~~ area health plan that
 251 permits each local health council to develop strategies and set
 252 priorities for implementation based on its unique local health
 253 needs. ~~The district or regional area health plan must contain~~
 254 ~~preferences for the development of health services and~~
 255 ~~facilities, which may be considered by the agency in its review~~
 256 ~~of certificate of need applications. The district health plan~~
 257 ~~shall be submitted to the agency and updated periodically. The~~
 258 ~~district health plans shall use a uniform format and be~~
 259 ~~submitted to the agency according to a schedule developed by the~~
 260 ~~agency in conjunction with the local health councils. The~~
 261 ~~schedule must provide for the development of district health~~

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262 ~~plans by major sections over a multiyear period. The elements~~
 263 ~~of a district plan which are necessary to the review of~~
 264 ~~certificate-of-need applications for proposed projects within~~
 265 ~~the district may be adopted by the agency as a part of its~~
 266 ~~rules.~~

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

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

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

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

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

285 7. Advise and assist local governments within each
 286 district on the development of an optional health plan element
 287 of the comprehensive plan provided in chapter 163, to assure
 288 compatibility with the health goals and policies in the State
 289 Comprehensive Plan and district health plan. To facilitate the
 290 implementation of this section, the local health council shall

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291 annually provide the local governments in its service area, upon
 292 request, with:

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

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

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

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

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

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

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

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

317 (d) Each local health council shall enter into a
 318 memorandum of agreement with each regional planning council in
 319 its district that elects to address health issues in its

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320 strategic regional policy plan. In addition, each local health
 321 council shall enter into a memorandum of agreement with each
 322 local government that includes an optional health element in its
 323 comprehensive plan. Each memorandum of agreement must specify
 324 the manner in which each local government, regional planning
 325 council, and local health council will coordinate its activities
 326 to ensure a unified approach to health planning and
 327 implementation efforts.

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

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

336 (g) Each local health council is authorized to accept and
 337 receive, in furtherance of its health planning functions, funds,
 338 grants, and services from governmental agencies and from private
 339 or civic sources and to perform studies related to local health
 340 planning in exchange for such funds, grants, or services. Each
 341 local health council shall, no later than January 30 of each
 342 year, render an accounting of the receipt and disbursement of
 343 such funds received by it to the Department of Health ~~agency~~.
 344 The department ~~agency~~ shall consolidate all such reports and
 345 submit such consolidated report to the Legislature no later than
 346 March 1 of each year. ~~Funds received by a local health council~~
 347 ~~pursuant to this paragraph shall not be deemed to be a~~
 348 ~~substitute for, or an offset against, any funding provided~~

349 ~~pursuant to subsection (2).~~

350 (2) FUNDING.--

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

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

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

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

377 (c)1. The agency shall, by rule, establish fees for

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378 hospitals and nursing homes based on an assessment of \$2 per
 379 bed. However, no such facility shall be assessed more than a
 380 total of \$500 under this subsection.

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

385 3. The agency shall, by rule, establish an annual fee of
 386 \$150 for all other facilities and organizations listed in
 387 paragraph (a).

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

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

397 (f) The agency shall deposit in the Health Care Trust Fund
 398 all health care facility assessments that are assessed under
 399 this subsection and ~~proceeds from the certificate-of-need~~
 400 ~~application fees.~~ The agency shall transfer such funds to the
 401 Department of Health for ~~an amount sufficient to maintain the~~
 402 ~~aggregate funding of level for~~ the local health councils ~~as~~
 403 ~~specified in the General Appropriations Act.~~ The remaining
 404 certificate-of-need application fees shall be used only for the
 405 purpose of administering the certificate-of-need program ~~Health~~
 406 ~~Facility and Services Development Act.~~

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

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

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

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

422 (c)(d) The Department of Health agency shall contract with
 423 the local health councils for the services specified in
 424 subsection (1). All contract funds shall be distributed
 425 according to an allocation plan developed by the department
 426 ~~agency that provides for a minimum and equal funding base for~~
 427 ~~each local health council. Any remaining funds shall be~~
 428 ~~distributed based on adjustments for workload. The agency may~~
 429 ~~also make grants to or reimburse local health councils from~~
 430 ~~federal funds provided to the state for activities related to~~
 431 ~~those functions set forth in this section. The department agency~~
 432 may withhold funds from a local health council or cancel its
 433 contract with a local health council which does not meet
 434 performance standards agreed upon by the department agency and
 435 local health councils.

436 Section 4. Subsections (1), (2), and (5) of section
 437 408.034, Florida Statutes, are amended to read:

438 408.034 Duties and responsibilities of agency; rules.--

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

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

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

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

460 408.035 Review criteria.--The agency shall determine the
 461 reviewability of applications and shall review applications for
 462 certificate-of-need determinations for health care facilities
 463 and health services in context with the following criteria:

464 (1) The need for the health care facilities and health

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465 services being proposed ~~in relation to the applicable district~~
 466 ~~health plan.~~

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

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

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

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

481 (4)~~(6)~~ The availability of resources, including health
 482 personnel, management personnel, and funds for capital and
 483 operating expenditures, for project accomplishment and
 484 operation.

485 (5)~~(7)~~ The extent to which the proposed services will
 486 enhance access to health care for residents of the service
 487 district.

488 (6)~~(8)~~ The immediate and long-term financial feasibility
 489 of the proposal.

490 (7)~~(9)~~ The extent to which the proposal will foster
 491 competition that promotes quality and cost-effectiveness.

492 (8)~~(10)~~ The costs and methods of the proposed
 493 construction, including the costs and methods of energy

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494 provision and the availability of alternative, less costly, or
 495 more effective methods of construction.

496 ~~(9)(11)~~ The applicant's past and proposed provision of
 497 health care services to Medicaid patients and the medically
 498 indigent.

499 ~~(10)(12)~~ The applicant's designation as a Gold Seal
 500 Program nursing facility pursuant to s. 400.235, when the
 501 applicant is requesting additional nursing home beds at that
 502 facility.

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

505 408.036 Projects subject to review; exemptions.--

506 (1) APPLICABILITY.--Unless exempt under subsection (3),
 507 all health-care-related projects, as described in paragraphs
 508 ~~(a)-(g)~~ ~~(a)-(h)~~, are subject to review and must file an
 509 application for a certificate of need with the agency. The
 510 agency is exclusively responsible for determining whether a
 511 health-care-related project is subject to review under ss.
 512 408.031-408.045.

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

516 (b) The new construction or establishment of additional
 517 health care facilities, including a replacement health care
 518 facility when the proposed project site is not located on the
 519 same site as or within 1 mile of the existing health care
 520 facility, if the number of beds in each licensed bed category
 521 will not increase.

522 (c) The conversion from one type of health care facility

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523 to another, including the conversion from a general hospital, a
 524 specialty hospital, or a long-term care hospital.

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

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

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

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

536 (f)(h) The establishment of tertiary health services,
 537 including inpatient comprehensive rehabilitation services.

538 (g) An increase in the number of beds for acute care in a
 539 hospital that is located in a low-growth county. A low-growth
 540 county is defined as a county that has:

- 541 1. A hospital with an occupancy rate for licensed acute
 542 care which has been below 60 percent for the previous 5 years;
- 543 2. Experienced a growth rate of 4 percent or less for the
 544 most recent 3-year period for which data are available, as
 545 determined using the population statistics published in the most
 546 recent edition of the Florida Statistical Abstract;
- 547 3. A population of 400,000 or fewer according to the most
 548 recent edition of the Florida Statistical Abstract; and
- 549 4. A hospital that has combined gross revenue from
 550 Medicaid and charity patients which exceeds \$60 million per year
 551 for the previous 2 years.

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This paragraph is repealed effective July 1, 2009.

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

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

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

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

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

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

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

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581 ~~this requirement shall be subject to the base fee of \$5,000~~
 582 ~~provided in s. 408.038.~~

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

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

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

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

600 The agency shall develop rules to implement the provisions for
 601 expedited review, including time schedule, application content
 602 which may be reduced from the full requirements of s.

603 408.037(1), and application processing.

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

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

609 (a)~~(b)~~ For hospice services or for swing beds in a rural

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610 hospital, as defined in s. 395.602, in a number that does not
 611 exceed one-half of its licensed beds.

612 (b)~~(e)~~ For the conversion of licensed acute care hospital
 613 beds to Medicare and Medicaid certified skilled nursing beds in
 614 a rural hospital, as defined in s. 395.602, so long as the
 615 conversion of the beds does not involve the construction of new
 616 facilities. The total number of skilled nursing beds, including
 617 swing beds, may not exceed one-half of the total number of
 618 licensed beds in the rural hospital as of July 1, 1993.
 619 Certified skilled nursing beds designated under this paragraph,
 620 excluding swing beds, shall be included in the community nursing
 621 home bed inventory. A rural hospital that ~~which~~ subsequently
 622 decertifies any acute care beds exempted under this paragraph
 623 shall notify the agency of the decertification, and the agency
 624 shall adjust the community nursing home bed inventory
 625 accordingly.

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

633 ~~(e) For an increase in the bed capacity of a nursing~~
 634 ~~facility licensed for at least 50 beds as of January 1, 1994,~~
 635 ~~under part II of chapter 400 which is not part of a continuing~~
 636 ~~care facility if, after the increase, the total licensed bed~~
 637 ~~capacity of that facility is not more than 60 beds and if the~~
 638 ~~facility has been continuously licensed since 1950 and has~~

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639 ~~received a superior rating on each of its two most recent~~
640 ~~licensure surveys.~~

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

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

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

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

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

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

660 ~~b. The applicant must certify it will meet and~~
661 ~~continuously maintain the minimum licensure requirements adopted~~
662 ~~by the agency governing such programs pursuant to subparagraph~~
663 ~~2.~~

664 ~~c. The applicant must certify it will provide a minimum of~~
665 ~~2 percent of its services to charity and Medicaid patients.~~

666 ~~2. The agency shall adopt licensure requirements by rule~~
667 ~~which govern the operation of adult inpatient diagnostic cardiac~~

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668 ~~catheterization programs established pursuant to the exemption~~
669 ~~provided in this paragraph. The rules shall ensure that such~~
670 ~~programs:~~

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

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

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

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

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

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

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

694 ~~(II) Beginning 18 months after a program first begins~~
695 ~~treating patients, the exemption for a program shall expire when~~
696 ~~the program fails to comply with the rules adopted pursuant to~~

697 ~~sub-subparagraphs 2.d. and e.~~

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

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

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

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

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

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

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

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

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

754 2. The timeframes and monitoring process specified in s.

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755 408.040(2)(a)-(c) apply to any exemption issued under this
756 paragraph.

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

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

767 (j)(p) For the addition of nursing home beds licensed
768 under chapter 400 in a number not exceeding 10 total beds or 10
769 percent of the number of beds licensed in the facility being
770 expanded, whichever is greater; or, for the addition of nursing
771 home beds licensed under chapter 400 at a facility that has been
772 designated as a Gold Seal nursing home under s. 400.235 in a
773 number not exceeding 20 total beds or 10 percent of the number
774 of licensed beds in the facility being expanded, whichever is
775 greater.

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

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

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

784 ~~400.235.~~

785 ~~b.e.~~ Certify that the prior 12-month average occupancy
786 rate for the nursing home beds at the facility meets or exceeds
787 96 percent.

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

792 2. The timeframes and monitoring process specified in s.
793 408.040(2)(a)-(c) apply to any exemption issued under this
794 paragraph.

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

798 (k) For the establishment of:

799 1. A Level II neonatal intensive care unit with at least
800 10 beds, upon documentation to the agency that the applicant
801 hospital had a minimum of 1,500 births during the previous 12
802 months; or

803 2. A Level III neonatal intensive care unit with at least
804 15 beds, upon documentation to the agency that the applicant
805 hospital has a Level II neonatal intensive care unit of at least
806 10 beds and had a minimum of 3,500 births during the previous 12
807 months,

808
809 if the applicant demonstrates that it meets the requirements for
810 quality of care, nurse staffing, physician staffing, physical
811 plant, equipment, emergency transportation, and data reporting
812 found in agency certificate-of-need rules for Level II and Level

813 III neonatal intensive care units and if the applicant commits
 814 to the provision of services to Medicaid and charity patients at
 815 a level equal to or greater than the district average. Such a
 816 commitment is subject to s. 408.040.

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

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

828 (1) Notwithstanding any other provisions of this chapter
 829 to the contrary:~~(s)~~

830 1. For an adult open-heart-surgery program to be located
 831 in a new hospital provided the new hospital is being established
 832 in the location of an existing hospital with an adult open-
 833 heart-surgery program, the existing hospital and the existing
 834 adult open-heart-surgery program are being relocated to a
 835 replacement hospital, and the replacement hospital will utilize
 836 a closed-staff model. A hospital is exempt from the certificate-
 837 of-need review for the establishment of an open-heart-surgery
 838 program if the application for exemption submitted under this
 839 paragraph complies with the following criteria:

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

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842 and any future licensure requirements governing adult open-heart
 843 programs adopted by the agency, including the most current
 844 guidelines of the American College of Cardiology and American
 845 Heart Association Guidelines for Adult Open Heart Programs.

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

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

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

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

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

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

870 h. In order to ensure continuity of available services,

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871 the applicant of the newly licensed hospital may apply for this
 872 certificate-of-need before taking possession of the physical
 873 facilities. The effective date of the certificate-of-need will
 874 be concurrent with the effective date of the newly issued
 875 hospital license.

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

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

882 ~~(m)(+)~~1. For the provision of adult open-heart services in
 883 a hospital located within the boundaries of a health service
 884 planning district, as defined in s. 408.032(5), which has
 885 experienced an annual net out-migration of at least 600 open-
 886 heart-surgery cases for 3 consecutive years according to the
 887 most recent data reported to the agency, and the district's
 888 population per licensed and operational open-heart programs
 889 exceeds the state average of population per licensed and
 890 operational open-heart programs by at least 25 percent Palm
 891 Beach, Polk, Martin, St. Lucie, and Indian River Counties if the
 892 following conditions are met: The exemption must be based upon
 893 objective criteria and address and solve the twin problems of
 894 geographic and temporal access. All hospitals within a health
 895 service planning district which meet the criteria reference in
 896 sub-subparagraphs 2.a.-h. shall be eligible for this exemption
 897 on July 1, 2004, and shall receive the exemption upon filing for
 898 it and subject to the following:

899 a. A hospital that has received a notice of intent to

900 grant a certificate of need or a final order of the agency
 901 granting a certificate of need for the establishment of an open-
 902 heart-surgery program is entitled to receive a letter of
 903 exemption for the establishment of an adult open-heart-surgery
 904 program upon filing a request for exemption and complying with
 905 the criteria enumerated in sub-subparagraphs 2.a.-h., and is
 906 entitled to immediately commence operation of the program.

907 b. An otherwise eligible hospital that has not received a
 908 notice of intent to grant a certificate of need or a final order
 909 of the agency granting a certificate of need for the
 910 establishment of an open-heart-surgery program is entitled to
 911 immediately receive a letter of exemption for the establishment
 912 of an adult open-heart-surgery program upon filing a request for
 913 exemption and complying with the criteria enumerated in sub-
 914 subparagraphs 2.a.-h., but is not entitled to commence operation
 915 of its program until December 31, 2006.

916 2. A hospital shall be exempt from the certificate-of-need
 917 review for the establishment of an open-heart-surgery program
 918 when the application for exemption submitted under this
 919 paragraph complies with the following criteria:

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

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

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

933 d. The applicant can demonstrate that it has discharged at
934 least 300 inpatients with a principal diagnosis of ischemic
935 heart disease for the most recent 12-month period as reported to
936 the agency ~~is referring 300 or more patients per year from the~~
937 ~~hospital, including the emergency room, for cardiac services at~~
938 ~~a hospital with cardiac services, or that the average wait for~~
939 ~~transfer for 50 percent or more of the cardiac patients exceeds~~
940 ~~4 hours.~~

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

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

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

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

955 ~~3.2.~~ By December 31, 2004, and annually thereafter, the
956 agency ~~for Health Care Administration~~ shall submit a report to
957 the Legislature providing information concerning the number of

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958 requests for exemption it has received under this paragraph
959 during the calendar year and the number of exemptions it has
960 granted or denied during the calendar year.

961 (n) For the provision of percutaneous coronary
962 intervention for patients presenting with emergency myocardial
963 infarctions in a hospital without an approved adult open-heart-
964 surgery program. In addition to any other documentation required
965 by the agency, a request for an exemption submitted under this
966 paragraph must comply with the following:

967 1. The applicant must certify that it will meet and
968 continuously maintain the requirements adopted by the agency for
969 the provisions of these services. These licensure requirements
970 must be adopted by rule pursuant to ss. 120.536(1) and 120.54
971 and must be consistent with the guidelines published by the
972 American College of Cardiology and the American Heart
973 Association for the provision of percutaneous coronary
974 interventions in hospitals without adult open-heart services. At
975 a minimum, the rules shall require that:

976 a. Cardiologists be experienced interventionalists who
977 have performed a minimum of 75 interventions within the previous
978 12 months.

979 b. The hospital provide a minimum of 36 emergency
980 interventions annually in order to continue to provide the
981 service.

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

985 d. Nursing and technical staff have demonstrated
986 experience in handling acutely ill patients requiring

987 intervention based on previous experience in dedicated
 988 interventional laboratories or surgical centers.

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

991 f. Formalized written transfer agreements be developed
 992 with a hospital with an adult open-heart-surgery program and
 993 written transport protocols be in place to ensure safe and
 994 efficient transfer of a patient within 60 minutes. Transfer and
 995 transport agreements must be received and tested, with
 996 appropriate documentation maintained at least every 3 months.

997 g. Hospitals implementing the service first undertake a
 998 training program of 3 to 6 months' duration, which includes
 999 establishing standard and testing logistics, creating quality
 1000 assessment and error management practices, and formalizing
 1001 patient-selection criteria.

1002 2. The applicant must certify that it will at all times
 1003 use the patient-selection criteria for the performance of
 1004 primary angioplasty at hospitals without adult open-heart-
 1005 surgery programs issued by the American College of Cardiology
 1006 and the American Heart Association. At a minimum, these criteria
 1007 must provide for:

1008 a. Avoidance of interventions in hemodynamically stable
 1009 patients who have identified symptoms or medical histories.

1010 b. Transfer of patients who have a history of coronary
 1011 disease and clinical presentation of hemodynamic instability.

1012 3. The applicant must agree to submit to the agency a
 1013 quarterly report detailing patient characteristics, treatment,
 1014 and outcomes for all patients receiving emergency percutaneous
 1015 coronary interventions pursuant to this paragraph. This report

1016 must be submitted within 15 days after the close of each
 1017 calendar quarter.

1018 4. The exemption provided by this paragraph does not apply
 1019 unless the agency determines that the hospital has taken all
 1020 necessary steps to be in compliance with all requirements of
 1021 this paragraph, including the training program required under
 1022 sub-subparagraph 1.g.

1023 5. If the hospital fails to continuously comply with the
 1024 requirements of sub-subparagraphs 1.c.-f. and subparagraphs 2.
 1025 and 3., this exemption immediately expires.

1026 6. If the hospital fails to meet the volume requirements
 1027 of sub-subparagraphs 1.a. and b. within 18 months after the
 1028 program begins offering the service, this exemption immediately
 1029 expires.

1030
 1031 If the exemption for this service expires under subparagraph 5.
 1032 or subparagraph 6., the agency may not grant another exemption
 1033 for this service to the same hospital for 2 years and then only
 1034 upon a showing that the hospital will remain in compliance with
 1035 the requirements of this paragraph through a demonstration of
 1036 corrections to the deficiencies that caused the exemption to
 1037 expire. Compliance with this paragraph includes compliance with
 1038 the rules adopted pursuant to this paragraph.

1039 (o) For the addition of mental health services or beds if
 1040 the applicant commits to providing services to Medicaid or
 1041 charity care patients at a level equal to or greater than the
 1042 district average. Such a commitment is subject to s. 408.040.

1043 (p) For replacement of a licensed nursing home on the same
 1044 site, or within 3 miles of the same site, if the number of

1045 licensed beds does not increase.

1046 (g) For consolidation or combination of licensed nursing
 1047 homes or transfer of beds between licensed nursing homes within
 1048 the same planning subdistrict, by providers that operate
 1049 multiple nursing homes within that planning subdistrict, if
 1050 there is no increase in the planning subdistrict total number of
 1051 nursing home beds and the site of the relocation is not more
 1052 than 30 miles from the original location.

1053 (r) For beds in state mental health treatment facilities
 1054 operated under s. 394.455(30) and state mental health forensic
 1055 facilities operated under s. 916.106(8).

1056 (s) For beds in state developmental services institutions
 1057 as defined in s. 393.063.

1058 (4) REQUESTS FOR EXEMPTION.--A request for exemption under
 1059 subsection (3) may be made at any time and is not subject to the
 1060 batching requirements of this section. The request shall be
 1061 supported by such documentation as the agency requires by rule.
 1062 The agency shall assess a fee of \$250 for each request for
 1063 exemption submitted under subsection (3).

1064 (5) NOTIFICATION.--Health care facilities and providers
 1065 must provide to the agency notification of:

1066 (a) Replacement of a health care facility when the
 1067 proposed project site is located in the same district and on the
 1068 existing site or within a 1-mile radius of the replaced health
 1069 care facility, if the number and type of beds do not increase.

1070 (b) The termination of a health care service, upon 30
 1071 days' written notice to the agency.

1072 (c) The addition or delicensure of beds.

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1074 Notification under this subsection may be made by electronic,
 1075 facsimile, or written means at any time before the described
 1076 action has been taken.

1077 Section 7. Section 408.0361, Florida Statutes, is amended
 1078 to read:

1079 408.0361 Cardiology services and burn unit licensure
 1080 ~~Diagnostic cardiac catheterization services providers;~~
 1081 ~~compliance with guidelines and requirements.--~~

1082 (1) Each provider of diagnostic cardiac catheterization
 1083 services shall comply with ~~the requirements of s.~~
 1084 ~~408.036(3)(i)2.a.-d., and~~ rules adopted by ~~of~~ the agency which
 1085 establish licensure standards for Health Care Administration
 1086 governing the operation of adult inpatient diagnostic cardiac
 1087 catheterization programs. The rules must ensure that the
 1088 programs:

1089 (a) Comply with, ~~including~~ the most recent guidelines of
 1090 the American College of Cardiology and American Heart
 1091 Association Guidelines for Cardiac Catheterization and Cardiac
 1092 Catheterization Laboratories.

1093 (b) Perform only adult inpatient diagnostic cardiac
 1094 catheterization services and do not provide therapeutic cardiac
 1095 catheterization or any other cardiology services.

1096 (c) Maintain sufficient appropriate equipment and health
 1097 care personnel to ensure quality and safety.

1098 (d) Maintain appropriate times of operation and protocols
 1099 to ensure availability and appropriate referrals in the event of
 1100 emergencies.

1101 (e) Demonstrate a plan to provide services to Medicaid and
 1102 charity patients.

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1103 (2) Each provider of adult interventional cardiology
1104 services or operator of a burn unit shall comply with rules
1105 adopted by the agency which establish licensure standards that
1106 govern the provision of adult interventional cardiology services
1107 or the operation of a burn unit. Such rules must consider, at a
1108 minimum, staffing, equipment, physical plant, operating
1109 protocols, the provision of services to Medicaid and charity
1110 patients, accreditation, licensure period and fees, and
1111 enforcement of minimum standards. The certificate-of-need rules
1112 for adult interventional cardiology services and burn units in
1113 effect on June 30, 2004, are ratified pursuant to this
1114 subsection and shall remain in effect and be enforceable by the
1115 agency until the licensure rules are adopted. Existing
1116 providers, any provider with an exemption for open heart
1117 surgery, and any provider with a notice of intent to grant a
1118 certificate of need or a final order of the agency granting a
1119 certificate of need for adult interventional cardiology services
1120 or burn units shall be considered grandfathered-in and shall
1121 receive a license for their programs effective on July 1, 2004,
1122 or the date their program becomes operational, whichever is
1123 later. That licensure shall remain valid for at least 3 years or
1124 a period specified in the rule, whichever is longer, but the
1125 programs must meet licensure standards applicable to existing
1126 programs for every subsequent licensure period.

1127 (3) In establishing rules for adult interventional
1128 cardiology services, the agency shall include provisions that
1129 allow for:

1130 (a) Establishment of two hospital program licensure
1131 levels: a Level I program authorizing the performance of adult

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1132 primary percutaneous cardiac intervention for emergent patients
 1133 without onsite cardiac surgery and a Level II program
 1134 authorizing the performance of percutaneous cardiac intervention
 1135 with onsite cardiac surgery.

1136 (b) For a hospital seeking a Level I program,
 1137 demonstration that, for the most recent 12-month period as
 1138 reported to the agency, it has provided a minimum of 300 adult
 1139 inpatient and outpatient diagnostic cardiac catheterizations or
 1140 has transferred at least 300 inpatients with the principal
 1141 diagnosis of ischemic heart disease and that it has a
 1142 formalized, written transfer agreement with a hospital that has
 1143 a Level II program, including written transport protocols to
 1144 ensure safe and efficient transfer of a patient within 60
 1145 minutes.

1146 (c) For a hospital seeking a Level II program,
 1147 demonstration that for the most recent 12-month period as
 1148 reported to the agency it has discharged at least 800 patients
 1149 with the principal diagnosis of ischemic heart disease.

1150 (d) Compliance with the most recent guidelines of the
 1151 American College of Cardiology and American Heart Association
 1152 guidelines for staffing, physician training and experience,
 1153 operating procedures, equipment, physical plant, and patient-
 1154 selection criteria to ensure patient quality and safety.

1155 (e) Establishment of appropriate hours of operation and
 1156 protocols to ensure availability and timely referral in the
 1157 event of emergencies.

1158 (f) Demonstration of a plan to provide services to
 1159 Medicaid and charity patients.

1160 (4) The agency shall establish a technical advisory panel

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1161 to develop procedures and standards for measuring outcomes of
1162 interventional cardiac programs. Members of the panel shall
1163 include representatives of the Florida Hospital Association, the
1164 Florida Society of Thoracic and Cardiovascular Surgeons, the
1165 Florida Chapter of the American College of Cardiology, and the
1166 Florida Chapter of the American Heart Association and others who
1167 have experience in statistics and outcome measurement. Based
1168 upon recommendations from the panel, the agency shall develop
1169 and adopt for the interventional cardiac programs rules that
1170 include at least the following:

1171 (a) A standard data set consisting primarily of data
1172 elements reported to the agency in accordance with s. 408.061.

1173 (b) A risk-adjustment procedure that accounts for the
1174 variations in severity and case mix found in hospitals in this
1175 state.

1176 (c) Outcome standards specifying expected levels of
1177 performance in Level I and Level II adult interventional
1178 cardiology services. Such standards may include, but are not
1179 limited to, inhospital mortality, infection rates, nonfatal
1180 myocardial infarctions, length of stay, postoperative bleeds,
1181 and returns to surgery.

1182 (d) Specific steps to be taken by the agency and licensing
1183 hospitals that do not meet the outcome standards within
1184 specified time periods, including time periods for detailed case
1185 reviews and development and implementation of corrective action
1186 plans.

1187 (9) The Secretary of Health Care Administration shall
1188 appoint an advisory group to study the issue of replacing
1189 certificate-of-need review of organ transplant programs under

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1190 this chapter with licensure regulation of organ transplant
1191 programs under chapter 395. The advisory group shall include
1192 three representatives of organ transplant providers, one
1193 representative of an organ procurement organization, one
1194 representative of the Division of Health Quality Assurance, one
1195 representative of Medicaid, and one advocate for organ
1196 transplant patients. The advisory group shall, at a minimum,
1197 make recommendations regarding access to organs, delivery of
1198 services to Medicaid and charity patients, staff training, and
1199 resource requirements for organ transplant programs in a report
1200 due to the secretary and the Legislature by July 1, 2005.

1201 (10) The Secretary of Health Care Administration shall
1202 appoint a work group to study certificate-of-need regulations
1203 and changing market conditions related to the supply and
1204 distribution of hospital beds. The assessment by the work group
1205 shall include, but need not be limited to:

1206 (a) The appropriateness of current certificate-of-need
1207 methodologies and other criteria for evaluating proposals for
1208 new hospitals and transfers of beds to new sites.

1209 (b) Additional factors that should be considered,
1210 including the viability of safety-net services, the extent of
1211 market competition, and the accessibility of hospital services.

1212
1213 The workgroup shall, by January 1, 2005, submit to the secretary
1214 and the Legislature a report identifying specific program areas
1215 and recommending needed changes in statutes and rules.

1216 Section 8. Section 408.038, Florida Statutes, is amended
1217 to read:

1218 408.038 Fees.--The agency shall assess fees on

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1219 certificate-of-need applications. Such fees shall be for the
 1220 purpose of funding the ~~functions of the local health councils~~
 1221 ~~and the~~ activities of the agency and shall be allocated as
 1222 provided in s. 408.033. The fee shall be determined as follows:

1223 (1) A minimum base fee of \$10,000 ~~\$5,000~~.

1224 (2) In addition to the base fee of \$10,000 ~~\$5,000~~, 0.015
 1225 of each dollar of proposed expenditure, except that a fee may
 1226 not exceed \$50,000 ~~\$22,000~~.

1227 Section 9. Subsections (1), paragraph (a) of subsection
 1228 (3), and paragraph (a) and (b) of subsection (4) of section
 1229 408.039, are amended to read:

1230 408.039 Review process.--The review process for
 1231 certificates of need shall be as follows:

1232 (1) REVIEW CYCLES.--The agency by rule shall provide for
 1233 applications to be submitted on a timetable or cycle basis;
 1234 provide for review on a timely basis; and provide for all
 1235 completed applications pertaining to similar types of services
 1236 or facilities affecting the same service district to be
 1237 considered in relation to each other no less often than annually
 1238 ~~two times a year~~.

1239 (3) APPLICATION PROCESSING.--

1240 (a) An applicant shall file an application with the
 1241 agency, and shall furnish a copy of the application to ~~the local~~
 1242 ~~health council and~~ the agency. Within 15 days after the
 1243 applicable application filing deadline established by agency
 1244 rule, the staff of the agency shall determine if the application
 1245 is complete. If the application is incomplete, the staff shall
 1246 request specific information from the applicant necessary for
 1247 the application to be complete; however, the staff may make only

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1248 one such request. If the requested information is not filed with
 1249 the agency within 21 days after ~~of~~ the receipt of the staff's
 1250 request, the application shall be deemed incomplete and deemed
 1251 withdrawn from consideration.

1252 (4) STAFF RECOMMENDATIONS.--

1253 (a) The agency's review of and final agency action on
 1254 applications shall be in accordance with ~~the district health~~
 1255 ~~plan, and~~ statutory criteria, and the implementing
 1256 administrative rules. In the application review process, the
 1257 agency shall give a preference, as defined by rule of the
 1258 agency, to an applicant which proposes to develop a nursing home
 1259 in a nursing home geographically underserved area.

1260 (b) Within 60 days after all the applications in a review
 1261 cycle are determined to be complete, the agency shall issue its
 1262 State Agency Action Report and Notice of Intent to grant a
 1263 certificate of need for the project in its entirety, to grant a
 1264 certificate of need for identifiable portions of the project, or
 1265 to deny a certificate of need. The State Agency Action Report
 1266 shall set forth in writing its findings of fact and
 1267 determinations upon which its decision is based. ~~If a finding~~
 1268 ~~of fact or determination by the agency is counter to the~~
 1269 ~~district health plan of the local health council, the agency~~
 1270 ~~shall provide in writing its reason for its findings, item by~~
 1271 ~~item, to the local health council.~~ If the agency intends to
 1272 grant a certificate of need, the State Agency Action Report or
 1273 the Notice of Intent shall also include any conditions which the
 1274 agency intends to attach to the certificate of need. The agency
 1275 shall designate by rule a senior staff person, other than the
 1276 person who issues the final order, to issue State Agency Action

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1277 Reports and Notices of Intent.

1278 Section 10. Section 408.040, Florida Statutes, is amended
 1279 to read:

1280 408.040 Conditions and monitoring.--

1281 (1)(a) The agency may issue a certificate of need, or an
 1282 exemption, predicated upon statements of intent expressed by an
 1283 applicant in the application for a certificate of need or an
 1284 exemption. Any conditions imposed on a certificate of need or an
 1285 exemption based on such statements of intent shall be stated on
 1286 the face of the certificate of need or in the exemption
 1287 approval.

1288 (b) The agency may consider, in addition to the other
 1289 criteria specified in s. 408.035, a statement of intent by the
 1290 applicant that a specified percentage of the annual patient days
 1291 at the facility will be utilized by patients eligible for care
 1292 under Title XIX of the Social Security Act. Any certificate of
 1293 need issued to a nursing home in reliance upon an applicant's
 1294 statements that a specified percentage of annual patient days
 1295 will be utilized by residents eligible for care under Title XIX
 1296 of the Social Security Act must include a statement that such
 1297 certification is a condition of issuance of the certificate of
 1298 need. The certificate-of-need program shall notify the Medicaid
 1299 program office and the Department of Elderly Affairs when it
 1300 imposes conditions as authorized in this paragraph in an area in
 1301 which a community diversion pilot project is implemented.

1302 (c) A certificateholder or an exemption holder may apply
 1303 to the agency for a modification of conditions imposed under
 1304 paragraph (a) or paragraph (b). If the holder of a certificate
 1305 of need or an exemption demonstrates good cause why the

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1306 certificate or exemption should be modified, the agency shall
 1307 reissue the certificate of need or exemption with such
 1308 modifications as may be appropriate. The agency shall by rule
 1309 define the factors constituting good cause for modification.

1310 (d) If the holder of a certificate of need or an exemption
 1311 fails to comply with a condition upon which the issuance of the
 1312 certificate or exemption was predicated, the agency may assess
 1313 an administrative fine against the certificateholder or
 1314 exemption holder in an amount not to exceed \$1,000 per failure
 1315 per day. Failure to annually report compliance with any
 1316 condition upon which the issuance of the certificate or
 1317 exemption was predicated constitutes noncompliance. In assessing
 1318 the penalty, the agency shall take into account as mitigation
 1319 the degree of noncompliance ~~relative lack of severity of a~~
 1320 ~~particular failure~~. Proceeds of such penalties shall be
 1321 deposited in the Public Medical Assistance Trust Fund.

1322 (2)(a) Unless the applicant has commenced construction, if
 1323 the project provides for construction, unless the applicant has
 1324 incurred an enforceable capital expenditure commitment for a
 1325 project, if the project does not provide for construction, or
 1326 unless subject to paragraph (b), a certificate of need shall
 1327 terminate 18 months after the date of issuance. The agency shall
 1328 monitor the progress of the holder of the certificate of need in
 1329 meeting the timetable for project development specified in the
 1330 application ~~with the assistance of the local health council as~~
 1331 ~~specified in s. 408.033(1)(b)5.~~, and may revoke the certificate
 1332 of need, if the holder of the certificate is not meeting such
 1333 timetable and is not making a good-faith effort, as defined by
 1334 rule, to meet it.

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1335 (b) A certificate of need issued to an applicant holding a
 1336 provisional certificate of authority under chapter 651 shall
 1337 terminate 1 year after the applicant receives a valid
 1338 certificate of authority from the Office of Insurance Regulation
 1339 of the Financial Services Commission.

1340 (c) The certificate-of-need validity period for a project
 1341 shall be extended by the agency, to the extent that the
 1342 applicant demonstrates to the satisfaction of the agency that
 1343 good-faith commencement of the project is being delayed by
 1344 litigation or by governmental action or inaction with respect to
 1345 regulations or permitting precluding commencement of the
 1346 project.

1347 (3) The agency shall require the submission of an executed
 1348 architect's certification of final payment for each certificate-
 1349 of-need project approved by the agency. Each project that
 1350 involves construction shall submit such certification to the
 1351 agency within 30 days following completion of construction.

1352 Section 11. Subsection (5) of section 408.043, Florida
 1353 Statutes, is repealed.

1354 Section 12. Section 408.0455, Florida Statutes, is amended
 1355 to read:

1356 408.0455 Rules; pending proceedings.--The rules of the
 1357 agency in effect on June 30, 2004 ~~1997~~, shall remain in effect
 1358 and shall be enforceable by the agency with respect to ss.
 1359 408.031-408.045 until such rules are repealed or amended by the
 1360 agency, ~~and no judicial or administrative proceeding pending on~~
 1361 ~~July 1, 1997, shall be abated as a result of the provisions of~~
 1362 ~~ss. 408.031-408.043(1) and (2); s. 408.044; or s. 408.045.~~

1363 Section 13. If any provision of this act or the

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1364 application thereof to any person or circumstance is held
 1365 invalid, the invalidity does not affect other provisions or
 1366 applications of the act which can be given effect without the
 1367 invalid provision or application, and to this end the provisions
 1368 of this act are declared severable.

1369 Section 14. Section 52 of chapter 2001-45, Laws of
 1370 Florida, as amended by section 1693 of chapter 2003-261, Laws of
 1371 Florida, is amended to read:

1372 Section 52. (1) Notwithstanding the establishment of need
 1373 as provided for in chapter 408, Florida Statutes, no certificate
 1374 of need for additional community nursing home beds shall be
 1375 approved by the agency until July 1, 2006.

1376 (2) The Legislature finds that the continued growth in the
 1377 Medicaid budget for nursing home care has constrained the
 1378 ability of the state to meet the needs of its elderly residents
 1379 through the use of less restrictive and less institutional
 1380 methods of long-term care. It is therefore the intent of the
 1381 Legislature to limit the increase in Medicaid nursing home
 1382 expenditures in order to provide funds to invest in long-term
 1383 care that is community-based and provides supportive services in
 1384 a manner that is both more cost-effective and more in keeping
 1385 with the wishes of the elderly residents of this state.

1386 (3) This moratorium on certificates of need shall not
 1387 apply to sheltered nursing home beds in a continuing care
 1388 retirement community certified by the former Department of
 1389 Insurance or by the Office of Insurance Regulation pursuant to
 1390 chapter 651, Florida Statutes.

1391 (4)(a) This moratorium on certificates of need shall not
 1392 apply, and a certificate of need for additional community

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1393 nursing home beds may be approved, for a county that meets the
 1394 following circumstances:

- 1395 1. The county has no community nursing home beds; and
- 1396 2. The lack of community nursing home beds occurs because
 1397 all nursing home beds in the county which were licensed on July
 1398 1, 2001, have subsequently closed.

1399 (b) The certificate-of-need review for such circumstances
 1400 shall be subject to the comparative review process consistent
 1401 with the provisions of section 408.039, Florida Statutes, and
 1402 the number of beds may not exceed the number of beds lost by the
 1403 county after July 1, 2001.

1404
 1405 This subsection shall be repealed upon the expiration of the
 1406 moratorium established in subsection (1).

1407 (5) This moratorium on certificates of need shall not
 1408 apply for the addition of nursing home beds licensed under
 1409 chapter 400 to a nursing home located in a county having up to
 1410 50,000 residents, in a number not exceeding 10 total beds or 10
 1411 percent of the number of beds licensed in the facility being
 1412 expanded, whichever is greater. In addition to any other
 1413 documentation required by the agency, a request submitted under
 1414 this paragraph must:

1415 (a) Certify that the facility has not had any class I or
 1416 class II deficiencies within the 30 months preceding the request
 1417 for addition.

1418 (b) Certify that the prior 12-month average occupancy rate
 1419 for the nursing home beds at the facility meets or exceeds 94
 1420 percent and the facility had not had any class I or class II
 1421 deficiencies since its initial licensure.

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1422 (c) For a facility that has been licensed for less than 24
1423 months, certify that the prior 6-month average occupancy rate
1424 for the nursing home beds at the facility meets or exceeds 94
1425 percent and that the facility has not had any class I or class
1426 II deficiencies since its initial licensure.

1427
1428 This subsection shall be repealed upon the expiration of the
1429 moratorium established in subsection (1).

1430 Section 15. This act shall take effect July 1, 2004.