1 A bill to be entitled 2 An act relating to certificates of need for hospitals; 3 amending s. 408.032, F.S.; revising and deleting definitions; amending s. 408.034, F.S.; revising 4 5 duties and responsibilities of the Agency for Health 6 Care Administration relating to issuance of licenses 7 to health care facilities and health service 8 providers; conforming a reference; amending s. 9 408.035, F.S.; excluding general hospitals from 10 certain agency review of applications for certificate-11 of-need determinations; amending s. 408.036, F.S.; 12 revising health-care-related projects subject to agency review for a certificate of need and exemptions 13 14 therefrom; deleting provisions requiring health care facilities and providers to provide certain notice to 15 16 the agency upon termination of a health care service 17 or the addition or delicensure of beds; conforming a provision; amending ss. 408.037 and 408.039, F.S.; 18 19 conforming provisions to changes made by the act; amending s. 408.043, F.S.; deleting certificate-of-20 21 need requirements for osteopathic acute care hospitals; amending s. 395.1055, F.S.; revising the 22 23 agency's rulemaking authority with respect to minimum standards for hospitals; requiring hospitals that 24 25 provide certain services to meet specified licensure

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26	requirements; conforming provisions to changes made by
27	the act; repealing s. 395.6025, F.S., relating to
28	rural hospital replacement facilities; amending ss.
29	395.603, 395.604, 395.605, and 408.033, F.S.;
30	conforming provisions and cross-references; amending
31	s. 408.0361, F.S.; deleting obsolete provisions;
32	providing an effective date.
33	
34	Be It Enacted by the Legislature of the State of Florida:
35	
36	Section 1. Subsections (8) through (17) of section
37	408.032, Florida Statutes, are amended to read:
38	408.032 Definitions relating to Health Facility and
39	Services Development ActAs used in ss. 408.031-408.045, the
40	term:
41	(8) "Health care facility" means a hospital, long-term
42	care hospital, skilled nursing facility, hospice, or
43	intermediate care facility for the developmentally disabled. A
44	facility relying solely on spiritual means through prayer for
45	healing is not included as a health care facility.
46	(9) "Health services" means inpatient diagnostic,
47	curative, or comprehensive medical rehabilitative services and
48	includes mental health services. Obstetric services are not
49	health services for purposes of ss. 408.031-408.045.

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50 (9) (10) "Hospice" or "hospice program" means a hospice as 51 defined in part IV of chapter 400. 52 (11) "Hospital" means a health care facility licensed 53 under chapter 395. 54 (10) (12) "Intermediate care facility for the 55 developmentally disabled" means a residential facility licensed under part VIII of chapter 400. 56 57 (13) "Long-term care hospital" means a hospital licensed under chapter 395 which meets the requirements of 42 C.F.R. s. 58 59 412.23(e) and seeks exclusion from the acute care Medicare 60 prospective payment system for inpatient hospital services. 61 (14) "Mental health services" means inpatient services 62 provided in a hospital licensed under chapter 395 and listed on 63 the hospital license as psychiatric beds for adults; psychiatric beds for children and adolescents; intensive residential 64 treatment beds for children and adolescents; substance abuse 65 66 beds for adults; or substance abuse beds for children and 67 adolescents. 68 (11) (15) "Nursing home geographically underserved area" 69 means: 70 A county in which there is no existing or approved (a) 71 nursing home; (b) An area with a radius of at least 20 miles in which 72 73 there is no existing or approved nursing home; or

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(c) An area with a radius of at least 20 miles in which all existing nursing homes have maintained at least a 95 percent occupancy rate for the most recent 6 months or a 90 percent occupancy rate for the most recent 12 months.

78 <u>(12)(16)</u> "Skilled nursing facility" means an institution, 79 or a distinct part of an institution, which is primarily engaged 80 in providing, to inpatients, skilled nursing care and related 81 services for patients who require medical or nursing care, or 82 rehabilitation services for the rehabilitation of injured, 83 disabled, or sick persons.

(17) "Tertiary health service" means a health service 84 85 which, due to its high level of intensity, complexity, 86 specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals 87 to ensure the quality, availability, and cost-effectiveness of 88 89 such service. Examples of such service include, but are not 90 limited to, pediatric cardiac catheterization, pediatric open-91 heart surgery, organ transplantation, neonatal intensive care 92 units, comprehensive rehabilitation, and medical or surgical 93 services which are experimental or developmental in nature to 94 the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or 95 96 treatment for the condition addressed by a given service. The agency shall establish by rule a list of all tertiary health 97 98 services.

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99 Section 2. Subsections (2) and (3) of section 408.034,100 Florida Statutes, are amended to read:

408.034 Duties and responsibilities of agency; rules.-

(2) In the exercise of its authority to issue licenses to health care facilities and health service providers, as provided under <u>chapter</u> chapters 393 and 395 and parts II, IV, and VIII of chapter 400, the agency may not issue a license to any health care facility or health service provider that fails to receive a certificate of need or an exemption for the licensed facility or service.

(3) The agency shall establish, by rule, uniform need methodologies for health services and health facilities. In developing uniform need methodologies, the agency shall, at a minimum, consider the demographic characteristics of the population, the health status of the population, service use patterns, standards and trends, geographic accessibility, and market economics.

116 Section 3. Section 408.035, Florida Statutes, is amended 117 to read:

118 408.035 Review criteria.-

119 (1) The agency shall determine the reviewability of 120 applications and shall review applications for certificate-of-121 need determinations for health care facilities and health 122 services in context with the following criteria, except for 123 general hospitals as defined in s. 395.002:

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124 <u>(1) (a)</u> The need for the health care facilities and health 125 services being proposed.

126 (2) (b) The availability, quality of care, accessibility, 127 and extent of utilization of existing health care facilities and 128 health services in the service district of the applicant.

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

131 <u>(4) (d)</u> The availability of resources, including health 132 personnel, management personnel, and funds for capital and 133 operating expenditures, for project accomplishment and 134 operation.

135 <u>(5) (c)</u> The extent to which the proposed services will 136 enhance access to health care for residents of the service 137 district.

138 <u>(6) (f)</u> The immediate and long-term financial feasibility 139 of the proposal.

140 (7) (g) The extent to which the proposal will foster
 141 competition that promotes quality and cost-effectiveness.

142 <u>(8) (h)</u> The costs and methods of the proposed construction, 143 including the costs and methods of energy provision and the 144 availability of alternative, less costly, or more effective 145 methods of construction.

146 <u>(9)(i)</u> The applicant's past and proposed provision of 147 health care services to Medicaid patients and the medically 148 indigent.

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149 (10) (i) The applicant's designation as a Gold Seal Program nursing facility pursuant to s. 400.235, when the applicant is 150 151 requesting additional nursing home beds at that facility. 152 (2) For a general hospital, the agency shall consider only 153 the criteria specified in paragraph (1)(a), paragraph (1)(b), 154 except for quality of care in paragraph (1) (b), and paragraphs 155 (1) (e), (g), and (i). 156 Section 4. Section 408.036, Florida Statutes, is amended 157 to read: 158 408.036 Projects subject to review; exemptions.-(1) APPLICABILITY.-Unless exempt under subsection (3), all 159 160 health-care-related projects, as described in this subsection paragraphs (a)-(f), are subject to review and must file an 161 162 application for a certificate of need with the agency. The 163 agency is exclusively responsible for determining whether a 164 health-care-related project is subject to review under ss. 165 408.031-408.045. The addition of beds in community nursing homes or 166 (a) 167 intermediate care facilities for the developmentally disabled by 168 new construction or alteration. 169 The new construction or establishment of additional (b) 170 health care facilities, including a replacement health care facility when the proposed project site is not located on the 171

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same site as or within 1 mile of the existing health care

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173 facility, if the number of beds in each licensed bed category 174 will not increase. 175 (c) The conversion from one type of health care facility 176 to another, including the conversion from a general hospital, a

177 specialty hospital, or a long-term care hospital.

(d) The establishment of a hospice or hospice inpatientfacility, except as provided in s. 408.043.

180 (e) An increase in the number of beds for comprehensive 181 rehabilitation.

182 (f) The establishment of tertiary health services,
 183 including inpatient comprehensive rehabilitation services.

(2) PROJECTS SUBJECT TO EXPEDITED REVIEW.-Unless exempt pursuant to subsection (3), the following projects are subject to expedited review:

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

(b) Replacement of a nursing home, if the proposed project site is within a 30-mile radius of the replaced nursing home. If the proposed project site is outside the subdistrict where the replaced nursing home is located, the prior 6-month occupancy rate for licensed community nursing homes in the proposed subdistrict must be at least 85 percent in accordance with the agency's most recently published inventory.

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198 Replacement of a nursing home within the same (C) district, if the proposed project site is outside a 30-mile 199 200 radius of the replaced nursing home but within the same 201 subdistrict or a geographically contiguous subdistrict. If the 202 proposed project site is in the geographically contiguous 203 subdistrict, the prior 6-month occupancy rate for licensed 204 community nursing homes for that subdistrict must be at least 85 205 percent in accordance with the agency's most recently published 206 inventory.

(d) Relocation of a portion of a nursing home's licensed beds to another facility or to establish a new facility within the same district or within a geographically contiguous district, if the relocation is within a 30-mile radius of the existing facility and the total number of nursing home beds in the state does not increase.

(e) New construction of a community nursing home in aretirement community as further provided in this paragraph.

215 1. Expedited review under this paragraph is available if 216 all of the following criteria are met:

a. The residential use area of the retirement community is
deed-restricted as housing for older persons as defined in s.
760.29(4)(b).

b. The retirement community is located in a county inwhich 25 percent or more of its population is age 65 and older.

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c. The retirement community is located in a county that has a rate of no more than 16.1 beds per 1,000 persons age 65 years or older. The rate shall be determined by using the current number of licensed and approved community nursing home beds in the county per the agency's most recent published inventory.

d. The retirement community has a population of at least
8,000 residents within the county, based on a population data
source accepted by the agency.

e. The number of proposed community nursing home beds in an application does not exceed the projected bed need after applying the rate of 16.1 beds per 1,000 persons aged 65 years and older projected for the county 3 years into the future using the estimates adopted by the agency reduced by the agency's most recently published inventory of licensed and approved community nursing home beds in the county.

238 2. No more than 120 community nursing home beds shall be 239 approved for a qualified retirement community under each request 240 for expedited review. Subsequent requests for expedited review 241 under this process may not be made until 2 years after 242 construction of the facility has commenced or 1 year after the 243 beds approved through the initial request are licensed, 244 whichever occurs first.

3. The total number of community nursing home beds whichmay be approved for any single deed-restricted community

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247 pursuant to this paragraph may not exceed 240, regardless of 248 whether the retirement community is located in more than one 249 qualifying county.

4. Each nursing home facility approved under this
paragraph must be dually certified for participation in the
Medicare and Medicaid programs.

5. Each nursing home facility approved under this paragraph must be at least 1 mile, as measured over publicly owned roadways, from an existing approved and licensed community nursing home.

6. A retirement community requesting expedited review under this paragraph shall submit a written request to the agency for expedited review. The request must include the number of beds to be added and provide evidence of compliance with the criteria specified in subparagraph 1.

262 7. After verifying that the retirement community meets the 263 criteria for expedited review specified in subparagraph 1., the 264 agency shall publicly notice in the Florida Administrative 265 Register that a request for an expedited review has been 266 submitted by a qualifying retirement community and that the 267 qualifying retirement community intends to make land available 268 for the construction and operation of a community nursing home. The agency's notice must identify where potential applicants can 269 270 obtain information describing the sales price of, or terms of 271 the land lease for, the property on which the project will be

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272 located and the requirements established by the retirement 273 community. The agency notice must also specify the deadline for 274 submission of the certificate-of-need application, which may not 275 be earlier than the 91st day or later than the 125th day after 276 the date the notice appears in the Florida Administrative 277 Register.

8. The qualified retirement community shall make land available to applicants it deems to have met its requirements for the construction and operation of a community nursing home but may sell or lease the land only to the applicant that is issued a certificate of need by the agency under this paragraph.

a. A certificate-of-need application submitted under this paragraph must identify the intended site for the project within the retirement community and the anticipated costs for the project based on that site. The application must also include written evidence that the retirement community has determined that both the provider submitting the application and the project satisfy its requirements for the project.

b. If the retirement community determines that more than
one provider satisfies its requirements for the project, it may
notify the agency of the provider it prefers.

9. The agency shall review each submitted application. If multiple applications are submitted for a project published pursuant to subparagraph 7., the agency shall review the competing applications.

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297 The agency shall develop rules to implement the expedited review 298 299 process, including time schedule, application content that may 300 be reduced from the full requirements of s. 408.037(1), and 301 application processing. 302 EXEMPTIONS.-Upon request, the following projects are (3) 303 subject to exemption from the provisions of subsection (1): 304 For hospice services or for swing beds in a rural (a) hospital, as defined in s. 395.602, in a number that does not 305 306 exceed one-half of its licensed beds, or for a hospice program 307 established by an entity that shares a controlling interest, as 308 defined in s. 408.803, with a not-for-profit retirement 309 community that offers independent living, assisted living, and 310 skilled nursing services provided in a facility on the same 311 premises and designated by the agency as a teaching nursing home 312 for a minimum of 5 years, in accordance with s. 430.80. Only one 313 hospice program per teaching nursing home may be established 314 under the exemption in this paragraph, and such program shall be 315 limited to serving patients residing in communities located 316 within the not-for-profit retirement community, including home and community-based service providers. 317 318 (b) For the conversion of licensed acute care hospital 319 beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital, as defined in s. 395.602, so long as the 320 321 conversion of the beds does not involve the construction

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322 facilities. The total number of skilled nursing beds, including 323 swing beds, may not exceed one-half of the total number of 324 licensed beds in the rural hospital as of July 1, 1993. 325 Certified skilled nursing beds designated under this paragraph, 326 excluding swing beds, shall be included in the community nursing 327 home bed inventory. A rural hospital that subsequently 328 decertifies any acute care beds exempted under this paragraph 329 shall notify the agency of the decertification, and the agency 330 shall adjust the community nursing home bed inventory 331 accordingly.

332 (b) (c) For the addition of nursing home beds at a skilled 333 nursing facility that is part of a retirement community that 334 provides a variety of residential settings and supportive 335 services and that has been incorporated and operated in this 336 state for at least 65 years on or before July 1, 1994. All 337 nursing home beds must not be available to the public but must 338 be for the exclusive use of the community residents.

339 <u>(c) (d)</u> For an inmate health care facility built by or for 340 the exclusive use of the Department of Corrections as provided 341 in chapter 945. This exemption expires when such facility is 342 converted to other uses.

343 <u>(d) (e)</u> For mobile surgical facilities and related health 344 care services provided under contract with the Department of 345 Corrections or a private correctional facility operating 346 pursuant to chapter 957.

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347 <u>(e) (f)</u> For the addition of nursing home beds licensed 348 under chapter 400 in a number not exceeding 30 total beds or 25 349 percent of the number of beds licensed in the facility being 350 replaced under paragraph (2) (b), paragraph (2) (c), or paragraph 351 (j) (p), whichever is less.

352 (f) (g) For state veterans' nursing homes operated by or on 353 behalf of the Florida Department of Veterans' Affairs in 354 accordance with part II of chapter 296 for which at least 50 percent of the construction cost is federally funded and for 355 356 which the Federal Government pays a per diem rate not to exceed 357 one-half of the cost of the veterans' care in such state nursing 358 homes. These beds shall not be included in the nursing home bed 359 inventory.

360 (g) (h) For combination within one nursing home facility of 361 the beds or services authorized by two or more certificates of 362 need issued in the same planning subdistrict. An exemption 363 granted under this paragraph shall extend the validity period of 364 the certificates of need to be consolidated by the length of the 365 period beginning upon submission of the exemption request and 366 ending with issuance of the exemption. The longest validity 367 period among the certificates shall be applicable to each of the combined certificates. 368

369 <u>(h) (i)</u> For division into two or more nursing home 370 facilities of beds or services authorized by one certificate of 371 need issued in the same planning subdistrict. An exemption

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372 granted under this paragraph shall extend the validity period of 373 the certificate of need to be divided by the length of the 374 period beginning upon submission of the exemption request and 375 ending with issuance of the exemption. 376 (j) For the addition of hospital beds licensed under 377 chapter 395 for comprehensive rehabilitation in a number that may not exceed 10 total beds or 10 percent of the licensed 378 379 capacity, whichever is greater. 380 1. In addition to any other documentation otherwise 381 required by the agency, a request for exemption submitted under 382 this paragraph must: 383 a. Certify that the prior 12-month average occupancy rate 384 for the licensed beds being expanded meets or exceeds 80 385 percent. 386 b. Certify that the beds have been licensed and 387 operational for at least 12 months. 388 2. The timeframes and monitoring process specified in s. 389 408.040(2)(a)-(c) apply to any exemption issued under this 390 paragraph. 391 3. The agency shall count beds authorized under this paragraph as approved beds in the published inventory of 392 393 hospital beds until the beds are licensed. 394 (i) (k) For the addition of nursing home beds licensed under chapter 400 in a number not exceeding 10 total beds or 10 395 396 percent of the number of beds licensed in the facility being Page 16 of 42

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397 expanded, whichever is greater; or, for the addition of nursing 398 home beds licensed under chapter 400 at a facility that has been 399 designated as a Gold Seal nursing home under s. 400.235 in a 400 number not exceeding 20 total beds or 10 percent of the number 401 of licensed beds in the facility being expanded, whichever is 402 greater.

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

406a. The facility has not had any class I or class II407deficiencies within the 30 months preceding the request.

408b. The prior 12-month average occupancy rate for the409nursing home beds at the facility meets or exceeds 94 percent.

410 c. Any beds authorized for the facility under this 411 paragraph before the date of the current request for an 412 exemption have been licensed and operational for at least 12 413 months.

414 2. The timeframes and monitoring process specified in s.
415 408.040(2)(a)-(c) apply to any exemption issued under this
416 paragraph.

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

420

(1) For the establishment of:

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421 1. A Level II neonatal intensive care unit with at least 422 10 beds, upon documentation to the agency that the applicant 423 hospital had a minimum of 1,500 births during the previous 12 424 months; 425 2. A Level III neonatal intensive care unit with at least 426 15 beds, upon documentation to the agency that the applicant 427 hospital has a Level II neonatal intensive care unit of at least 428 10 beds and had a minimum of 3,500 births during the previous 12 429 months; or 430 3. A Level III neonatal intensive care unit with at least 431 5 beds, upon documentation to the agency that the applicant 432 hospital is a verified trauma center pursuant to s. 433 395.4001(14), and has a Level II neonatal intensive care unit, 434 435 if the applicant demonstrates that it meets the requirements for 436 quality of care, nurse staffing, physician staffing, physical 437 plant, equipment, emergency transportation, and data reporting 438 found in agency certificate-of-need rules for Level II and Level 439 III neonatal intensive care units and if the applicant commits 440 to the provision of services to Medicaid and charity patients at 441 a level equal to or greater than the district average. Such a 442 commitment is subject to s. 408.040. 443 (m)1. For the provision of adult open-heart services in a 444 hospital located within the boundaries of a health service planning district, as defined in s. 408.032(5), which has 445

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446	experienced an annual net out-migration of at least 600 open-
447	heart-surgery cases for 3 consecutive years according to the
448	most recent data reported to the agency, and the district's
449	population per licensed and operational open-heart programs
450	exceeds the state average of population per licensed and
451	operational open-heart programs by at least 25 percent. All
452	hospitals within a health service planning district which meet
453	the criteria reference in sub-subparagraphs 2.ah. shall be
454	eligible for this exemption on July 1, 2004, and shall receive
455	the exemption upon filing for it and subject to the following:
456	a. A hospital that has received a notice of intent to
457	grant a certificate of need or a final order of the agency
458	granting a certificate of need for the establishment of an open-
459	heart-surgery program is entitled to receive a letter of
460	exemption for the establishment of an adult open-heart-surgery
461	program upon filing a request for exemption and complying with
462	the criteria enumerated in sub-subparagraphs 2.ah., and is
463	entitled to immediately commence operation of the program.
464	b. An otherwise eligible hospital that has not received a
465	notice of intent to grant a certificate of need or a final order
466	of the agency granting a certificate of need for the
467	establishment of an open-heart-surgery program is entitled to
468	immediately receive a letter of exemption for the establishment
469	of an adult open-heart-surgery program upon filing a request for
470	exemption and complying with the criteria enumerated in sub-
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471 subparagraphs 2.a.-h., but is not entitled to commence operation 472 of its program until December 31, 2006. 473 2. A hospital shall be exempt from the certificate-of-need 474 review for the establishment of an open-heart-surgery program 475 when the application for exemption submitted under this 476 paragraph complies with the following criteria: 477 a. The applicant must certify that it will meet and 478 continuously maintain the minimum licensure requirements adopted by the agency governing adult open-heart programs, including the 479 480 most current guidelines of the American College of Cardiology 481 and American Heart Association Guidelines for Adult Open Heart 482 Programs. 483 b. The applicant must certify that it will maintain 484 sufficient appropriate equipment and health personnel to ensure 485 quality and safety. 486 c. The applicant must certify that it will maintain 487 appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of 488 489 emergencies. 490 d. The applicant can demonstrate that it has discharged at 491 least 300 inpatients with a principal diagnosis of ischemic 492 heart disease for the most recent 12-month period as reported to the agency. 493 494 e. The applicant is a general acute care hospital that is in operation for 3 years or more. 495

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f. The applicant is performing more than 300 diagnostic 496 497 cardiac catheterization procedures per year, combined inpatient 498 and outpatient. 499 q. The applicant's payor mix at a minimum reflects the 500 community average for Medicaid, charity care, and self-pay 501 patients or the applicant must certify that it will provide a minimum of 5 percent of Medicaid, charity care, and self-pay to 502 503 open-heart-surgery patients. h. If the applicant fails to meet the established criteria 504 505 for open-heart programs or fails to reach 300 surgeries per year 506 by the end of its third year of operation, it must show cause 507 why its exemption should not be revoked. 508 3. By December 31, 2004, and annually thereafter, the 509 agency shall submit a report to the Legislature providing 510 information concerning the number of requests for exemption it 511 has received under this paragraph during the calendar year and 512 the number of exemptions it has granted or denied during the 513 calendar year. 514 (n) For the provision of percutaneous coronary 515 intervention for patients presenting with emergency myocardial infarctions in a hospital without an approved adult open-heart-516 517 surgery program. In addition to any other documentation required by the agency, a request for an exemption submitted under this 518 paragraph must comply with the following: 519

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520	1. The applicant must certify that it will meet and
521	continuously maintain the requirements adopted by the agency for
522	the provision of these services. These licensure requirements
523	shall be adopted by rule and must be consistent with the
524	guidelines published by the American College of Cardiology and
525	the American Heart Association for the provision of percutaneous
526	coronary interventions in hospitals without adult open-heart
527	services. At a minimum, the rules must require the following:
528	a. Cardiologists must be experienced interventionalists
529	who have performed a minimum of 75 interventions within the
530	previous 12 months.
531	b. The hospital must provide a minimum of 36 emergency
532	interventions annually in order to continue to provide the
533	service.
534	c. The hospital must offer sufficient physician, nursing,
535	and laboratory staff to provide the services 24 hours a day, 7
536	days a week.
537	d. Nursing and technical staff must have demonstrated
538	experience in handling acutely ill patients requiring
539	intervention based on previous experience in dedicated
540	interventional laboratories or surgical centers.
541	e. Cardiac care nursing staff must be adept in hemodynamic
542	monitoring and Intra-aortic Balloon Pump (IABP) management.
543	f. Formalized written transfer agreements must be
544	developed with a hospital with an adult open-heart-surgery
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545 program, and written transport protocols must be in place to ensure safe and efficient transfer of a patient within 60 546 547 minutes. Transfer and transport agreements must be reviewed and 548 tested, with appropriate documentation maintained at least every 549 3 months. However, a hospital located more than 100 road miles 550 from the closest Level II adult cardiovascular services program 551 does not need to meet the 60-minute transfer time protocol if 552 the hospital demonstrates that it has a formalized, written transfer agreement with a hospital that has a Level II program. 553 554 The agreement must include written transport protocols that 555 ensure the safe and efficient transfer of a patient, taking into 556 consideration the patient's clinical and physical 557 characteristics, road and weather conditions, and viability of 558 ground and air ambulance service to transfer the patient. 559 g. Hospitals implementing the service must first undertake 560 a training program of 3 to 6 months' duration, which includes 561 establishing standards and testing logistics, creating quality 562 assessment and error management practices, and formalizing 563 patient-selection criteria. 564 The applicant must certify that it will use at all 2. 565 times the patient-selection criteria for the performance of 566 primary angioplasty at hospitals without adult open-heart-567 surgery programs issued by the American College of Cardiology 568 and the American Heart Association. At a minimum, these criteria 569 would provide for the following:

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570 a. Avoidance of interventions in hemodynamically stable 571 patients who have identified symptoms or medical histories. 572 b. Transfer of patients who have a history of coronary disease and clinical presentation of hemodynamic instability. 573 574 3. The applicant must agree to submit a quarterly report to the agency detailing patient characteristics, treatment, and 575 outcomes for all patients receiving emergency percutaneous 576 577 coronary interventions pursuant to this paragraph. This report must be submitted within 15 days after the close of each 578 579 calendar quarter. 580 4. The exemption provided by this paragraph does not apply 581 unless the agency determines that the hospital has taken all 582 necessary steps to be in compliance with all requirements of 583 this paragraph, including the training program required under 584 sub-subparagraph 1.g. 585 5. Failure of the hospital to continuously comply with the 586 requirements of sub-subparagraphs 1.c.-f. and subparagraphs 2. 587 and 3. will result in the immediate expiration of this 588 exemption. 589 6. Failure of the hospital to meet the volume requirements 590 of sub-subparagraphs 1.a. and b. within 18 months after the 591 program begins offering the service will result in the immediate 592 expiration of the exemption. 593

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If the exemption for this service expires under subparagraph 5. 594 595 or subparagraph 6., the agency may not grant another exemption 596 for this service to the same hospital for 2 years and then only 597 upon a showing that the hospital will remain in compliance with 598 the requirements of this paragraph through a demonstration of 599 corrections to the deficiencies that caused expiration of the 600 exemption. Compliance with the requirements of this paragraph 601 includes compliance with the rules adopted pursuant to this 602 paragraph.

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

607 <u>(j)(p)</u> For replacement of a licensed nursing home on the 608 same site, or within 5 miles of the same site if within the same 609 subdistrict, if the number of licensed beds does not increase 610 except as permitted under paragraph <u>(e)</u> (f).

611 <u>(k) (q)</u> For consolidation or combination of licensed 612 nursing homes or transfer of beds between licensed nursing homes 613 within the same planning district, by nursing homes with any 614 shared controlled interest within that planning district, if 615 there is no increase in the planning district total number of 616 nursing home beds and the site of the relocation is not more 617 than 30 miles from the original location.

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618 (1) (r) For beds in state mental health treatment 619 facilities defined in s. 394.455 and state mental health 620 forensic facilities operated under chapter 916. 621 (m) (s) For beds in state developmental disabilities centers as defined in s. 393.063. 622 623 (n) (t) For the establishment of a health care facility or 624 project that meets all of the following criteria: 625 The applicant was previously licensed within the past 1. 21 days as a health care facility or provider that is subject to 626 627 subsection (1). 628 2. The applicant failed to submit a renewal application 629 and the license expired on or after January 1, 2015. 630 The applicant does not have a license denial or 3. 631 revocation action pending with the agency at the time of the 632 request. 633 4. The applicant's request is for the same service type, 634 district, service area, and site for which the applicant was 635 previously licensed. 636 5. The applicant's request, if applicable, includes the 637 same number and type of beds as were previously licensed. 638 6. The applicant agrees to the same conditions that were 639 previously imposed on the certificate of need or on an exemption related to the applicant's previously licensed health care 640 facility or project. 641

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642 7. The applicant applies for initial licensure as required 643 under s. 408.806 within 21 days after the agency approves the 644 exemption request. If the applicant fails to apply in a timely 645 manner, the exemption expires on the 22nd day following the 646 agency's approval of the exemption.

Notwithstanding subparagraph 1., an applicant whose license expired between January 1, 2015, and the effective date of this act may apply for an exemption within 30 days of this act becoming law.

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

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

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

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

(c) The addition or delicensure of beds.

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667 Notification under this subsection may be made by electronic, 668 669 facsimile, or written means at any time before the described 670 action has been taken. 671 Section 5. Section 408.037, Florida Statutes, is amended 672 to read: 673 408.037 Application content.-674 Except as provided in subsection (2) for a general (1)hospital, An application for a certificate of need must contain: 675 676 (a) A detailed description of the proposed project and 677 statement of its purpose and need in relation to the district 678 health plan. 679 A statement of the financial resources needed by and (b) 680 available to the applicant to accomplish the proposed project. 681 This statement must include: 682 A complete listing of all capital projects, including 1. 683 new health facility development projects and health facility acquisitions applied for, pending, approved, or underway in any 684 685 state at the time of application, regardless of whether or not 686 that state has a certificate-of-need program or a capital 687 expenditure review program pursuant to s. 1122 of the Social 688 Security Act. The agency may, by rule, require less-detailed information from major health care providers. This listing must 689 include the applicant's actual or proposed financial commitment 690

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691 to those projects and an assessment of their impact on the 692 applicant's ability to provide the proposed project.

693 2. A detailed listing of the needed capital expenditures,694 including sources of funds.

695 3. A detailed financial projection, including a statement 696 of the projected revenue and expenses for the first 2 years of 697 operation after completion of the proposed project. This 698 statement must include a detailed evaluation of the impact of 699 the proposed project on the cost of other services provided by 700 the applicant.

(c) An audited financial statement of the applicant or the applicant's parent corporation if audited financial statements of the applicant do not exist. In an application submitted by an existing health care facility, health maintenance organization, or hospice, financial condition documentation must include, but need not be limited to, a balance sheet and a profit-and-loss statement of the 2 previous fiscal years' operation.

708 (2) An application for a certificate of need for a general 709 hospital must contain a detailed description of the proposed 710 general hospital project and a statement of its purpose and the 711 needs it will meet. The proposed project's location, as well as 712 its primary and secondary service areas, must be identified by zip code. Primary service area is defined as the zip codes from 713 714 which the applicant projects that it will draw 75 percent of its 715 discharges. Secondary service area is defined as the zip codes

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from which the applicant projects that it will draw its 716 717 remaining discharges. If, subsequent to issuance of a final 718 order approving the certificate of need, the proposed location 719 of the general hospital changes or the primary service area 720 materially changes, the agency shall revoke the certificate of 721 need. However, if the agency determines that such changes are 722 deemed to enhance access to hospital services in the service 723 district, the agency may permit such changes to occur. A party 724 participating in the administrative hearing regarding the 725 issuance of the certificate of need for a general hospital has 726 standing to participate in any subsequent proceeding regarding 727 the revocation of the certificate of need for a hospital for 728 which the location has changed or for which the primary service 729 area has materially changed. In addition, the application for 730 the certificate of need for a general hospital must include a 731 statement of intent that, if approved by final order of the 732 agency, the applicant shall within 120 days after issuance of 733 the final order or, if there is an appeal of the final order, 734 within 120 days after the issuance of the court's mandate on 735 appeal, furnish satisfactory proof of the applicant's financial 736 ability to operate. The agency shall establish documentation 737 requirements, to be completed by each applicant, which show 738 anticipated provider revenues and expenditures, the basis for 739 financing the anticipated cash-flow requirements of the 740 provider, and an applicant's access to contingency financing. A

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party participating in the administrative hearing regarding the 741 742 issuance of the certificate of need for a general hospital may 743 provide written comments concerning the adequacy of the 744 financial information provided, but such party does not have 745 standing to participate in an administrative proceeding 746 regarding proof of the applicant's financial ability to operate. 747 The agency may require a licensee to provide proof of financial ability to operate at any time if there is evidence of financial 748 instability, including, but not limited to, unpaid expenses 749 750 necessary for the basic operations of the provider. 751 (2) (3) The applicant must certify that it will license and 752 operate the health care facility. For an existing health care 753 facility, the applicant must be the licenseholder of the 754 facility. 755 Section 6. Paragraphs (c) and (d) of subsection (3), 756 paragraphs (b) and (c) of subsection (5), and paragraph (d) of 757 subsection (6) of section 408.039, Florida Statutes, are amended 758 to read: 759 408.039 Review process.-The review process for 760 certificates of need shall be as follows: 761 (3) APPLICATION PROCESSING.-762 (c) Except for competing applicants, in order to be eligible to challenge the agency decision on a general hospital 763 application under review pursuant to paragraph (5)(c), existing 764 765 hospitals must submit a detailed written statement of opposition

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766 to the agency and to the applicant. The detailed written 767 statement must be received by the agency and the applicant 768 within 21 days after the general hospital application is deemed 769 complete and made available to the public. 770 (d) In those cases where a written statement of opposition 771 has been timely filed regarding a certificate of need 772 application for a general hospital, the applicant for the 773 general hospital may submit a written response to the agency. 774 Such response must be received by the agency within 10 days of 775 the written statement due date. 776 ADMINISTRATIVE HEARINGS.-(5) 777 (b) Hearings shall be held in Tallahassee unless the 778 administrative law judge determines that changing the location 779 will facilitate the proceedings. The agency shall assign 780 proceedings requiring hearings to the Division of Administrative 781 Hearings of the Department of Management Services within 10 days 782 after the time has expired for requesting a hearing. Except upon 783 unanimous consent of the parties or upon the granting by the 784 administrative law judge of a motion of continuance, hearings 785 shall commence within 60 days after the administrative law judge 786 has been assigned. For an application for a general hospital, 787 administrative hearings shall commence within 6 months after the administrative law judge has been assigned, and a continuance 788 789 may not be granted absent a finding of extraordinary 790 circumstances by the administrative law judge. All parties,

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791 except the agency, shall bear their own expense of preparing a 792 transcript. In any application for a certificate of need which 793 is referred to the Division of Administrative Hearings for 794 hearing, the administrative law judge shall complete and submit 795 to the parties a recommended order as provided in ss. 120.569 796 and 120.57. The recommended order shall be issued within 30 days 797 after the receipt of the proposed recommended orders or the 798 deadline for submission of such proposed recommended orders, 799 whichever is earlier. The division shall adopt procedures for 800 administrative hearings which shall maximize the use of 801 stipulated facts and shall provide for the admission of prepared 802 testimony.

803 (c) In administrative proceedings challenging the issuance 804 or denial of a certificate of need, only applicants considered 805 by the agency in the same batching cycle are entitled to a 806 comparative hearing on their applications. Existing health care 807 facilities may initiate or intervene in an administrative 808 hearing upon a showing that an established program will be 809 substantially affected by the issuance of any certificate of 810 need, whether reviewed under s. 408.036(1) or (2), to a 811 competing proposed facility or program within the same district. 812 With respect to an application for a general hospital, competing applicants and only those existing hospitals that submitted a 813 814 detailed written statement of opposition to an application as 815 provided in this paragraph may initiate or intervene in an

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816	administrative hearing. Such challenges to a general hospital
817	application shall be limited in scope to the issues raised in
818	the detailed written statement of opposition that was provided
819	to the agency. The administrative law judge may, upon a motion
820	showing good cause, expand the scope of the issues to be heard
821	at the hearing. Such motion shall include substantial and
822	detailed facts and reasons for failure to include such issues in
823	the original written statement of opposition.
824	(6) JUDICIAL REVIEW
825	(d) The party appealing a final order that grants a
826	general hospital certificate of need shall pay the appellee's
827	attorney's fees and costs, in an amount up to \$1 million, from
828	the beginning of the original administrative action if the
829	appealing party loses the appeal, subject to the following
830	limitations and requirements:
831	1. The party appealing a final order must post a bond in
832	the amount of \$1 million in order to maintain the appeal.
833	2. Except as provided under s. 120.595(5), in no event
834	shall the agency be held liable for any other party's attorney's
835	fees or costs.
836	Section 7. Subsection (1) of section 408.043, Florida
837	Statutes, is amended to read:
838	408.043 Special provisions
839	(1) OSTEOPATHIC ACUTE CARE HOSPITALSWhen an application
840	is made for a certificate of need to construct or to expand an
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841	osteopathic acute care hospital, the need for such hospital
842	shall be determined on the basis of the need for and
843	availability of osteopathic services and osteopathic acute care
844	hospitals in the district. When a prior certificate of need to
845	establish an osteopathic acute care hospital has been issued in
846	a district, and the facility is no longer used for that purpose,
847	the agency may continue to count such facility and beds as an
848	existing osteopathic facility in any subsequent application for
849	construction of an ostcopathic acute care hospital.
850	Section 8. Paragraph (f) of subsection (1) of section
851	395.1055, Florida Statutes, is amended to read:
852	395.1055 Rules and enforcement
853	(1) The agency shall adopt rules pursuant to ss.
854	120.536(1) and 120.54 to implement the provisions of this part,
855	which shall include reasonable and fair minimum standards for
856	ensuring that:
857	(f) All hospitals providing pediatric cardiac
858	catheterization, pediatric open-heart surgery, organ
859	transplantation, neonatal intensive care services, psychiatric
860	services, or comprehensive medical rehabilitation meet the
861	minimum licensure requirements adopted by the agency. Such
862	licensure requirements shall include quality of care, nurse
863	staffing, physician staffing, physical plant, equipment,
864	emergency transportation, and data reporting standards submit
865	such data as necessary to conduct certificate-of-need reviews

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866 required under part I of chapter 408. Such data shall include, 867 but shall not be limited to, patient origin data, hospital 868 utilization data, type of service reporting, and facility 869 staffing data. The agency may not collect data that -identifies 870 or could disclose the identity of individual patients. The 871 agency shall utilize existing uniform statewide data sources 872 when available and shall minimize reporting costs to hospitals. Section 9. Section 395.6025, Florida Statutes, is 873 874 repealed. 875 Section 10. Subsection (1) of section 395.603, Florida 876 Statutes, is amended to read: 877 395.603 Deactivation of general hospital beds; rural 878 hospital impact statement.-879 (1)The agency shall establish, by rule, a process by 880 which a rural hospital, as defined in s. 395.602, that seeks 881 licensure as a rural primary care hospital or as an emergency 882 care hospital, or becomes a certified rural health clinic as 883 defined in Pub. L. No. 95-210, or becomes a primary care program 884 such as a county health department, community health center, or 885 other similar outpatient program that provides preventive and 886 curative services, may deactivate general hospital beds. Rural 887 primary care hospitals and emergency care hospitals shall maintain the number of actively licensed general hospital beds 888 necessary for the facility to be certified for Medicare 889 890 reimbursement. Hospitals that discontinue inpatient care to

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891 become rural health care clinics or primary care programs shall 892 deactivate all licensed general hospital beds. All hospitals, 893 clinics, and programs with inactive beds shall provide 24-hour 894 emergency medical care by staffing an emergency room. Providers 895 with inactive beds shall be subject to the criteria in s. 896 395.1041. The agency shall specify in rule requirements for 897 making 24-hour emergency care available. Inactive general 898 hospital beds shall be included in the acute care bed inventory, 899 maintained by the agency for certificate-of-need purposes, for 900 10 years from the date of deactivation of the beds. After 10 901 years have elapsed, inactive beds shall be excluded from the inventory. The agency shall, at the request of the licensee, 902 903 reactivate the inactive general beds upon a showing by the 904 licensee that licensure requirements for the inactive general 905 beds are met. 906 Section 11. Subsection (1) of section 395.604, Florida 907 Statutes, is amended to read: 908 395.604 Other rural hospital programs.-909 The agency may license rural primary care hospitals (1)910 subject to federal approval for participation in the Medicare 911 and Medicaid programs. Rural primary care hospitals shall be 912 treated in the same manner as emergency care hospitals and rural hospitals with respect to ss. $395.605(2) - (7)(a) \frac{395.605(2)}{395.605(2)}$ 913

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(8) (a), 408.033(2) (b) 3., and 408.038.

Section 12. Subsection (5) of section 395.605, Florida 915 916 Statutes, is amended to read: 917 395.605 Emergency care hospitals.-918 (5) Rural hospitals that make application under the 919 certificate-of-need program to be licensed as emergency care hospitals shall receive expedited review as defined in s. 920 921 408.032. Emergency care hospitals seeking relicensure as acute 922 care general hospitals shall also receive expedited review. 923 Section 13. Paragraph (b) of subsection (1) of section 924 408.033, Florida Statutes, is amended to read: 925 408.033 Local and state health planning.-926 (1) LOCAL HEALTH COUNCILS.-927 (b) Each local health council may: 928 1. Develop a district area health plan that permits each 929 local health council to develop strategies and set priorities 930 for implementation based on its unique local health needs. 931 2. Advise the agency on health care issues and resource 932 allocations. 933 3. Promote public awareness of community health needs, 934 emphasizing health promotion and cost-effective health service 935 selection. 936 4. Collect data and conduct analyses and studies related to health care needs of the district, including the needs of 937 medically indigent persons, and assist the agency and other 938 939 state agencies in carrying out data collection activities that

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940 relate to the functions in this subsection.

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

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

Advise and assist local governments within each 949 7. 950 district on the development of an optional health plan element 951 of the comprehensive plan provided in chapter 163, to assure 952 compatibility with the health goals and policies in the State 953 Comprehensive Plan and district health plan. To facilitate the 954 implementation of this section, the local health council shall 955 annually provide the local governments in its service area, upon 956 request, with:

957 a. A copy and appropriate updates of the district health958 plan;

b. A report of <u>health facility</u> hospital and nursing home
utilization statistics for facilities within the local
government jurisdiction; and

962 c. Applicable agency rules and calculated need
963 methodologies for health facilities and services regulated under
964 s. 408.034 for the district served by the local health council.

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965 8. Monitor and evaluate the adequacy, appropriateness, and 966 effectiveness, within the district, of local, state, federal, 967 and private funds distributed to meet the needs of the medically 968 indigent and other underserved population groups.

969 9. In conjunction with the Department of Health, plan for
970 services at the local level for persons infected with the human
971 immunodeficiency virus.

972 10. Provide technical assistance to encourage and support 973 activities by providers, purchasers, consumers, and local, 974 regional, and state agencies in meeting the health care goals, 975 objectives, and policies adopted by the local health council.

976 11. Provide the agency with data required by rule for the 977 review of certificate-of-need applications and the projection of 978 need for health services and facilities in the district.

979 Section 14. Subsections (2) and (4) of section 408.0361, 980 Florida Statutes, are amended to read:

981

408.0361 Cardiovascular services and burn unit licensure.-

Each provider of adult cardiovascular services or 982 (2) 983 operator of a burn unit shall comply with rules adopted by the 984 agency that establish licensure standards that govern the 985 provision of adult cardiovascular services or the operation of a 986 burn unit. Such rules shall consider, at a minimum, staffing, equipment, physical plant, operating protocols, the provision of 987 services to Medicaid and charity care patients, accreditation, 988 989 licensure period and fees, and enforcement of minimum standards.

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990 The certificate-of-need rules for adult cardiovascular services 991 and burn units in effect on June 30, 2004, are authorized 992 pursuant to this subsection and shall remain in effect and shall 993 be enforceable by the agency until the licensure rules are adopted. Existing providers and any provider with a notice of 994 995 intent to grant a certificate of need or a final order of the 996 agency granting a certificate of need for adult cardiovascular 997 services or burn units shall be considered grandfathered and 998 receive a license for their programs effective on the effective 999 date of this act. The grandfathered licensure shall be for at 1000 least 3 years or until July 1, 2008, whichever is longer, but 1001 shall be required to meet licensure standards applicable to 1002 existing programs for every subsequent licensure period. 1003 (4) In order to ensure continuity of available services,

1004 the holder of a certificate of need for a newly licensed 1005 hospital that meets the requirements of this subsection may 1006 apply for and shall be granted Level I program status regardless 1007 of whether rules relating to Level I programs have been adopted. 1008 To qualify for a Level I program under this subsection, 1009 hospital seeking a Level I program must be a newly licensed 1010 hospital established pursuant to a certificate of need in a 1011 physical location previously licensed and operated as a 1012 hospital, the former hospital must have provided a minimum of 1013 300 adult inpatient and outpatient diagnostic cardiac 1014 catheterizations for the most recent 12-month period as reported

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1015 to the agency, and the newly licensed hospital must have a 1016 formalized, written transfer agreement with a hospital that has 1017 a Level II program, including written transport protocols to 1018 ensure safe and efficient transfer of a patient within 60 1019 minutes. A hospital meeting the requirements of this subsection 1020 may apply for certification of Level I program status before 1021 taking possession of the physical location of the former hospital, and the effective date of Level I program status shall 1022 1023 be concurrent with the effective date of the newly issued 1024 hospital license. 1025 Section 15. This act shall take effect July 1, 2018.

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