1

A bill to be entitled

2 An act relating to the Department of Health; amending s. 3 20.435, F.S.; revising provisions for administration and 4 use of funds in the Administrative Trust Fund and the 5 Emergency Medical Services Trust Fund; providing for such 6 administration and use under specified provisions; 7 amending ss. 318.14, 318.18, and 318.21, F.S.; providing 8 that funds collected from disposition of certain motor 9 vehicle infractions shall be deposited into the Emergency 10 Medical Services Trust Fund; removing provisions for 11 deposit of such funds into the Administrative Trust Fund; providing for use of the funds; correcting a reference; 12 amending ss. 320.131, 327.35, 381.765, and 938.07, F.S.; 13 14 correcting references to the Brain and Spinal Cord Injury 15 Program Trust Fund; amending ss. 381.78 and 381.79, F.S.; 16 correcting references; amending s. 395.403, F.S., relating 17 to reimbursement of trauma centers; revising eligibility provisions to remove provisional trauma centers and 18 19 certain hospitals; providing for payments to be made from the Emergency Medical Services Trust Fund; removing 20 21 provisions for one-time payments from the Administrative 22 Trust Fund; amending s. 395.4036, F.S.; providing for use 23 of funds in the Emergency Medical Services Trust Fund for 24 verified trauma centers; removing provisions for such use 25 of funds in the Administrative Trust Fund; reenacting and 26 amending s. 215.5602, F.S., relating to James and Esther 27 King Biomedical Research Program; specifying that a certain amount of the revenue deposited into the Health 28

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29 Care Trust Fund be reserved for tobacco-related and 30 cancer-related research; providing for specified amounts 31 of revenue to be appropriated to the James and Esther King 32 Biomedical Research Program, the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, 33 34 and the H. Lee Moffitt Cancer Center and Research Institute; deleting obsolete language; reenacting and 35 36 amending s. 381.922, F.S., relating to William G. "Bill" 37 Bankhead, Jr., and David Coley Cancer Research Program; 38 providing that the program give emphasis to certain goals; 39 specifying sources of funding for the program; providing for a portion of the funds to be made available to the 40 Florida Center for Universal Research to Eradicate 41 42 Disease; deleting obsolete language; amending s. 20.43, 43 F.S.; removing a provision authorizing division directors 44 in the Department of Health to appoint certain committees; 45 prohibiting the department from establishing new programs or modifying current programs without legislative 46 47 approval; requiring the department to notify the Governor and the Legislature before applying for continuation of or 48 49 new federal or private grants over a specified amount; 50 providing for content of the notification; amending s. 51 381.0011, F.S.; requiring the department to manage 52 emergency preparedness and disaster response functions; 53 amending s. 381.006, F.S.; revising the definition of the 54 term "group care facility"; revising rulemaking authority; 55 amending s. 381.0072, F.S.; revising the definition of the 56 term "food service establishment"; authorizing the

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57 department to advise and consult with other agencies 58 concerning the provision of food services; revising 59 entities that are exempt from rules developed for manager 60 certification; repealing ss. 411.23, 411.231, and 411.232, F.S., relating to the Children's Early Investment Program; 61 62 amending ss. 411.01 and 411.224, F.S.; conforming 63 provisions to changes made by the act; amending s. 499.003, F.S.; defining the term "medical convenience kit" 64 for purposes of the Florida Drug and Cosmetic Act; 65 66 correcting cross-references; amending s. 499.01, F.S.; 67 providing exceptions from requirements for a device manufacturer permit; amending s. 499.01212, F.S.; 68 69 exempting wholesale distribution of prescription drugs 70 within a medical convenience kit from requirements for the 71 wholesaler to provide a pedigree paper if certain 72 conditions are met; providing that the exemption does not 73 apply to a kit containing certain controlled substances; 74 amending s. 509.013, F.S.; revising exclusions to the 75 definition of the terms "public lodging establishment" and 76 "public food service establishment" to provide for certain 77 facilities certified or licensed by the Agency for Health 78 Care Administration or the Department of Children and 79 Family Services; requiring the department to develop a 80 plan to provide tuberculosis services; requiring the 81 department to submit the plan to the Governor and 82 Legislature by a specified date; providing plan elements; 83 transferring and reassigning certain functions and 84 responsibilities, including records, personnel, property, Page 3 of 82

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85 and unexpended balances of appropriations and other 86 resources, from the Department of Health to the Department 87 of Business and Professional Regulation by a type two 88 transfer; providing for the continued validity of pending 89 judicial or administrative actions to which the Department 90 of Health is a party; providing for the continued validity 91 of lawful orders issued by the Department of Health; 92 transferring rules created by the Department of Health to 93 the Department of Business and Professional Regulation; 94 providing for the continued validity of permits and 95 certifications issued by the Department of Health; amending s. 381.0403, F.S., deleting provisions relating 96 97 to the program for graduate medical education innovations 98 and the graduate medical education committee and report; 99 conforming a cross-reference; amending s. 381.4018, F.S.; 100 revising provisions for physician workforce assessment and 101 development; providing definitions; creating the Physician 102 Workforce Advisory Council; providing for membership and 103 organization; providing duties of the council; amending 104 ss. 458.3192 and 459.0082, F.S.; revising provisions for 105 analysis by the department of physician surveys under 106 specified provisions; amending s. 458.315; revising provisions for issuance by the Board of Medicine of a 107 108 temporary certificate to practice medicine in certain 109 areas; creating s. 459.0076, F.S.; providing for issuance 110 by the Board of Osteopathic Medicine of a temporary 111 certificate to practice osteopathic medicine in certain 112 areas; directing the department to conduct an evaluation Page 4 of 82

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113 and justification review of its divisions; providing 114 review requirements; requiring the department to submit a 115 report to the Governor, the Legislature, and the State 116 Surgeon General by a specified date; amending s. 117 381.00315, F.S.; directing the Department of Health to 118 accept funds from counties, municipalities, and certain 119 other entities for the purchase of certain products made available under a contract with the United States 120 121 Department of Health and Human Services for the 122 manufacture and delivery of such products in response to a 123 public health emergency; authorizing the department to submit a budget amendment requesting additional budget 124 125 authority for the Florida Center for Nursing to make 126 certain expenditures; amending ss. 409.9201, 465.0265, 499.01, 499.01211, 499.01212, 499.03, 499.05, and 794.075, 127 128 F.S.; correcting cross-references; providing effective 129 dates. 130 131 Be It Enacted by the Legislature of the State of Florida: 132 133 Section 1. Paragraph (a) of subsection (1) and paragraph 134 (a) of subsection (14) of section 20.435, Florida Statutes, are 135 amended to read: 136 20.435 Department of Health; trust funds.-The following 137 trust funds shall be administered by the Department of Health: 138 (1)Administrative Trust Fund. 139 (a) Funds to be credited to and uses of the trust fund shall be administered in accordance with s. 215.32 consist of 140 Page 5 of 82

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141 regulatory fees such as those pertaining to the licensing, permitting, and inspection of septic tanks, food hygiene, onsite 142 143 sewage, Superfund compliance, solid waste management, tanning 144 facilities, mobile home and recreational vehicle park 145 inspection, other departmental regulatory and health care 146 programs, and indirect earnings from grants. Funds shall be used 147 for the purpose of supporting the regulatory activities of the 148 department and for other such purposes as may be appropriate and 149 shall be expended only pursuant to legislative appropriation or 150 an approved amendment to the department's operating budget 151 pursuant to the provisions of chapter 216. 152 Emergency Medical Services Trust Fund. (14)153 Funds to be credited to and uses of the trust fund (a) 154 shall be administered in accordance with ss. 318.14, 318.18, 155 318.21, 395.403, and 395.4036 and the provisions of parts I and 156 II of chapter 401. 157 Section 2. Subsection (5) of section 318.14, Florida 158 Statutes, is amended to read: 159 318.14 Noncriminal traffic infractions; exception; 160 procedures.-161 Any person electing to appear before the designated (5) 162 official or who is required so to appear shall be deemed to have 163 waived his or her right to the civil penalty provisions of s. 164 318.18. The official, after a hearing, shall make a 165 determination as to whether an infraction has been committed. If the commission of an infraction has been proven, the official 166 167 may impose a civil penalty not to exceed \$500, except that in cases involving unlawful speed in a school zone or involving 168 Page 6 of 82

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169 unlawful speed in a construction zone, the civil penalty may not 170 exceed \$1,000; or require attendance at a driver improvement 171 school, or both. If the person is required to appear before the 172 designated official pursuant to s. 318.19(1) and is found to 173 have committed the infraction, the designated official shall 174 impose a civil penalty of \$1,000 in addition to any other 175 penalties and the person's driver's license shall be suspended 176 for 6 months. If the person is required to appear before the 177 designated official pursuant to s. 318.19(2) and is found to 178 have committed the infraction, the designated official shall 179 impose a civil penalty of \$500 in addition to any other 180 penalties and the person's driver's license shall be suspended for 3 months. If the official determines that no infraction has 181 182 been committed, no costs or penalties shall be imposed and any 183 costs or penalties that have been paid shall be returned. Moneys 184 received from the mandatory civil penalties imposed pursuant to 185 this subsection upon persons required to appear before a 186 designated official pursuant to s. 318.19(1) or (2) shall be 187 remitted to the Department of Revenue and deposited into the Department of Health Emergency Medical Services Administrative 188 189 Trust Fund to provide financial support to certified trauma 190 centers to assure the availability and accessibility of trauma 191 services throughout the state. Funds deposited into the 192 Emergency Medical Services Administrative Trust Fund under this section shall be allocated as follows: 193

(a) Fifty percent shall be allocated equally among all
Level I, Level II, and pediatric trauma centers in recognition
of readiness costs for maintaining trauma services.

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(b) Fifty percent shall be allocated among Level I, Level
II, and pediatric trauma centers based on each center's relative
volume of trauma cases as reported in the Department of Health
Trauma Registry.

201 Section 3. Paragraph (h) of subsection (3), paragraph (c) 202 of subsection (5), and subsection (20) of section 318.18, 203 Florida Statutes, are amended to read:

204 318.18 Amount of penalties.—The penalties required for a 205 noncriminal disposition pursuant to s. 318.14 or a criminal 206 offense listed in s. 318.17 are as follows:

207

(3)

208 A person cited for a second or subsequent conviction (h) 209 of speed exceeding the limit by 30 miles per hour and above 210 within a 12-month period shall pay a fine that is double the 211 amount listed in paragraph (b). For purposes of this paragraph, 212 the term "conviction" means a finding of guilt as a result of a 213 jury verdict, nonjury trial, or entry of a plea of guilty. 214 Moneys received from the increased fine imposed by this 215 paragraph shall be remitted to the Department of Revenue and 216 deposited into the Department of Health Emergency Medical 217 Services Administrative Trust Fund to provide financial support 218 to certified trauma centers to assure the availability and 219 accessibility of trauma services throughout the state. Funds 220 deposited into the Emergency Medical Services Administrative 221 Trust Fund under this section shall be allocated as follows:

Fifty percent shall be allocated equally among all
 Level I, Level II, and pediatric trauma centers in recognition
 of readiness costs for maintaining trauma services.

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(5)

225 2. Fifty percent shall be allocated among Level I, Level 226 II, and pediatric trauma centers based on each center's relative 227 volume of trauma cases as reported in the Department of Health 228 Trauma Registry.

229

230 In addition to the penalty under paragraph (a) or (C) 231 paragraph (b), \$65 for a violation of s. 316.172(1)(a) or (b). 232 If the alleged offender is found to have committed the offense, 233 the court shall impose the civil penalty under paragraph (a) or 234 paragraph (b) plus an additional \$65. The additional \$65 235 collected under this paragraph shall be remitted to the 236 Department of Revenue for deposit into the Emergency Medical 237 Services Administrative Trust Fund of the Department of Health 238 to be used as provided in s. 395.4036.

(20) In addition to any other penalty, \$65 for a violation of s. 316.191, prohibiting racing on highways, or s. 316.192, prohibiting reckless driving. The additional \$65 collected under this subsection shall be remitted to the Department of Revenue for deposit into the <u>Emergency Medical Services</u> Administrative Trust Fund of the Department of Health to be used as provided in s. 395.4036.

Section 4. Paragraph (d) of subsection (2) and subsection
(15) of section 318.21, Florida Statutes, are amended to read:
318.21 Disposition of civil penalties by county courts.—
All civil penalties received by a county court pursuant to the
provisions of this chapter shall be distributed and paid monthly

251 as follows:

252

(2) Of the remainder:

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(d) Eight and two-tenths percent shall be remitted to the Department of Revenue for deposit in the Brain and Spinal Cord Injury <u>Program</u> Rehabilitation Trust Fund for the purposes set forth in s. 381.79.

257 (15) Of the additional fine assessed under s. 318.18(3)(e) 258 for a violation of s. 316.1893, 50 percent of the moneys 259 received from the fines shall be appropriated to the Agency for 260 Health Care Administration as general revenue to provide an 261 enhanced Medicaid payment to nursing homes that serve Medicaid recipients with brain and spinal cord injuries. The remaining 50 262 percent of the moneys received from the enhanced fine imposed 263 264 under s. 318.18(3)(e) shall be remitted to the Department of 265 Revenue and deposited into the Department of Health Emergency 266 Medical Services Administrative Trust Fund to provide financial 267 support to certified trauma centers in the counties where 268 enhanced penalty zones are established to ensure the 269 availability and accessibility of trauma services. Funds 270 deposited into the Emergency Medical Services Administrative 271 Trust Fund under this subsection shall be allocated as follows:

(a) Fifty percent shall be allocated equally among all
Level I, Level II, and pediatric trauma centers in recognition
of readiness costs for maintaining trauma services.

(b) Fifty percent shall be allocated among Level I, Level II, and pediatric trauma centers based on each center's relative volume of trauma cases as reported in the Department of Health Trauma Registry.

279 Section 5. Subsection (2) of section 320.131, Florida 280 Statutes, is amended to read:

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281

320.131 Temporary tags.-

282 (2)The department is authorized to sell temporary tags, 283 in addition to those listed above, to their agents and where 284 need is demonstrated by a consumer complainant. The fee shall be 285 \$2 each. One dollar from each tag sold shall be deposited into 286 the Brain and Spinal Cord Injury Program Rehabilitation Trust 287 Fund, with the remaining proceeds being deposited into the 288 Highway Safety Operating Trust Fund. Agents of the department 289 shall sell temporary tags for \$2 each and shall charge the service charge authorized by s. 320.04 per transaction, 290 291 regardless of the quantity sold. Requests for purchase of 292 temporary tags to the department or its agents shall be made, 293 where applicable, on letterhead stationery and notarized. Except 294 as specifically provided otherwise, a temporary tag shall be 295 valid for 30 days, and no more than two shall be issued to the 296 same person for the same vehicle.

297 Section 6. Subsection (9) of section 327.35, Florida 298 Statutes, is amended to read:

299 327.35 Boating under the influence; penalties; "designated 300 drivers".-

301 (9) Notwithstanding any other provision of this section, 302 for any person convicted of a violation of subsection (1), in 303 addition to the fines set forth in subsections (2) and (4), an 304 additional fine of \$60 shall be assessed and collected in the same manner as the fines set forth in subsections (2) and (4). 305 All fines collected under this subsection shall be remitted by 306 307 the clerk of the court to the Department of Revenue for deposit 308 into the Brain and Spinal Cord Injury Program Rehabilitation

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309 Trust Fund and used for the purposes set forth in s. 381.79, 310 after 5 percent is deducted therefrom by the clerk of the court 311 for administrative costs.

Section 7. Subsection (2) of section 381.765, Florida 312 313 Statutes, is amended to read:

314

381.765 Retention of title to and disposal of equipment.-315 The department may offer for sale any surplus items (2)acquired in operating the brain and spinal cord injury program 316 317 when they are no longer necessary or exchange them for necessary 318 items that may be used to greater advantage. When any such 319 surplus equipment is sold or exchanged, a receipt for the 320 equipment shall be taken from the purchaser showing the consideration given for such equipment and forwarded to the 321 322 Chief Financial Officer, and any funds received by the brain and 323 spinal cord injury program pursuant to any such transaction 324 shall be deposited in the Brain and Spinal Cord Injury Program 325 Rehabilitation Trust Fund and shall be available for expenditure 326 for any purpose consistent with ss. 381.739-381.79 this part.

327 Section 8. Subsection (7) of section 381.78, Florida 328 Statutes, is amended to read:

329 381.78 Advisory council on brain and spinal cord 330 injuries.-

331 (7) A member of the advisory council may be removed from office by the State Surgeon General for malfeasance, 332 misfeasance, neglect of duty, incompetence, or permanent 333 inability to perform official duties or for pleading nolo 334 contendere to, or being found quilty of, a crime. Malfeasance 335 336 includes, but is not limited to, a violation of any specific

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337 prohibition within ss. 381.739-381.79 this part.

338 Section 9. Subsection (6) of section 381.79, Florida339 Statutes, is amended to read:

340 381.79 Brain and Spinal Cord Injury Program Trust Fund.-341 The department may accept, deposit into the trust (6) 342 fund, and use for carrying out the purposes of ss. 381.739-343 381.79 this part gifts made unconditionally by will or 344 otherwise. Any gift made under conditions that, in the judgment 345 of the department, are proper and consistent with this section, the laws of the United States, and the laws of this state may be 346 347 accepted and shall be held, invested, reinvested, and used in 348 accordance with the conditions of the gift.

349 Section 10. Subsections (1) and (2) of section 395.403, 350 Florida Statutes, are amended to read:

351

395.403 Reimbursement of trauma centers.-

352 (1)All provisional trauma centers and trauma centers 353 shall be considered eligible to receive state funding when state 354 funds are specifically appropriated for state-sponsored trauma 355 centers in the General Appropriations Act. Effective July 1, 356 2010 2004, the department shall make one-time payments from the 357 Emergency Medical Services Administrative Trust Fund under s. 358 20.435 to the trauma centers and a hospital with a pending 359 application for a Level I trauma center in recognition of the 360 capital investment made by the hospital to establish the trauma service. Payments shall be in equal amounts for the trauma 361 centers approved by the department as of July 1 of the fiscal 362 year in which funding is appropriated, with lesser amounts for 363 364 the hospital with an application pending for a Level trauma Page 13 of 82

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365 center at the department as of April 1, 2004. In the event a 366 trauma center does not maintain its status as a trauma center 367 for any state fiscal year in which such funding is appropriated, 368 the provisional trauma center or trauma center shall repay the 369 state for the portion of the year during which it was not a 370 trauma center.

371 (2) Provisional trauma centers and Trauma centers eligible
 372 to receive distributions from the <u>Emergency Medical Services</u>
 373 Administrative Trust Fund under s. 20.435 in accordance with
 374 subsection (1) may request that such funds be used as
 375 intergovernmental transfer funds in the Medicaid program.

376 Section 11. Subsections (1) and (2) of section 395.4036, 377 Florida Statutes, are amended to read:

395.4036 Trauma payments.-

379 Recognizing the Legislature's stated intent to provide (1)380 financial support to the current verified trauma centers and to 381 provide incentives for the establishment of additional trauma 382 centers as part of a system of state-sponsored trauma centers, 383 the department shall utilize funds collected under s. 318.18 and 384 deposited into the Emergency Medical Services Administrative 385 Trust Fund of the department to ensure the availability and 386 accessibility of trauma services throughout the state as 387 provided in this subsection.

388 (a) Funds collected under s. 318.18(15) shall be 389 distributed as follows:

Twenty percent of the total funds collected during the
 state fiscal year shall be distributed to verified trauma
 centers that have a local funding contribution as of December

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393 31. Distribution of funds under this subparagraph shall be based 394 on trauma caseload volume for the most recent calendar year 395 available.

396 2. Forty percent of the total funds collected shall be 397 distributed to verified trauma centers based on trauma caseload 398 volume for the most recent calendar year available. The 399 determination of caseload volume for distribution of funds under 400 this subparagraph shall be based on the department's Trauma 401 Registry data.

Forty percent of the total funds collected shall be 402 3. 403 distributed to verified trauma centers based on severity of 404 trauma patients for the most recent calendar year available. The 405 determination of severity for distribution of funds under this 406 subparagraph shall be based on the department's International 407 Classification Injury Severity Scores or another statistically 408 valid and scientifically accepted method of stratifying a trauma 409 patient's severity of injury, risk of mortality, and resource 410 consumption as adopted by the department by rule, weighted based 411 on the costs associated with and incurred by the trauma center 412 in treating trauma patients. The weighting of scores shall be 413 established by the department by rule.

(b) Funds collected under s. 318.18(5)(c) and (19) shall be distributed as follows:

1. Thirty percent of the total funds collected shall be
distributed to Level II trauma centers operated by a public
hospital governed by an elected board of directors as of
December 31, 2008.

420

2.

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Thirty-five percent of the total funds collected shall

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421 be distributed to verified trauma centers based on trauma 422 caseload volume for the most recent calendar year available. The 423 determination of caseload volume for distribution of funds under 424 this subparagraph shall be based on the department's Trauma 425 Registry data.

426 Thirty-five percent of the total funds collected shall 3. 427 be distributed to verified trauma centers based on severity of 428 trauma patients for the most recent calendar year available. The 429 determination of severity for distribution of funds under this 430 subparagraph shall be based on the department's International 431 Classification Injury Severity Scores or another statistically 432 valid and scientifically accepted method of stratifying a trauma patient's severity of injury, risk of mortality, and resource 433 consumption as adopted by the department by rule, weighted based 434 435 on the costs associated with and incurred by the trauma center 436 in treating trauma patients. The weighting of scores shall be 437 established by the department by rule.

438 Funds deposited in the department's Emergency Medical (2) 439 Services Administrative Trust Fund for verified trauma centers 440 may be used to maximize the receipt of federal funds that may be 441 available for such trauma centers. Notwithstanding this section 442 and s. 318.14, distributions to trauma centers may be adjusted 443 in a manner to ensure that total payments to trauma centers 444 represent the same proportional allocation as set forth in this 445 section and s. 318.14. For purposes of this section and s. 318.14, total funds distributed to trauma centers may include 446 447 revenue from the Emergency Medical Services Administrative Trust Fund and federal funds for which revenue from the Administrative 448 Page 16 of 82

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449 Trust Fund is used to meet state or local matching requirements. 450 Funds collected under ss. 318.14 and 318.18 and deposited in the 451 Emergency Medical Services Administrative Trust Fund of the 452 department shall be distributed to trauma centers on a quarterly 453 basis using the most recent calendar year data available. Such 454 data shall not be used for more than four quarterly 455 distributions unless there are extenuating circumstances as 456 determined by the department, in which case the most recent 457 calendar year data available shall continue to be used and 458 appropriate adjustments shall be made as soon as the more recent data becomes available. 459

460 Section 12. Section 938.07, Florida Statutes, is amended to 461 read:

462 938.07 Driving or boating under the influence.-463 Notwithstanding any other provision of s. 316.193 or s. 327.35, 464 a court cost of \$135 shall be added to any fine imposed pursuant 465 to s. 316.193 or s. 327.35. The clerks shall remit the funds to 466 the Department of Revenue, \$25 of which shall be deposited in 467 the Emergency Medical Services Trust Fund, \$50 shall be 468 deposited in the Operating Trust Fund of the Department of Law 469 Enforcement to be used for operational expenses in conducting 470 the statewide criminal analysis laboratory system established in s. 943.32, and \$60 shall be deposited in the Brain and Spinal 471 472 Cord Injury Program Rehabilitation Trust Fund created in s. 473 381.79.

474 Section 13. Section 215.5602, Florida Statutes, is 475 reenacted and amended to read:

476 215.5602 James and Esther King Biomedical Research Page 17 of 82

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477 Program.-

478 (1)There is established within the Department of Health 479 the James and Esther King Biomedical Research Program funded by 480 the proceeds of the Lawton Chiles Endowment Fund pursuant to s. 481 215.5601. The purpose of the James and Esther King Biomedical 482 Research Program is to provide an annual and perpetual source of 483 funding in order to support research initiatives that address 484 the health care problems of Floridians in the areas of tobacco-485 related cancer, cardiovascular disease, stroke, and pulmonary 486 disease. The long-term goals of the program are to:

(a) Improve the health of Floridians by researching better
prevention, diagnoses, treatments, and cures for cancer,
cardiovascular disease, stroke, and pulmonary disease.

(b) Expand the foundation of biomedical knowledge relating
to the prevention, diagnosis, treatment, and cure of diseases
related to tobacco use, including cancer, cardiovascular
disease, stroke, and pulmonary disease.

(c) Improve the quality of the state's academic health
centers by bringing the advances of biomedical research into the
training of physicians and other health care providers.

(d) Increase the state's per capita funding for research by undertaking new initiatives in public health and biomedical research that will attract additional funding from outside the state.

(e) Stimulate economic activity in the state in areas related to biomedical research, such as the research and production of pharmaceuticals, biotechnology, and medical devices.

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505 Funds appropriated for the James and Esther King (2)506 Biomedical Research Program shall be used exclusively for the 507 award of grants and fellowships as established in this section; 508 for research relating to the prevention, diagnosis, treatment, 509 and cure of diseases related to tobacco use, including cancer, 510 cardiovascular disease, stroke, and pulmonary disease; and for 511 expenses incurred in the administration of this section. 512 Priority shall be granted to research designed to prevent or 513 cure disease.

514 (3) There is created within the Department of Health the515 Biomedical Research Advisory Council.

516 The council shall consist of 11 members, including: (a) 517 the chief executive officer of the Florida Division of the 518 American Cancer Society, or a designee; the chief executive officer of the Florida/Puerto Rico Affiliate of the American 519 520 Heart Association, or a designee; and the chief executive 521 officer of the American Lung Association of Florida, or a 522 designee. The remaining 8 members of the council shall be 523 appointed as follows:

1. The Governor shall appoint four members, two members with expertise in the field of biomedical research, one member from a research university in the state, and one member representing the general population of the state.

528 2. The President of the Senate shall appoint two members, 529 one member with expertise in the field of behavioral or social 530 research and one representative from a cancer program approved 531 by the American College of Surgeons.

532

3. The Speaker of the House of Representatives shall

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appoint two members, one member from a professional medical organization and one representative from a cancer program approved by the American College of Surgeons.

537 In making these appointments, the Governor, the President of the 538 Senate, and the Speaker of the House of Representatives shall 539 select primarily, but not exclusively, Floridians with 540 biomedical and lay expertise in the general areas of cancer, cardiovascular disease, stroke, and pulmonary disease. The 541 542 appointments shall be for a 3-year term and shall reflect the diversity of the state's population. An appointed member may not 543 544 serve more than two consecutive terms.

545 (b) The council shall adopt internal organizational 546 procedures as necessary for its efficient organization.

547 (c) The department shall provide such staff, information,
548 and other assistance as is reasonably necessary to assist the
549 council in carrying out its responsibilities.

(d) Members of the council shall serve without
compensation, but may receive reimbursement as provided in s.
112.061 for travel and other necessary expenses incurred in the
performance of their official duties.

(4) The council shall advise the State Surgeon General as
to the direction and scope of the biomedical research program.
The responsibilities of the council may include, but are not
limited to:

- 558 (a) Providing advice on program priorities and emphases.
- (b) Providing advice on the overall program budget.

560 (c) Participating in periodic program evaluation.

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(d) Assisting in the development of guidelines to ensure
fairness, neutrality, and adherence to the principles of merit
and quality in the conduct of the program.

(e) Assisting in the development of appropriate linkages to nonacademic entities, such as voluntary organizations, health care delivery institutions, industry, government agencies, and public officials.

568 (f) Developing criteria and standards for the award of 569 research grants.

(g) Developing administrative procedures relating to solicitation, review, and award of research grants and fellowships, to ensure an impartial, high-quality peer review system.

574 (h) Developing and supervising research peer review575 panels.

576 (i) Reviewing reports of peer review panels and making577 recommendations for research grants and fellowships.

578 (j) Developing and providing oversight regarding 579 mechanisms for the dissemination of research results.

(5) (a) Applications for biomedical research funding under the program may be submitted from any university or established research institute in the state. All qualified investigators in the state, regardless of institution affiliation, shall have equal access and opportunity to compete for the research funding.

(b) Grants and fellowships shall be awarded by the State
Surgeon General, after consultation with the council, on the
basis of scientific merit, as determined by an open competitive

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589 peer review process that ensures objectivity, consistency, and 590 high quality. The following types of applications shall be 591 considered for funding:

592

1. Investigator-initiated research grants.

593

2. Institutional research grants.

594

3. Predoctoral and postdoctoral research fellowships.

595 (6) To ensure that all proposals for research funding are 596 appropriate and are evaluated fairly on the basis of scientific 597 merit, the State Surgeon General, in consultation with the council, shall appoint a peer review panel of independent, 598 599 scientifically qualified individuals to review the scientific 600 content of each proposal and establish its scientific priority score. The priority scores shall be forwarded to the council and 601 602 must be considered in determining which proposals shall be recommended for funding. 603

604 (7)The council and the peer review panel shall establish 605 and follow rigorous quidelines for ethical conduct and adhere to 606 a strict policy with regard to conflict of interest. A member of 607 the council or panel may not participate in any discussion or 608 decision with respect to a research proposal by any firm, 609 entity, or agency with which the member is associated as a 610 member of the governing body or as an employee, or with which 611 the member has entered into a contractual arrangement. Meetings 612 of the council and the peer review panels shall be subject to the provisions of chapter 119, s. 286.011, and s. 24, Art. I of 613 614 the State Constitution.

(8) The department may contract on a competitive-bid basiswith an appropriate entity to administer the program.

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617 Administrative expenses may not exceed 15 percent of the total618 funds available to the program in any given year.

(9) The department, after consultation with the council,may adopt rules as necessary to implement this section.

(10) The council shall submit an annual progress report on
the state of biomedical research in this state to the Florida
Center for Universal Research to Eradicate Disease and to the
Governor, the State Surgeon General, the President of the
Senate, and the Speaker of the House of Representatives by
February 1. The report must include:

627 (a) A list of research projects supported by grants or628 fellowships awarded under the program.

629

(b) A list of recipients of program grants or fellowships.

(c) A list of publications in peer reviewed journals
involving research supported by grants or fellowships awarded
under the program.

(d) The total amount of biomedical research fundingcurrently flowing into the state.

(e) New grants for biomedical research which were funded
based on research supported by grants or fellowships awarded
under the program.

(f) Progress in the prevention, diagnosis, treatment, and
cure of diseases related to tobacco use, including cancer,
cardiovascular disease, stroke, and pulmonary disease.

(11) The council shall award grants for cancer research
through the William G. "Bill" Bankhead, Jr., and David Coley
Cancer Research Program created in s. 381.922.

644 (12) From funds appropriated to accomplish the goals of

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this section, up to \$250,000 shall be available for the
operating costs of the Florida Center for Universal Research to
Eradicate Disease.

648 (a) Beginning in the 2010-2011 2009-2010 fiscal year and 649 thereafter, \$50 million from 5 percent of the revenue deposited 650 into the Health Care Trust Fund pursuant to ss. 210.011(9) and 651 210.276(7) shall be reserved for research of tobacco-related or 652 cancer-related illnesses; however, the sum of the revenue 653 reserved pursuant to ss. 210.011(9) and 210.276(7) may not 654 exceed \$50 million in any fiscal year. Of the revenue deposited 655 in the Health Care Trust Fund pursuant to this section, \$50 656 million shall be transferred to the Biomedical Research Trust 657 Fund within the Department of Health. Subject to annual 658 appropriations in the General Appropriations Act, \$20 million 659 shall be appropriated to the James and Esther King Biomedical 660 Research Program, \$20 million shall be appropriated to the 661 William G. "Bill" Bankhead, Jr., and David Coley Cancer Research 662 Program created under s. 381.922, and \$10 million shall be 663 appropriated to the H. Lee Moffitt Cancer Center and Research 664 Institute established under s. 1004.43.

665 (b) In the 2009-2010 fiscal year, 2.5 percent, not to
666 exceed \$25 million, of the revenue deposited into the Health
667 Care Trust Fund pursuant to this subsection shall be transferred
668 to the Biomedical Research Trust Fund within the Department of
669 Health for the James and Esther King Biomedical Research
670 Program.

671 (13) By June 1, 2009, the Division of Statutory Revision
 672 of the Office of Legislative Services shall certify to the
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| 673 | President of the Senate and the Speaker of the House of |
|-----|--|
| 674 | Representatives the language and statutory citation of this |
| 675 | section, which is scheduled to expire January 1, 2011. |
| 676 | (14) The Legislature shall review the performance, the |
| 677 | outcomes, and the financial management of the James and Esther |
| 678 | King Biomedical Research Program during the 2010 Regular Session |
| 679 | of the Legislature and shall determine the most appropriate |
| 680 | funding source and means of funding the program based on its |
| 681 | review. |
| 682 | (15) This section expires January 1, 2011, unless reviewed |
| 683 | and reenacted by the Legislature before that date. |
| 684 | Section 14. Section 381.922, Florida Statutes, is |
| 685 | reenacted and amended to read: |
| 686 | 381.922 William G. "Bill" Bankhead, Jr., and David Coley |
| 687 | Cancer Research Program |
| 688 | (1) The William G. "Bill" Bankhead, Jr., and David Coley |
| 689 | Cancer Research Program, which may be otherwise cited as the |
| 690 | "Bankhead-Coley Program," is created within the Department of |
| 691 | Health. The purpose of the program shall be to advance progress |
| 692 | towards cures for cancer through grants awarded through a peer- |
| 693 | reviewed, competitive process. |
| 694 | (2) The program shall provide grants for cancer research |
| 695 | to further the search for cures for cancer. |
| 696 | (a) Emphasis shall be given to the <u>following</u> goals |
| 697 | enumerated in s. 381.921, as those goals support the advancement |
| 698 | of such cures: |
| 699 | 1. Efforts to significantly expand cancer research |
| 700 | capacity in the state by: |
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| 701 | a. Identifying ways to attract new research talent and |
|-----|---|
| 702 | attendant national grant-producing researchers to cancer |
| 703 | research facilities in this state; |
| 704 | b. Implementing a peer-reviewed, competitive process to |
| 705 | identify and fund the best proposals to expand cancer research |
| 706 | institutes in this state; |
| 707 | c. Funding through available resources for those proposals |
| 708 | that demonstrate the greatest opportunity to attract federal |
| 709 | research grants and private financial support; |
| 710 | d. Encouraging the employment of bioinformatics in order |
| 711 | to create a cancer informatics infrastructure that enhances |
| 712 | information and resource exchange and integration through |
| 713 | researchers working in diverse disciplines, to facilitate the |
| 714 | full spectrum of cancer investigations; |
| 715 | e. Facilitating the technical coordination, business |
| 716 | development, and support of intellectual property as it relates |
| 717 | to the advancement of cancer research; and |
| 718 | f. Aiding in other multidisciplinary research-support |
| 719 | activities as they inure to the advancement of cancer research. |
| 720 | 2. Efforts to improve both research and treatment through |
| 721 | greater participation in clinical trials networks by: |
| 722 | a. Identifying ways to increase adult enrollment in cancer |
| 723 | clinical trials; |
| 724 | b. Supporting public and private professional education |
| 725 | programs designed to increase the awareness and knowledge about |
| 726 | cancer clinical trials; |
| 727 | c. Providing tools to cancer patients and community-based |
| 728 | oncologists to aid in the identification of cancer clinical |
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729 trials available in the state; and 730 d. Creating opportunities for the state's academic cancer 731 centers to collaborate with community-based oncologists in 732 cancer clinical trials networks. 733 3. Efforts to reduce the impact of cancer on disparate 734 groups by: 735 a. Identifying those cancers that disproportionately impact certain demographic groups; and 736 737 b. Building collaborations designed to reduce health disparities as they relate to cancer. 738 739 Preference may be given to grant proposals that foster (b) 740 collaborations among institutions, researchers, and community 741 practitioners, as such proposals support the advancement of 742 cures through basic or applied research, including clinical 743 trials involving cancer patients and related networks. 744 (3)(a) Applications for funding for cancer research may be 745 submitted by any university or established research institute in 746 the state. All qualified investigators in the state, regardless 747 of institutional affiliation, shall have equal access and 748 opportunity to compete for the research funding. Collaborative 749 proposals, including those that advance the program's goals 750 enumerated in subsection (2), may be given preference. Grants 751 shall be awarded by the State Surgeon General, after 752 consultation with the Biomedical Research Advisory Council, on 753 the basis of scientific merit, as determined by an open, 754 competitive peer review process that ensures objectivity, 755 consistency, and high quality. The following types of 756 applications shall be considered for funding:

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Investigator-initiated research grants. 1.

758

Institutional research grants. 2.

757

759 Collaborative research grants, including those that 3. 760 advance the finding of cures through basic or applied research.

761 In order to ensure that all proposals for research (b) 762 funding are appropriate and are evaluated fairly on the basis of 763 scientific merit, the State Surgeon General, in consultation 764 with the council, shall appoint a peer review panel of 765 independent, scientifically qualified individuals to review the scientific content of each proposal and establish its priority 766 score. The priority scores shall be forwarded to the council and 767 768 must be considered in determining which proposals shall be 769 recommended for funding.

770 (C) The council and the peer review panel shall establish and follow rigorous guidelines for ethical conduct and adhere to 771 772 a strict policy with regard to conflicts of interest. A member 773 of the council or panel may not participate in any discussion or 774 decision with respect to a research proposal by any firm, 775 entity, or agency with which the member is associated as a 776 member of the governing body or as an employee or with which the 777 member has entered into a contractual arrangement. Meetings of 778 the council and the peer review panels are subject to chapter 779 119, s. 286.011, and s. 24, Art. I of the State Constitution.

780 By December 15 of each year, the Department of Health (4) shall submit to the Governor, the President of the Senate, and 781 the Speaker of the House of Representatives a report indicating 782 progress towards the program's mission and making 783

784 recommendations that further its purpose.

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785 The William G. "Bill" Bankhead, Jr., and David Coley (5)786 Cancer Research Program is funded pursuant to s. 215.5602(12). 787 Funds appropriated for the William G. "Bill" Bankhead, Jr., and 788 David Coley Cancer Research Program shall be distributed 789 pursuant to this section to provide grants to researchers 790 seeking cures for cancer and cancer-related illnesses, with 791 emphasis given to the goals enumerated in this section s. 792 381.921. From the total funds appropriated, an amount of up to 793 10 percent may be used for administrative expenses. From funds 794 appropriated to accomplish the goals of this section, up to 795 \$250,000 shall be available for the operating costs of the 796 Florida Center for Universal Research to Eradicate Disease. In 797 the 2009-2010 fiscal year, 2.5 percent, not to exceed \$25 798 million, of the revenue deposited into the Health Care Trust 799 Fund pursuant to s. 215.5602(12)(a) shall be transferred to the 800 Biomedical Research Trust Fund within the Department of Health 801 for the William G. "Bill" Bankhead, Jr., and David Coley Cancer 802 Research Program. (6) By June 1, 2009, the Division of Statutory Revision of 803 804 the Office of Legislative Services shall certify to the 805 President of the Senate and the Speaker of the House of 806 Representatives the language and statutory citation of this 807 section, which is scheduled to expire January 1, 2011. 808 (7) The Legislature shall review the performance, the 809 outcomes, and the financial management of the William G. "Bill" 810 Bankhead, Jr., and David Coley Cancer Research Program during the 2010 Regular Session of the Legislature and shall determine 811 812 the most appropriate funding source and means of funding the Page 29 of 82

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813 program based on its review.

814 (8) This section expires January 1, 2011, unless reviewed 815 and reenacted by the Legislature before that date.

816 Section 15. Subsection (6) of section 20.43, Florida 817 Statutes, is amended, and subsection (10) is added to that 818 section, to read:

819 20.43 Department of Health.—There is created a Department 820 of Health.

821 The State Surgeon General is and division directors (6) are authorized to appoint ad hoc advisory committees as 822 necessary. The issue or problem that the ad hoc committee shall 823 824 address, and the timeframe within which the committee is to 825 complete its work, shall be specified at the time the committee 826 is appointed. Ad hoc advisory committees shall include representatives of groups or entities affected by the issue or 827 828 problem that the committee is asked to examine. Members of ad 829 hoc advisory committees shall receive no compensation, but may, 830 within existing departmental resources, receive reimbursement 831 for travel expenses as provided in s. 112.061.

832 (10) (a) Beginning in fiscal year 2010-2011, the department 833 shall initiate or commence new programs only when the 834 Legislative Budget Commission or the Legislature expressly 835 authorizes the department to do so.

(b) Beginning in fiscal year 2010-2011, before applying
 for any continuation of or new federal or private grants that
 are for an amount of \$50,000 or greater, the department shall
 provide written notification to the Governor, the President of
 the Senate, and the Speaker of the House of Representatives. The

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841 notification must include detailed information about the purpose 842 of the grant, the intended use of the funds, and the number of 843 full-time permanent or temporary employees needed to administer 844 the program funded by the grant. 845 Section 16. Subsection (14) of section 381.0011, Florida 846 Statutes, is renumbered as subsection (15), and a new subsection 847 (14) is added to that section, to read: 848 381.0011 Duties and powers of the Department of Health.-It 849 is the duty of the Department of Health to: 850 (14) Manage and coordinate emergency preparedness and 851 disaster response functions to: investigate and control the 852 spread of disease; coordinate the availability and staffing of 853 special needs shelters; support patient evacuation; ensure the 854 safety of food and drugs; provide critical incident stress 855 debriefing; and provide surveillance and control of 856 radiological, chemical, biological, and other environmental 857 hazards. 858 Section 17. Subsection (16) of section 381.006, Florida 859 Statutes, is amended to read: 860 381.006 Environmental health.-The department shall conduct 861 an environmental health program as part of fulfilling the state's public health mission. The purpose of this program is to 862 863 detect and prevent disease caused by natural and manmade factors 864 in the environment. The environmental health program shall 865 include, but not be limited to: 866 (16) A group-care-facilities function. As used in this 867 subsection, the term, where a "group care facility" means any 868 public or private school, assisted living facility, adult Page 31 of 82

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| 869 | family-care home, adult day care center, short-term residential |
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| 870 | treatment center, residential treatment facility, home for |
| 871 | special services, transitional living facility, crisis |
| 872 | stabilization unit, hospice, prescribed pediatric extended care |
| 873 | center, intermediate care facility for persons with |
| 874 | developmental disabilities, or boarding school housing, building |
| 875 | or buildings, section of a building, or distinct part of a |
| 876 | building or other place, whether operated for profit or not, |
| 877 | which undertakes, through its ownership or management, to |
| 878 | provide one or more personal services, care, protection, and |
| 879 | supervision to persons who require such services and who are not |
| 880 | related to the owner or administrator. The department may adopt |
| 881 | rules necessary to protect the health and safety of residents, |
| 882 | staff, and patrons of group care facilities. Rules related to |
| 883 | public and private schools shall be developed by, such as child |
| 884 | care facilities, family day care homes, assisted living |
| 885 | facilities, adult day care centers, adult family care homes, |
| 886 | hospices, residential treatment facilities, crisis stabilization |
| 887 | units, pediatric extended care centers, intermediate care |
| 888 | facilities for the developmentally disabled, group care homes, |
| 889 | and, jointly with the Department of Education in consultation |
| 890 | with the department, private and public schools. These Rules |
| 891 | adopted under this subsection may include definitions of terms; |
| 892 | provisions relating to operation and maintenance of facilities, |
| 893 | buildings, grounds, equipment, furnishings, and occupant-space |
| 894 | requirements; lighting; heating, cooling, and ventilation; food |
| 895 | service; water supply and plumbing; sewage; sanitary facilities; |
| 896 | insect and rodent control; garbage; safety; personnel health, |
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897 hygiene, and work practices; and other matters the department 898 finds are appropriate or necessary to protect the safety and 899 health of the residents, staff, students, faculty, or patrons. 900 The department may not adopt rules that conflict with rules 901 adopted by the licensing or certifying agency. The department 902 may enter and inspect at reasonable hours to determine 903 compliance with applicable statutes or rules. In addition to any 904 sanctions that the department may impose for violations of rules 905 adopted under this section, the department shall also report 906 such violations to any agency responsible for licensing or 907 certifying the group care facility. The licensing or certifying 908 agency may also impose any sanction based solely on the findings 909 of the department.

911 The department may adopt rules to carry out the provisions of 912 this section.

913 Section 18. Subsections (1), (2), (3), and (6) of section 914 381.0072, Florida Statutes, are amended to read:

915 381.0072 Food service protection.-It shall be the duty of 916 the Department of Health to adopt and enforce sanitation rules 917 consistent with law to ensure the protection of the public from 918 food-borne illness. These rules shall provide the standards and 919 requirements for the storage, preparation, serving, or display 920 of food in food service establishments as defined in this section and which are not permitted or licensed under chapter 921 922 500 or chapter 509.

923 924

910

(1) DEFINITIONS.—As used in this section, the term:(a) "Department" means the Department of Health or its

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925 representative county health department. 926 (b) "Food service establishment" means detention 927 facilities, public or private schools, migrant labor camps, 928 assisted living facilities, adult family-care homes, adult day 929 care centers, short-term residential treatment centers, 930 residential treatment facilities, homes for special services, 931 transitional living facilities, crisis stabilization units, 932 hospices, prescribed pediatric extended care centers, 933 intermediate care facilities for persons with developmental 934 disabilities, boarding schools, civic or fraternal 935 organizations, bars and lounges, vending machines that dispense 936 potentially hazardous foods at facilities expressly named in 937 this paragraph, and facilities used as temporary food events or 938 mobile food units at any facility expressly named any facility, 939 as described in this paragraph, where food is prepared and 940 intended for individual portion service, including and includes the site at which individual portions are provided, . The term 941 942 includes any such facility regardless of whether consumption is 943 on or off the premises and regardless of whether there is a 944 charge for the food. The term includes detention facilities, 945 child care facilities, schools, institutions, civic or fraternal 946 organizations, bars and lounges and facilities used at temporary 947 food events, mobile food units, and vending machines at any 948 facility regulated under this section. The term does not include any entity not expressly named in this paragraph private homes 949 950 where food is prepared or served for individual family 951 consumption; nor does the term include churches, synagoques, 952 other not-for-profit religious organizations as long as these Page 34 of 82

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| 953 | organizations serve only their members and guests and do not |
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| 954 | advertise food or drink for public consumption, or any facility |
| 955 | or establishment permitted or licensed under chapter 500 or |
| 956 | chapter 509; nor does the term include any theater, if the |
| 957 | primary use is as a theater and if patron service is limited to |
| 958 | food items customarily served to the admittees of theaters; nor |
| 959 | does the term include a research and development test kitchen |
| 960 | limited to the use of employees and which is not open to the |
| 961 | general public. |
| 962 | (c) "Operator" means the owner, operator, keeper, |
| 963 | proprietor, lessee, manager, assistant manager, agent, or |
| 964 | employee of a food service establishment. |
| 965 | (2) DUTIES |
| 966 | (a) The department may advise and consult with the Agency |
| 967 | for Health Care Administration, the Department of Business and |
| 968 | Professional Regulation, the Department of Agriculture and |
| 969 | Consumer Services, and the Department of Children and Family |
| 970 | Services concerning procedures related to the storage, |
| 971 | preparation, serving, or display of food at any building, |
| 972 | structure, or facility not expressly included in this section |
| 973 | that is inspected, licensed, or regulated by those agencies. |
| 974 | <u>(b)</u> The department shall adopt rules, including |
| 975 | definitions of terms which are consistent with law prescribing |
| 976 | minimum sanitation standards and manager certification |
| 977 | requirements as prescribed in s. 509.039, and which shall be |
| 978 | enforced in food service establishments as defined in this |
| 979 | section. The sanitation standards must address the construction, |
| 980 | operation, and maintenance of the establishment; lighting, |
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981 ventilation, laundry rooms, lockers, use and storage of toxic 982 materials and cleaning compounds, and first-aid supplies; plan 983 review; design, construction, installation, location, 984 maintenance, sanitation, and storage of food equipment and 985 utensils; employee training, health, hygiene, and work 986 practices; food supplies, preparation, storage, transportation, 987 and service, including access to the areas where food is stored 988 or prepared; and sanitary facilities and controls, including 989 water supply and sewage disposal; plumbing and toilet 990 facilities; garbage and refuse collection, storage, and 991 disposal; and vermin control. Public and private schools, if the 992 food service is operated by school employees, ; hospitals 993 licensed under chapter 395; nursing homes licensed under part II 994 of chapter 400; child care facilities as defined in s. 402.301; 995 residential facilities colocated with a nursing home or 996 hospital, if all food is prepared in a central kitchen that 997 complies with nursing or hospital regulations; and bars and 998 lounges, civic organizations, and any other facility that is not 999 regulated under this section as defined by department rule, are 1000 exempt from the rules developed for manager certification. The 1001 department shall administer a comprehensive inspection, 1002 monitoring, and sampling program to ensure such standards are 1003 maintained. With respect to food service establishments 1004 permitted or licensed under chapter 500 or chapter 509, the 1005 department shall assist the Division of Hotels and Restaurants of the Department of Business and Professional Regulation and 1006 1007 the Department of Agriculture and Consumer Services with 1008 rulemaking by providing technical information.

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1009 <u>(c) (b)</u> The department shall carry out all provisions of 1010 this chapter and all other applicable laws and rules relating to 1011 the inspection or regulation of food service establishments as 1012 defined in this section, for the purpose of safeguarding the 1013 public's health, safety, and welfare.

1014 (d) (c) The department shall inspect each food service 1015 establishment as often as necessary to ensure compliance with 1016 applicable laws and rules. The department shall have the right 1017 of entry and access to these food service establishments at any 1018 reasonable time. In inspecting food service establishments as 1019 provided under this section, the department shall provide each 1020 inspected establishment with the food recovery brochure 1021 developed under s. 570.0725.

1022 <u>(e) (d)</u> The department or other appropriate regulatory 1023 entity may inspect theaters exempted in subsection (1) to ensure 1024 compliance with applicable laws and rules pertaining to minimum 1025 sanitation standards. A fee for inspection shall be prescribed 1026 by rule, but the aggregate amount charged per year per theater 1027 establishment shall not exceed \$300, regardless of the entity 1028 providing the inspection.

1029

(3) LICENSES REQUIRED.-

(a) Licenses; annual renewals.—Each food service establishment regulated under this section shall obtain a license from the department annually. Food service establishment licenses shall expire annually and are not transferable from one place or individual to another. However, those facilities licensed by the department's Office of Licensure and Certification, the Child Care Services Program Office, or the

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1037 Agency for Persons with Disabilities are exempt from this subsection. It shall be a misdemeanor of the second degree, 1038 1039 punishable as provided in s. 381.0061, s. 775.082, or s. 1040 775.083, for such an establishment to operate without this 1041 license. The department may refuse a license, or a renewal 1042 thereof, to any establishment that is not constructed or 1043 maintained in accordance with law and with the rules of the 1044 department. Annual application for renewal is not required.

(b) Application for license.-Each person who plans to open
a food service establishment <u>regulated under this section and</u>
not regulated under chapter 500 or chapter 509 shall apply for
and receive a license prior to the commencement of operation.

1049

(6) IMMINENT DANGERS; STOP-SALE ORDERS.-

1050 (a) In the course of epidemiological investigations or for those establishments regulated by the department under this 1051 1052 chapter, the department, to protect the public from food that is 1053 unwholesome or otherwise unfit for human consumption, may 1054 examine, sample, seize, and stop the sale or use of food to 1055 determine its condition. The department may stop the sale and 1056 supervise the proper destruction of food when the State Health 1057 Officer or his or her designee determines that such food 1058 represents a threat to the public health.

(b) The department may determine that a food service establishment regulated under this section is an imminent danger to the public health and require its immediate closure when such establishment fails to comply with applicable sanitary and safety standards and, because of such failure, presents an imminent threat to the public's health, safety, and welfare. The

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| FLORIDA HOUSE OF REPRESENTATIVE | F | L | 0 | R | | D | Α | ļ | Н | 0 | U | S | Е | 0 | F | R | Е | Р | R | Е | S | Е | Ν | Т | Α | Т | | V | Е | S |
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department may accept inspection results from state and local building and firesafety officials and other regulatory agencies as justification for such actions. Any facility so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.

 1070
 Section 19.
 Sections 411.23, 411.231, and 411.232, Florida

 1071
 Statutes, are repealed.

1072 Section 20. Paragraph (d) of subsection (5) of section 1073 411.01, Florida Statutes, is amended to read:

1074 411.01 School readiness programs; early learning 1075 coalitions.-

1076

(5) CREATION OF EARLY LEARNING COALITIONS.-

1077

(d) Implementation.-

1078 1. An early learning coalition may not implement the
 1079 school readiness program until the coalition is authorized
 1080 through approval of the coalition's school readiness plan by the
 1081 Agency for Workforce Innovation.

1082 Each early learning coalition shall develop a plan for 2. 1083 implementing the school readiness program to meet the 1084 requirements of this section and the performance standards and 1085 outcome measures adopted by the Agency for Workforce Innovation. 1086 The plan must demonstrate how the program will ensure that each 1087 3-year-old and 4-year-old child in a publicly funded school readiness program receives scheduled activities and instruction 1088 1089 designed to enhance the age-appropriate progress of the children 1090 in attaining the performance standards adopted by the Agency for 1091 Workforce Innovation under subparagraph (4)(d)8. Before 1092 implementing the school readiness program, the early learning

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1093 coalition must submit the plan to the Agency for Workforce 1094 Innovation for approval. The Agency for Workforce Innovation may 1095 approve the plan, reject the plan, or approve the plan with 1096 conditions. The Agency for Workforce Innovation shall review 1097 school readiness plans at least annually.

1098 If the Agency for Workforce Innovation determines 3. 1099 during the annual review of school readiness plans, or through 1100 monitoring and performance evaluations conducted under paragraph 1101 (4) (1), that an early learning coalition has not substantially 1102 implemented its plan, has not substantially met the performance 1103 standards and outcome measures adopted by the agency, or has not 1104 effectively administered the school readiness program or 1105 Voluntary Prekindergarten Education Program, the Agency for 1106 Workforce Innovation may dissolve the coalition and temporarily 1107 contract with a qualified entity to continue school readiness 1108 and prekindergarten services in the coalition's county or 1109 multicounty region until the coalition is reestablished through 1110 resubmission of a school readiness plan and approval by the 1111 agency.

1112 4. The Agency for Workforce Innovation shall adopt 1113 criteria for the approval of school readiness plans. The 1114 criteria must be consistent with the performance standards and 1115 outcome measures adopted by the agency and must require each 1116 approved plan to include the following minimum standards and 1117 provisions:

a. A sliding fee scale establishing a copayment for
parents based upon their ability to pay, which is the same for
all program providers, to be implemented and reflected in each

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1121 program's budget.

b. A choice of settings and locations in licensed, registered, religious-exempt, or school-based programs to be provided to parents.

1125 c. Instructional staff who have completed the training 1126 course as required in s. 402.305(2)(d)1., as well as staff who 1127 have additional training or credentials as required by the 1128 Agency for Workforce Innovation. The plan must provide a method 1129 for assuring the qualifications of all personnel in all program 1130 settings.

1131 d. Specific eligibility priorities for children within the 1132 early learning coalition's county or multicounty region in 1133 accordance with subsection (6).

e. Performance standards and outcome measures adopted bythe Agency for Workforce Innovation.

1136 f. Payment rates adopted by the early learning coalition 1137 and approved by the Agency for Workforce Innovation. Payment 1138 rates may not have the effect of limiting parental choice or 1139 creating standards or levels of services that have not been 1140 authorized by the Legislature.

1141 g. Systems support services, including a central agency, 1142 child care resource and referral, eligibility determinations, 1143 training of providers, and parent support and involvement.

h. Direct enhancement services to families and children. System support and direct enhancement services shall be in addition to payments for the placement of children in school readiness programs.

1148

i. The business organization of the early learning Page 41 of 82

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1149 coalition, which must include the coalition's articles of 1150 incorporation and bylaws if the coalition is organized as a 1151 corporation. If the coalition is not organized as a corporation 1152 or other business entity, the plan must include the contract 1153 with a fiscal agent. An early learning coalition may contract 1154 with other coalitions to achieve efficiency in multicounty 1155 services, and these contracts may be part of the coalition's 1156 school readiness plan.

j. Strategies to meet the needs of unique populations,such as migrant workers.

As part of the school readiness plan, the early learning 1160 1161 coalition may request the Governor to apply for a waiver to allow the coalition to administer the Head Start Program to 1162 1163 accomplish the purposes of the school readiness program. If a 1164 school readiness plan demonstrates that specific statutory goals can be achieved more effectively by using procedures that 1165 require modification of existing rules, policies, or procedures, 1166 1167 a request for a waiver to the Agency for Workforce Innovation may be submitted as part of the plan. Upon review, the Agency 1168 1169 for Workforce Innovation may grant the proposed modification.

1170 5. Persons with an early childhood teaching certificate 1171 may provide support and supervision to other staff in the school 1172 readiness program.

6. An early learning coalition may not implement its school readiness plan until it submits the plan to and receives approval from the Agency for Workforce Innovation. Once the plan is approved, the plan and the services provided under the plan

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1177 shall be controlled by the early learning coalition. The plan 1178 shall be reviewed and revised as necessary, but at least 1179 biennially. An early learning coalition may not implement the 1180 revisions until the coalition submits the revised plan to and 1181 receives approval from the Agency for Workforce Innovation. If 1182 the Agency for Workforce Innovation rejects a revised plan, the 1183 coalition must continue to operate under its prior approved 1184 plan.

Sections 125.901(2)(a)3. and, 411.221, and 411.232 do 1185 7. 1186 not apply to an early learning coalition with an approved school 1187 readiness plan. To facilitate innovative practices and to allow the regional establishment of school readiness programs, an 1188 early learning coalition may apply to the Governor and Cabinet 1189 1190 for a waiver of, and the Governor and Cabinet may waive, any of the provisions of ss. 411.223, 411.232, and 1003.54, if the 1191 1192 waiver is necessary for implementation of the coalition's school 1193 readiness plan.

1194 8. Two or more counties may join for purposes of planning 1195 and implementing a school readiness program.

9. An early learning coalition may, subject to approval by the Agency for Workforce Innovation as part of the coalition's school readiness plan, receive subsidized child care funds for all children eligible for any federal subsidized child care program.

1201 10. An early learning coalition may enter into multiparty 1202 contracts with multicounty service providers in order to meet 1203 the needs of unique populations such as migrant workers. 1204 Section 21. Subsection (2) of section 411.224, Florida

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1205 Statutes, is amended to read:

1206 411.224 Family support planning process.—The Legislature 1207 establishes a family support planning process to be used by the 1208 Department of Children and Family Services as the service 1209 planning process for targeted individuals, children, and 1210 families under its purview.

1211 (2) To the extent possible within existing resources, the 1212 following populations must be included in the family support 1213 planning process:

(a) Children from birth to age 5 who are served by the
clinic and programs of the Division of Children's Medical
Services of the Department of Health.

(b) Children participating in the developmental evaluation
and intervention program of the Division of Children's Medical
Services of the Department of Health.

(c) Children from age 3 through age 5 who are served bythe Agency for Persons with Disabilities.

(d) Children from birth through age 5 who are served by the Mental Health Program Office of the Department of Children and Family Services.

1225 (e) Participants who are served by the Children's Early 1226 Investment Program established in s. 411.232.

1227 <u>(e) (f)</u> Healthy Start participants in need of ongoing 1228 service coordination.

1229 <u>(f) (g)</u> Children from birth through age 5 who are served by 1230 the voluntary family services, protective supervision, foster 1231 care, or adoption and related services programs of the Child 1232 Care Services Program Office of the Department of Children and

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Family Services, and who are eligible for ongoing services from one or more other programs or agencies that participate in family support planning; however, children served by the voluntary family services program, where the planned length of intervention is 30 days or less, are excluded from this population.

1239 Section 22. Subsections (32) through (54) of section 1240 499.003, Florida Statutes, are renumbered as subsections (33) 1241 through (55), respectively, present subsection (42) is amended, 1242 and a new subsection (32) is added to that section, to read:

1243 499.003 Definitions of terms used in this part.—As used in 1244 this part, the term:

1245 (32) "Medical convenience kit" means packages or units
1246 that contain combination products as defined in 21 C.F.R. s.
1247 3.2(e)(2).

1248 (43)(42) "Prescription drug" means a prescription, 1249 medicinal, or legend drug, including, but not limited to, 1250 finished dosage forms or active ingredients subject to, defined 1251 by, or described by s. 503(b) of the Federal Food, Drug, and 1252 Cosmetic Act or s. 465.003(8), s. 499.007(13), or subsection 1253 (11), subsection (46) (45), or subsection (53) (52).

1254 Section 23. Paragraph (q) of subsection (2) of section 1255 499.01, Florida Statutes, is amended to read:

- 1256 499.01 Permits.-
- 1257 (2) The following permits are established:

1258 (q) Device manufacturer permit.-

12591.A device manufacturer permit is required for any person1260that engages in the manufacture, repackaging, or assembly of

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| 1261 | medical devices for human use in this state, except that a |
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| 1262 | permit is not required if: |
| 1263 | a. The person is engaged only in manufacturing, |
| 1264 | repackaging, or assembling a medical device pursuant to a |
| 1265 | practitioner's order for a specific patient <u>; or</u> |
| 1266 | b. The person does not manufacture, repackage, or assemble |
| 1267 | any medical devices or components for such devices, except those |
| 1268 | devices or components which are exempt from registration |
| 1269 | pursuant to s. 499.015(8). |
| 1270 | 2.1. A manufacturer or repackager of medical devices in |
| 1271 | this state must comply with all appropriate state and federal |
| 1272 | good manufacturing practices and quality system rules. |
| 1273 | 3.2. The department shall adopt rules related to storage, |
| 1274 | handling, and recordkeeping requirements for manufacturers of |
| 1275 | medical devices for human use. |
| 1276 | Section 24. Paragraph (i) is added to subsection (3) of |
| 1277 | section 499.01212, Florida Statutes, to read: |
| 1278 | 499.01212 Pedigree paper |
| 1279 | (3) EXCEPTIONSA pedigree paper is not required for: |
| 1280 | (i) The wholesale distribution of prescription drugs |
| 1281 | within a medical convenience kit if: |
| 1282 | 1. The medical convenience kit is assembled in an |
| 1283 | establishment that is registered with the United States Food and |
| 1284 | Drug Administration as a medical device manufacturer; |
| 1285 | 2. The medical convenience kit manufacturer purchased the |
| 1286 | prescription drug directly from the manufacturer or from a |
| 1287 | wholesaler that purchased the prescription drug directly from |
| 1288 | the manufacturer; |

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| 1289 | 3. The medical convenience kit manufacturer complies with |
|------|--|
| 1290 | federal law for the distribution of the prescription drugs |
| 1291 | within the kit; and |
| 1292 | 4. The drugs contained in the medical kit are: |
| 1293 | a. Intravenous solutions intended for the replenishment of |
| 1294 | fluids and electrolytes; |
| 1295 | b. Products intended to maintain the equilibrium of water |
| 1296 | and minerals in the body; |
| 1297 | c. Products intended for irrigation or reconstitution; |
| 1298 | d. Anesthetics; or |
| 1299 | e. Anticoagulants. |
| 1300 | |
| 1301 | This exemption does not apply to a convenience kit containing |
| 1302 | any controlled substance that appears in a schedule contained in |
| 1303 | or subject to chapter 893 or the federal Comprehensive Drug |
| 1304 | Abuse Prevention and Control Act of 1970. |
| 1305 | Section 25. Subsections (4) and (5) of section 509.013, |
| 1306 | Florida Statutes, are amended to read: |
| 1307 | 509.013 DefinitionsAs used in this chapter, the term: |
| 1308 | (4)(a) "Public lodging establishment" includes a transient |
| 1309 | public lodging establishment as defined in subparagraph 1. and a |
| 1310 | nontransient public lodging establishment as defined in |
| 1311 | subparagraph 2. |
| 1312 | 1. "Transient public lodging establishment" means any |
| 1313 | unit, group of units, dwelling, building, or group of buildings |
| 1314 | within a single complex of buildings which is rented to guests |
| 1315 | more than three times in a calendar year for periods of less |
| 1316 | than 30 days or 1 calendar month, whichever is less, or which is |
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1317 advertised or held out to the public as a place regularly rented 1318 to guests.

1319 2. "Nontransient public lodging establishment" means any 1320 unit, group of units, dwelling, building, or group of buildings 1321 within a single complex of buildings which is rented to guests 1322 for periods of at least 30 days or 1 calendar month, whichever 1323 is less, or which is advertised or held out to the public as a 1324 place regularly rented to guests for periods of at least 30 days 1325 or 1 calendar month.

1326

1327 License classifications of public lodging establishments, and 1328 the definitions therefor, are set out in s. 509.242. For the 1329 purpose of licensure, the term does not include condominium 1330 common elements as defined in s. 718.103.

1331 (b) The following are excluded from the definitions in 1332 paragraph (a):

Any dormitory or other living or sleeping facility
 maintained by a public or private school, college, or university
 for the use of students, faculty, or visitors;

1336 2. Any <u>facility certified or licensed and regulated by the</u> 1337 <u>Agency for Health Care Administration or the Department of</u> 1338 <u>Children and Family Services hospital, nursing home, sanitarium,</u> 1339 <u>assisted living facility</u>, or other similar place <u>regulated under</u> 1340 <u>s. 381.0072</u>;

1341 3. Any place renting four rental units or less, unless the
1342 rental units are advertised or held out to the public to be
1343 places that are regularly rented to transients;

4. Any unit or group of units in a condominium,

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1345 cooperative, or timeshare plan and any individually or 1346 collectively owned one-family, two-family, three-family, or 1347 four-family dwelling house or dwelling unit that is rented for 1348 periods of at least 30 days or 1 calendar month, whichever is 1349 less, and that is not advertised or held out to the public as a place regularly rented for periods of less than 1 calendar 1350 1351 month, provided that no more than four rental units within a 1352 single complex of buildings are available for rent;

1353 5. Any migrant labor camp or residential migrant housing 1354 permitted by the Department of Health; under ss. 381.008-1355 381.00895; and

1356 6. Any establishment inspected by the Department of Health1357 and regulated by chapter 513.

(5) (a) "Public food service establishment" means any building, vehicle, place, or structure, or any room or division in a building, vehicle, place, or structure where food is prepared, served, or sold for immediate consumption on or in the vicinity of the premises; called for or taken out by customers; or prepared prior to being delivered to another location for consumption.

1365 (b) The following are excluded from the definition in 1366 paragraph (a):

Any place maintained and operated by a public or
 private school, college, or university:

a. For the use of students and faculty; or

1370 b. Temporarily to serve such events as fairs, carnivals,1371 and athletic contests.

 Any eating place maintained and operated by a church or Page 49 of 82

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| 1373 | a religious, nonprofit fraternal, or nonprofit civic |
| 1374 | organization: |
| 1375 | a. For the use of members and associates; or |
| 1376 | b. Temporarily to serve such events as fairs, carnivals, |
| 1377 | or athletic contests. |
| 1378 | 3. Any eating place located on an airplane, train, bus, or |
| 1379 | watercraft which is a common carrier. |
| 1380 | 4. Any eating place maintained by a <u>facility certified or</u> |
| 1381 | licensed and regulated by the Agency for Health Care |
| 1382 | Administration or the Department of Children and Family Services |
| 1383 | hospital, nursing home, sanitarium, assisted living facility, |
| 1384 | adult day care center, or other similar place that is regulated |
| 1385 | under s. 381.0072. |
| 1386 | 5. Any place of business issued a permit or inspected by |
| 1387 | the Department of Agriculture and Consumer Services under s. |
| 1388 | 500.12. |
| 1389 | 6. Any place of business where the food available for |
| 1390 | consumption is limited to ice, beverages with or without |
| 1391 | garnishment, popcorn, or prepackaged items sold without |
| 1392 | additions or preparation. |
| 1393 | 7. Any theater, if the primary use is as a theater and if |
| 1394 | patron service is limited to food items customarily served to |
| 1395 | the admittees of theaters. |
| 1396 | 8. Any vending machine that dispenses any food or |
| 1397 | beverages other than potentially hazardous foods, as defined by |
| 1398 | division rule. |
| 1399 | 9. Any vending machine that dispenses potentially |
| 1400 | hazardous food and which is located in a facility regulated |
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1401 under s. 381.0072.

1402 Any research and development test kitchen limited to 10. 1403 the use of employees and which is not open to the general 1404 public. 1405 Section 26. The Department of Health shall develop a plan 1406 that exclusively uses private and nonstate public hospitals to 1407 provide treatment to cure, hospitalization, and isolation for 1408 persons with contagious cases of tuberculosis who pose a threat 1409 to the public. The department shall submit the plan to the 1410 Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1, 2010. The plan shall 1411 1412 include the following elements: Identification of hospitals functionally capable of 1413 (1) 1414 caring for such patients. (2) Reimbursement for hospital inpatient services at the 1415 1416 Medicaid rate and reimbursement for other medically necessary 1417 services that are not hospital inpatient services at the 1418 relevant Medicaid rate. 1419 (3) Projected cost estimates. (4) A transition plan for closing the A. G. Holley State 1420 1421 Hospital and transferring patients to private and nonstate public hospitals over a 90-day period of time. 1422 1423 Section 27. (1) All of the statutory powers, duties, and 1424 functions, records, personnel, property, and unexpended balances 1425 of appropriations, allocations, or other funds for the administration of chapter 499, Florida Statutes, relating to 1426 drugs, devices, cosmetics, and household products shall be 1427 1428 transferred by a type two transfer, as defined in s. 20.06(2),

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| FLORIDA HOUSE OF REPRESENT | ΓΑΤΙΥΕS |
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| 1429 | Florida Statutes, from the Department of Health to the |
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| 1430 | Department of Business and Professional Regulation. |
| 1431 | (2) The transfer of regulatory authority under chapter |
| 1432 | 499, Florida Statutes, provided by this section shall not affect |
| 1433 | the validity of any judicial or administrative action pending as |
| 1434 | of 11:59 p.m. on the day before the effective date of this |
| 1435 | section to which the Department of Health is at that time a |
| 1436 | party, and the Department of Business and Professional |
| 1437 | Regulation shall be substituted as a party in interest in any |
| 1438 | such action. |
| 1439 | (3) All lawful orders issued by the Department of Health |
| 1440 | implementing or enforcing or otherwise in regard to any |
| 1441 | provision of chapter 499, Florida Statutes, issued prior to the |
| 1442 | effective date of this section shall remain in effect and be |
| 1443 | enforceable after the effective date of this section unless |
| 1444 | thereafter modified in accordance with law. |
| 1445 | (4) The rules of the Department of Health relating to the |
| 1446 | implementation of chapter 499, Florida Statutes, that were in |
| 1447 | effect at 11:59 p.m. on the day prior to the effective date of |
| 1448 | this section shall become the rules of the Department of |
| 1449 | Business and Professional Regulation and shall remain in effect |
| 1450 | until amended or repealed in the manner provided by law. |
| 1451 | (5) Notwithstanding the transfer of regulatory authority |
| 1452 | under chapter 499, Florida Statutes, provided by this section, |
| 1453 | persons and entities holding in good standing any permit under |
| 1454 | chapter 499, Florida Statutes, as of 11:59 p.m. on the day prior |
| 1455 | to the effective date of this section shall, as of the effective |
| 1456 | date of this section, be deemed to hold in good standing a |
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1457 permit in the same capacity as that for which the permit was 1458 formerly issued. 1459 (6) Notwithstanding the transfer of regulatory authority 1460 under chapter 499, Florida Statutes, provided by this section, 1461 persons holding in good standing any certification under chapter 1462 499, Florida Statutes, as of 11:59 p.m. on the day prior to the 1463 effective date of this section shall, as of the effective date of this section, be deemed to be certified in the same capacity 1464 1465 in which they were formerly certified. 1466 This section shall take effect October 1, 2011. (7) 1467 Section 28. Paragraph (a) of subsection (3) and 1468 subsections (9) and (10) of section 381.0403, Florida Statutes, are amended to read: 1469 1470 381.0403 The Community Hospital Education Act.-1471 (3)PROGRAM FOR COMMUNITY HOSPITAL EDUCATION; STATE AND 1472 LOCAL PLANNING.-1473 There is established under the Department of Health a (a) 1474 program for statewide graduate medical education. It is intended 1475 that continuing graduate medical education programs for interns 1476 and residents be established on a statewide basis. The program 1477 shall provide financial support for primary care specialty 1478 interns and residents based on policies recommended and approved 1479 by the Community Hospital Education Council, herein established, 1480 and the Department of Health. Only those programs with at least 1481 three residents or interns in each year of the training program 1482 are qualified to apply for financial support. Programs with 1483 fewer than three residents or interns per training year are 1484 qualified to apply for financial support, but only if the

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1485 appropriate accrediting entity for the particular specialty has 1486 approved the program for fewer positions. Programs added after 1487 fiscal year 1997-1998 shall have 5 years to attain the requisite 1488 number of residents or interns. When feasible and to the extent 1489 allowed through the General Appropriations Act, state funds 1490 shall be used to generate federal matching funds under Medicaid, 1491 or other federal programs, and the resulting combined state and 1492 federal funds shall be allocated to participating hospitals for 1493 the support of graduate medical education. The department may 1494 spend up to \$75,000 of the state appropriation for 1495 administrative costs associated with the production of the 1496 annual report as specified in subsection (9), and for 1497 administration of the program.

1498 (9) ANNUAL REPORT ON GRADUATE MEDICAL EDUCATION; 1499 COMMITTEE. The Executive Office of the Governor, the Department 1500 of Health, and the Agency for Health Care Administration shall 1501 collaborate to establish a committee that shall produce an 1502 annual report on graduate medical education. The committee shall 1503 be comprised of 11 members: five members shall be deans of the 1504 medical schools or their designees; the Governor shall appoint 1505 two members, one of whom must be a representative of the Florida 1506 Medical Association who has supervised or currently supervises 1507 residents or interns and one of whom must be a representative of 1508 the Florida Hospital Association; the Secretary of Health Care 1509 Administration shall appoint two members, one of whom must be a 1510 representative of a statutory teaching hospital and one of whom 1511 must be a physician who has supervised or is currently 1512 supervising residents or interns; and the State Surgeon General Page 54 of 82

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| 1513 | shall appoint two members, one of whom must be a representative |
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| 1514 | of a statutory family practice teaching hospital and one of whom |
| 1515 | must be a physician who has supervised or is currently |
| 1516 | supervising residents or interns. With the exception of the |
| 1517 | deans, members shall serve 4-year terms. In order to stagger the |
| 1518 | terms, the Governor's appointees shall serve initial terms of 4 |
| 1519 | years, the State Surgeon General's appointees shall serve |
| 1520 | initial terms of 3 years, and the Secretary of Health Care |
| 1521 | Administration's appointees shall serve initial terms of 2 |
| 1522 | years. A member's term shall be deemed terminated when the |
| 1523 | member's representative status no longer exists. Once the |
| 1524 | committee is appointed, it shall elect a chair to serve for a 1- |
| 1525 | year term. The report shall be provided to the Governor, the |
| 1526 | President of the Senate, and the Speaker of the House of |
| 1527 | Representatives by January 15 annually. Committee members shall |
| 1528 | serve without compensation. The report shall address the |
| 1529 | following: |
| 1530 | (a) The role of residents and medical faculty in the |
| 1531 | provision of health care. |
| 1532 | (b) The relationship of graduate medical education to the |
| 1533 | state's physician workforce. |
| 1534 | (c) The costs of training medical residents for hospitals, |
| 1535 | medical schools, teaching hospitals, including all hospital- |
| 1536 | medical affiliations, practice plans at all of the medical |
| 1537 | schools, and municipalities. |
| 1538 | (d) The availability and adequacy of all sources of |
| 1539 | revenue to support graduate medical education and recommend |
| 1540 | alternative sources of funding for graduate medical education. |
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| 1541 | (e) The use of state and federal appropriated funds for |
|------|--|
| 1542 | graduate medical education by hospitals receiving such funds. |
| 1543 | (9) (10) RULEMAKING.—The department has authority to adopt |
| 1544 | rules pursuant to ss. 120.536(1) and 120.54 to implement the |
| 1545 | provisions of this section. |
| 1546 | Section 29. Section 381.4018, Florida Statutes, is amended |
| 1547 | to read: |
| 1548 | 381.4018 Physician workforce assessment and development |
| 1549 | (1) DEFINITIONSAs used in this section, the term: |
| 1550 | (a) "Consortium" or "consortia" means a combination of |
| 1551 | statutory teaching hospitals, specialty children's hospitals, |
| 1552 | statutory rural hospitals, other hospitals, accredited medical |
| 1553 | schools, clinics operated by the Department of Health, clinics |
| 1554 | operated by the Department of Veterans' Affairs, area health |
| 1555 | education centers, community health centers, federally qualified |
| 1556 | health centers, prison clinics, local community clinics, or |
| 1557 | other programs. At least one member of the consortium shall be a |
| 1558 | sponsoring institution accredited or currently seeking |
| 1559 | accreditation by the Accreditation Council for Graduate Medical |
| 1560 | Education or the American Osteopathic Association. |
| 1561 | (b) "Council" means the Physician Workforce Advisory |
| 1562 | Council. |
| 1563 | (c) "Department" means the Department of Health. |
| 1564 | (d) "Graduate medical education program" means a program |
| 1565 | accredited by the Accreditation Council for Graduate Medical |
| 1566 | Education or the American Osteopathic Association. |
| 1567 | (e) "Primary care specialty" means emergency medicine, |
| 1568 | family practice, internal medicine, pediatrics, psychiatry, |
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1569 geriatrics, general surgery, obstetrics and gynecology, and 1570 combined pediatrics and internal medicine and other specialties 1571 as determined by the Physician Workforce Advisory Council or the 1572 Department of Health.

1573 (2) (1) LEGISLATIVE INTENT. - The Legislature recognizes that 1574 physician workforce planning is an essential component of 1575 ensuring that there is an adequate and appropriate supply of 1576 well-trained physicians to meet this state's future health care 1577 service needs as the general population and elderly population 1578 of the state increase. The Legislature finds that items to 1579 consider relative to assessing the physician workforce may 1580 include physician practice status; specialty mix; geographic 1581 distribution; demographic information, including, but not 1582 limited to, age, gender, race, and cultural considerations; and 1583 needs of current or projected medically underserved areas in the 1584 state. Long-term strategic planning is essential as the period 1585 from the time a medical student enters medical school to 1586 completion of graduate medical education may range from 7 to 10 1587 years or longer. The Legislature recognizes that strategies to 1588 provide for a well-trained supply of physicians must include 1589 ensuring the availability and capacity of quality graduate 1590 medical schools and graduate medical education programs in this 1591 state, as well as using new or existing state and federal 1592 programs providing incentives for physicians to practice in 1593 needed specialties and in underserved areas in a manner that 1594 addresses projected needs for physician manpower.

1595 <u>(3) (2)</u> PURPOSE.—The department of Health shall serve as a 1596 coordinating and strategic planning body to actively assess the Page 57 of 82

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1597 state's current and future physician workforce needs and work
1598 with multiple stakeholders to develop strategies and
1599 alternatives to address current and projected physician
1600 workforce needs.

1601 <u>(4)</u> (3) GENERAL FUNCTIONS.—The department shall maximize 1602 the use of existing programs under the jurisdiction of the 1603 department and other state agencies and coordinate governmental 1604 and nongovernmental stakeholders and resources in order to 1605 develop a state strategic plan and assess the implementation of 1606 such strategic plan. In developing the state strategic plan, the 1607 department shall:

(a) Monitor, evaluate, and report on the supply and
distribution of physicians licensed under chapter 458 or chapter
459. The department shall maintain a database to serve as a
statewide source of data concerning the physician workforce.

(b) Develop a model and quantify, on an ongoing basis, the adequacy of the state's current and future physician workforce as reliable data becomes available. Such model must take into account demographics, physician practice status, place of education and training, generational changes, population growth, economic indicators, and issues concerning the "pipeline" into medical education.

(c) Develop and recommend strategies to determine whether the number of qualified medical school applicants who might become competent, practicing physicians in this state will be sufficient to meet the capacity of the state's medical schools. If appropriate, the department shall, working with representatives of appropriate governmental and nongovernmental

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1625 entities, develop strategies and recommendations and identify 1626 best practice programs that introduce health care as a 1627 profession and strengthen skills needed for medical school 1628 admission for elementary, middle, and high school students, and 1629 improve premedical education at the precollege and college level 1630 in order to increase this state's potential pool of medical 1631 students.

(d) Develop strategies to ensure that the number of
graduates from the state's public and private allopathic and
osteopathic medical schools <u>is</u> are adequate to meet physician
workforce needs, based on the analysis of the physician
workforce data, so as to provide a high-quality medical
education to students in a manner that recognizes the uniqueness
of each new and existing medical school in this state.

1639 Pursue strategies and policies to create, expand, and (e) 1640 maintain graduate medical education positions in the state based on the analysis of the physician workforce data. Such strategies 1641 1642 and policies must take into account the effect of federal 1643 funding limitations on the expansion and creation of positions 1644 in graduate medical education. The department shall develop 1645 options to address such federal funding limitations. The 1646 department shall consider options to provide direct state 1647 funding for graduate medical education positions in a manner 1648 that addresses requirements and needs relative to accreditation 1649 of graduate medical education programs. The department shall 1650 consider funding residency positions as a means of addressing 1651 needed physician specialty areas, rural areas having a shortage 1652 of physicians, and areas of ongoing critical need, and as a

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1653 means of addressing the state's physician workforce needs based 1654 on an ongoing analysis of physician workforce data.

1655 Develop strategies to maximize federal and state (f) 1656 programs that provide for the use of incentives to attract 1657 physicians to this state or retain physicians within the state. 1658 Such strategies should explore and maximize federal-state 1659 partnerships that provide incentives for physicians to practice 1660 in federally designated shortage areas. Strategies shall also 1661 consider the use of state programs, such as the Florida Health 1662 Service Corps established pursuant to s. 381.0302 and the 1663 Medical Education Reimbursement and Loan Repayment Program 1664 pursuant to s. 1009.65, which provide for education loan 1665 repayment or loan forgiveness and provide monetary incentives 1666 for physicians to relocate to underserved areas of the state.

Coordinate and enhance activities relative to 1667 (q) 1668 physician workforce needs, undergraduate medical education, and 1669 graduate medical education, and reentry of retired military and 1670 other physicians into the physician workforce provided by the 1671 Division of Medical Quality Assurance, the Community Hospital 1672 Education Program and the Graduate Medical Education Committee 1673 established pursuant to s. 381.0403, area health education 1674 center networks established pursuant to s. 381.0402, and other 1675 offices and programs within the department of Health as 1676 designated by the State Surgeon General.

(h) Work in conjunction with and act as a coordinating body for governmental and nongovernmental stakeholders to address matters relating to the state's physician workforce assessment and development for the purpose of ensuring an

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1681 adequate supply of well-trained physicians to meet the state's 1682 future needs. Such governmental stakeholders shall include, but 1683 need not be limited to, the State Surgeon General or his or her 1684 designee, the Commissioner of Education or his or her designee, 1685 the Secretary of Health Care Administration or his or her 1686 designee, and the Chancellor of the State University System or 1687 his or her designee from the Board of Governors of the State 1688 University System, and, at the discretion of the department, 1689 other representatives of state and local agencies that are 1690 involved in assessing, educating, or training the state's 1691 current or future physicians. Other stakeholders shall include, 1692 but need not be limited to, organizations representing the 1693 state's public and private allopathic and osteopathic medical 1694 schools; organizations representing hospitals and other institutions providing health care, particularly those that 1695 1696 currently provide or have an interest in providing accredited 1697 medical education and graduate medical education to medical 1698 students and medical residents; organizations representing 1699 allopathic and osteopathic practicing physicians; and, at the 1700 discretion of the department, representatives of other 1701 organizations or entities involved in assessing, educating, or 1702 training the state's current or future physicians.

(i) Serve as a liaison with other states and federal
agencies and programs in order to enhance resources available to
the state's physician workforce and medical education continuum.

(j) Act as a clearinghouse for collecting and
disseminating information concerning the physician workforce and
medical education continuum in this state.

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| 1709 | (5) PHYSICIAN WORKFORCE ADVISORY COUNCILThere is created |
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| 1710 | in the department the Physician Workforce Advisory Council, an |
| 1711 | advisory council as defined in s. 20.03. The council shall |
| 1712 | comply with the requirements of s. 20.052, except as otherwise |
| 1713 | provided in this section. |
| 1714 | (a) The council shall consist of 19 members. Members |
| 1715 | appointed by the State Surgeon General shall include: |
| 1716 | 1. A designee from the department who is a physician |
| 1717 | licensed under chapter 458 or chapter 459 and recommended by the |
| 1718 | State Surgeon General. |
| 1719 | 2. An individual who is affiliated with the Science |
| 1720 | Students Together Reaching Instructional Diversity and |
| 1721 | Excellence program and recommended by the area health education |
| 1722 | center network. |
| 1723 | 3. Two individuals recommended by the Council of Florida |
| 1724 | Medical School Deans, one representing a college of allopathic |
| 1725 | medicine and one representing a college of osteopathic medicine. |
| 1726 | 4. One individual recommended by the Florida Hospital |
| 1727 | Association, representing a hospital that is licensed under |
| 1728 | chapter 395, has an accredited graduate medical education |
| 1729 | program, and is not a statutory teaching hospital. |
| 1730 | 5. One individual representing a statutory teaching |
| 1731 | hospital as defined in s. 408.07 and recommended by the Safety |
| 1732 | Net Hospital Alliance. |
| 1733 | 6. One individual representing a family practice teaching |
| 1734 | hospital as defined in s. 395.805 and recommended by the Council |
| 1735 | of Family Medicine and Community Teaching Hospitals. |
| 1736 | 7. Two individuals recommended by the Florida Medical |
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| 1737 | Association, one representing a primary care specialty and one |
|------|--|
| 1738 | representing a nonprimary care specialty. |
| 1739 | 8. Two individuals recommended by the Florida Osteopathic |
| 1740 | Medical Association, one representing a primary care specialty |
| 1741 | and one representing a nonprimary care specialty. |
| 1742 | 9. Two individuals who are program directors of accredited |
| 1743 | graduate medical education programs, one representing a program |
| 1744 | that is accredited by the Accreditation Council for Graduate |
| 1745 | Medical Education and one representing a program that is |
| 1746 | accredited by the American Osteopathic Association. |
| 1747 | 10. An individual recommended by the Florida Association |
| 1748 | of Community Health Centers representing a federally qualified |
| 1749 | health center located in a rural area as defined in s. |
| 1750 | <u>381.0406(2)(a).</u> |
| 1751 | 11. An individual recommended by the Florida Academy of |
| 1752 | Family Physicians. |
| 1753 | 12. An individual recommended by the Florida Alliance for |
| 1754 | Health Professions Diversity. |
| 1755 | 13. The Chancellor of the State University System or his |
| 1756 | or her designee. |
| 1757 | 14. A layperson member as determined by the State Surgeon |
| 1758 | General. |
| 1759 | |
| 1760 | Appointments to the council shall be made by the State Surgeon |
| 1761 | General. Each entity authorized to make recommendations under |
| 1762 | this subsection shall make at least two recommendations to the |
| 1763 | State Surgeon General for each appointment to the council. The |
| 1764 | State Surgeon General shall name one appointee for each position |
| | Page 63 of 82 |

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| 1765 | from the recommendations made by each authorized entity. |
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| 1766 | (b) Each council member shall be appointed to a 4-year |
| 1767 | term. An individual may not serve more than two terms. Any |
| 1768 | council member may be removed from office for malfeasance; |
| 1769 | misfeasance; neglect of duty; incompetence; permanent inability |
| 1770 | to perform official duties; or pleading guilty or nolo |
| 1771 | contendere to, or being found guilty of, a felony. Any council |
| 1772 | member who meets the criteria for removal, or who is otherwise |
| 1773 | unwilling or unable to properly fulfill the duties of the |
| 1774 | office, shall be succeeded by an individual chosen by the State |
| 1775 | Surgeon General to serve out the remainder of the council |
| 1776 | member's term. If the remainder of the replaced council member's |
| 1777 | term is less than 18 months, notwithstanding the provisions of |
| 1778 | this paragraph, the succeeding council member may be reappointed |
| 1779 | twice by the State Surgeon General. |
| 1780 | (c) The chair of the council is the State Surgeon General, |
| 1781 | who shall designate a vice chair from the membership of the |
| 1782 | council to serve in the absence of the State Surgeon General. A |
| 1783 | vacancy shall be filled for the remainder of the unexpired term |
| 1784 | in the same manner as the original appointment. |
| 1785 | (d) Council members are not entitled to receive |
| 1786 | compensation or reimbursement for per diem or travel expenses. |
| 1787 | (e) The council shall meet at least twice a year in person |
| 1788 | or by teleconference. |
| 1789 | (f) The council shall: |
| 1790 | 1. Advise the State Surgeon General and the department on |
| 1791 | matters concerning current and future physician workforce needs |
| 1792 | <u>in this state;</u> |
| 1 | Page 64 of 82 |

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| <u>2</u> . | Review survey materials and the compilation of survey |
| informa | tion; |
| <u>3.</u> | Annually review the number, location, cost, and |
| reimbur | sement of graduate medical education programs and |
| positic | ns; |
| <u>4</u> . | Provide recommendations to the department regarding the |
| survey | completed by physicians licensed under chapter 458 or |
| chapter | 459; |
| <u>5</u> . | Assist the department in preparing the annual report to |
| the Leg | islature pursuant to ss. 458.3192 and 459.0082; |
| 6. | Assist the department in preparing an initial strategic |
| plan, c | onduct ongoing strategic planning in accordance with this |
| section | , and provide ongoing advice on implementing the |
| recomme | ndations; |
| 7. | Monitor and provide recommendations regarding the need |
| for an | increased number of primary care or other physician |
| special | ties to provide the necessary current and projected |
| health | and medical services for the state; and |
| 8. | Monitor and make recommendations regarding the status |
| of the | needs relating to graduate medical education in this |
| state. | |
| Se | ction 30. Section 458.3192, Florida Statutes, is amended |
| to read | : |
| 45 | 8.3192 Analysis of survey results; report |
| (1 |) Each year, the Department of Health shall analyze the |
| results | of the physician survey required by s. 458.3191 and |
| determi | ne by geographic area and specialty the number of |
| physici | ans who: |
| | Page 65 of 82 |

2010 HB 5311, Engrossed 1 1821 Perform deliveries of children in this state Florida. (a) 1822 (b) Read mammograms and perform breast-imaging-guided 1823 procedures in this state Florida. 1824 Perform emergency care on an on-call basis for a (C) 1825 hospital emergency department. 1826 Plan to reduce or increase emergency on-call hours in (d) 1827 a hospital emergency department. Plan to relocate their allopathic or osteopathic 1828 (e) 1829 practice outside the state. 1830 (f) Practice medicine in this state. 1831 Plan to reduce or modify the scope of their practice. (g) 1832 The Department of Health must report its findings to (2) 1833 the Governor, the President of the Senate, and the Speaker of 1834 the House of Representatives by November 1 each year. The 1835 department shall also include in its report findings, 1836 recommendations, and strategic planning activities as provided 1837 in s. 381.4018. The department may also include other 1838 information requested by the Physician Workforce Advisory 1839 Council. 1840 Section 31. Section 459.0082, Florida Statutes, is amended 1841 to read: 1842 459.0082 Analysis of survey results; report.-1843 Each year, the Department of Health shall analyze the (1)results of the physician survey required by s. 459.0081 and 1844 1845 determine by geographic area and specialty the number of 1846 physicians who: 1847 (a) Perform deliveries of children in this state Florida. 1848 Read mammograms and perform breast-imaging-quided (b) Page 66 of 82

2010 HB 5311, Engrossed 1 1849 procedures in this state Florida. 1850 (C) Perform emergency care on an on-call basis for a 1851 hospital emergency department. 1852 Plan to reduce or increase emergency on-call hours in (d) 1853 a hospital emergency department. 1854 Plan to relocate their allopathic or osteopathic (e) 1855 practice outside the state. 1856 (f) Practice medicine in this state. 1857 (q) Plan to reduce or modify the scope of their practice. 1858 The Department of Health must report its findings to (2) 1859 the Governor, the President of the Senate, and the Speaker of 1860 the House of Representatives by November 1 each year. The 1861 department shall also include in its report findings, 1862 recommendations, and strategic planning activities as provided 1863 in s. 381.4018. The department may also include other 1864 information requested by the Physician Workforce Advisory 1865 Council. 1866 Section 32. Section 458.315, Florida Statutes, is amended 1867 to read: 1868 458.315 Temporary certificate for practice in areas of 1869 critical need.-1870 (1) Any physician who: 1871 Is licensed to practice in any jurisdiction in the (a) 1872 United States and other state, whose license is currently valid; 1873 or 1874 (b) Has served as a physician in the United States Armed 1875 Forces for at least 10 years and received an honorable discharge 1876 from the military;

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1877 1878 and who pays an application fee of \$300 may be issued a 1879 temporary certificate for to practice in areas of communities of 1880 Florida where there is a critical need for physicians. 1881 A certificate may be issued to a physician who: (2) 1882 Will practice in an area of critical need; (a) Will be employed by or practice in a county health 1883 (b) department, correctional facility, Department of Veterans' 1884 1885 Affairs clinic, community health center funded by s. 329, s. 1886 330, or s. 340 of the United States Public Health Services Act, 1887 or other agency or institution that is approved by the State 1888 Surgeon General and provides health care to meet the needs of 1889 underserved populations in this state; or 1890 Will practice for a limited time to address critical (C) physician-specialty, demographic, or geographic needs for this 1891 1892 state's physician workforce as determined by the State Surgeon 1893 General entity that provides health care to indigents and that 1894 is approved by the State Health Officer. 1895 The Board of Medicine may issue this temporary (3) certificate with the following restrictions: 1896 1897 (a) (1) The State Surgeon General board shall determine the 1898 areas of critical need, and the physician so certified may 1899 practice in any of those areas for a time to be determined by 1900 the board. Such areas shall include, but are not be limited to, 1901 health professional shortage areas designated by the United 1902 States Department of Health and Human Services. 1903 1.(a) A recipient of a temporary certificate for practice 1904 in areas of critical need may use the certificate license to Page 68 of 82

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1905 work for any approved <u>entity</u> <u>employer</u> in any area of critical 1906 need <u>or as authorized by the State Surgeon General</u> approved by 1907 the board.

1908 <u>2.(b)</u> The recipient of a temporary certificate for 1909 practice in areas of critical need shall, within 30 days after 1910 accepting employment, notify the board of all approved 1911 institutions in which the licensee practices and of all approved 1912 institutions where practice privileges have been denied.

1913 (b) (2) The board may administer an abbreviated oral 1914 examination to determine the physician's competency, but a no written regular examination is not required necessary. Within 60 1915 1916 days after receipt of an application for a temporary 1917 certificate, the board shall review the application and issue 1918 the temporary certificate, or notify the applicant of denial, or notify the applicant that the board recommends additional 1919 1920 assessment, training, education, or other requirements as a 1921 condition of certification. If the applicant has not actively 1922 practiced during the prior 3 years and the board determines that 1923 the applicant may lack clinical competency, possess diminished 1924 or inadequate skills, lack necessary medical knowledge, or 1925 exhibit patterns of deficits in clinical decisionmaking, the 1926 board may: 1927 1. Deny the application; 1928 2. Issue a temporary certificate having reasonable restrictions that may include, but are not limited to, a 1929 1930 requirement for the applicant to practice under the supervision

- 1931 of a physician approved by the board; or
- 1932 3. Issue a temporary certificate upon receipt of

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1933 <u>documentation confirming that the applicant has met any</u> 1934 <u>reasonable conditions of the board which may include, but are</u> 1935 <u>not limited to, completing continuing education or undergoing an</u> 1936 assessment of skills and training.

1937 (c) (3) Any certificate issued under this section is shall 1938 be valid only so long as the State Surgeon General determines 1939 that the reason area for which it was is issued remains a an 1940 area of critical need to the state. The Board of Medicine shall 1941 review each temporary certificateholder not the service within 1942 said area not less than annually to ascertain that the minimum 1943 requirements of the Medical Practice Act and its adopted the 1944 rules and regulations promulgated thereunder are being complied 1945 with. If it is determined that such minimum requirements are not 1946 being met, the board shall forthwith revoke such certificate or shall impose restrictions or conditions, or both, as a condition 1947 1948 of continued practice under the certificate.

1949 <u>(d) (4)</u> The board <u>may shall</u> not issue a temporary 1950 certificate for practice in an area of critical need to any 1951 physician who is under investigation in <u>any jurisdiction in the</u> 1952 <u>United States</u> another state for an act <u>that</u> which would 1953 constitute a violation of this chapter until such time as the 1954 investigation is complete, at which time the provisions of s. 1955 458.331 shall apply.

1956 <u>(4) (5)</u> The application fee and all licensure fees, 1957 including neurological injury compensation assessments, shall be 1958 waived for those persons obtaining a temporary certificate to 1959 practice in areas of critical need for the purpose of providing 1960 volunteer, uncompensated care for low-income <u>residents</u>

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| | HB 5311, Engrossed 1 2010 |
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| 1961 | Floridians. The applicant must submit an affidavit from the |
| 1962 | employing agency or institution stating that the physician will |
| 1963 | not receive any compensation for any service involving the |
| 1964 | practice of medicine. |
| 1965 | Section 33. Section 459.0076, Florida Statutes, is created |
| 1966 | to read: |
| 1967 | 459.0076 Temporary certificate for practice in areas of |
| 1968 | critical need |
| 1969 | (1) Any physician who: |
| 1970 | (a) Is licensed to practice in any jurisdiction in the |
| 1971 | United States and whose license is currently valid; or |
| 1972 | (b) Has served as a physician in the United States Armed |
| 1973 | Forces for at least 10 years and received an honorable discharge |
| 1974 | from the military; |
| 1975 | |
| 1976 | and who pays an application fee of \$300 may be issued a |
| 1977 | temporary certificate for practice in areas of critical need. |
| 1978 | (2) A certificate may be issued to a physician who: |
| 1979 | (a) Will practice in an area of critical need; |
| 1980 | (b) Will be employed by or practice in a county health |
| 1981 | department, correctional facility, Department of Veterans' |
| 1982 | Affairs clinic, community health center funded by s. 329, s. |
| 1983 | 330, or s. 340 of the United States Public Health Services Act, |
| 1984 | or other agency or institution that is approved by the State |
| 1985 | Surgeon General and provides health care to meet the needs of |
| 1986 | underserved populations in this state; or |
| 1987 | (c) Will practice for a limited time to address critical |
| 1988 | physician-specialty, demographic, or geographic needs for this |
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1989 state's physician workforce as determined by the State Surgeon
1990 General.

1991(3) The Board of Osteopathic Medicine may issue this1992temporary certificate with the following restrictions:

(a) The State Surgeon General shall determine the areas of
 critical need. Such areas include, but are not limited to,
 health professional shortage areas designated by the United
 States Department of Health and Human Services.

1997 <u>1. A recipient of a temporary certificate for practice in</u> 1998 <u>areas of critical need may use the certificate to work for any</u> 1999 <u>approved entity in any area of critical need or as authorized by</u> 2000 the State Surgeon General.

2001 <u>2. The recipient of a temporary certificate for practice</u> 2002 <u>in areas of critical need shall, within 30 days after accepting</u> 2003 <u>employment, notify the board of all approved institutions in</u> 2004 <u>which the licensee practices and of all approved institutions</u> 2005 where practice privileges have been denied.

2006 The board may administer an abbreviated oral (b) 2007 examination to determine the physician's competency, but a 2008 written regular examination is not required. Within 60 days 2009 after receipt of an application for a temporary certificate, the 2010 board shall review the application and issue the temporary 2011 certificate, notify the applicant of denial, or notify the 2012 applicant that the board recommends additional assessment, 2013 training, education, or other requirements as a condition of 2014 certification. If the applicant has not actively practiced 2015 during the prior 3 years and the board determines that the 2016 applicant may lack clinical competency, possess diminished or

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2017 inadequate skills, lack necessary medical knowledge, or exhibit 2018 patterns of deficits in clinical decisionmaking, the board may: 2019 1. Deny the application; 2020 2. Issue a temporary certificate having reasonable 2021 restrictions that may include, but are not limited to, a 2022 requirement for the applicant to practice under the supervision 2023 of a physician approved by the board; or 2024 3. Issue a temporary certificate upon receipt of 2025 documentation confirming that the applicant has met any 2026 reasonable conditions of the board which may include, but are 2027 not limited to, completing continuing education or undergoing an 2028 assessment of skills and training. 2029 Any certificate issued under this section is valid (C) 2030 only so long as the State Surgeon General determines that the 2031 reason for which it was issued remains a critical need to the 2032 state. The Board of Osteopathic Medicine shall review each 2033 temporary certificateholder not less than annually to ascertain 2034 that the minimum requirements of the Osteopathic Medical 2035 Practice Act and its adopted rules are being complied with. If 2036 it is determined that such minimum requirements are not being 2037 met, the board shall revoke such certificate or shall impose 2038 restrictions or conditions, or both, as a condition of continued 2039 practice under the certificate. 2040 The board may not issue a temporary certificate for (d) 2041 practice in an area of critical need to any physician who is 2042 under investigation in any jurisdiction in the United States for 2043 an act that would constitute a violation of this chapter until 2044 such time as the investigation is complete, at which time the

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| 2045 | provisions of s. 459.015 apply. |
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| 2046 | (4) The application fee and all licensure fees, including |
| 2047 | neurological injury compensation assessments, shall be waived |
| 2048 | for those persons obtaining a temporary certificate to practice |
| 2049 | in areas of critical need for the purpose of providing |
| 2050 | volunteer, uncompensated care for low-income residents. The |
| 2051 | applicant must submit an affidavit from the employing agency or |
| 2052 | institution stating that the physician will not receive any |
| 2053 | compensation for any service involving the practice of medicine. |
| 2054 | Section 34. (1) The Department of Health shall conduct an |
| 2055 | evaluation and justification review of each division established |
| 2056 | under s. 20.43, Florida Statutes. The review shall be |
| 2057 | comprehensive in its scope and, at a minimum, must be conducted |
| 2058 | in such a manner as to specifically determine the following, and |
| 2059 | to consider and determine what changes, if any, are needed with |
| 2060 | respect thereto: |
| 2061 | (a) The identifiable cost of each division and programs |
| 2062 | within the division. |
| 2063 | (b) The specific purpose of each division and programs |
| 2064 | within the division, and the specific public health benefit |
| 2065 | derived therefrom. |
| 2066 | (c) Progress toward achieving the outputs and outcomes |
| 2067 | associated with each division and programs within the division. |
| 2068 | (d) An explanation of circumstances contributing to the |
| 2069 | department's ability to achieve, not achieve, or exceed its |
| 2070 | projected outputs and outcomes, as defined in s. 216.011, |
| 2071 | associated with each division and programs within the division. |
| 2072 | (e) Alternate courses of action that would result in |
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2073 administration of the same program in a more efficient or 2074 effective manner. The courses of action to be considered must 2075 include, but are not limited to: 2076 1. Whether the department could be organized in a more 2077 efficient and effective manner, including whether each 2078 division's mission, goals, or objectives should be redefined. 2079 The report must include a rationale for each department division 2080 and programs within the division, the return on investment of 2081 each division and programs within the division, the relatedness 2082 of the division and programs within the division to a public 2083 health function, and any federal funding support for each 2084 division and programs within the division. The review should 2085 recommend the reduction and restructuring of department bureaus 2086 and divisions. 2087 Whether the division and programs within the division 2. 2088 could be administered more efficiently or effectively to avoid 2089 duplication of activities and ensure that activities are 2090 adequately coordinated. 2091 3. Whether the division and programs within that division 2092 could be performed more efficiently or more effectively by 2093 another unit of government or a private entity. 2094 4. When compared to costs, whether effectiveness warrants 2095 elimination of the division or programs within the division or, 2096 if the division or a program within the division serves a limited interest, whether the division or program should be 2097 2098 redesigned to require users to finance program costs. 2099 5. Whether the cost to administer the division or program 2100 within the division exceeds license and other fee revenues paid

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2101 by those being regulated. 2102 Whether other changes could improve the efficiency and 6. 2103 effectiveness of the division or program within the division. 2104 The consequences of discontinuing such division or (f) 2105 programs within the division. If any discontinuation is 2106 recommended, such recommendation must be accompanied by a 2107 description of alternatives to implement such recommendation, 2108 including an implementation schedule for discontinuation and 2109 recommended procedures for assisting state agency employees 2110 affected by the discontinuation. 2111 Whether current performance measures and standards (g) 2112 should be reviewed or amended to assist department efforts in 2113 achieving outputs and outcome measures. Whether the information reported as part of the 2114 (h) 2115 state's performance-based program budgeting system has relevance 2116 and utility for the evaluation of each division and programs 2117 within the division. 2118 Whether department management has established control (i) 2119 systems sufficient to ensure that performance data are 2120 maintained and supported by department records and accurately 2121 presented in department performance reports. 2122 (3) No later than March 1, 2011, the department shall 2123 submit a report on its evaluation and justification review 2124 findings and recommendations to the President of the Senate, the 2125 Speaker of the House of Representatives, the chairs of the 2126 appropriate substantive committees, the chairs of the appropriations committees, the Legislative Auditing Committee, 2127 2128 the Governor, and the State Surgeon General. Page 76 of 82

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2129 Section 35. Subsection (3) is added to section 381.00315, 2130 Florida Statutes, to read:

2131 381.00315 Public health advisories; public health 2132 emergencies.—The State Health Officer is responsible for 2133 declaring public health emergencies and issuing public health 2134 advisories.

2135 (3) To facilitate effective emergency management, when the 2136 United States Department of Health and Human Services contracts 2137 for the manufacture and delivery of licensable products in 2138 response to a public health emergency and the terms of those 2139 contracts are made available to the states, the department shall 2140 accept funds provided by counties, municipalities, and other 2141 entities designated in the state emergency management plan 2142 required under s. 252.35(2)(a) for the purpose of participation in those contracts. The department shall deposit those funds in 2143 2144 the Grants and Donations Trust Fund and expend those funds on 2145 behalf of the donor county, municipality, or other entity for 2146 the purchase of the licensable products made available under the 2147 contract. 2148 Section 36. For fiscal year 2010-2011 only, and notwithstanding s. 216.181, Florida Statutes, the Department of 2149 2150 Health is authorized to submit a budget amendment requesting 2151 additional Grants and Donations Trust Fund budget authority for

2152 the Florida Center for Nursing to make expenditures supported by

2153 grants and donations.

2154 Section 37. Paragraph (a) of subsection (1) of section 2155 409.9201, Florida Statutes, is amended to read: 2156 409.9201 Medicaid fraud.-

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2157 As used in this section, the term: (1)2158 (a) "Prescription drug" means any drug, including, but not 2159 limited to, finished dosage forms or active ingredients that are 2160 subject to, defined by, or described by s. 503(b) of the Federal 2161 Food, Drug, and Cosmetic Act or by s. 465.003(8), s. 2162 499.003(46)(45) or (53) (52), or s. 499.007(13). 2163 2164 The value of individual items of the legend drugs or goods or 2165 services involved in distinct transactions committed during a 2166 single scheme or course of conduct, whether involving a single 2167 person or several persons, may be aggregated when determining the punishment for the offense. 2168 2169 Section 38. Subsection (3) of section 465.0265, Florida Statutes, is amended to read: 2170 2171 465.0265 Centralized prescription filling.-2172 (3) The filling, delivery, and return of a prescription by 2173 one pharmacy for another pursuant to this section shall not be 2174 construed as the filling of a transferred prescription as set forth in s. 465.026 or as a wholesale distribution as set forth 2175 in s. 499.003(54)(53). 2176 2177 Section 39. Paragraph (g) of subsection (2) of section 2178 499.01, Florida Statutes, are amended to read: 2179 499.01 Permits.-2180 The following permits are established: (2) 2181 (g) Restricted prescription drug distributor permit.-A 2182 restricted prescription drug distributor permit is required for 2183 any person that engages in the distribution of a prescription drug, which distribution is not considered "wholesale 2184 Page 78 of 82

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2185 distribution" under s. 499.003(54)(53)(a).

2186 1. A person who engages in the receipt or distribution of 2187 a prescription drug in this state for the purpose of processing 2188 its return or its destruction must obtain a permit as a 2189 restricted prescription drug distributor if such person is not 2190 the person initiating the return, the prescription drug 2191 wholesale supplier of the person initiating the return, or the 2192 manufacturer of the drug.

2193 2. Storage, handling, and recordkeeping of these 2194 distributions must comply with the requirements for wholesale 2195 distributors under s. 499.0121, but not those set forth in s. 2196 499.01212.

2197 3. A person who applies for a permit as a restricted 2198 prescription drug distributor, or for the renewal of such a 2199 permit, must provide to the department the information required 2200 under s. 499.012.

4. The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, or other persons not involved in wholesale distribution, which rules are necessary for the protection of the public health, safety, and welfare.

2206 Section 40. Paragraph (d) of subsection (4) of section 2207 499.0121, Florida Statutes, is amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs

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2213 and for the establishment and maintenance of prescription drug 2214 distribution records.

2215

(4) EXAMINATION OF MATERIALS AND RECORDS.-

(d) Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved. This includes authenticating each transaction listed on a pedigree paper, as defined in s. 499.003(37)(36).

2223 Section 41. Paragraphs (a) and (b) of subsection (2) of 2224 section 499.01211, Florida Statutes, are amended to read:

499.01211 Drug Wholesale Distributor Advisory Council.(2) The State Surgeon General, or his or her designee, and
the Secretary of Health Care Administration, or her or his
designee, shall be members of the council. The State Surgeon

2229 General shall appoint nine additional members to the council who 2230 shall be appointed to a term of 4 years each, as follows:

(a) Three different persons each of whom is employed by a different prescription drug wholesale distributor licensed under this part which operates nationally and is a primary wholesale distributor, as defined in s. 499.003(47)(46).

(b) One person employed by a prescription drug wholesale distributor licensed under this part which is a secondary wholesale distributor, as defined in s. 499.003(52)(51).

2238 Section 42. Subsection (1) of section 499.03, Florida 2239 Statutes, is amended to read:

2240 499.03 Possession of certain drugs without prescriptions Page 80 of 82

2241 unlawful; exemptions and exceptions.-

2242 (1) A person may not possess, or possess with intent to 2243 sell, dispense, or deliver, any habit-forming, toxic, harmful, 2244 or new drug subject to s. 499.003(33)(32), or prescription drug 2245 as defined in s. 499.003(43)(42), unless the possession of the drug has been obtained by a valid prescription of a practitioner 2246 2247 licensed by law to prescribe the drug. However, this section 2248 does not apply to the delivery of such drugs to persons included 2249 in any of the classes named in this subsection, or to the agents 2250 or employees of such persons, for use in the usual course of 2251 their businesses or practices or in the performance of their 2252 official duties, as the case may be; nor does this section apply 2253 to the possession of such drugs by those persons or their agents 2254 or employees for such use:

(a) A licensed pharmacist or any person under the licensed pharmacist's supervision while acting within the scope of the licensed pharmacist's practice;

(b) A licensed practitioner authorized by law to prescribe prescription drugs or any person under the licensed practitioner's supervision while acting within the scope of the licensed practitioner's practice;

(c) A qualified person who uses prescription drugs forlawful research, teaching, or testing, and not for resale;

(d) A licensed hospital or other institution that procures such drugs for lawful administration or dispensing by practitioners;

(e) An officer or employee of a federal, state, or local government; or

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2269 A person that holds a valid permit issued by the (f) 2270 department pursuant to this part which authorizes that person to 2271 possess prescription drugs. 2272 Section 43. Paragraphs (i) and (m) of subsection (1) of 2273 section 499.05, Florida Statutes, are amended to read: 2274 499.05 Rules.-2275 The department shall adopt rules to implement and (1)2276 enforce this part with respect to: 2277 (i) Additional conditions that qualify as an emergency 2278 medical reason under s. 499.003(54)(53)(b)2. 2279 The recordkeeping, storage, and handling with respect (m) 2280 to each of the distributions of prescription drugs specified in 2281 s. 499.003(54)(53)(a)-(d). 2282 Section 44. Subsection (1) of section 794.075, Florida 2283 Statutes, is amended to read: 2284 794.075 Sexual predators; erectile dysfunction drugs.-2285 (1) A person may not possess a prescription drug, as 2286 defined in s. 499.003(43)(42), for the purpose of treating 2287 erectile dysfunction if the person is designated as a sexual 2288 predator under s. 775.21. 2289 Section 45. Except as otherwise expressly provided in this 2290 act, this act shall take effect July 1, 2010.

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