## CHAPTER 2010-161

## House Bill No. 5311

An act relating to the Department of Health; amending s. 20.435, F.S.; revising provisions for administration and use of funds in the Administrative Trust Fund and the Emergency Medical Services Trust Fund; providing for such administration and use under specified provisions; amending ss. 318.14, 318.18, and 318.21, F.S.; providing that funds collected from disposition of certain motor vehicle infractions shall be deposited into the Emergency Medical Services Trust Fund; removing provisions for deposit of such funds into the Administrative Trust Fund; providing for use of the funds: correcting a reference; amending ss. 320.131, 327.35, 381.765, and 938.07, F.S.; correcting references to the Brain and Spinal Cord Injury Program Trust Fund; amending ss. 381.78 and 381.79, F.S.; correcting references; amending s. 395.403, F.S., relating to reimbursement of trauma centers; revising eligibility provisions to remove provisional trauma centers and certain hospitals; providing for payments to be made from the Emergency Medical Services Trust Fund; removing provisions for one-time payments from the Administrative Trust Fund; amending s. 395.4036, F.S.; providing for use of funds in the Emergency Medical Services Trust Fund for verified trauma centers; removing provisions for such use of funds in the Administrative Trust Fund; reenacting and amending s. 215.5602, F.S., relating to James and Esther King Biomedical Research Program; specifying that a certain amount of the revenue deposited into the Health Care Trust Fund be reserved for tobacco-related and cancer-related research; providing for specified amounts of revenue to be appropriated to the James and Esther King Biomedical Research Program, the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, and the H. Lee Moffitt Cancer Center and Research Institute; deleting obsolete language; reenacting and amending s. 381.922, F.S., relating to William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; providing that the program give emphasis to certain goals; specifying sources of funding for the program; providing for a portion of the funds to be made available to the Florida Center for Universal Research to Eradicate Disease; deleting obsolete language; amending s. 20.43, F.S.; removing a provision authorizing division directors in the Department of Health to appoint certain committees; prohibiting the department from establishing new programs or modifying current programs without legislative approval; requiring the department to notify the Governor and the Legislature before applying for continuation of or new federal or private grants over a specified amount; providing for content of the notification; amending s. 381.0011, F.S.; requiring the department to manage emergency preparedness and disaster response functions; amending s. 381.006, F.S.; revising the definition of the term "group care facility"; revising rulemaking authority; amending s. 381.0072, F.S.; revising the definition of the term "food service establishment"; authorizing the department to advise and consult with

other agencies concerning the provision of food services; revising entities that are exempt from rules developed for manager certification; repealing ss. 411.23, 411.231, and 411.232, F.S., relating to the Children's Early Investment Program: amending ss. 411.01 and 411.224, F.S.: conforming provisions to changes made by the act; amending s. 499.003, F.S.; defining the term "medical convenience kit" for purposes of the Florida Drug and Cosmetic Act; correcting cross-references; amending s. 499.01, F.S.; providing exceptions from requirements for a device manufacturer permit; amending s. 499.01212, F.S.; exempting wholesale distribution of prescription drugs within a medical convenience kit from requirements for the wholesaler to provide a pedigree paper if certain conditions are met; providing that the exemption does not apply to a kit containing certain controlled substances; amending s. 509.013, F.S.; revising exclusions to the definition of the terms "public lodging establishment" and "public food service establishment" to provide for certain facilities certified or licensed by the Agency for Health Care Administration or the Department of Children and Family Services; requiring the department to develop a plan to provide tuberculosis services; requiring the department to submit the plan to the Governor and Legislature by a specified date; providing plan elements; transferring and reassigning certain functions and responsibilities, including records, personnel, property, and unexpended balances of appropriations and other resources, from the Department of Health to the Department of Business and Professional Regulation by a type two transfer; providing for the continued validity of pending judicial or administrative actions to which the Department of Health is a party; providing for the continued validity of lawful orders issued by the Department of Health; transferring rules created by the Department of Health to the Department of Business and Professional Regulation; providing for the continued validity of permits and certifications issued by the Department of Health; amending s. 381.0403, F.S., deleting provisions relating to the program for graduate medical education innovations and the graduate medical education committee and report; conforming a cross-reference; amending s. 381.4018, F.S.; revising provisions for physician workforce assessment and development; providing definitions; creating the Physician Workforce Advisory Council; providing for membership and organization; providing duties of the council; amending ss. 458.3192 and 459.0082, F.S.; revising provisions for analysis by the department of physician surveys under specified provisions; amending s. 458.315; revising provisions for issuance by the Board of Medicine of a temporary certificate to practice medicine in certain areas; creating s. 459.0076, F.S.; providing for issuance by the Board of Osteopathic Medicine of a temporary certificate to practice osteopathic medicine in certain areas; directing the department to conduct an evaluation and justification review of its divisions; providing review requirements; requiring the department to submit a report to the Governor, the Legislature, and the State Surgeon General by a specified date; amending s. 381.00315, F.S.; directing the Department of Health to accept funds from counties, municipalities, and certain other entities for the purchase of certain products made available under a contract with the United States

Department of Health and Human Services for the manufacture and delivery of such products in response to a public health emergency; authorizing the department to submit a budget amendment requesting additional budget authority for the Florida Center for Nursing to make certain expenditures; amending ss. 409.9201, 465.0265, 499.01, 499.01211, 499.01212, 499.03, 499.05, and 794.075, F.S.; correcting cross-references; providing effective dates.

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

Section 1. Paragraph (a) of subsection (1) and paragraph (a) of subsection (14) of section 20.435, Florida Statutes, are amended to read:

20.435 Department of Health; trust funds.—The following trust funds shall be administered by the Department of Health:

(1) Administrative Trust Fund.

(a) Funds to be credited to <u>and uses of</u> the trust fund shall <u>be</u> <u>administered in accordance with s. 215.32</u> consist of regulatory fees such as those pertaining to the licensing, permitting, and inspection of septic tanks, food hygiene, onsite sewage, Superfund compliance, solid waste management, tanning facilities, mobile home and recreational vehicle park inspection, other departmental regulatory and health care programs, and indirect earnings from grants. Funds shall be used for the purpose of supporting the regulatory activities of the department and for other such purposes as may be appropriate and shall be expended only pursuant to legislative appropriation or an approved amendment to the department's operating budget pursuant to the provisions of chapter 216.

(14) Emergency Medical Services Trust Fund.

(a) Funds to be credited to and uses of the trust fund shall be administered in accordance with <u>ss. 318.14, 318.18, 318.21, 395.403, and 395.4036 and the provisions of parts I and II of chapter 401.</u>

Section 2. Subsection (5) of section 318.14, Florida Statutes, is amended to read:

318.14 Noncriminal traffic infractions; exception; procedures.—

(5) Any person electing to appear before the designated official or who is required so to appear shall be deemed to have waived his or her right to the civil penalty provisions of s. 318.18. The official, after a hearing, shall make a determination as to whether an infraction has been committed. If the commission of an infraction has been proven, the official may impose a civil penalty not to exceed \$500, except that in cases involving unlawful speed in a school zone or involving unlawful speed in a construction zone, the civil penalty may not exceed \$1,000; or require attendance at a driver improvement school, or both. If the person is required to appear before the designated official pursuant to s. 318.19(1) and is found to have committed the infraction, the designated official shall impose a civil penalty of \$1,000 in addition to any other penalties and the person's driver's license shall be suspended for 6 months. If the person is required to appear before the designated official pursuant to s. 318.19(2) and is found to have committed the infraction, the designated official shall impose a civil penalty of \$500 in addition to any other penalties and the person's driver's license shall be suspended for 3 months. If the official determines that no infraction has been committed, no costs or penalties shall be imposed and any costs or penalties that have been paid shall be returned. Moneys received from the mandatory civil penalties imposed pursuant to this subsection upon persons required to appear before a designated official pursuant to s. 318.19(1) or (2) shall be remitted to the Department of Revenue and deposited into the Department of Health Emergency Medical Services Administrative Trust Fund to provide financial support to certified trauma centers to assure the availability and accessibility of trauma services throughout the state. Funds deposited into the Emergency Medical Services Administrative Trust Fund under this section 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.

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

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

(3)

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

4

1. 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.

2. 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.

(5)

(c) In addition to the penalty under paragraph (a) or paragraph (b), 655 for a violation of s. 316.172(1)(a) or (b). If the alleged offender is found to have committed the offense, the court shall impose the civil penalty under paragraph (a) or paragraph (b) plus an additional 655. The additional 655 collected under this paragraph 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.

(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 as follows:

(2) Of the remainder:

(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.

(15) Of the additional fine assessed under s. 318.18(3)(e) for a violation of s. 316.1893, 50 percent of the moneys received from the fines shall be appropriated to the Agency for Health Care Administration as general revenue to provide an enhanced Medicaid payment to nursing homes that serve Medicaid recipients with brain and spinal cord injuries. The remaining 50 percent of the moneys received from the enhanced fine imposed under s. 318.18(3)(e) shall be remitted to the Department of Revenue and deposited into the Department of Health <u>Emergency Medical Services Administrative</u> Trust Fund to provide financial support to certified trauma centers in the counties where enhanced penalty zones are established to ensure the availability and accessibility of trauma services. Funds deposited into the

<u>Emergency Medical Services</u> Administrative 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.

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

320.131 Temporary tags.—

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

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

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

(9) Notwithstanding any other provision of this section, for any person convicted of a violation of subsection (1), in addition to the fines set forth in subsections (2) and (4), an additional fine of \$60 shall be assessed and collected in the same manner as the fines set forth in subsections (2) and (4). All fines collected under this subsection shall be remitted by the clerk of the court to the Department of Revenue for deposit into the Brain and Spinal Cord Injury Program Rehabilitation Trust Fund and used for the purposes set forth in s. 381.79, after 5 percent is deducted therefrom by the clerk of the court for administrative costs.

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

381.765 Retention of title to and disposal of equipment.—

(2) The department may offer for sale any surplus items acquired in operating the brain and spinal cord injury program when they are no longer

necessary or exchange them for necessary items that may be used to greater advantage. When any such surplus equipment is sold or exchanged, a receipt for the equipment shall be taken from the purchaser showing the consideration given for such equipment and forwarded to the Chief Financial Officer, and any funds received by the brain and spinal cord injury program pursuant to any such transaction shall be deposited in the Brain and Spinal Cord Injury <u>Program Rehabilitation</u> Trust Fund and shall be available for expenditure for any purpose consistent with <u>ss. 381.739-381.79</u> this part.

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

381.78 Advisory council on brain and spinal cord injuries.—

(7) A member of the advisory council may be removed from office by the State Surgeon General for malfeasance, misfeasance, neglect of duty, incompetence, or permanent inability to perform official duties or for pleading nolo contendere to, or being found guilty of, a crime. Malfeasance includes, but is not limited to, a violation of any specific prohibition within <u>ss.</u> <u>381.739-381.79</u> this part.

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

381.79 Brain and Spinal Cord Injury Program Trust Fund.—

(6) The department may accept, deposit into the trust fund, and use for carrying out the purposes of <u>ss. 381.739-381.79</u> this part gifts made unconditionally by will or otherwise. Any gift made under conditions that, in the judgment of the department, are proper and consistent with this section, the laws of the United States, and the laws of this state may be accepted and shall be held, invested, reinvested, and used in accordance with the conditions of the gift.

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

395.403 Reimbursement of trauma centers.—

(1) All provisional trauma centers and trauma centers shall be considered eligible to receive state funding when state funds are specifically appropriated for state-sponsored trauma centers in the General Appropriations Act. Effective July 1, <u>2010</u> 2004, the department shall make one-time payments from the <u>Emergency Medical Services</u> Administrative Trust Fund under s. 20.435 to the trauma centers and a hospital with a pending application for a Level I trauma center in recognition of the capital investment made by the hospital to establish the trauma service. Payments shall be in equal amounts for the trauma centers approved by the department as of July 1 of the fiscal year in which funding is appropriated, with lesser amounts for the hospital with an application pending for a Level I trauma center at the department as of April 1, 2004. In the event a trauma

center does not maintain its status as a trauma center for any state fiscal year in which such funding is appropriated, the <del>provisional trauma center or</del> trauma center shall repay the state for the portion of the year during which it was not a trauma center.

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

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

395.4036 Trauma payments.—

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

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

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

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

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

8

(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.

2. Thirty-five percent of the total funds collected shall be distributed to verified trauma centers based on trauma caseload volume for the most recent calendar year available. The determination of caseload volume for distribution of funds under this subparagraph shall be based on the department's Trauma Registry data.

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

(2) Funds deposited in the department's Emergency Medical Services Administrative Trust Fund for verified trauma centers may be used to maximize the receipt of federal funds that may be available for such trauma centers. Notwithstanding this section and s. 318.14, distributions to trauma centers may be adjusted in a manner to ensure that total payments to trauma centers represent the same proportional allocation as set forth in this section and s. 318.14. For purposes of this section and s. 318.14, total funds distributed to trauma centers may include revenue from the Emergency Medical Services Administrative Trust Fund and federal funds for which revenue from the Administrative Trust Fund is used to meet state or local matching requirements. Funds collected under ss. 318.14 and 318.18 and deposited in the Emergency Medical Services Administrative Trust Fund of the department shall be distributed to trauma centers on a quarterly basis using the most recent calendar year data available. Such data shall not be used for more than four quarterly distributions unless there are extenuating circumstances as determined by the department, in which case the most recent calendar year data available shall continue to be used and appropriate adjustments shall be made as soon as the more recent data becomes available.

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

938.07 Driving or boating under the influence.—Notwithstanding any other provision of s. 316.193 or s. 327.35, a court cost of \$135 shall be added to any fine imposed pursuant to s. 316.193 or s. 327.35. The clerks shall remit the funds to the Department of Revenue, \$25 of which shall be deposited in

the Emergency Medical Services Trust Fund, \$50 shall be deposited in the Operating Trust Fund of the Department of Law Enforcement to be used for operational expenses in conducting the statewide criminal analysis laboratory system established in s. 943.32, and \$60 shall be deposited in the Brain and Spinal Cord Injury <u>Program</u> Rehabilitation Trust Fund created in s. 381.79.

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

215.5602 James and Esther King Biomedical Research Program.—

(1) There is established within the Department of Health the James and Esther King Biomedical Research Program funded by the proceeds of the Lawton Chiles Endowment Fund pursuant to s. 215.5601. The purpose of the James and Esther King Biomedical Research Program is to provide an annual and perpetual source of funding in order to support research initiatives that address the health care problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary 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.

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

10

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

(a) The council shall consist of 11 members, including: the chief executive officer of the Florida Division of the American Cancer Society, or a designee; the chief executive officer of the Florida/Puerto Rico Affiliate of the American Heart Association, or a designee; and the chief executive officer of the American Lung Association of Florida, or a designee. The remaining 8 members of the council shall be 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.

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

3. The Speaker of the House of Representatives shall appoint two members, one member from a professional medical organization and one representative from a cancer program approved by the American College of Surgeons.

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

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

(c) The department shall provide such staff, information, and other assistance as is reasonably necessary to assist the 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:

(a) Providing advice on program priorities and emphases.

(b) Providing advice on the overall program budget.

(c) Participating in periodic program evaluation.

(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.

(f) Developing criteria and standards for the award of 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.

(h) Developing and supervising research peer review panels.

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

(j) Developing and providing oversight regarding 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 peer review process that ensures objectivity, consistency, and high quality. The following types of applications shall be considered for funding:

1. Investigator-initiated research grants.

2. Institutional research grants.

3. Predoctoral and postdoctoral research fellowships.

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

(7) The council and the peer review panel shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with

regard to conflict of interest. A member of the council or panel may not participate in any discussion or decision with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee, or with which the member has entered into a contractual arrangement. Meetings 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 the State Constitution.

(8) The department may contract on a competitive-bid basis with an appropriate entity to administer the program. Administrative expenses may not exceed 15 percent of the total 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:

 $(a) \quad A \ list of research projects supported by grants or fellowships awarded under the program.$ 

(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 funding currently 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.

(12) From funds appropriated to accomplish the goals of this section, up to \$250,000 shall be available for the operating costs of the Florida Center for Universal Research to Eradicate Disease.

(a) Beginning in the <u>2010-2011</u> <u>2009-2010</u> fiscal year and thereafter, <u>\$50</u> <u>million from</u> <u>5 percent of</u> the revenue deposited into the Health Care Trust Fund pursuant to ss. 210.011(9) and 210.276(7) shall be reserved for research

13

of tobacco-related or cancer-related illnesses; however, the sum of the revenue reserved pursuant to ss. 210.011(9) and 210.276(7) may not exceed \$50 million in any fiscal year. Of the revenue deposited in the Health Care Trust Fund pursuant to this section, \$50 million shall be transferred to the Biomedical Research Trust Fund within the Department of Health. Subject to annual appropriations in the General Appropriations Act, \$20 million shall be appropriated to the James and Esther King Biomedical Research Program, \$20 million shall be appropriated to the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program created under s. 381.922, and \$10 million shall be appropriated to the H. Lee Moffitt Cancer Center and Research Institute established under s. 1004.43.

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

(13) By June 1, 2009, the Division of Statutory Revision of the Office of Legislative Services shall certify to the President of the Senate and the Speaker of the House of Representatives the language and statutory citation of this section, which is scheduled to expire January 1, 2011.

(14) The Legislature shall review the performance, the outcomes, and the financial management of the James and Esther King Biomedical Research Program during the 2010 Regular Session of the Legislature and shall determine the most appropriate funding source and means of funding the program based on its review.

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

Section 14. Section 381.922, Florida Statutes, is reenacted and amended to read:

381.922 William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.—

(1) The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, which may be otherwise cited as the "Bankhead-Coley Program," is created within the Department of Health. The purpose of the program shall be to advance progress towards cures for cancer through grants awarded through a peer-reviewed, competitive process.

(2) The program shall provide grants for cancer research to further the search for cures for cancer.

(a) Emphasis shall be given to the <u>following</u> goals <del>enumerated in s.</del> <del>381.921</del>, as those goals support the advancement of such cures:</del>

1. Efforts to significantly expand cancer research capacity in the state by:

a. Identifying ways to attract new research talent and attendant national grant-producing researchers to cancer research facilities in this state;

b. Implementing a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research institutes in this state;

c. Funding through available resources for those proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support;

d. Encouraging the employment of bioinformatics in order to create a cancer informatics infrastructure that enhances information and resource exchange and integration through researchers working in diverse disciplines, to facilitate the full spectrum of cancer investigations;

e. Facilitating the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research; and

f. Aiding in other multidisciplinary research-support activities as they inure to the advancement of cancer research.

2. Efforts to improve both research and treatment through greater participation in clinical trials networks by:

a. Identifying ways to increase adult enrollment in cancer clinical trials;

b. Supporting public and private professional education programs designed to increase the awareness and knowledge about cancer clinical trials;

c. Providing tools to cancer patients and community-based oncologists to aid in the identification of cancer clinical trials available in the state; and

d. Creating opportunities for the state's academic cancer centers to collaborate with community-based oncologists in cancer clinical trials networks.

3. Efforts to reduce the impact of cancer on disparate groups by:

a. Identifying those cancers that disproportionately impact certain demographic groups; and

b. Building collaborations designed to reduce health disparities as they relate to cancer.

(b) Preference may be given to grant proposals that foster collaborations among institutions, researchers, and community practitioners, as such proposals support the advancement of cures through basic or applied research, including clinical trials involving cancer patients and related networks. (3)(a) Applications for funding for cancer research may be submitted by any university or established research institute in the state. All qualified investigators in the state, regardless of institutional affiliation, shall have equal access and opportunity to compete for the research funding. Collaborative proposals, including those that advance the program's goals enumerated in subsection (2), may be given preference. Grants shall be awarded by the State Surgeon General, after consultation with the Biomedical Research Advisory Council, on the basis of scientific merit, as determined by an open, competitive peer review process that ensures objectivity, consistency, and high quality. The following types of applications shall be considered for funding:

1. Investigator-initiated research grants.

2. Institutional research grants.

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

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

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

(4) By December 15 of each year, the Department of Health shall submit to the Governor, the President of the Senate, and the Speaker of the House of Representatives a report indicating progress towards the program's mission and making recommendations that further its purpose.

(5) <u>The William G. "Bill" Bankhead, Jr., and David Coley Cancer</u> <u>Research Program is funded pursuant to s. 215.5602(12).</u> Funds appropriated for the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program shall be distributed pursuant to this section to provide grants to researchers seeking cures for cancer and cancer-related illnesses, with emphasis given to the goals enumerated in <u>this section s. 381.921</u>. From the total funds appropriated, an amount of up to 10 percent may be used for administrative expenses. <u>From funds appropriated to accomplish the goals of</u> this section, up to \$250,000 shall be available for the operating costs of the Florida Center for Universal Research to Eradicate Disease. In the 2009-2010 fiscal year, 2.5 percent, not to exceed \$25 million, of the revenue deposited into the Health Care Trust Fund pursuant to s. 215.5602(12)(a) shall be transferred to the Biomedical Research Trust Fund within the Department of Health for the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.

(6) By June 1, 2009, the Division of Statutory Revision of the Office of Legislative Services shall certify to the President of the Senate and the Speaker of the House of Representatives the language and statutory citation of this section, which is scheduled to expire January 1, 2011.

(7) The Legislature shall review the performance, the outcomes, and the financial management of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program during the 2010 Regular Session of the Legislature and shall determine the most appropriate funding source and means of funding the program based on its review.

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

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

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

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

(10)(a) Beginning in fiscal year 2010-2011, the department shall initiate or commence new programs only when the Legislative Budget Commission or the Legislature expressly 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 notification must include detailed information about the purpose of the grant, the intended use of the funds, and the number of full-time permanent or temporary employees needed to administer the program funded by the grant. Section 16. Subsection (14) of section 381.0011, Florida Statutes, is renumbered as subsection (15), and a new subsection (14) is added to that section, to read:

381.0011 Duties and powers of the Department of Health.—It is the duty of the Department of Health to:

(14) Manage and coordinate emergency preparedness and disaster response functions to: investigate and control the spread of disease; coordinate the availability and staffing of special needs shelters; support patient evacuation; ensure the safety of food and drugs; provide critical incident stress debriefing; and provide surveillance and control of radiological, chemical, biological, and other environmental hazards.

Section 17. Subsection (16) of section 381.006, Florida Statutes, is amended to read:

381.006 Environmental health.—The department shall conduct an environmental health program as part of fulfilling the state's public health mission. The purpose of this program is to detect and prevent disease caused by natural and manmade factors in the environment. The environmental health program shall include, but not be limited to:

(16) A group-care-facilities function. As used in this subsection, the term, where a "group care facility" means any public or private school, assisted living facility, adult family-care home, adult day care center, short-term residential treatment center, residential treatment facility, home for special services, transitional living facility, crisis stabilization unit, hospice, prescribed pediatric extended care center, intermediate care facility for persons with developmental disabilities, or boarding school housing, building or buildings, section of a building, or distinct part of a building or other place, whether operated for profit or not, which undertakes, through its ownership or management, to provide one or more personal services, care, protection, and supervision to persons who require such services and who are not related to the owner or administrator. The department may adopt rules necessary to protect the health and safety of residents, staff, and patrons of group care facilities. Rules related to public and private schools shall be developed by such as child care facilities, family day care homes, assisted living facilities, adult day care centers, adult family care homes, hospices, residential treatment facilities, crisis stabilization units, pediatric extended care centers, intermediate care facilities for the developmentally disabled, group care homes, and, jointly with the Department of Education in consultation with the department, private and public schools. These Rules adopted under this subsection may include definitions of terms; provisions relating to operation and maintenance of facilities, buildings, grounds, equipment, furnishings, and occupant-space requirements; lighting; heating, cooling, and ventilation; food service; water supply and plumbing; sewage; sanitary facilities; insect and rodent control; garbage; safety; personnel health, hygiene, and work practices; and other matters the department finds are appropriate or necessary to protect the safety and health of the residents,

staff, <u>students</u>, <u>faculty</u>, or patrons. The department may not adopt rules that conflict with rules adopted by the licensing or certifying agency. The department may enter and inspect at reasonable hours to determine compliance with applicable statutes or rules. In addition to any sanctions that the department may impose for violations of rules adopted under this section, the department shall also report such violations to any agency responsible for licensing or certifying the group care facility. The licensing or certifying agency may also impose any sanction based solely on the findings of the department.

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

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

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

(1) DEFINITIONS.—As used in this section, the term:

(a) "Department" means the Department of Health or its representative county health department.

(b) "Food service establishment" means detention facilities, public or private schools, migrant labor camps, assisted living facilities, adult familycare homes, adult day care centers, short-term residential treatment centers, residential treatment facilities, homes for special services, transitional living facilities, crisis stabilization units, hospices, prescribed pediatric extended care centers, intermediate care facilities for persons with developmental disabilities, boarding schools, civic or fraternal organizations, bars and lounges, vending machines that dispense potentially hazardous foods at facilities expressly named in this paragraph, and facilities used as temporary food events or mobile food units at any facility expressly named any facility, as described in this paragraph, where food is prepared and intended for individual portion service, including and includes the site at which individual portions are provided. The term includes any such facility regardless of whether consumption is on or off the premises and regardless of whether there is a charge for the food. The term includes detention facilities, child care facilities, schools, institutions, civic or fraternal organizations, bars and lounges and facilities used at temporary food events, mobile food units, and vending machines at any facility regulated under this section. The term does not include any entity not expressly named in this paragraph private homes where food is prepared or served for individual family consumption; nor does the term include churches, synagogues, or other not-for-profit religious organizations as long as these organizations

serve only their members and guests and do not advertise food or drink for public consumption, or any facility or establishment permitted or licensed under chapter 500 or chapter 509; nor does the term include any theater, if the primary use is as a theater and if patron service is limited to food items customarily served to the admittees of theaters; nor does the term include a research and development test kitchen limited to the use of employees and which is not open to the general public.

(c) "Operator" means the owner, operator, keeper, proprietor, lessee, manager, assistant manager, agent, or employee of a food service establishment.

(2) DUTIES.—

(a) The department may advise and consult with the Agency for Health Care Administration, the Department of Business and Professional Regulation, the Department of Agriculture and Consumer Services, and the Department of Children and Family Services concerning procedures related to the storage, preparation, serving, or display of food at any building, structure, or facility not expressly included in this section that is inspected, licensed, or regulated by those agencies.

(b)(a) The department shall adopt rules, including definitions of terms which are consistent with law prescribing minimum sanitation standards and manager certification requirements as prescribed in s. 509.039, and which shall be enforced in food service establishments as defined in this section. The sanitation standards must address the construction, operation, and maintenance of the establishment; lighting, ventilation, laundry rooms, lockers, use and storage of toxic materials and cleaning compounds, and firstaid supplies; plan review; design, construction, installation, location, maintenance, sanitation, and storage of food equipment and utensils; employee training, health, hygiene, and work practices; food supplies, preparation, storage, transportation, and service, including access to the areas where food is stored or prepared; and sanitary facilities and controls, including water supply and sewage disposal; plumbing and toilet facilities; garbage and refuse collection, storage, and disposal; and vermin control. Public and private schools, if the food service is operated by school employees,; hospitals licensed under chapter 395; nursing homes licensed under part II of chapter 400; child care facilities as defined in s. 402.301; residential facilities colocated with a nursing home or hospital, if all food is prepared in a central kitchen that complies with nursing or hospital regulations; and bars and lounges, civic organizations, and any other facility that is not regulated under this section as defined by department rule, are exempt from the rules developed for manager certification. The department shall administer a comprehensive inspection, monitoring, and sampling program to ensure such standards are maintained. With respect to food service establishments permitted or licensed under chapter 500 or chapter 509, the department shall assist the Division of Hotels and Restaurants of the Department of Business and Professional Regulation and the

20

Department of Agriculture and Consumer Services with rulemaking by providing technical information.

 $(\underline{c})(\underline{b})$  The department shall carry out all provisions of this chapter and all other applicable laws and rules relating to the inspection or regulation of food service establishments as defined in this section, for the purpose of safeguarding the public's health, safety, and welfare.

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

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

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

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

(a) In the course of epidemiological investigations or for those establishments regulated <u>by the department</u> under this chapter, the department, to protect the public from food that is unwholesome or otherwise unfit for human consumption, may examine, sample, seize, and stop the sale or use of food to determine its condition. The department may stop the sale and

supervise the proper destruction of food when the State Health Officer or his or her designee determines that such food 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 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.

Section 19. <u>Sections 411.23, 411.231, and 411.232, Florida Statutes, are repealed.</u>

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

411.01 School readiness programs; early learning coalitions.—

(5) CREATION OF EARLY LEARNING COALITIONS.—

(d) Implementation.—

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

2. Each early learning coalition shall develop a plan for implementing the school readiness program to meet the requirements of this section and the performance standards and outcome measures adopted by the Agency for Workforce Innovation. The plan must demonstrate how the program will ensure that each 3-year-old and 4-year-old child in a publicly funded school readiness program receives scheduled activities and instruction designed to enhance the age-appropriate progress of the children in attaining the performance standards adopted by the Agency for Workforce Innovation under subparagraph (4)(d)8. Before implementing the school readiness program, the early learning coalition must submit the plan to the Agency for Workforce Innovation for approval. The Agency for Workforce Innovation may approve the plan, reject the plan, or approve the plan with conditions. The Agency for Workforce Innovation shall review school readiness plans at least annually.

3. If the Agency for Workforce Innovation determines during the annual review of school readiness plans, or through monitoring and performance evaluations conducted under paragraph (4)(1), that an early learning coalition has not substantially implemented its plan, has not substantially met the performance standards and outcome measures adopted by the agency, or has not effectively administered the school readiness program or

Voluntary Prekindergarten Education Program, the Agency for Workforce Innovation may dissolve the coalition and temporarily contract with a qualified entity to continue school readiness and prekindergarten services in the coalition's county or multicounty region until the coalition is reestablished through resubmission of a school readiness plan and approval by the agency.

4. The Agency for Workforce Innovation shall adopt criteria for the approval of school readiness plans. The criteria must be consistent with the performance standards and outcome measures adopted by the agency and must require each approved plan to include the following minimum standards and 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 program's budget.

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

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

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

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

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

g. Systems support services, including a central agency, child care resource and referral, eligibility determinations, 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.

i. The business organization of the early learning coalition, which must include the coalition's articles of incorporation and bylaws if the coalition is organized as a corporation. If the coalition is not organized as a corporation or other business entity, the plan must include the contract with a fiscal agent. An early learning coalition may contract with other coalitions to achieve efficiency in multicounty services, and these contracts may be part of the coalition's 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 coalition may request the Governor to apply for a waiver to allow the coalition to administer the Head Start Program to accomplish the purposes of the school readiness program. If a school readiness plan demonstrates that specific statutory goals can be achieved more effectively by using procedures that require modification of existing rules, policies, or procedures, a request for a waiver to the Agency for Workforce Innovation may be submitted as part of the plan. Upon review, the Agency for Workforce Innovation may grant the proposed modification.

5. Persons with an early childhood teaching certificate may provide support and supervision to other staff in the school 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 shall be controlled by the early learning coalition. The plan shall be reviewed and revised as necessary, but at least biennially. An early learning coalition may not implement the revisions until the coalition submits the revised plan to and receives approval from the Agency for Workforce Innovation. If the Agency for Workforce Innovation rejects a revised plan, the coalition must continue to operate under its prior approved plan.

7. Sections 125.901(2)(a)3. and, 411.221, and 411.232 do not apply to an early learning coalition with an approved school readiness plan. To facilitate innovative practices and to allow the regional establishment of school readiness programs, an early learning coalition may apply to the Governor and Cabinet 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 waiver is necessary for implementation of the coalition's school readiness plan.

8. Two or more counties may join for purposes of planning 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.

10. An early learning coalition may enter into multiparty contracts with multicounty service providers in order to meet the needs of unique populations such as migrant workers.

Section 21. Subsection (2) of section 411.224, Florida Statutes, is amended to read:

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

(2) To the extent possible within existing resources, the following populations must be included in the family support 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 by the 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.

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

(e)(f) Healthy Start participants in need of ongoing service coordination.

(f)(g) Children from birth through age 5 who are served by the voluntary family services, protective supervision, foster care, or adoption and related services programs of the Child Care Services Program Office of the Department of Children and 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.

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

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

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

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

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

499.01 Permits.-

(2) The following permits are established:

(q) Device manufacturer permit.—

<u>1.</u> A device manufacturer permit is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this state, except that a permit is not required if:

<u>a.</u> The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner's order for a specific patient; or

b. The person does not manufacture, repackage, or assemble any medical devices or components for such devices, except those devices or components which are exempt from registration pursuant to s. 499.015(8).

<u>2.1.</u> A manufacturer or repackager of medical devices in this state must comply with all appropriate state and federal good manufacturing practices and quality system rules.

<u>3.2.</u> The department shall adopt rules related to storage, handling, and recordkeeping requirements for manufacturers of medical devices for human use.

Section 24. Paragraph (i) is added to subsection (3) of section 499.01212, Florida Statutes, to read:

499.01212 Pedigree paper.—

(3) EXCEPTIONS.—A pedigree paper is not required for:

(i) The wholesale distribution of prescription drugs within a medical convenience kit if:

1. The medical convenience kit is assembled in an establishment that is registered with the United States Food and Drug Administration as a medical device manufacturer;

2. The medical convenience kit manufacturer purchased the prescription drug directly from the manufacturer or from a wholesaler that purchased the prescription drug directly from the manufacturer;

3. The medical convenience kit manufacturer complies with federal law for the distribution of the prescription drugs within the kit; and

4. The drugs contained in the medical kit are:

a. Intravenous solutions intended for the replenishment of fluids and electrolytes;

b. Products intended to maintain the equilibrium of water and minerals in the body;

c. Products intended for irrigation or reconstitution;

d. Anesthetics; or

e. Anticoagulants.

This exemption does not apply to a convenience kit containing any controlled substance that appears in a schedule contained in or subject to chapter 893 or the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

Section 25. Subsections (4) and (5) of section 509.013, Florida Statutes, are amended to read:

509.013 Definitions.—As used in this chapter, the term:

(4)(a) "Public lodging establishment" includes a transient public lodging establishment as defined in subparagraph 1. and a nontransient public lodging establishment as defined in subparagraph 2.

1. "Transient public lodging establishment" means any unit, group of units, dwelling, building, or group of buildings within a single complex of buildings which is rented to guests more than three times in a calendar year for periods of less than 30 days or 1 calendar month, whichever is less, or which is advertised or held out to the public as a place regularly rented to guests.

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

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

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

1. 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;

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

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

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

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

6. Any establishment inspected by the Department of Health 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.

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

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

a. For the use of students and faculty; or

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

2. Any eating place maintained and operated by a church or a religious, nonprofit fraternal, or nonprofit civic organization:

a. For the use of members and associates; or

b. Temporarily to serve such events as fairs, carnivals, or athletic contests.

28

3. Any eating place located on an airplane, train, bus, or watercraft which is a common carrier.

4. Any eating place maintained by a <u>facility certified or licensed and</u> regulated by the Agency for Health Care Administration or the Department of Children and Family Services hospital, nursing home, sanitarium, assisted living facility, adult day care center, or other similar place that is regulated under s. 381.0072.

5. Any place of business issued a permit or inspected by the Department of Agriculture and Consumer Services under s. 500.12.

6. Any place of business where the food available for consumption is limited to ice, beverages with or without garnishment, popcorn, or prepackaged items sold without additions or preparation.

7. Any theater, if the primary use is as a theater and if patron service is limited to food items customarily served to the admittees of theaters.

8. Any vending machine that dispenses any food or beverages other than potentially hazardous foods, as defined by division rule.

9. Any vending machine that dispenses potentially hazardous food and which is located in a facility regulated under s. 381.0072.

10. Any research and development test kitchen limited to the use of employees and which is not open to the general public.

Section 26. The Department of Health shall develop a plan that exclusively uses private and nonstate public hospitals to provide treatment to cure, hospitalization, and isolation for persons with contagious cases of tuberculosis who pose a threat to the public. The department shall submit the plan to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1, 2010. The plan shall include the following elements:

(1) Identification of hospitals functionally capable of caring for such patients.

(2) Reimbursement for hospital inpatient services at the Medicaid rate and reimbursement for other medically necessary services that are not hospital inpatient services at the relevant Medicaid rate.

(3) Projected cost estimates.

(4) A transition plan for closing the A. G. Holley State Hospital and transferring patients to private and nonstate public hospitals over a 90-day period of time.

Section 27. (1) All of the statutory powers, duties, and functions, records, personnel, property, and unexpended balances of appropriations,

allocations, or other funds for the administration of chapter 499, Florida Statutes, relating to drugs, devices, cosmetics, and household products shall be transferred by a type two transfer, as defined in s. 20.06(2), Florida Statutes, from the Department of Health to the Department of Business and Professional Regulation.

(2) The transfer of regulatory authority under chapter 499, Florida Statutes, provided by this section shall not affect the validity of any judicial or administrative action pending as of 11:59 p.m. on the day before the effective date of this section to which the Department of Health is at that time a party, and the Department of Business and Professional Regulation shall be substituted as a party in interest in any such action.

(3) All lawful orders issued by the Department of Health implementing or enforcing or otherwise in regard to any provision of chapter 499, Florida Statutes, issued prior to the effective date of this section shall remain in effect and be enforceable after the effective date of this section unless thereafter modified in accordance with law.

(4) The rules of the Department of Health relating to the implementation of chapter 499, Florida Statutes, that were in effect at 11:59 p.m. on the day prior to the effective date of this section shall become the rules of the Department of Business and Professional Regulation and shall remain in effect until amended or repealed in the manner provided by law.

(5) Notwithstanding the transfer of regulatory authority under chapter 499, Florida Statutes, provided by this section, persons and entities holding in good standing any permit under chapter 499, Florida Statutes, as of 11:59 p.m. on the day prior to the effective date of this section shall, as of the effective date of this section, be deemed to hold in good standing a permit in the same capacity as that for which the permit was formerly issued.

(6) Notwithstanding the transfer of regulatory authority under chapter 499, Florida Statutes, provided by this section, persons holding in good standing any certification under chapter 499, Florida Statutes, as of 11:59 p.m. on the day prior to the effective date of this section shall, as of the effective date of this section, be deemed to be certified in the same capacity in which they were formerly certified.

(7) This section shall take effect October 1, 2011.

Section 28. Paragraph (a) of subsection (3) and subsections (9) and (10) of section 381.0403, Florida Statutes, are amended to read:

381.0403 The Community Hospital Education Act.—

(3) PROGRAM FOR COMMUNITY HOSPITAL EDUCATION; STATE AND LOCAL PLANNING.—

(a) There is established under the Department of Health a program for statewide graduate medical education. It is intended that continuing

graduate medical education programs for interns and residents be established on a statewide basis. The program shall provide financial support for primary care specialty interns and residents based on policies recommended and approved by the Community Hospital Education Council, herein established, and the Department of Health. Only those programs with at least three residents or interns in each year of the training program are qualified to apply for financial support. Programs with fewer than three residents or interns per training year are qualified to apply for financial support, but only if the appropriate accrediting entity for the particular specialty has approved the program for fewer positions. Programs added after fiscal year 1997-1998 shall have 5 years to attain the requisite number of residents or interns. When feasible and to the extent allowed through the General Appropriations Act, state funds shall be used to generate federal matching funds under Medicaid, or other federal programs, and the resulting combined state and federal funds shall be allocated to participating hospitals for the support of graduate medical education. The department may spend up to \$75,000 of the state appropriation for administrative costs associated with the production of the annual report as specified in subsection (9), and for administration of the program.

(9) ANNUAL REPORT ON GRADUATE MEDICAL EDUCATION; COMMITTEE. The Executive Office of the Governor, the Department of Health, and the Agency for Health Care Administration shall collaborate to establish a committee that shall produce an annual report on graduate medical education. The committee shall be comprised of 11 members: five members shall be deans of the medical schools or their designees; the Governor shall appoint two members, one of whom must be a representative of the Florida Medical Association who has supervised or currently supervises residents or interns and one of whom must be a representative of the Florida Hospital Association; the Secretary of Health Care Administration shall appoint two members, one of whom must be a representative of a statutory teaching hospital and one of whom must be a physician who has supervised or is currently supervising residents or interns; and the State Surgeon General shall appoint two members, one of whom must be a representative of a statutory family practice teaching hospital and one of whom must be a physician who has supervised or is currently supervising residents or interns. With the exception of the deans, members shall serve 4year terms. In order to stagger the terms, the Governor's appointees shall serve initial terms of 4 years, the State Surgeon General's appointees shall serve initial terms of 3 years, and the Secretary of Health Care Administration's appointees shall serve initial terms of 2 years. A member's term shall be deemed terminated when the member's representative status no longer exists. Once the committee is appointed, it shall elect a chair to serve for a 1-year term. The report shall be provided to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 15 annually. Committee members shall serve without compensation. The report shall address the following:

(a) The role of residents and medical faculty in the provision of health care.

(b) The relationship of graduate medical education to the state's physician workforce.

(c) The costs of training medical residents for hospitals, medical schools, teaching hospitals, including all hospital-medical affiliations, practice plans at all of the medical schools, and municipalities.

(d) The availability and adequacy of all sources of revenue to support graduate medical education and recommend alternative sources of funding for graduate medical education.

(e) The use of state and federal appropriated funds for graduate medical education by hospitals receiving such funds.

(9)(10) RULEMAKING.—The department has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this section.

Section 29. Section 381.4018, Florida Statutes, is amended to read:

381.4018 Physician workforce assessment and development.-

(1) DEFINITIONS.—As used in this section, the term:

(a) "Consortium" or "consortia" means a combination of statutory teaching hospitals, specialty children's hospitals, statutory rural hospitals, other hospitals, accredited medical schools, clinics operated by the Department of Health, clinics operated by the Department of Veterans' Affairs, area health education centers, community health centers, federally qualified health centers, prison clinics, local community clinics, or other programs. At least one member of the consortium shall be a sponsoring institution accredited or currently seeking accreditation by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.

(b) "Council" means the Physician Workforce Advisory Council.

(c) "Department" means the Department of Health.

(d) "Graduate medical education program" means a program accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association.

(e) "Primary care specialty" means emergency medicine, family practice, internal medicine, pediatrics, psychiatry, geriatrics, general surgery, obstetrics and gynecology, and combined pediatrics and internal medicine and other specialties as determined by the Physician Workforce Advisory Council or the Department of Health.

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

(3)(2) PURPOSE.—The department of Health shall serve as a coordinating and strategic planning body to actively assess the state's current and future physician workforce needs and work with multiple stakeholders to develop strategies and alternatives to address current and projected physician workforce needs.

 $(\underline{4})(\underline{3})$  GENERAL FUNCTIONS.—The department shall maximize the use of existing programs under the jurisdiction of the department and other state agencies and coordinate governmental and nongovernmental stakeholders and resources in order to develop a state strategic plan and assess the implementation of such strategic plan. In developing the state strategic plan, the 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 entities, develop strategies and recommendations and identify best practice programs that introduce health care as a profession and strengthen skills needed for medical school admission for elementary, middle, and high school students, and improve premedical education at the precollege and college level in order to increase this state's potential pool of medical 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.

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

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

(g) Coordinate and enhance activities relative to physician workforce needs, undergraduate medical education, and graduate medical education, and reentry of retired military and other physicians into the physician workforce provided by the Division of Medical Quality Assurance, the Community Hospital Education Program and the Graduate Medical Education Committee established pursuant to s. 381.0403, area health education center networks established pursuant to s. 381.0402, and other offices and programs within the department of Health as 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 adequate supply of well-trained physicians to meet the state's future needs. Such governmental stakeholders shall include, but need not be limited to, the State Surgeon General or his or her designee, the Commissioner of Education or his or her designee, the Secretary of Health Care Administration or his or her designee, and the Chancellor of the State University System or his or her designee from the Board of Governors of the State University System, and, at the discretion of the department, other representatives of state and local agencies that are involved in assessing, educating, or training the state's current or future physicians. Other stakeholders shall include, but need not be limited to, organizations representing the state's public and private allopathic and osteopathic medical schools; organizations representing hospitals and other institutions providing health care, particularly those that currently provide or have an interest in providing accredited medical education and graduate medical education to medical students and medical residents: organizations representing allopathic and osteopathic practicing physicians; and, at the discretion of the department, representatives of other organizations or entities involved in assessing, educating, or 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.

(5) PHYSICIAN WORKFORCE ADVISORY COUNCIL.—There is created in the department the Physician Workforce Advisory Council, an advisory council as defined in s. 20.03. The council shall comply with the requirements of s. 20.052, except as otherwise provided in this section.

(a) The council shall consist of 19 members. Members appointed by the State Surgeon General shall include:

<u>1. A designee from the department who is a physician licensed under chapter 458 or chapter 459 and recommended by the State Surgeon General.</u>

2. An individual who is affiliated with the Science Students Together Reaching Instructional Diversity and Excellence program and recommended by the area health education center network.

<u>3. Two individuals recommended by the Council of Florida Medical</u> <u>School Deans, one representing a college of allopathic medicine and one</u> <u>representing a college of osteopathic medicine.</u>

4. One individual recommended by the Florida Hospital Association, representing a hospital that is licensed under chapter 395, has an accredited

graduate medical education program, and is not a statutory teaching hospital.

5. One individual representing a statutory teaching hospital as defined in s. 408.07 and recommended by the Safety Net Hospital Alliance.

6. One individual representing a family practice teaching hospital as defined in s. 395.805 and recommended by the Council of Family Medicine and Community Teaching Hospitals.

7. Two individuals recommended by the Florida Medical Association, one representing a primary care specialty and one representing a nonprimary care specialty.

8. Two individuals recommended by the Florida Osteopathic Medical Association, one representing a primary care specialty and one representing a nonprimary care specialty.

9. Two individuals who are program directors of accredited graduate medical education programs, one representing a program that is accredited by the Accreditation Council for Graduate Medical Education and one representing a program that is accredited by the American Osteopathic Association.

10. An individual recommended by the Florida Association of Community Health Centers representing a federally qualified health center located in a rural area as defined in s. 381.0406(2)(a).

11. An individual recommended by the Florida Academy of Family Physicians.

<u>12. An individual recommended by the Florida Alliance for Health</u> <u>Professions Diversity.</u>

13. The Chancellor of the State University System or his or her designee.

14. A layperson member as determined by the State Surgeon General.

Appointments to the council shall be made by the State Surgeon General. Each entity authorized to make recommendations under this subsection shall make at least two recommendations to the State Surgeon General for each appointment to the council. The State Surgeon General shall name one appointee for each position from the recommendations made by each authorized entity.

(b) Each council member shall be appointed to a 4-year term. An individual may not serve more than two terms. Any council member may be removed from office for malfeasance; misfeasance; neglect of duty; incompetence; permanent inability to perform official duties; or pleading guilty or nolo contendere to, or being found guilty of, a felony. Any council member who meets the criteria for removal, or who is otherwise unwilling or
unable to properly fulfill the duties of the office, shall be succeeded by an individual chosen by the State Surgeon General to serve out the remainder of the council member's term. If the remainder of the replaced council member's term is less than 18 months, notwithstanding the provisions of this paragraph, the succeeding council member may be reappointed twice by the State Surgeon General.

(c) The chair of the council is the State Surgeon General, who shall designate a vice chair from the membership of the council to serve in the absence of the State Surgeon General. A vacancy shall be filled for the remainder of the unexpired term in the same manner as the original appointment.

(d) Council members are not entitled to receive compensation or reimbursement for per diem or travel expenses.

(e) The council shall meet at least twice a year in person or by teleconference.

(f) The council shall:

1. Advise the State Surgeon General and the department on matters concerning current and future physician workforce needs in this state;

2. Review survey materials and the compilation of survey information;

<u>3.</u> Annually review the number, location, cost, and reimbursement of graduate medical education programs and positions;

<u>4. Provide recommendations to the department regarding the survey</u> completed by physicians licensed under chapter 458 or chapter 459;

<u>5. Assist the department in preparing the annual report to the Legislature pursuant to ss. 458.3192 and 459.0082;</u>

<u>6.</u> Assist the department in preparing an initial strategic plan, conduct ongoing strategic planning in accordance with this section, and provide ongoing advice on implementing the recommendations;

7. Monitor and provide recommendations regarding the need for an increased number of primary care or other physician specialties 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.

Section 30. Section 458.3192, Florida Statutes, is amended to read:

458.3192 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 determine by geographic area and specialty the number of physicians who:

(a) Perform deliveries of children in this state Florida.

(b) Read mammograms and perform breast-imaging-guided procedures in this state Florida.

(c) Perform emergency care on an on-call basis for a hospital emergency department.

(d) Plan to reduce or increase emergency on-call hours in a hospital emergency department.

(e) Plan to relocate their allopathic or osteopathic practice outside the state.

(f) Practice medicine in this state.

(g) Plan to reduce or modify the scope of their practice.

(2) The Department of Health must report its findings to the Governor, the President of <u>the</u> Senate, and the Speaker of the House of Representatives by November 1 each year. <u>The department shall also include in its report findings</u>, recommendations, and strategic planning activities as provided in <u>s. 381.4018</u>. The department may also include other information requested by the Physician Workforce Advisory Council.

Section 31. Section 459.0082, Florida Statutes, is amended to read:

459.0082 Analysis of survey results; report.—

(1) Each year, the Department of Health shall analyze the results of the physician survey required by s. 459.0081 and determine by geographic area and specialty the number of physicians who:

(a) Perform deliveries of children in this state Florida.

(b) Read mammograms and perform breast-imaging-guided procedures in <u>this state</u> Florida.

(c) Perform emergency care on an on-call basis for a hospital emergency department.

(d) Plan to reduce or increase emergency on-call hours in a hospital emergency department.

(e) Plan to relocate their allopathic or osteopathic practice outside the state.

(f) Practice medicine in this state.

(g) Plan to reduce or modify the scope of their practice.

(2) The Department of Health must report its findings to the Governor, the President of <u>the</u> Senate, and the Speaker of the House of Representatives by November 1 each year. <u>The department shall also include in its report findings</u>, recommendations, and strategic planning activities as provided in <u>s. 381.4018</u>. The department may also include other information requested by the Physician Workforce Advisory Council.

Section 32. Section 458.315, Florida Statutes, is amended to read:

458.315 Temporary certificate for practice in areas of critical need.—

(1) Any physician who:

(a) Is licensed to practice in any jurisdiction in the United States and other state, whose license is currently valid; or,

(b) Has served as a physician in the United States Armed Forces for at least 10 years and received an honorable discharge from the military;

and who pays an application fee of 300 may be issued a temporary certificate for to practice in areas of communities of Florida where there is a critical need for physicians.

(2) A certificate may be issued to a physician who:

(a) Will practice in an area of critical need;

(b) Will be employed by <u>or practice in</u> a county health department, correctional facility, <u>Department of Veterans' Affairs clinic</u>, community health center funded by s. 329, s. 330, or s. 340 of the United States Public Health Services Act, or other <u>agency or institution that is approved by the State Surgeon General and provides health care to meet the needs of underserved populations in this state; or</u>

(c) Will practice for a limited time to address critical physician-specialty, demographic, or geographic needs for this state's physician workforce as determined by the State Surgeon General entity that provides health care to indigents and that is approved by the State Health Officer.

(3) The Board of Medicine may issue this temporary certificate with the following restrictions:

(a)(1) The <u>State Surgeon General board</u> shall determine the areas of critical need, and the physician so certified may practice in any of those areas for a time to be determined by the board. Such areas shall include, but <u>are</u> not be limited to, health professional shortage areas designated by the United States Department of Health and Human Services.

<u>1.(a)</u> A recipient of a temporary certificate for practice in areas of critical need may use the <u>certificate license</u> to work for any approved <u>entity employer</u>

in any area of critical need <u>or as authorized by the State Surgeon General</u> approved by the board.

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

(b)(2) The board may administer an abbreviated oral examination to determine the physician's competency, but <u>a no</u> written regular examination is <u>not required necessary</u>. Within 60 days after receipt of an application for a temporary certificate, the board shall review the application and issue the temporary certificate, <del>or</del> notify the applicant of denial, <u>or notify the applicant</u> that the board recommends additional assessment, training, education, or other requirements as a condition of certification. If the applicant has not actively practiced during the prior 3 years and the board determines that the applicant may lack clinical competency, possess diminished or inadequate skills, lack necessary medical knowledge, or exhibit patterns of deficits in clinical decisionmaking, the board may:

1. Deny the application;

2. Issue a temporary certificate having reasonable restrictions that may include, but are not limited to, a requirement for the applicant to practice under the supervision of a physician approved by the board; or

3. Issue a temporary certificate upon receipt of documentation confirming that the applicant has met any reasonable conditions of the board which may include, but are not limited to, completing continuing education or undergoing an assessment of skills and training.

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

(d)(4) The board <u>may shall</u> not issue a temporary certificate for practice in an area of critical need to any physician who is under investigation in <u>any</u> <u>jurisdiction in the United States</u> another state for an act <u>that which</u> would constitute a violation of this chapter until such time as the investigation is complete, at which time the provisions of s. 458.331 shall apply.  $(\underline{4})(\underline{5})$  The application fee and all licensure fees, including neurological injury compensation assessments, shall be waived for those persons obtaining a temporary certificate to practice in areas of critical need for the purpose of providing volunteer, uncompensated care for low-income residents Floridians. The applicant must submit an affidavit from the employing agency or institution stating that the physician will not receive any compensation for any service involving the practice of medicine.

Section 33. Section 459.0076, Florida Statutes, is created to read:

459.0076 Temporary certificate for practice in areas of critical need.—

(1) Any physician who:

(a) Is licensed to practice in any jurisdiction in the United States and whose license is currently valid; or

(b) Has served as a physician in the United States Armed Forces for at least 10 years and received an honorable discharge from the military;

and who pays an application fee of \$300 may be issued a temporary certificate for practice in areas of critical need.

(2) A certificate may be issued to a physician who:

(a) Will practice in an area of critical need;

(b) Will be employed by or practice in a county health department, correctional facility, Department of Veterans' Affairs clinic, community health center funded by s. 329, s. 330, or s. 340 of the United States Public Health Services Act, or other agency or institution that is approved by the State Surgeon General and provides health care to meet the needs of underserved populations in this state; or

(c) Will practice for a limited time to address critical physician-specialty, demographic, or geographic needs for this state's physician workforce as determined by the State Surgeon General.

(3) The Board of Osteopathic Medicine may issue this temporary 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.

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

2. The recipient of a temporary certificate for practice in areas of critical need shall, within 30 days after accepting employment, notify the board of all

approved institutions in which the licensee practices and of all approved institutions where practice privileges have been denied.

(b) The board may administer an abbreviated oral examination to determine the physician's competency, but a written regular examination is not required. Within 60 days after receipt of an application for a temporary certificate, the board shall review the application and issue the temporary certificate, notify the applicant of denial, or notify the applicant that the board recommends additional assessment, training, education, or other requirements as a condition of certification. If the applicant has not actively practiced during the prior 3 years and the board determines that the applicant may lack clinical competency, possess diminished or inadequate skills, lack necessary medical knowledge, or exhibit patterns of deficits in clinical decisionmaking, the board may:

1. Deny the application;

2. Issue a temporary certificate having reasonable restrictions that may include, but are not limited to, a requirement for the applicant to practice under the supervision of a physician approved by the board; or

3. Issue a temporary certificate upon receipt of documentation confirming that the applicant has met any reasonable conditions of the board which may include, but are not limited to, completing continuing education or undergoing an assessment of skills and training.

(c) Any certificate issued under this section is valid only so long as the State Surgeon General determines that the reason for which it was issued remains a critical need to the state. The Board of Osteopathic Medicine shall review each temporary certificateholder not less than annually to ascertain that the minimum requirements of the Osteopathic Medical Practice Act and its adopted rules are being complied with. If it is determined that such minimum requirements are not being met, the board shall revoke such certificate or shall impose restrictions or conditions, or both, as a condition of continued practice under the certificate.

(d) The board may not issue a temporary certificate for practice in an area of critical need to any physician who is under investigation in any jurisdiction in the United States for an act that would constitute a violation of this chapter until such time as the investigation is complete, at which time the provisions of s. 459.015 apply.

(4) The application fee and all licensure fees, including neurological injury compensation assessments, shall be waived for those persons obtaining a temporary certificate to practice in areas of critical need for the purpose of providing volunteer, uncompensated care for low-income residents. The applicant must submit an affidavit from the employing agency or institution stating that the physician will not receive any compensation for any service involving the practice of medicine. Section 34. (1) The Department of Health shall conduct an evaluation and justification review of each division established under s. 20.43, Florida Statutes. The review shall be comprehensive in its scope and, at a minimum, must be conducted in such a manner as to specifically determine the following, and to consider and determine what changes, if any, are needed with respect thereto:

(a) The identifiable cost of each division and programs within the division.

(b) The specific purpose of each division and programs within the division, and the specific public health benefit derived therefrom.

(c) Progress toward achieving the outputs and outcomes associated with each division and programs within the division.

(d) An explanation of circumstances contributing to the department's ability to achieve, not achieve, or exceed its projected outputs and outcomes, as defined in s. 216.011, associated with each division and programs within the division.

(e) Alternate courses of action that would result in administration of the same program in a more efficient or effective manner. The courses of action to be considered must include, but are not limited to:

1. Whether the department could be organized in a more efficient and effective manner, including whether each division's mission, goals, or objectives should be redefined. The report must include a rationale for each department division and programs within the division, the return on investment of each division and programs within the division, the relatedness of the division and programs within the division to a public health function, and any federal funding support for each division and programs within the division. The review should recommend the reduction and restructuring of department bureaus and divisions.

2. Whether the division and programs within the division could be administered more efficiently or effectively to avoid duplication of activities and ensure that activities are adequately coordinated.

<u>3.</u> Whether the division and programs within that division could be performed more efficiently or more effectively by another unit of government or a private entity.

4. When compared to costs, whether effectiveness warrants elimination of the division or programs within the division or, if the division or a program within the division serves a limited interest, whether the division or program should be redesigned to require users to finance program costs.

5. Whether the cost to administer the division or program within the division exceeds license and other fee revenues paid by those being regulated.

6. Whether other changes could improve the efficiency and effectiveness of the division or program within the division.

(f) The consequences of discontinuing such division or programs within the division. If any discontinuation is recommended, such recommendation must be accompanied by a description of alternatives to implement such recommendation, including an implementation schedule for discontinuation and recommended procedures for assisting state agency employees affected by the discontinuation.

(g) Whether current performance measures and standards should be reviewed or amended to assist department efforts in achieving outputs and outcome measures.

(h) Whether the information reported as part of the state's performancebased program budgeting system has relevance and utility for the evaluation of each division and programs within the division.

(i) Whether department management has established control systems sufficient to ensure that performance data are maintained and supported by department records and accurately presented in department performance reports.

(3) No later than March 1, 2011, the department shall submit a report on its evaluation and justification review findings and recommendations to the President of the Senate, the Speaker of the House of Representatives, the chairs of the appropriate substantive committees, the chairs of the appropriations committees, the Legislative Auditing Committee, the Governor, and the State Surgeon General.

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

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

(3) To facilitate effective emergency management, when the United States Department of Health and Human Services contracts for the manufacture and delivery of licensable products in response to a public health emergency and the terms of those contracts are made available to the states, the department shall accept funds provided by counties, municipalities, and other entities designated in the state emergency management plan required under s. 252.35(2)(a) for the purpose of participation in those contracts. The department shall deposit those funds in the Grants and Donations Trust Fund and expend those funds on behalf of the donor county, municipality, or other entity for the purchase of the licensable products made available under the contract.

Section 36. For fiscal year 2010-2011 only, and notwithstanding s. 216.181, Florida Statutes, the Department of Health is authorized to submit

a budget amendment requesting additional Grants and Donations Trust Fund budget authority for the Florida Center for Nursing to make expenditures supported by grants and donations.

Section 37. Paragraph (a) of subsection (1) of section 409.9201, Florida Statutes, is amended to read:

409.9201 Medicaid fraud.—

(1) As used in this section, the term:

(a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or by s. 465.003(8), s.  $499.003(\underline{46})(\underline{45})$  or  $(\underline{53})(\underline{52})$ , or s. 499.007(13).

The value of individual items of the legend drugs or goods or services involved in distinct transactions committed during a single scheme or course of conduct, whether involving a single person or several persons, may be aggregated when determining the punishment for the offense.

Section 38. Subsection (3) of section 465.0265, Florida Statutes, is amended to read:

465.0265 Centralized prescription filling.—

(3) The filling, delivery, and return of a prescription by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription as set forth in s. 465.026 or as a wholesale distribution as set forth in s. 499.003(54)(53).

Section 39. Paragraph (g) of subsection (2) of section 499.01, Florida Statutes, are amended to read:

499.01 Permits.-

(2) The following permits are established:

(g) Restricted prescription drug distributor permit.—A restricted prescription drug distributor permit is required for any person that engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(54)(53)(a).

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

45

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

3. A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required 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.

Section 40. Paragraph (d) of subsection (4) of section 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 and for the establishment and maintenance of prescription drug distribution records.

(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).

Section 41. Paragraphs (a) and (b) of subsection (2) of 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 General shall appoint nine additional members to the council who 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.  $499.003(\underline{47})(\underline{46})$ .

(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).

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

499.03 Possession of certain drugs without prescriptions unlawful; exemptions and exceptions.—

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

(f) A person that holds a valid permit issued by the department pursuant to this part which authorizes that person to possess prescription drugs.

Section 43. Paragraphs (i) and (m) of subsection (1) of section 499.05, Florida Statutes, are amended to read:

499.05 Rules.—

(1) The department shall adopt rules to implement and enforce this part with respect to:

(i) Additional conditions that qualify as an emergency medical reason under s.  $499.003(\underline{54})(\underline{53})(b)2$ .

(m) The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s.  $499.003(\underline{54})(\underline{53})(a)-(d)$ .

Section 44. Subsection (1) of section 794.075, Florida Statutes, is amended to read:

794.075 Sexual predators; erectile dysfunction drugs.—

(1) A person may not possess a prescription drug, as defined in s.  $499.003(\underline{43})(\underline{42})$ , for the purpose of treating erectile dysfunction if the person is designated as a sexual predator under s. 775.21.

Section 45. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2010.

Approved by the Governor May 28, 2010.

Filed in Office Secretary of State May 28, 2010.