### **Committee on Health Policy**

#### CS/SB 86 — Dentists

by Appropriations Committee and Senator Latvala

The bill prohibits an insurer, health maintenance organization, or prepaid limited health service organization from contracting with a licensed dentist to provide services to an insured or subscriber at a specified fee unless such services are "covered services" under the applicable contract. "Covered services" are defined as dental care services for which a reimbursement is available under the insured's contract, or for which a reimbursement would be available for the application of a contractual limitation. The bill also prohibits an insurer from requiring that a contracted health care provider accept the terms of other practitioner contracts with a prepaid limited health service organization that is under common management and control with the contracting insurer.

If approved by the Governor, these provisions take effect July 1, 2014.

Vote: Senate 27-0; House 115-0

CS/SB 86 Page: 1

### **Committee on Health Policy**

#### HB 97 — Access to Health Care for the Underserved

by Reps. Magar, Spano, and others (CS/SB 142 by Appropriations Committee and Senator Hays)

The bill expands the circumstances under which a volunteer dentist or dental hygienist is not personally liable for negligence. Under existing law, the liability protections apply to free dental services provided to low-income patients pursuant to a government contract. Under the bill, the dentist or dental hygienist may accept voluntary contributions for the cost of laboratory work and retain the protections from personal liability.

The bill does not change the liability of the government entity that contracts with the dentist or dental hygienist to provide the free dental services. The government entity remains liable, subject to the state's sovereign immunity limitations, for any negligent dental services.

The bill also authorizes any volunteer health care provider—not just dentists or dental hygienists—to retain sovereign immunity and provide care for up to 30 days after a patient is determined not to meet the financial eligibility standard of the program to allow the patient time to find a new provider.

Finally, the bill extends the future repeal date of the health access dental license by 5 years to January 1, 2020. The Health Access Dental License authorizes out-of-state dentists to practice in facilities that provide care to low income patients in underserved areas.

If approved by the Governor, these provisions take effect July 1, 2014.

Vote: Senate 34-0; House 118-0

### **Committee on Health Policy**

#### CS/CS/HB 287 — Certificates of Need

by Health and Human Services Committee; Health Innovation Subcommittee; and Reps. Artiles, A. Williams, and others (CS/CS/SB 268 by Children, Families, and Elder Affairs Committee; Health Policy Committee; and Senators Grimsley and Diaz de la Portilla)

The bill amends various section of the Florida Statutes relating to nursing home certificates of need (CON).

The bill repeals the moratorium on CONs for new nursing homes, but imposes a cap on the AHCA issuing any CONs for new nursing home beds after 3,750 new nursing home beds have been approved between July 1, 2014, and June 30, 2017.

The bill reduces the nursing home bed-need methodology threshold from 94 to 92 percent, allows applicants to combine need numbers for geographically contiguous subdistricts, and establishes a positive CON factor for an applicant who voluntarily relinquishes licensed nursing home beds in a subdistrict with no bed-need.

The bill provides for an expedited CON review for relocating a portion of a nursing home's beds within a contiguous subdistrict to an established or new facility if the total number of beds in the state does not increase. Expedited CON review is also available for the replacement of a nursing home:

- Within a 30-mile radius of the existing nursing home, regardless of district boundaries. If the new site is in another subdistrict, the occupancy rate in that subdistrict must be at least 85 percent; or
- Outside of a 30-mile radius, if the new nursing home will be within the same or a contiguous subdistrict. If the new site is in a contiguous subdistrict, the occupancy rate in that subdistrict must be at least 85 percent.

The bill amends exemptions from the CON process for nursing homes as follows:

- Creates a new exemption for nursing homes to add up to the lesser of 30 beds or 25 percent of its current beds when replacing a nursing home;
- Reduces from 96 to 94 percent the required average occupancy rate when adding the greater of 10 beds or 10 percent of the nursing home's beds;
- Increases, from three to five miles, the distance from the original nursing home that a replacement nursing home in the same subdistrict may be located; and
- Allows the consolidation of nursing home beds under shared controlled interest in the same district, changing the previous subdistrict limit, if the relocation site is within 30 miles of all the nursing homes from which the beds are moved.

If approved by the Governor, these provisions take effect July 1, 2014.

Vote: Senate 38-0; House 116-0

### **Committee on Health Policy**

### CS/HB 323 — Pharmacy

by Health and Human Services Committee; and Reps. LaRosa, Campbell, and others (CS/CS/CS/SB 278 by Rules Committee; Regulated Industries Committee; Health Policy Committee; and Senator Grimsley)

The bill removes the cap on the number of pharmacy technicians the Board of Pharmacy may authorize one pharmacist to supervise and revises the composition of the board. The number of pharmacists representing community and Class II institutional pharmacies is increased from a minimum of one in each category, to a minimum of two each. The bill directs the Governor to appoint members reflecting the new composition as current members' terms expire or when a vacancy occurs.

The bill authorizes pharmacists to administer the meningococcal vaccine under physician protocol and removes the requirement for a pharmacist to have a prescription from a physician to administer the shingles vaccine.

The bill revises the format for written prescriptions for controlled substances by permitting the date to be in numeric month/day/year format or the month written out in whole, and by removing the requirement that the quantity and date appear on the face of the prescription.

If approved by the Governor, these provisions take effect July 1, 2014.

Vote: Senate 38-0; House 111-0

CS/HB 323 Page: 1

### **Committee on Health Policy**

# CS/SB 390 — Public Records/Identifying Information of Personnel of Department of Health

by Health Policy Committee and Senator Hays

The bill creates a public records exemption for identification and location information of certain current and former personnel of the Department of Health (DOH), their spouses, and their children. The exemption applies to records of those personnel whose duties include, or result in, the determination or adjudication of eligibility for social security disability benefits, the investigation or prosecution of complaints against health care practitioners, or the inspection of health care practitioners or health care facilities. The information that is exempt includes:

- The home addresses, telephone numbers, dates of birth, and photographs of the DOH personnel;
- The names, home addresses, telephone numbers, dates of birth, and places of employment of their spouses and children; and
- The names and locations of schools and day care facilities attended by the children of the DOH personnel.

The exemption is subject to the Open Government Sunset Review Act and will stand repealed on October 2, 2019, unless reviewed and reenacted by the Legislature.

If approved by the Governor, these provisions take effect upon becoming law.

Vote: Senate 37-0; House 116-0

CS/SB 390 Page: 1

### **Committee on Health Policy**

#### CS/CS/HB 511 — Cancer Control and Research

By Health and Human Services Committee; Health Quality Subcommittee; and Rep. Coley and others (CS/SB 734 by Appropriations Committee; and Senators Sobel and Abruzzo)

The bill reduces the number of members of the Cancer Control and Research Advisory Council (CCRAB) from 35 to 15 and reduces the required number of members that constitute a quorum to eight. The bill revises which organizations are represented on the CCRAB as well as how CCRAB members are appointed and states that members of the CCRAB, rather than the Governor, select the chairperson of the CCRAB.

The membership of the CCRAB is revised to include:

- The State Surgeon General or his or her designee;
- One member appointed by the Chief Executive Officer (CEO), or the CEO's designee, from each of the following institutions:
  - o The American Cancer Society;
  - o The Sylvester Comprehensive Cancer Center of the University of Miami;
  - o The University of Florida Shands Cancer Center;
  - The Florida Nurses Association who specializes in the field of oncology and is not from an institution or organization already represented on the CCRAB;
  - The Florida Osteopathic Medical Association who specializes in the field of oncology;
  - The Florida Medical Association (FMA) who is a member of the FMA, specializes in the field of oncology, and represents a cancer center not already represented on the CCRAB;
  - o The H. Lee Moffitt Cancer Center and Research Institute;
  - The Florida Hospital Association (FHA) who specializes in the field of oncology, is a member of the FHA, and represents a comprehensive cancer center not already represented on the CCRAB; and
  - o The Association of Community Cancer Centers.
- One member, appointed by the Governor, who specializes in pediatric oncology;
- One member, appointed by the President of the Senate, who specializes in oncology clinical care or research;
- One member, appointed by the Speaker of the House of Representatives, who is a current or former cancer patient or caregiver;
- One member of the House of Representatives appointed by the Speaker of the House of Representatives; and
- One member of the Senate, appointed by the President of the Senate.

#### The bill provides that:

- At least four members must be minority persons;
- A member's term is 4 years with the option of reappointment;

• The institution that a member represents may reimburse that member for travel expenses, or if a member does not represent an institution, then Moffitt is required to reimburse that member for travel expenses.

The bill also revises the duties of the CCRAB by eliminating the CCRAB's responsibility for recommending the awarding of grants and contracts to private entities and government agencies for cancer control, prevention, education, or research. The bill renames the "Florida Cancer Plan" as the "Florida Cancer Control and Research Plan" and requires the CCRAB to collaborate with the Florida Biomedical Research Advisory Council to annually recommend to the state surgeon general a statewide research plan for the care and treatment of persons suffering from cancer.

If approved by the Governor, these provisions take effect July 1, 2014.

Vote: Senate 38-0; House 115-0

### **Committee on Health Policy**

### SB 520 — Public Records/Dental Workforce Surveys

by Senator Richter

The bill creates a public records exemption for personal identifying information provided by dentists or dental hygienists to the Department of Health (DOH) in their responses to dental workforce surveys. The DOH administers the surveys as part of license renewal, and participation is voluntary. Data collected through the surveys are used by the DOH and other stakeholders to plan for an adequate workforce and to support programs and policies which aim to improve oral health in Florida.

The bill makes the information confidential and exempt, but requires disclosure of the data with written consent of the licensee or his or her authorized representative or by court order, and allows disclosure to a research entity pursuant to an approved research protocol and purchase and use agreement. The DOH may deny the request of a research entity if it is intrusive to the licensees or administratively burdensome, or lacks scientific merit or a plan for disposing of records.

The exemption is subject to the Open Government Sunset Review Act and will stand repealed on October 2, 2019, unless reviewed and reenacted by the Legislature.

If approved by the Governor, these provisions take effect upon becoming law.

Vote: Senate 39-0; House 116-0

SB 520 Page: 1

### **Committee on Health Policy**

#### **HB 531 — Public Health Trusts**

by Rep. Richardson and others (SB 640 by Senator Braynon)

The bill authorizes the board of trustees of a public health trust to lease out office space without first advertising and soliciting bids for the office space.

If approved by the Governor, these provisions take effect July 1, 2014.

Vote: Senate 39-0; House 119-0

### **Committee on Health Policy**

### CS/HB 591 — Newborn Health Screening

by Health and Human Services Committee; and Rep. Harrell (CS/CS/SB 722 by Judiciary Committee; Children, Families, and Elder Affairs Committee; Health Policy Committee; and Senators Garcia, Soto, Bean, and Richter)

The bill expands the list of health care practitioners who may receive the results of a newborn's hearing and metabolic tests or screenings from the State Public Health Laboratory to include additional health care practitioners who may treat a child. This change is expected to expedite and simplify treatment since these practitioners will no longer be required to wait for the results to be transferred from the primary care physician. The bill revises the definition of "hearing impairment" to conform to national standards.

Additionally, if an audiologist diagnoses an infant or toddler with hearing loss, the bill requires that the audiologist or his or her designee ask the parent or guardian if he or she would like to receive information about services directly from Early Steps providers. This provision is expected to assist parents and guardians of newly-diagnosed children with hearing impairment in obtaining access to needed services.

The bill also makes two technical corrections, deleting an obsolete date and updating a cross-reference to federal law.

If approved by the Governor, these provisions take effect July 1, 2014.

Vote: Senate 38-0: House 116-0

CS/HB 591 Page: 1

### **Committee on Health Policy**

### CS/CS/SB 670 — Nursing Home Litigation

by Judiciary Committee; Health Policy Committee; and Senator Thrasher

The bill amends statutory provisions relating to civil causes of action against nursing homes, establishes provisions to help ensure timely payment of adverse final judgments, and amends provisions relating to the release of nursing home resident records.

### Civil Causes of Action against Nursing Homes

The bill limits the classes of persons who may be sued in the initial pleading for negligence or a violation of a nursing home resident's rights to only the nursing home licensee and its management or consulting company, managing employees, and direct caregivers, whether employees or contracted. The bill defines the terms licensee, management or consulting company, and passive investor. Passive investors are shielded from liability.

In order to sue a party other than one of the classes noted above, the bill requires the court, or an arbitration panel as applicable, to hold a hearing on a motion for leave to amend the initial pleading. The court or panel must determine that there is sufficient evidence in the record or proffered by the claimant to establish a reasonable showing that the individual or entity owed and breached a duty of reasonable care to the resident and that the breach is the legal cause of the loss, injury, death, or damage to the resident before the other parties may be sued.

The bill makes these provisions of law the exclusive remedy against a nursing home licensee, its management or consulting company, managing employees, and direct caregivers for a cause of action alleging direct or vicarious liability for the recovery of damages for the personal injury or death of a nursing home resident arising out of negligence or a violation of a resident's statutory rights. The bill also specifies that the claimant must elect either survival damages or wrongful death damages after the verdict but before the judgment is entered, and requires certain proposed amended pleadings to relate back to the original pleading.

The court must also hold an evidentiary hearing to determine if there is sufficient admissible evidence for a punitive damages claim relating to direct liability or vicarious liability. The claimant must show a reasonable basis to believe that the claimant will be able to demonstrate at trial by clear and convincing evidence that punitive damages are warranted before a claim for punitive damages may be brought. A defendant may be held liable for punitive damages if the defendant actively and knowingly participated in intentional misconduct or engaged in conduct that constitutes gross negligence and contributed to the loss, damages, or injury suffered by the claimant. The terms intentional misconduct and gross negligence are defined in current law.

The bill specifies that these provisions only apply to causes of action accruing on or after the bill takes effect.

CS/CS/SB 670 Page: 1

#### Failure of a Nursing Home to Satisfy a Judgment

Once a final judgment has been entered by a Florida court against a nursing home for a claim arising under s. 400.023, F.S., the nursing home is required to pay the judgment within 60 days unless a different timeframe is mutually agreed to among the parties. Failure to make such a payment results in additional grounds for the Agency for Health Care Administration (AHCA) to revoke or refuse to renew a nursing home license. The bill specifies when the AHCA is placed on notice of an unsatisfied judgment and that, within 30 days of receiving such notice, the licensee must provide proof of satisfaction of the judgment. If no such proof is provided, the AHCA must issue an emergency order declaring that the facility lacks the financial ability to operate and a notice of intent to revoke or deny the facility's license. The bill also specifies that the AHCA may refuse to renew the facility's license or refuse to approve a change of ownership for a facility that is out of compliance with these provisions.

#### Nursing Home Resident Records

The bill revises provisions relating to the release of a nursing home resident's records to comply with the federal Health Insurance Portability and Accountability Act (HIPAA) and to provide for release of a deceased resident's medical records. Specifically, the bill requires nursing homes to furnish copies of a resident's paper and electronic records if the request complies with HIPAA and the person requesting is authorized to make the request under HIPAA. The records released must include medical records and records concerning the care and treatment of the resident except for progress notes and consultation reports of a psychiatric nature.

The facility is required to provide the records within 14 working days for a request relating to a current resident or within 30 working days for a request concerning a former resident. Records for deceased residents may be made by a specified person appointed by the court. If no judicial appointment has been made, a person designated by the resident to act on his or her behalf may request such records. If no judicial appointment or resident designation has been made, the surviving spouse, child, or parent may request such records. The bill details the documentation that must be submitted for deceased resident's records.

The bill also details the fees which a facility may charge to furnish records, provides for indemnification of facilities for releasing records in good faith, and specifies that facilities are not required to release records more than once per month except that physician reports must be released as often as necessary to allow effective monitoring of a resident's condition.

The bill specifies that a nursing home may not be cited by AHCA for noncompliance with these requirements and that these requirements do not limit any right to obtain records by subpoena or other court process.

If approved by the Governor, these provisions take effect upon becoming law.

Vote: Senate 36-3; House 109-7

CS/CS/SB 670 Page: 2

### **Committee on Health Policy**

### CS/CS/SB 674 — Background Screening

by Criminal Justice Committee; Health Policy Committee; and Senator Bean

The bill revises the background screening provisions for persons required by law to undergo criminal background screening.

The bill updates the disqualifying offenses to include additional offenses involving fraudulent activity for persons screened as a part of health care facility licensure and adds offenses involving attempting, soliciting, or conspiring to commit a listed disqualifying offense for any person subject to background screening. A person may apply for an exemption from disqualification due to rescreening if the person was previously screened and qualified under the applicable statutes but has a disqualifying offense that became effective July 1, 2014 and the disqualifying offense was committed before last screening.

The 3-year waiting period after payment of court-ordered monetary amounts in order to be eligible for an exemption from disqualification for certain felony convictions is eliminated. Screenings handled through the Care Provider Background Screening Clearinghouse (clearinghouse) must now be initiated and registered through the clearinghouse prior to referring the employee or potential employee for fingerprinting. Additionally, certain identifying information of the person to be fingerprinted must be submitted on behalf of all persons to be screened.

The bill provides for the submission of an individual taxpayer identification number if a social security number cannot be obtained and allows health care facilities and employers that are required to conduct background screenings to submit an attestation, rather than an affidavit, that they have complied with the screening requirements.

The statutory placement of the requirement for submission of a photograph taken at the time of fingerprinting is relocated so that it is not a requirement for all screenings but only for those handled through the clearinghouse.

The Department of Highway Safety and Motor Vehicles is authorized to provide driver's license photographs to the Department of Health and the Agency for Health Care Administration pursuant to an interagency agreement with each agency.

If approved by the Governor, these provisions take effect July 1, 2014.

Vote: Senate 27-0; House 117-0

CS/CS/SB 674 Page: 1

### **Committee on Health Policy**

### CS/CS/SB 702 — Pharmacy Audits

by Appropriations Committee; Judiciary Committee; Regulated Industries Committee; and Senators Bean and Sobel

The bill establishes the rights of a pharmacy when it is audited by a managed care company, insurance company, third-party payor, pharmacy benefit manager, or an entity that represents responsible parties such as companies or groups, collectively referred to as an "entity" in the bill. The rights include:

- To have at least 7 days prior notice of each initial on-site audit;
- To have an on-site audit scheduled after the first 3 days of the month;
- To limit the audit period to 24 months after the date a claim is submitted to or adjudicated by the entity;
- To have an audit that requires clinical or professional judgment conducted by or in consultation with a pharmacist;
- To use the written and verifiable records of a hospital, physician, or other authorized practitioner to validate the pharmacy records in accordance with state and federal law;
- To be reimbursed for a claim that was retroactively denied for a clerical, typographical, scrivener's, or computer error, if the prescription was properly dispensed, unless the pharmacy has a pattern of such errors or fraudulent billing is alleged or the error results in actual financial loss to the entity;
- To receive the preliminary audit report within 120 days after the audit is concluded and to receive the final audit report within 6 months after receiving the preliminary report;
- To have 10 business days after the preliminary audit report is delivered to produce documentation to address a discrepancy or audit finding; and
- To have recoupment or penalties based on actual overpayments, not extrapolation.

The rights do not apply to audits that are based on a suspicion of fraud or wilful misrepresentation; audits of claims paid for by federally-funded programs; or concurrent reviews or desk audits that occur within 3 business days after transmission where no chargeback or recoupment is demanded.

An entity that audits a pharmacy located within a Health Care Fraud Prevention and Enforcement Action Team Task Force area designated by the United States Department of Health and Human Services and the United States Department of Justice is not required to provide 7 days prior notice of an audit if the pharmacy has been a member of a credentialed provider network for less than 12 months.

If approved by the Governor, these provisions take effect October 1, 2014.

Vote: Senate 37-0; House 116-0

CS/CS/SB 702 Page: 1

### **Committee on Health Policy**

#### CS/CS/HB 709 — Alzheimer's Disease

by Health and Human Services Committee; Health Quality Subcommittee; and Rep. Hudson and others (CS/CS/SB 872 by Appropriations Committee; Health Policy Committee; and Senators Richter and Soto)

The bill makes a number of changes related to Alzheimer's disease to implement recommendations of the Purple Ribbon Task Force which was created by the Legislature in 2012.

The bill requires the Division of Emergency Management (DEM) to develop a special needs shelter registration program by January 1, 2015, and to fully implement the program by March 1, 2015. The effect is to shift primary responsibility for maintaining a registry from the local emergency management agencies to the DEM, working in coordination with the local agencies. The bill directs the DEM to develop a uniform electronic registration form and database, as a minimum component of the registration program, which the local agencies can use to upload registration information they receive. The bill adds memory disorder clinics and aging and disability resource centers to the existing list of providers and agencies that are required to provide information and assistance to individuals with special needs and their caregivers regarding special needs shelter registration, and to register their clients annually. The bill authorizes, but does not require, licensed physicians and pharmacies to provide these same services.

The bill requires county health departments to staff special needs shelters with a person who is familiar with the needs of persons with Alzheimer's disease and requires that all special needs shelters establish sheltering areas for persons with Alzheimer's disease or related dementia.

The bill creates the Ed and Ethel Moore Alzheimer's Disease Research Program (Moore program) to fund research for the prevention and cure of Alzheimer's disease. Long-term goals of the Moore program are to:

- Enhance the health of Floridians by researching improved prevention, diagnosis, treatment, and cure of Alzheimer's disease;
- Expand the foundation of knowledge relating to the prevention, diagnosis, treatment, and cure of Alzheimer's disease; and
- Stimulate activity in the state related to Alzheimer's disease research.

Moore program grants and fellowships will be awarded by the State Surgeon General on the basis of scientific merit. Funding applications may be submitted from any university or established research institute in the state, and qualified investigators, regardless of institution, will have equal access to competitive funding. Implementation of the program is contingent upon a legislative appropriation. The 2014 Legislature approved \$3 million to fund the program as part of the General Appropriations Act.

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The bill also creates the Alzheimer's Disease Research Grant Advisory Board, which is an 11-member board of clinical professionals, to advise the State Surgeon General. The board must submit a fiscal year progress report to the Governor, the President of the Senate, the Speaker of the House of Representatives, and the State Surgeon General annually that includes:

- A list of funded projects;
- A list of funded researchers;
- A list of publications in peer-reviewed journals involving research supported by grants or fellowships awarded under the Moore program;
- The state ranking and total amount of Alzheimer's disease research funding received from the National Institutes of Health;
- New grants for Alzheimer's disease research which were based on research funded by the Moore program;
- Progress toward the goals of the Moore program; and,
- Recommendations to further the mission of the Moore program.

Finally, the bill requires the Department of Elder Affairs to develop performance standards for memory disorders clinics and to condition contract funding on compliance with the standards. The bill also renames the memory disorder clinic in Brevard County.

If approved by the Governor, these provisions take effect July 1, 2014. *Vote: Senate 38-0; House 113-0* 

CS/CS/HB 709 Page: 2

### **Committee on Health Policy**

# CS/CS/HB 711 — Public Meetings and Public Records/Alzheimer's Disease Research Grant Advisory Board

by Government Operations Subcommittee; Health Quality Subcommittee; and Rep. Hudson and others (CS/SB 840 by Health Policy and Senator Richter)

The bill creates a public records exemption for applications submitted to the Alzheimer's Disease Research Grant Advisory Board and records, except the final recommendations, generated by the board during its review. The information is confidential and exempt, but may be released, however, with the express written consent of the person to whom the information pertains or the person's legally authorized representative, or by court order upon showing of good cause.

The bill further provides that those portions of the board's meeting at which the grant applications are discussed are exempt from the public meetings law. However, the meeting must be recorded and the recording may be released under the same circumstances as the records.

The exemptions are subject to the Open Government Sunset Review Act and will stand repealed on October 2, 2019, unless reviewed and saved from repeal by the Legislature.

If approved by the Governor, these provisions take effect on the same date that SB 872 takes effect.

*Vote: Senate 40-0; House 111-2* 

CS/CS/HB 711 Page: 1

### **Committee on Health Policy**

#### CS/CS/SB 1030 — Cannabis

by Appropriations Committee; Health Policy Committee; and Senators Bradley, Bean, Brandes, Galvano, Sobel, Soto, Gardiner, Stargel, and Simpson

The bill creates the Compassionate Medical Cannabis Act of 2014.

Notwithstanding the criminal prohibitions in ch. 893, F.S., the act allows:

- Patients and their legal representatives to possess and purchase low-THC cannabis;
- Owners, managers, and employees of a dispensing organization to manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of low-THC cannabis;
- Recognized medical centers to conduct research on cannabidiol and low-THC cannabis; and
- State universities, with both medical and agricultural research programs, to conduct research on cannabidiol and low-THC cannabis.

The act also creates an exception from the definition of "cannabis" in s. 893.02, F.S., for low-THC cannabis that is manufactured, possessed, sold, purchased, delivered, distributed, or dispensed, in conformance with newly created s. 381.986, F.S.

#### The Medical Use and Ordering of Low-THC Cannabis

The bill creates s. 381.986, F.S., which specifies the conditions under which low-THC cannabis may be ordered and dispensed to, and used by, a patient. Low-THC cannabis is defined as "a plant of the genus *Cannabis* the dried flowers of which contain .8 percent or less of tetrahydrocannabinol (THC) and more than 10 percent of cannabidiol weight for weight." The definition includes extracted resin and any compound, manufacture, salt, derivative, mixture, or preparation of such a plant. In order to meet the definition low-THC cannabis must also be dispensed only from a dispensing organization. The term "medical use" is also defined to exclude smoking and the transfer of low-THC cannabis to a person other than the patient for whom it was ordered or that patient's legal representative.

#### Physician Ordering

Beginning on January 1, 2015, the bill allows allopathic and osteopathic physicians licensed in Florida to order low-THC cannabis for their patients' medical use. The bill specifies that a physician may only order low-THC cannabis for patients who are Florida residents, suffer from cancer or a physical medical condition that chronically produces seizures or severe and persistent muscle spasms, and have no acceptable alternative treatment options available to them.

The bill establishes a first degree misdemeanor penalty for physicians who order low-THC cannabis for patients without a reasonable belief that the patient suffers from the required conditions or symptoms and for any person who fraudulently represents that he or she has such symptoms. The Department of Health (DOH) is required to monitor physician registration and

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CS/CS/SB 1030 Page: 1

ordering of low-THC cannabis for practices that could facilitate unlawful distribution or misuse and take disciplinary action as needed.

Physicians who order low-THC cannabis must obtain the voluntary informed consent of the patient or the patient's legal guardian to the treatment after explaining the current state of medical knowledge on the treatment of the patient's condition with low-THC cannabis, medically acceptable alternatives, and the potential risks and side effects. Physicians must also maintain a treatment plan that includes dose, route of administration, planned duration, and monitoring of their patient's symptoms and other indicators of tolerance or reaction to the low-THC cannabis. This treatment plan must be submitted quarterly to the University of Florida, College of Pharmacy, for research on the safety and efficacy of low-THC cannabis.

Physicians who wish to order low-THC cannabis must complete an 8-hour course and examination offered by the Florida Medical Association (FMA) or the Florida Osteopathic Medical Association (FOMA) before ordering for a patient. Physicians who order low-THC cannabis must retake and pass the course and examination upon licensure renewal. The bill requires the first such course to be offered by October 1, 2014, and at least annually afterwards, and allows for the course to be offered in distance learning format. The course must encompass clinical indications for the appropriate use of low-THC cannabis; the appropriate delivery mechanisms, the contraindications for such use; and the relevant state and federal laws governing ordering, possessing and dispensing low-THC cannabis. Failing to comply with these training requirements may subject a physician to disciplinary action against his or her license.

#### Compassionate Use Registry

The DOH is required to create a compassionate use registry (registry) by January 1, 2015, for the registration of physicians and patients who order or are ordered, respectively, low-THC cannabis. The registry must be secure, online, be able to be accessed by physicians, law enforcement agencies, and dispensing organizations in order to verify patient authorization for low-THC cannabis, to record any low-THC cannabis dispensed, and to prevent active registrations of a single patient by multiple physicians.

Physicians are responsible for registering themselves and the patients for whom they order low-THC cannabis. Physicians must also update the registry to reflect order contents and to deactivate a patient's registration when treatment is discontinued.

Dispensing organizations are responsible for checking the registry before dispensing low-THC cannabis to a patient in order to verify a patient's active registration, that the order presented matches the order recorded in the registry, and that the order has not previously been filled. Dispensing organizations must also update the registry with the date, time, quantity, and form of the low-THC cannabis dispensed after dispensing to a patient.

CS/CS/SB 1030 Page: 2

#### Dispensing Organizations

By January 1, 2015, the DOH must authorize the establishment of five dispensing organizations to cultivate, process, and dispense low-THC cannabis. The DOH must authorize one dispensing organization in each of northwest, northeast, central, southwest, and southeast Florida. In order to be considered, an applicant must be able to demonstrate:

- Possession of a valid certificate of registration issued by the Department of Agriculture and Consumer Services for the cultivation of more than 400,000 plants, are operated by a nurseryman, and have been operated as a registered nursery in Florida for at least 30 continuous years;
- Technical and technological ability to cultivate and produce low-THC cannabis;
- Ability to secure the premises, resources, and personnel necessary to operate as a dispensing organization;
- Ability to maintain accountability of all raw materials, finished product, and byproducts;
- Infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide, or regionally, as determined by the DOH;
- Financial ability to maintain operations for a 2-year approval cycle, including the provision of certified financials to the DOH;
- Posting of a \$5 million performance bond, upon approval as a dispensing organization;
- Fingerprinting of all owners and managers and successful passing of a Level 2 background screening;
- The employment of a Florida licensed allopathic or osteopathic physician as a medical director to supervise the activities of the dispensing organization.

Approved dispensing organizations must maintain compliance with all of the above listed criteria. In addition, the dispensing organization's medical director must complete and pass a 2-hour course and examination offered by the FMA or the FOMA upon initially becoming the medical director and upon license renewal. The course and exam must encompass appropriate safety procedures and knowledge of low-THC cannabis.

Dispensing organizations and their owners, managers, and employees are not required to be licensed under ch. 465, F.S., relating to the practice of pharmacy.

#### The Office of Compassionate Use

The bill creates s. 385.212, F.S. to require the DOH to establish an Office of Compassionate Use (office) under the direction of the Deputy State Health Officer. The office is authorized to enhance access to investigational new drugs for Florida patients through approved clinical treatment plans or studies. The office is also authorized to create a network of state universities and medical centers, make necessary applications to the United States Food and Drug Administration (FDA) or pharmaceutical manufacturers to facilitate enhanced access to compassionate use for Florida patients, and enter into any agreements necessary to facilitate

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enhanced access for such patients. The DOH may adopt rules necessary to implement the Office of Compassionate Use.

#### Research

The bill creates ss. 385.211 and 1004.441, F.S., to authorize recognized medical centers and state universities with both medical and agricultural research programs, respectively, to conduct research on cannabidiol and low-THC cannabis notwithstanding ch. 893, F.S. The authorized research includes, but is not limited to, agricultural development, production, clinical research, and use of liquid medical derivatives of cannabidiol and low-THC cannabis for the treatment of refractory or intractable epilepsy. The bill allows state or privately obtained research funds to be used to support such research.

The bill also creates a new, unnumbered section of the Florida Statutes which appropriates \$1 million of nonrecurring general revenue funding for Fiscal Year 2014-2015 to the DOH's James and Esther King Biomedical Research Program for the research of cannabidiol and its effects on intractable childhood epilepsy. In order to apply for the funds, the bill requires that a state university must have received approval from the FDA for an exploratory investigational new drug study of cannabidiol and its effects on intractable childhood epilepsy. The Biomedical Research Advisory Council must advise the State Surgeon General as to the direction and scope of such research and the awarding of research funding.

If approved by the Governor, these provisions take effect upon becoming law.

Vote: Senate 30-9; House 111-7

This summary is provided for information only and does not represent the opinion of any Senator, Senate Office, or Senate Office. CS/CS/SB 1030 Page: 4

### **Committee on Health Policy**

### CS/CS/SB 1036 — Nursing Education Programs

by Education Committee; Health Policy Committee; and Senator Grimsley

The bill establishes a schedule for all registered nurse (RN) prelicensure education programs to become accredited by a specialized nursing accrediting agency that is recognized by the U.S. Secretary of Education. The accrediting agencies that are currently recognized include the Commission on Collegiate Nursing Education and the Accreditation Commission for Education in Nursing.

The bill requires an applicant for licensure who takes the exam more than 6 months after graduation to take a licensure examination preparatory course. The applicant may not use state or federal financial aid to pay for the course.

The bill revises the graduate passage rate a licensed practical nurse or RN education program which is not accredited must have in order to retain its approval from the Board of Nursing to operate. The rate must be based only on the results for first-time test takers who take the licensure examination within 6 months of graduation. In addition, the board must exclude the test scores of a student who transfers with 12 or more credits from a program that was terminated by the board, when it recalculates the passage rate of the school that accepts the transferring student. If a program falls below the required rate and has been placed on probation, the board is authorized to extend its probationary period for one year if the program is meeting a majority of the benchmarks in its plan for remediation. This would allow a program to continue operating for up to 3 years without being terminated. The bill extends the study of the implementation of the nursing program approval process to January 30, 2020.

#### In addition, the bill:

- Increases the limit on clinical training that can be by simulation from 25 percent to 50 percent; adds clinical simulation to the definition of clinical training, thereby allowing it to count toward the required amount; and specifies that the required clinical training be completed in the United States, the District of Columbia, or a possession or territory of the United States.
- Exempts a nurse who is certified by a health care specialty program that is accredited by the National Commission for Certifying Agencies or Accreditation Board for Specialty Nursing Certification from the biennial continuing education requirement.
- Modifies the definition of practice of practical nursing to include the teaching of general principles of health and wellness to the public.

If approved by the Governor, these provisions take effect July 1, 2014.

Vote: Senate 37-0; House 118-0

CS/CS/SB 1036 Page: 1

### **Committee on Health Policy**

### CS/HB 1047 — Termination of Pregnancies

by Health and Human Services Committee; and Rep. Adkins and others (CS/SB 918 by Health Policy Committee; and Senators Flores and Benacquisto)

The bill amends sections of the Florida Statues related to abortions.

The bill limits the circumstances in which an abortion may be lawfully performed on a viable fetus. "Viable or viability" is defined in the bill as the state of fetal development when the life of a fetus is sustainable outside the womb through standard medical measures. "Standard medical measure" is also defined in the bill as the medical care that a physician would provide based on the particular facts of the pregnancy, the information available to the physician, and the technology reasonably available in a hospital to preserve the life and health of the fetus, with or without temporary artificial life-sustaining support, if the fetus were born at the same stage of fetal development.

Before performing any termination of pregnancy, a physician must determine if the fetus is viable by, at a minimum, performing a medical examination of the woman and the fetus to the maximum extent possible through reasonably available tests and the required ultrasound. The physician must also document his or her determination on viability as well as the method, fetal measurements, and other information used to determine viability.

The bill creates exceptions from the prohibitions on abortions during viability, and modifies the current exceptions to the prohibition on abortions in the third trimester, so that an abortion may be performed if two physicians certify in writing that in their reasonable medical judgment the abortion is necessary to save the pregnant woman's life or avert a serious risk of substantial and irreversible physical impairment of a major bodily function other than a psychological condition. If a second physician is not available, one physician may certify in writing that, in reasonable medical judgment, there is a medical necessity for emergency medical procedures for termination of the pregnancy to save the pregnant woman's life or avert a serious risk of imminent substantial and irreversible physical impairment of a major bodily function of the pregnant woman other than a psychological condition. "Reasonable medical judgment" is defined in the bill to mean medical judgment that would be made by a reasonably prudent physician, knowledgeable about the case and the treatment possibilities with respect the medical conditions involved.

Abortions after viability, similar to abortions during the third trimester, must be performed in a hospital. When performing such abortions the physician must use the same level of care to preserve the life of the fetus as would be used to preserve the life and health of a fetus intended to be born unless doing so conflicts with preserving the life and health of the pregnant woman.

Any person who performs, or actively participates in, an abortion, except as authorized by law, after the physician determines that, in his or her reasonable medical judgment, the fetus has achieved viability commits a felony of the third degree, or felony of the second degree if the termination of pregnancy results in the death of the woman.

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The bill provides that the provisions of the act are severable and, if the provisions relating to termination of pregnancy during viability are found unconstitutional, the Florida Statutes revert to the law as it existed on January 1, 2014.

If approved by the Governor, these provisions take effect July 1, 2014.

Vote: Senate 24-15; House 70-45

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### **Committee on Health Policy**

### CS/HB 1065 — Licensed Massage Therapists

by Health Quality Subcommittee; and Rep. Kerner and others (CS/SB 1068 by Health Policy Committee and Senator Latvala)

The bill requires certain persons to submit to background screening. Such persons include applicants for licensure as a massage therapist and persons with an ownership interest in, or management responsibilities for a corporation that has more than \$250,000 of business assets in this state, the owner, officer, or individual directly involved in the management of, a massage establishment. Current licensees must comply by January 1, 2015. The applicant or licensee must submit fingerprints electronically to the Florida Department of Law Enforcement for an FBI national criminal history check and ongoing verification against incoming Florida arrests. The fingerprints and the results of the screens are entered into the Care Provider Background Clearinghouse for use by the Department of Health (DOH) in its licensing activities.

The bill requires the Board of Massage Therapy and the DOH to deny an application for new or renewed licensure if the applicant is determined to have been convicted of, or entered a plea of guilty or nolo contendere to, any of the following disqualifying offenses:

- Section 787.01, F.S., relating to kidnapping;
- Section 787.02, F.S., relating to false imprisonment;
- Section 787.025, F.S., relating to luring or enticing a child;
- Section 787.06, F.S., relating to human trafficking;
- Section 787.07, F.S., relating to human smuggling;
- Section 794.011, F.S., relating to sexual battery;
- Section 794.08, F.S., relating to female genital mutilation;
- Section 796.03, F.S., relating to procuring a person under the age of 18 for prostitution;
- Section 796.035, F.S., relating to the selling or buying of minors into prostitution;
- Section 796.04, F.S., relating to forcing, compelling, or coercing another to become a prostitute;
- Section 796.05, F.S. relating to deriving support from the proceeds of a prostitute;
- Section 796.07(4)(c), F.S., relating to a felony of the third degree for a third or subsequent violation as provided in s. 775.082, s. 775.083, or s. 775.084, F.S.;
- Section 800.04, F.S., relating to lewd or lascivious offenses committed upon or in the presence of persons less than 16 years of age;
- Section 825.1025(2)(b), F.S., relating to lewd or lascivious offenses committed upon or in the presence of an elderly or disabled person;
- Section 827.071, F.S., relating to sexual performance by a child;
- Section 847.0133, F.S., relating to the protection of minors;
- Section 847.0135, F.S., relating to computer pornography;
- Section 847.0138, F.S., relating to the transmission of material harmful to minors to a minor by electronic device or equipment; or

• Section 847.0145, F.S., relating to the selling or buying of minors.

The bill also requires the DOH to enter an emergency order suspending the license of a massage therapist or massage establishment if it learns that the massage therapist or person who is subject to background screening for the massage establishment license has been convicted of, or entered a plea of guilty or nolo contendere to, one of the specified criminal acts.

Finally, the bill exempts physicians and chiropractors who employ a licensed massage therapist to provide service to patients in their office from the requirement to obtain a massage establishment license.

If approved by the Governor, these provisions take effect July 1, 2014.

Vote: Senate 38-0; House 117-0

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### **Committee on Health Policy**

### CS/CS/HB 1131 — Emergency Allergy Treatment

by Health and Human Services Committee; Health Quality Subcommittee; Rep. Hudson and others (CS/CS/SB 1122 by Appropriations Committee; Health Policy Committee; Senators Bean, Gibson, Bradley, and Galvano)

The bill renames the Insect Sting Emergency Treatment Act to the Emergency Allergy Treatment Act. The act's scope is expanded to include all emergency allergy reactions and to broaden the availability of epinephrine auto-injectors to additional authorized entities.

For persons who administer lifesaving treatment to persons who have severe allergic reactions when a physician is not immediately available, the requirements for certification are modified to require training to be conducted by a nationally recognized organization or entity approved by the Department of Health, rather than a physician. Additionally, the list of those persons eligible for certification is expanded to include, but not be limited to, camp counselors, scout leaders, school teachers, forest rangers, tour guides, and chaperones who successfully complete the training program.

Authorized entities may also obtain a prescription for epinephrine auto-injectors, then stock and store it for later use by a certified individual on a person who the individual believes in good faith is experiencing a severe allergic reaction. An authorized entity may make an epinephrine auto-injector available to a person who does not have a certification upon remote authorization from a health care practitioner.

Immunity from civil liability is provided under s. 768.13, F.S., the Good Samaritan Act, to certain persons who possess, administer, or store an epinephrine auto-injector in compliance with the Emergency Allergy Treatment Act under specific parameters.

Outdated references to epinephrine delivery devices are removed from statute and specific references to the use and prescription of epinephrine auto-injectors are updated.

If approved by the Governor, these provisions take effect July 1, 2014.

Vote: Senate 38-0; House 116-0

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### **Committee on Health Policy**

#### CS/CS/HB 1179 — Home Health Care

by Health and Human Services Committee; Health Innovation Subcommittee; and Rep. Stone (CS/CS/SB 976 by Judiciary Committee; Health Policy Committee; and Senator Bean)

The bill amends provisions of law relating to home health care.

The bill exempts a home health agency that is not Medicare or Medicaid certified and does not provide skilled care from the requirement to obtain and maintain accreditation from an accreditation organization recognized by the Agency for Health Care Administration (AHCA).

The bill also amends the requirements placed on a nurse registry to clarify that caregivers referred by a registry are independent contractors and not employees of the registry and that it is not the obligation of the nurse registry to monitor, supervise, manage, or train the referred caregiver. The bill requires that a nurse registry advise the patient, patient's family, or other person acting on behalf of the patient of the above details of the relationship between the registry and the referred caregiver.

A nurse registry is required to ensure that each caregiver has presented credentials demonstrating that he or she is adequately trained. In the event of a violation of law by a referred caregiver that comes to the attention of the nurse registry, the nurse registry is required to recommend that the patient terminate the referred caregiver's contract; provide a reason for the recommendation; cease referring the caregiver; and, if practice violations are involved, notify the relevant licensing board. The bill also clarifies that a nurse registry is required to maintain records filed with the registry in accordance with the AHCA's rules, but the registry is not obligated to review or act upon such records except as detailed in the requirements placed on the registry in the event of a violation by the referred caregiver.

If approved by the Governor, these provisions take effect July 1, 2014.

Vote: Senate 31-2; House 109-6

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### **Committee on Health Policy**

# SB 1700 — Public Records/Personal Identifying Information/Compassionate Use Registry

by Senator Bean

The bill creates a new public records exemption for patient and physician personal identifying information held by the Department of Health (DOH) in the compassionate use registry (created by the passage of CS/CS/SB 1030). The bill makes such information confidential and exempt from the public records requirements of s. 119.07(1), F.S., and Art. I, s. 24(a), State Constitution. The bill allows law enforcement agencies, low-THC marijuana dispensing organizations, physicians, the DOH's relevant health care regulatory boards, and persons engaged in bona fide research to access the information in the registry under certain circumstances. The bill also requires that such confidential information remain confidential once released from the registry, provides penalties for violating the provisions of the exemption, and states the public necessity of creating the public records exemption.

The provisions in the bill are subject to the Open Government Sunset Review Act and, as such, will be automatically repealed on October 2, 2019, unless reviewed and reenacted by the Legislature.

If approved by the Governor, these provisions take effect upon becoming law.

Vote: Senate 33-2; House 112-2

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### **Committee on Health Policy**

### **HB 7077** — Nonresident Sterile Compounding Permits

by Health and Human Services Committee; Health Quality Subcommittee; and Rep. Patronis and others (CS/CS/SB 662 by Appropriations Committee; Regulated Industries Committee; and Health Policy Committee)

The bill requires a nonresident pharmacy or an outsourcing facility that is not located in this state to obtain a nonresident sterile compounding permit prior to sending a compounded sterile product into this state. Currently-registered nonresident pharmacies must be permitted by February 28, 2015. However, any compounded sterile product shipped, mailed, delivered, or dispensed into this state must meet or exceed this state's standards for sterile compounding.

An outsourcing facility is defined in the bill as a single physical location registered as an outsourcing facility under the federal Drug Quality and Security Act, Pub. L. No. 113-54, at which sterile compounding of a drug or product is conducted.

The bill establishes application and inspection requirements for the nonresident sterile compounding permit as well as responsibilities for the Department of Health (department) and the Board of Pharmacy (board) to develop application forms, fees, and additional procedures to administer the permit.

The department and board are provided with enhanced oversight responsibility for these entities including authority to inspect a nonresident pharmacy or a nonresident sterile compounding permittee; the cost of which is to be borne by the pharmacy or permittee. The board is authorized to discipline a nonresident pharmacy for conduct which causes or could cause serious bodily or psychological injury to a human or serious bodily injury to an animal immediately, without waiting 180 days for the resident state to act. The board is also authorized to discipline nonresident pharmacies and nonresident sterile compounding permittees for specified acts of noncompliance.

If approved by the Governor, these provisions take effect October 1, 2014.

Vote: Senate 39-0; House 117-0

### **Committee on Health Policy**

### **HB 7177 — OGSR/Prescription Drug Monitoring Program**

By State Affairs Committee and Rep. Brodeur (CS/SB 866 by Government Oversight and Accountability Committee; and Health Policy Committee)

The bill reenacts the public records exemption for personal identifying information held by the Department of Health (DOH) in the Prescription Drug Monitoring Program database (PDMP). If not reenacted by the Legislature the public records exemption would have been automatically repealed on October 2, 2014.

The bill also makes several substantive changes to the public records exemption. The bill requires a law enforcement agency to enter into a user agreement with the DOH before the DOH may release PDMP information to that agency. Information released to the Attorney General's Medicaid fraud investigators, the DOH's health care regulatory boards, and law enforcement agencies may only be shared with criminal justice agencies if the information is relevant to the investigation that prompted the request. Before sharing such information, the person or entity disclosing the information must take steps to ensure the continued confidentiality of all confidential and exempt information including, but not limited to, redacting any nonrelevant information.

The bill prohibits a state attorney from releasing confidential and exempt information shared by the Attorney General's Medicaid fraud investigators or law enforcement agencies in response to a discovery demand unless the information is directly related to the criminal case for which the information was requested. Unrelated information may be released upon a court order.

If approved by the Governor, these provisions take effect October 1, 2014.

Vote: Senate 37-0; House 117-0

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