Senate Committee on Health Regulation

HEALTH CARE PRACTITIONERS

CS/HB 607 — Orthotics, Prosthetics, and Pedorthics

by Healthcare Council and Rep. Cretul and others (CS/CS/SB 1696 by Health and Human Services Appropriations Committee; Health Regulation Committee; and Senator Baker)

This bill substantially revises ch. 468, part XIV, F.S., relating to the practice of orthotics, prosthetics, and pedorthics. The bill adds new definitions and modifies existing definitions to clarify current scope of practice of orthotists, prosthetists, pedorthists, orthotic fitters, and orthotic fitter assistants to more accurately reflect industry practices. The bill modifies the professional and educational requirements of the members of the Board of Orthotists and Prosthetists and expands the definition of consumer members of the board.

The bill requires registration of residents (persons who practice orthotics or prosthetics under the supervision of a licensed orthotist or prosthetist in order to attain required orthotics or prosthetics experience). Each initial applicant for registration, examination, or licensure is required to submit fingerprints for a complete criminal history check by the Florida Department of Law Enforcement and the Federal Bureau of Investigation. Licensure renewal applicants are required to submit information for a statewide criminal history check.

The bill modifies minimum educational requirements for applicants for examination in orthotics or prosthetics to include certain advanced degrees in orthotics and prosthetics in lieu of a bachelor's degree as evidence of meeting these educational requirements and allows the board to require, by rule, mandatory courses as a pre-licensure requirement.

The bill repeals the authorization for the board to issue temporary licenses. The bill allows, effective January 1, 2009, a licensed orthotist, prosthetist, or pedorthist to delegate duties to support personnel, excluding patient evaluation, treatment formulation, or the final fitting of a device prior to patient use. Other delegated duties must be performed under the supervision of a licensed orthotist, prosthetist, or pedorthist. The bill requires support personnel performing these activities to wear identification so that the public is aware that they are not a licensed professional.

The bill establishes requirements for practitioners and resident identification and creates additional grounds for discipline. The bill also exempts from licensure persons engaged exclusively in the fabrication of orthoses, pedorthic devices, or prostheses who have no patient contact.

The bill expands the title protection for certain licensed or registered orthotists, prosthetists, prosthetist-orthotist, orthotic fitter, orthotic fitter assistants, pedorthists, prosthetic residents, and orthotic residents.

If approved by the Governor, except as otherwise expressly provided in this act, these provisions take effect July 1, 2008.

Vote: Senate 39-0; House 114-0

CS/SB 736 — Certification of Clinical Nurse Specialists

by Health Regulation Committee and Senators Saunders, Lynn, and Justice

The bill provides an additional avenue to state certification for an applicant seeking certification as a clinical nurse specialist. The additional avenue is available to a registered nurse who holds a master's degree in a clinical nursing specialty area for which no private certification exists. The nurse must show proof that he or she holds a master's degree as a clinical nurse specialist in a specialty area for which no certification exists and that he or she has completed 1,000 hours of clinical experience in that specialty, with a minimum of 500 hours of clinical practice after graduation. The applicant for certification as a clinical nurse specialist must submit an affidavit to the Board of Nursing affirming the required hours of clinical experience. If a nurse falsifies the affidavit, she or he is subject to discipline.

If approved by the Governor, these provisions take effect October 1, 2008.

Vote: Senate 39-0: House 119-0

CS/HB 803 — Licensure of Psychologists

by Healthcare Council and Rep. Brisé and others (CS/SB 1478 by Health Regulation Committee and Senator Margolis)

Effective January 1, 2009, the Board of Psychology (Board) must close the application file of any applicant who fails to pass the psychology licensure examination and the Florida law and rules portion of the examination or who fails to submit evidence of completion of the postdoctoral, supervised experience within a timeframe no longer than 24 months. The Board must implement a procedure for applicants to request an extension beyond the 24-month timeframe. An individual who completes the required postdoctoral training residency may continue to practice under supervision if she or he does so in a manner prescribed by board rule, has a current application on file, and no final order of denial has been issued.

If approved by the Governor, these provisions take effect January 1, 2009.

Vote: Senate 39-0; House 119-0

HB 989 — Physician Assistants/Formulary

by Rep. Bogdanoff and others (SB 1106 by Senator Saunders)

The bill deletes antipsychotics and parenteral preparations from the formulary of drugs that physician assistants are prohibited from prescribing. Physician assistants would still be prohibited from prescribing controlled substances as defined in ch. 893, F.S., general anesthetics, and radiographic contrast materials.

If approved by the Governor, these provisions take effect July 1, 2008.

Vote: Senate 37-0; House 110-0

CS/CS/SB 1360 — Pharmacy Technicians

by Health and Human Services Appropriations Committee; Health Regulation Committee; and Senator Peaden

The bill revises the requirements for pharmacy licensure by endorsement by deleting the requirement that an applicant must have obtained a passing score on the licensure examination not more than 12 years prior to applying for licensure.

The bill requires the Board of Pharmacy to adopt rules for the registration application process and registration systems administration process so that the rules can be in place upon full implementation of the bill.

The bill changes the regulatory provisions for pharmacy technicians. Effective January 1, 2010, pharmacy technicians must be registered. The Board of Pharmacy must register pharmacy technician applicants who are at least 17 years of age, have completed an approved application form, have submitted the required fees, and otherwise meet registration requirements. A person whose license to practice pharmacy has been suspended, denied, or restricted, is prohibited from registering as a pharmacy technician.

Effective January 1, 2011, an applicant to become a registered pharmacy technician must also have completed an approved pharmacy technician training program. The bill specifies that a registered pharmacy technician registered before January 1, 2011, who has worked as a pharmacy technician for a minimum of 1,500 hours under a licensed pharmacist's supervision or who has received certification as a pharmacy technician from the national Commission for Certifying Agencies is exempt from the requirement to complete an initial training program for purposes of registration.

Pharmacy technician students obtaining practical training and persons licensed as pharmacy interns are exempted from the registration requirements. The bill specifies registration renewal requirements for pharmacy technicians. Grounds for discipline against an applicant for registration as a pharmacy technician or a registered pharmacy technician are specified.

Effective January 1, 2010, it will be unlawful for a person who is not registered as a pharmacy technician, or who is not otherwise exempt, to perform the functions of a registered pharmacy technician or hold herself or himself out as a pharmacy technician.

If approved by the Governor, these provisions, except as otherwise expressly provided in the bill, take effect upon becoming a law.

Vote: Senate 39-0; House 115-2

CS/SB 1694 — 911 Emergency Dispatchers/Denise Amber Lee Act

by Governmental Operations Committee and Senators Aronberg, Fasano, and Margolis

The bill may be cited as the "Denise Amber Lee Act." The bill creates a voluntary certification of 911 emergency dispatchers. The bill requires the Department of Health to establish, by rule, educational and training criteria for certification and requirements for certificate renewal. The requirements must include, at a minimum:

- Completion of an appropriate 911 emergency dispatcher training program that is equivalent to the most recently approved emergency dispatcher course of the Department of Education and consisting of not less than 208 hours;
- Completion and documentation of at least 2 years of supervised full-time employment as a 911 emergency dispatcher since January 1, 2002;
- Certification under oath that the applicant is not addicted to alcohol or any controlled substance and that the applicant is free from any physical or mental defect or disease that might impair the applicant's ability to perform his or her duties; and
- Submission of an application and fees.

The department is authorized to suspend or revoke a certificate at any time if it is determined that the certificate holder does not meet the qualifications. A certificate holder is allowed to request inactivation of his or her certification and may renew the inactive certification for a fee. The department must establish, by rule, a procedure for the initial certification of 911 emergency dispatchers who have documentation of at least 5 years of supervised full-time employment as a 911 emergency dispatcher since January 1, 2002.

If approved by the Governor, these provisions take effect October 1, 2008.

Vote: Senate 39-0; House 117-0

CS/SB 2366 — Medical Faculty Certificates

by Higher Education Committee and Senators Diaz de la Portilla, Constantine, and Lynn

This bill adds the Florida International University and the University of Central Florida to the list of medical schools or teaching institutions where a physician who is not licensed to practice in Florida may be issued a medical faculty certificate that would authorize the physician to practice medicine in conjunction with a full-time faculty position. The number of medical faculty certificates that could be issued at each university would be limited to 15 per year.

If approved by the Governor, these provisions take effect July 1, 2008.

Vote: Senate 38-0; House 117-0

CS/CS/SB 2598 — Impaired Medical Practitioners/Treatment Programs

by Health and Human Services Appropriations Committee; Health Regulation Committee; and Senator Atwater

The bill provides additional rule-making authority to the Department of Health (department) for treatment programs for impaired health care practitioners to require the consultants and providers to meet specified criteria in order to participate in the program.

The bill expands the list of persons who may be retained by the department to work as a consultant for the impaired practitioners' treatment program to include an entity employing a medical director who must be a practitioner or recovered practitioner who holds a Florida license as a medical physician, osteopathic physician, physician assistant, anesthesiology assistant, or nurse.

The bill authorizes the impaired practitioner treatment program consultants to contract to provide services to students enrolled in schools for licensure as allopathic physicians or physician assistants, osteopathic physicians or physician assistants, nurses, or pharmacists, if the school requests such services. The department is not responsible under any circumstances for paying the costs of care provided by the approved treatment providers, and the department is not responsible for paying the costs of the consultants' services provided for students. The bill provides immunity from civil liability, under specified circumstances, to the medical and osteopathic schools for the referral of a student to a consultant or for disciplinary actions that adversely affect the status of the student.

The bill designates an impaired practitioner consultant, a consultant's officers or employees, and persons acting at the direction of the consultant for emergency intervention, when the consultant is unable to perform the intervention, agents of the department or other state agency for purposes of sovereign immunity and the waiver of sovereign immunity for actions taken within the scope of the contract with the department or other state agency. Contracts with the consultants must provide for the indemnification of the state by the consultant for any liabilities incurred up to the

limits set out in ch. 768, F.S. The bill specifies other requirements for the contract. The bill also requires the Department of Financial Services to defend any claim, suit, action, or proceeding against the consultant for acts or omissions arising out of the consultant's duties under the contract.

If approved by the Governor, these provisions take effect July 1, 2008.

Vote: Senate 37-0; House 118-0

CS/CS/SB 2760 — Dentistry

by Health and Human Services Appropriations Committee; Health Regulation Committee; and Senator Peaden

The bill creates a new avenue for a person to apply to take the examination to practice dentistry in this state. An applicant is entitled to take the dental licensure examination if the applicant has:

- An active health access dental license in this state; and
 - o Has at least 5,000 hours within 4 consecutive years of clinical practice experience providing direct patient care in a health access setting;
 - o Is a retired veteran dentist of any branch of the United States Armed Services who has practiced dentistry while on active duty and has at least 3,000 hours within 3 consecutive years of clinical practice experience providing direct patient care in a health access setting; or
 - O Has provided a portion of his or her salaried time teaching health profession students in any public education setting, including, but not limited to, a community college, college, or university, and has at least 3,000 hours within 3 consecutive years of clinical practice experience providing direct patient care in a health access setting;
- Not been disciplined by the board, except for citation offenses or minor violations;
- Not filed a report of a malpractice claim pursuant to s. 456.049, F.S.; and
- Has not been convicted or pled guilty or nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession.

The bill defines "health access settings" to mean programs and institutions of the Department of Children and Family Services, the Department of Health, the Department of Juvenile Justice, nonprofit community health centers, Head Start centers, federally qualified health centers, and clinics operated by accredited colleges of dentistry in this state if such community service programs and institutions immediately report to the Board of Dentistry (board) specified practice act or standard of care violations related to the actions or inactions of a dentist, dental hygienist, or dental assistant engaged in the delivery of dental care in such settings.

The bill also creates examination requirements, an application process, license renewal requirements, and license revocation requirements for a health access dental license. The bill requires the board to grant a health access dental license to practice dentistry in health access settings to an applicant if the applicant meets certain educational and practice standards, files the appropriate application, and pays appropriate fees. The bill provides an individual with a health access dental license the ability to take the Florida dental license examination if these conditions are met. The bill specifies that the failure of an individual with a health access dental license to limit the practice of dentistry to health access settings is the unlicensed practice of dentistry. The bill requires the board to adopt rules to administer the application process, renewal requirements, and revocation requirements for a health access dental license created under this act, and provides a sunset date of January 1, 2015, for the health access dental license statute. Any health access dental license issued before January 1, 2015, remains valid, without effect from repeal.

The bill requires a licensed dentist who uses the services of a dental laboratory to furnish the laboratory a written prescription that, in addition to existing requirements, must include the license number of the dentist and a specification of materials to be contained in each work product. The bill requires the laboratory to disclose to the prescribing dentist in writing, the materials used and all certificates of authenticity for each product with the point of origin of manufacture and the address and contact information of the dental laboratory.

The bill requires dental laboratory owners, or at least one employee of each lab, to complete 18 hours of continuing education biennially beginning on or after July 1, 2010. The bill specifies the types of courses, the objective of continuing education for dental technicians, and the areas that must be addressed in the continuing education courses. A dental laboratory that is physically located within a dental practice operated by a dentist licensed under this chapter is exempt from these requirements and a dental laboratory in another state or country which provides service to a dentist licensed under ch. 466, F.S., is not required to register with the state and may continue to provide services to such dentist with a proper prescription.

The bill limits the board's authority to require a dental hygienist applicant for examination who graduated from a nonaccredited dental college or school to complete additional coursework to only those situations in which the applicant has failed the initial examination.

If approved by the Governor, these provisions take effect January 1, 2009.

Vote: Senate 40-0; House 118-0

HEALTH CARE FACILITIES AND SERVICES

CS/CS/SB 686 — Nursing Facilities

by Judiciary Committee; Health Regulation Committee; and Senator Bennett

The bill authorizes nursing homes with a standard license to offer certified nursing assistant training. The Agency for Health Care Administration (Agency) is authorized to adopt rules for the approval, suspension, or termination of a certified nursing assistant training program.

The bill revises the provisions related to a nursing home reporting adverse incidents to the Agency by clarifying that one of the reportable events is an event that is reported to a law enforcement agency regarding a resident, other than a request for transportation. In addition, the bill eliminates the requirement for a risk manager of a nursing home to notify the Agency of an incident, prior to investigation and a determination that it is a reportable adverse incident. Compliance with federal reporting requirements and reporting of an adverse incident to the Agency within 15 calendar days after its occurrence remain unchanged.

The bill provides that, if additional surveys of a licensed nursing facility have been conducted due to cited deficiencies and those deficiencies are overturned as the result of administrative action, the most recent survey must be considered a licensure survey for purposes of scheduling future surveys.

Finally, a nursing home may allocate a licensed nurse's time between certified nursing assistant duties and licensed nursing duties for purposes of compliance with minimum staffing requirements without seeking agency approval for the allocation.

If approved by the Governor, these provisions take effect July 1, 2008. *Vote: Senate 38-0; House 109-0*

CS/HB 1059 — Exemptions/Tax on Sales, Use and Other Transactions by Healthcare Council and Rep. Llorente (CS/CS/SB 1962 by Finance and Tax Committee; Health Regulation Committee; and Senators Rich, Margolis, Joyner, Lynn, and Bullard)

This bill requires a member of a nonprofit cooperative hospital laundry to discontinue participation in the cooperative within 90 days after the member loses its tax exempt status under s. 501(c)(3) of the Internal Revenue Code. The bill also protects from revocation a nonprofit hospital laundry cooperative's certificate of exemption from sales tax for providing laundry supplies and services to a business that is not a member of the cooperative if the laundry supplies and services are provided pursuant to a declared emergency and a written emergency plan of operation that has been executed by the members of the cooperative.

If approved by the Governor, these provisions take effect July 1, 2008.

Vote: Senate 35-4; House 117-0

CS/CS/SB 1488 — Health Care Consumer's Right to Information Act

by Banking and Insurance Committee; Health Regulation Committee; and Senator Dean

This bill creates the "Health Care Consumer's Right to Information Act" to provide health care consumers with reliable and understandable information about health care charges.

The bill requires a health care provider (allopathic physicians, osteopathic physicians, and podiatric physicians) or health care facility (hospitals, ambulatory surgical centers, and mobile surgical facilities) to automatically furnish to an uninsured patient a reasonable estimate of charges for any planned nonemergency medical service and information on the facility's discount or charity policies for which the uninsured patient may be eligible. The estimate must be written in language that is comprehensible to an ordinary layperson.

The bill requires health care facilities not operated by the state to provide the estimate of reasonably anticipated charges within 7 days after the person notifies the facility and the facility confirms that the person is uninsured. The estimate may be the average charge for the diagnosis-related group or average charge for that procedure. If requested, the facility must also notify the person upon a revision of the estimate.

The bill requires the facility to place a notice in the reception area where the discount or charity care discount policy is available and a facility that fails to provide the estimate and information is subject to a \$500 fine for each time the facility fails to do so.

The Agency for Health Care Administration must publish on its website for public access, undiscounted charges for no fewer than 150 of the most commonly performed adult and pediatric procedures, including outpatient, inpatient, diagnostic, or preventative procedures.

If approved by the Governor, these provisions take effect January 1, 2009.

Vote: Senate 37-0; House 115-0

CS/SB 2326 — Certificates of Need/General Hospitals

by Health and Human Services Appropriations Committee and Senator Peaden

This bill modifies the certificate-of-need (CON) requirements for general hospitals. The Agency for Health Care Administration's (Agency) review criteria are limited to consideration of the need for the hospital; the availability, accessibility, and the extent of utilization of existing hospitals in the service district of the applicant; the extent to which the proposed hospital will enhance access to health care for residents of the service district; the extent to which the proposal

will foster competition that promotes quality and cost-effectiveness; and the applicant's past and proposed provision of health care services to Medicaid patients and the medically indigent.

The application for a CON for a general hospital is revised to require a detailed description of the proposed general hospital project; a statement of its purpose and the needs it will meet; the proposed project's location and the primary service area (location from which 75 percent of the discharges will be drawn) and secondary service area (location from which the remainder of the discharges will be drawn), identified by zip codes. If after the CON is approved, the primary service area materially changes, the Agency must revoke the CON unless the Agency determines that the changes will enhance access to hospital services in the service district. The application must include a statement of intent that, within 120 days after the final order or resolution of all appeals, the applicant will provide satisfactory proof of its financial ability to operate. The Agency must establish documentation requirements for an applicant to show anticipated provider revenues and expenditures, the basis for financing the anticipated cash-flow requirements, and the applicant's access to contingency financing.

If an applicant or substantially affected person requests a public hearing [for any CON application], and the Agency determines that the proposed project involves issues of great local public interest sufficient to warrant a public hearing, the Agency must attend that public hearing.

Except for a competing applicant, in order to be eligible to challenge an Agency decision or intervene in an administrative hearing on a general hospital CON application, an existing hospital must submit a detailed written statement of opposition to the Agency and to the applicant within 21 days after the application is determined complete and made available to the public. A challenge by an existing hospital that is not a competing applicant is limited in scope to the issues raised in the detailed written statement of opposition unless the administrative law judge expands the scope of the issues to be heard at the hearing.

An administrative hearing for a CON application for a general hospital must commence within 6 months after the administrative law judge has been assigned. A continuance may only be granted upon a finding of extraordinary circumstance by the administrative law judge.

The bill requires a party appealing a final order that grants a general hospital CON to post a \$1 million bond in order to maintain the appeal, and if the appealing party loses, to pay the appellee's attorney's fees and costs, up to \$1 million. The attorney's fees and costs are calculated from the beginning of the original administrative action. The Agency may not be liable for any other party's attorney's fees and costs unless the court finds that the Agency improperly rejected or modified findings of fact in a recommended order or that the Agency's action which precipitated the appeal was a gross abuse of the Agency's discretion.

The requirement for an architect's certification of final payment for a completed CON project that involves construction is repealed.

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

Vote: Senate 39-0; House 118-0

CS/HB 7083 — Health Care Fraud and Abuse

by Policy and Budget Council; Healthcare Council; and Rep. Garcia (CS/CS/SB 1374 by Health and Human Services Appropriations Committee; Banking and Insurance Committee; Health Regulation Committee; and Senator Jones)

This bill addresses health care fraud and abuse primarily by home health agencies, nurse registries, and durable medical equipment and medical supply providers. It also authorizes nurse registries to refer appropriately licensed professionals to provide home infusion therapy.

The bill requires applicants for an initial home health agency license to submit additional business and financial information including: a business plan that details the proposed home health agency's methods to obtain patients and recruit and maintain staff, provides evidence of contingency funding and documentation related to accreditation, and demonstrates financial ability to operate with projected operating margins limited to less than 15 percent for any month in the first year of operation, ownership interests. The AHCA may not issue an initial license for a home health agency if the applicant shares common controlling interests with another licensed home health agency that is located within 10 miles of the applicant and is in the same county. A licensure application may not be transferred to another home health agency or controlling interest before the license is issued and an initial licensure application must be submitted if a licensed home health agency seeks to relocate to a different geographic service area. The AHCA may accept the submission of a non-provisional accreditation survey to satisfy the periodic licensure survey requirements, if certain conditions are met.

The bill prohibits certain fraudulent conduct by home health agencies and nurse registries related to patient services and referrals. Administrative fines are increased for class I through IV deficiencies.

The bill limits the number of home health agencies that an administrator may manage and a director of nursing may serve. With certain exceptions, a home health agency may not operate for longer than 30 days without a director of nursing. Both the home health agency and the director of nursing must notify the AHCA upon the termination of the director of nursing and the home health agency must notify the AHCA within 10 business days after a new director of nursing is hired. A home health agency that fails to notify the AHCA is subject to fines and may have a moratorium placed on its license or its license revoked for operating without a director of nursing beyond 30 days.

The AHCA must develop rules related to oversight responsibilities by the director of nursing for services provided by the home health agency's staff; reporting requirements; a quality assurance program; and conditions for unannounced licensure inspections.

The bill defines a change in ownership for purposes of Medicaid provider enrollment. If a change of ownership occurs, both the transferor and the transferee are liable for all moneys owed to the AHCA before the effective date of the change of ownership. If the transferor fails to notify the AHCA of the change of ownership or the transferee fails to submit a Medicaid provider enrollment application at least 60 days prior to the proposed effective date of the change of ownership, both the transferor and transferee are liable for all moneys due to the AHCA even though a liability was not identified prior to the effective date of the change of ownership. The AHCA's approval of the transferee's Medicaid provider enrollment application is contingent upon a written payment plan for any outstanding liabilities.

The bill specifies the Medicaid provider enrollment effective date for a provider that requires a Medicare certification survey, a change of ownership, and a provider of emergency medical services transportation or emergency services and care.

The bill requires the AHCA to limit the network of durable medical equipment and medical supply providers (DME provider) in Medicaid for dates of service after January 1, 2009. After this date, a DME provider, with certain exceptions, must meet specified requirements related to accreditation, physical location, inventory, surety bond, and background screening in order to obtain reimbursement under the Medicaid program.

The AHCA is required to review prior authorization procedures for home health agency visits that are in excess of 60 visits over the lifetime of a Medicaid recipient and to report to the Legislature by January 1, 2009, on the feasibility and costs of accessing the Medicare system to disallow Medicaid payment for home health services that have already been paid for by Medicare for recipients who are dually eligible for Medicaid and Medicare.

If approved by the Governor, these provisions take effect July 1, 2008.

Vote: Senate 39-0; House 118-0

PUBLIC HEALTH

CS/CS/SB 564 — Automated External Defibrillators

by Judiciary Committee; Health Regulation Committee; and Senators Constantine, King, Lynn, and Baker

The bill revises the requirements for the use of an automated external defibrillator (AED) in cases of cardiac arrest. Under the bill, any person who uses an AED is encouraged, rather than required, to obtain appropriate training. Any person or entity in possession of an AED is encouraged to notify the local emergency medical services medical director of the location of the AED, rather than register the existence and location of the AED with the local emergency medical services medical director.

The bill also revises requirements under which a person who acquires an AED may obtain immunity from civil liability for harm resulting from the use of an AED. The bill provides that the immunity applies to a person who acquires the AED *and* makes the device available for use. Furthermore, the bill eliminates a requirement that those who acquire and make available an AED must notify the local emergency medical services medical director of the most recent placement of the device. Finally, an employer or principal who acquired an AED may still enjoy immunity if he or she did not provide appropriate training to his or her employee or agent provided that the device is equipped with audible, visual, or written instructions on its use.

If approved by the Governor, these provisions take effect July 1, 2008.

Vote: Senate 38-0; House 118-0

CS/SB 646 — HIV/AIDS Educational Requirements

by Health Regulation Committee and Senator Margolis

The bill revises the HIV/AIDS educational course requirements for employees and clients of specified licensed health and social services facilities. Employees and clients of the facilities will only need to complete the HIV/AIDS course once rather than every two years. An employee of one of these facilities who has completed the course is not required to repeat the course upon changing employment to another licensed facility.

These requirements for HIV/AIDS training do not apply to any employee who is licensed or certified as an acupuncturist, medical physician, physician assistant, anesthesiology assistant, osteopathic physician, chiropractic physician, podiatric physician, optometrist, nurse, advanced registered nurse practitioner, pharmacist, dentist, dental hygienist, occupational therapist, nursing home administrator, respiratory therapist, dietitian/nutritionist, physical therapist, or physical therapy assistant. However, these employees must comply with the HIV/AIDS educational requirements for the employee's profession.

The bill requires nurse registries to require every applicant for a contract to complete an application form, which includes proof of completion of a continuing educational course on modes of transmission, infection control procedures, clinical management, and prevention of HIV/AIDS with an emphasis on appropriate behavior and attitude change. The course must include information on current Florida law and its effect on HIV/AIDS testing and reporting.

If approved by the Governor, these provisions take effect July 1, 2008.

Vote: Senate 38-0; House 111-0

CS/SB 1318 — Onsite Sewage Treatment and Disposal Systems

by Community Affairs Committee and Senators Gaetz and Lynn

The bill revises the membership of the Research Review and Advisory Committee and the Technical Review and Advisory Panel established by the Department of Health for the purposes of onsite sewage treatment and disposal system regulation to include a representative from local government who is knowledgeable about domestic wastewater treatment.

The bill also provides an exemption from certification requirements for certain persons who are working under the direct responsible charge of an engineer licensed under ch. 471, F.S. This exemption applies to persons determining proper placement and installation of onsite wastewater treatment and disposal systems and who have successfully completed a department-approved soils morphology course.

If approved by the Governor, these provisions take effect July 1, 2008.

Vote: Senate 39-0; House 115-0

CS/CS/SB 1648 — HIV Testing/Informed Consent

by Health Policy Committee; Health Regulation Committee; and Senators Saunders and Lynn

The bill modifies three of the exceptions to the requirement that informed consent be obtained from a person before a human imunodeficiency virus (HIV) test is performed on the person. The three exceptions that are modified in the bill relate to cases in which a significant exposure to the HIV has occurred involving medical and nonmedical personnel providing treatment, assistance, or care. The bill authorizes HIV testing without consent, if consent cannot be timely obtained or if the individual who is the source of the significant exposure is incapable of providing consent. The bill requires the HIV testing to be conducted only after appropriate medical personnel under the supervision of a licensed physician documents in the medical record of the exposed personnel that a significant exposure has occurred and the testing is done in accordance with written protocols based on the Centers for Disease Control and Prevention guidelines on HIV postexposure prophylaxis and, in the physician's medical judgment, the information is medically necessary to determine the course of treatment.

If approved by the Governor, these provisions take effect July 1, 2008.

Vote: Senate 39-0; House 117-0

CS/CS/SB 2630 — Organ and Tissue Donation

by Health and Human Services Appropriations Committee; Governmental Operations Committee; and Senators Oelrich, Gaetz, and Lynn

This bill modernizes the law for the organ and tissue donation program by establishing an online donor registry and revising provisions to more closely track the revised Uniform Anatomical Gift Act. The organ and tissue donor registry is named the Joshua Abbott Organ and Tissue Registry.

The bill modifies the list of persons who may make an anatomical gift and the persons whose objections prevent a gift from being made or accepted. Two classes of persons are added to the list of person who may make an anatomical gift, an adult grandchild of the decedent and a close personal friend. A member of one of the classes is no longer prohibited from making an anatomical gift if another member of the same class objects and a spouse may make an anatomical gift notwithstanding an objection by an adult son or daughter.

The bill also modifies the suggested form to authorize a designated health care surrogate to make a health care decision for an anatomical gift without the principal having executed an anatomical gift declaration.

The bill requires the Agency for Health Care Administration and the Department of Highway Safety and Motor Vehicles to contract for the operation of an organ and tissue donor registry and education program. The bill specifies the duties of the contractor and the sources of funds for the registry and education program.

If approved by the Governor, these provisions take effect July 1, 2008.

Vote: Senate 36-0: House 114-0

CS/SB 2610 — Public Records/Organ and Tissue Donor Registry

by Governmental Operations Committee and Senator Oelrich

This bill makes information which identifies a donor in the organ and tissue donor registry confidential and exempt from the public records law and the constitutional provisions related to public records. However, information in the registry may be disclosed to organ, tissue, and eye procurement organizations for the purpose of ascertaining or effectuating the existence of an anatomical gift and to persons engaged in bona fide research under specified conditions.

This public records exemption is set to be repealed on October 1, 2013, subject to legislative review and reenactment. The bill provides a statement of the public necessity for the public records exemption.

If approved by the Governor and CS/CS/SB 2630 is approved by the Governor, these provisions take effect July 1, 2008.

Vote: Senate 37-0; House 116-0

HB 7049 — Drugs, Devices, and Cosmetics

by Healthcare Council and Rep. Bean and others (CS/CS/SB 2756 by Judiciary Committee; Health Regulation Committee; and Senator Peaden)

This bill reorganizes the Florida Drug and Cosmetic Act to consolidate regulatory provisions for all regulated permits and activity, and provides for consistent terminology throughout the act.

The bill also modifies definitions for terms used in the regulation of the manufacture and wholesale distribution of prescription drugs. The definition of authenticate is modified to specify that a wholesale distributor is not required to open a sealed, medical convenience kit to authenticate a pedigree paper for a prescription drug contained in the kit and that the authentication of a prescription drug in a sealed, medical convenience kit is limited to verifying the transaction and pedigree information received.

Up to two intracompany transfers are authorized in the definition of the normal distribution chain for purposes of providing a direct purchase pedigree statement upon the wholesale distribution of a prescription drug that was purchased directly from the manufacturer of the prescription drug and distributed to a chain pharmacy warehouse or person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug.

The bill changes the timing for receiving a pedigree paper in the prohibited acts for purposes of administrative or criminal penalties to authorize receipt of a pedigree paper prior to or simultaneously with the receipt of the prescription drug.

The bill specifies that an active pharmaceutical ingredient in bulk form must be labeled with the name and place of business of the manufacturer, repackager, or distributor; and contain an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, otherwise the drug is misbranded.

The bill establishes new permits, with fees, and authorizes activities for a third party logistics provider and a health care clinic establishment. The third party logistics provider permit is available to a contracted distribution facility, which does not take title to the prescription drug, for a prescription drug manufacturer or prescription drug wholesale distributor. The health care clinic establishment permit, which becomes effective on January 1, 2009, allows a business entity with a qualifying practitioner, who is a licensed health care practitioner or a veterinarian authorized to prescribe and administer a prescription, to purchase prescription drugs.

An exemption from the requirement to obtain a nonresident prescription drug manufacturer permit is provided for a manufacturer to distribute limited quantities of a prescription drug active pharmaceutical ingredient to a prescription drug manufacturer for research and development purposes only, as provided in rules adopted by the Department of Health. A temporary transit storage facility, which may store a prescription drug for no longer than 16 hours when a wholesale distributor is temporarily unable to complete the delivery of the prescription drug to a recipient, is exempted from the permitting requirements.

The bill also corrects a glitch in the eligibility criteria for a limited prescription drug veterinary wholesale distributor.

If approved by the Governor, these provisions take effect July 1, 2008.

Vote: Senate 38-0; House 119-0