

THE FLORIDA SENATE  
2011 SUMMARY OF LEGISLATION PASSED  
**Committee on Health Regulation**

**CS/HB 1085 — Women's Health**

by Health and Human Services Quality Subcommittee and Rep. Plakon (SB 1282 by Senator Storms)

The bill creates the Kelly Smith Gynecologic and Ovarian Cancer Education and Awareness Act within the Department of Health (DOH). The bill adds one member from the Florida Ovarian Cancer Alliance Speaks organization to the Florida Cancer Control and Research Advisory Council, increasing the membership from 34 to 35.

The bill directs the DOH to encourage women to discuss the risks of gynecological cancers with their health care providers. Furthermore, the DOH is directed to encourage health care providers and certain entities to disseminate and display information about gynecological cancers, including signs and symptoms, risk factors, benefits of early detection, and treatment options. The DOH is encouraged to seek any available federal or private grants to promote gynecological cancer awareness and to collaborate with other entities to create a systematic approach to increasing public awareness. The State Surgeon General is required to post on the DOH website a link to the Centers for Disease Control and Prevention website for gynecological cancer information.

If approved by the Governor, these provisions take effect July 1, 2011.

*Vote: Senate 37-0; House 114-0*

THE FLORIDA SENATE  
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**Committee on Health Regulation**

**CS/HB 1127 — Abortions**

by Health and Human Services Committee and Reps. Porter and others (CS/SB 1744 by Health Regulation Committee and Senators Storms and Oelrich)

Except in a medical emergency, this bill provides that consent to a termination of pregnancy is voluntary and informed if, among other things, a woman seeking an abortion has the gestational age of the fetus verified by an ultrasound, regardless of the woman's stage of pregnancy. The bill prescribes who is authorized to perform the ultrasound.

The person performing the ultrasound must offer the woman the opportunity to view the live ultrasound images and hear an explanation of them before she gives informed consent to having the abortion procedure, unless the woman presents certain documentation evidencing that the woman is obtaining the abortion because she is a victim of rape, incest, domestic violence, or human trafficking or the delay in the abortion procedure would cause substantial and irreversible impairment of a major bodily function of the woman.

The bill provides that a woman has a right to decline to view the ultrasound images and hear an explanation of the images after she has been offered an opportunity to view and hear an explanation of the images. However, if the woman declines to view and hear an explanation of the ultrasound images, she is required to complete a form acknowledging that she was offered an opportunity to view the images and hear the explanation of the images, that she has declined that opportunity, and that her refusal to view and hear an explanation of the images was of her own free will.

The bill provides that consent to a termination of pregnancy is voluntary and informed if, among other things, a description of the fetus, including a description of the various stages of development, has been provided to the woman.

The bill provides that the failure of a health care practitioner to comply with the requirements under s. 390.0111, F.S., is grounds for disciplinary action and authorizes the DOH, or the appropriate board, to adopt rules necessary to implement the provisions under s. 390.0111, F.S.

The bill requires the Agency for Health Care Administration (AHCA) to adopt rules requiring an abortion clinic that performs abortions after the first trimester of pregnancy to take a urine or blood test, regardless of whether the woman seeking an abortion will have an ultrasound performed. The AHCA must also adopt rules requiring clinics to be in compliance with the provisions of s. 390.0111, F.S.

The bill also includes a severability clause, which severs any provision of the bill that is held invalid.

If approved by the Governor, these provisions take effect July 1, 2011.

*Vote: Senate 24-15; House 81-37*

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THE FLORIDA SENATE  
2011 SUMMARY OF LEGISLATION PASSED  
**Committee on Health Regulation**

**CS/HJR 1179 — Abortion/Public Funding/Construction of Rights**

by Health and Human Services Committee; Rep. Baxley and others (CS/CS/SJR 1538 by Rules Committee; Judiciary Committee; and Senators Flores, Haridopolos, and Oelrich)

This is a joint resolution proposing the creation of s. 28, Art. I of the Florida Constitution to prohibit public funds from being expended for any abortion or for health-benefits coverage that includes coverage of abortion. However, public funds may be expended when required by federal law; a woman suffers from a physical disorder, physical injury, or physical illness which would, as certified by a physician, place the woman in danger of death; or a pregnancy results from rape or incest.

The joint resolution also prohibits the Florida Constitution from being interpreted to create broader rights to an abortion than those contained in the U.S. Constitution.

The joint resolution includes a summary statement that is to be placed on the ballot for the next general election.

If adopted by the voters at the 2012 General Election, this resolution will take effect January 3, 2013.

*Vote: Senate 27-12; House 79-34*

THE FLORIDA SENATE  
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**HB 1247 — Parental Notice of Abortion**

by Rep. Stargel and others (SB 1770 by Senators Hays and Oelrich)

This bill amends s. 390.01114, F.S., relating to parental notification of an abortion to be performed on a minor. This bill amends the law as it relates to parental notification of an abortion by:

- Redefining “constructive notice” to include notice by writing that must be mailed to a minor’s parent or legal guardian prior to the abortion by first-class mail and by certified mail, return receipt requested, with restricted delivery to the parent or legal guardian.
- Requiring notice that is given by telephone to a parent or legal guardian to be confirmed in writing, signed by the physician, and mailed to the parent or legal guardian of the minor by first-class mail and by certified mail, return receipt requested, with restricted delivery to the parent or legal guardian.
- Requiring a physician to make reasonable attempts to contact the parent or legal guardian, whenever possible, during a medical emergency that renders the abortion medically necessary, without endangering the minor.
- Requiring the physician to provide notice directly to a parent or legal guardian of the medical emergency requiring an abortion and any additional risks to the minor and if no notice is directly provided, then notice is required in writing to the parent or legal guardian, which must be mailed by first-class and certified mail.
- Providing that a parent or guardian’s legal right to be noticed can only be waived if the written waiver is notarized, dated not more than 30 days before the abortion, and contains a specific waiver of the parent or legal guardian’s right to notice of the minor’s abortion.
- Reducing the number of courts in which a minor is able to file a petition for waiver of parental notice.
- Extending the time within which a court must rule on a minor’s petition for a waiver of parental notice from 48 hours to 3 business days.
- Removing the automatic grant of a petition when a court fails to rule within a certain time.
- Providing that a minor may have her petition heard by a chief judge of the circuit within 48 hours of filing the petition when a circuit court has not ruled within 3 business days.
- Providing the minor with the right to appeal a court decision that does not grant judicial waiver of parental notice, providing the timeline within which the appellate court must rule, and providing the standard of review the appellate court must use.
- Requiring the court to consider specific factors when determining whether the minor is sufficiently mature to decide whether to terminate her pregnancy.
- Changing the standard upon which a court must find that the notification of a parent or guardian of the abortion is not in the best interest of the minor, from preponderance of the evidence to clear and convincing evidence.
- Providing that when the court considers what is in the best-interest of the minor, the court is not to consider financial implications for the minor or the minor’s family.

- Requiring the final written order by the court to include its factual findings determining the maturity of the minor.
- Requiring the Office of State Courts Administrator to include in its annual report to the Governor and Legislature the number of petitions filed for a waiver of parental notice and the reason for each waiver of notice granted.

The bill also includes a severability clause, which severs any provision of the bill that is held invalid and saves the remaining provisions.

If approved by the Governor, these provisions take effect October 1, 2011, or upon the adoption of rules and forms by the Supreme Court, whichever occurs earlier.

*Vote: Senate 26-12; House 82-35*

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**CS/CS/CS/HB 1319 — Certificates/Licenses/Health Care Practitioners**

by Health and Human Services Committee; Health Care Appropriations Subcommittee; Health and Human Services Quality Subcommittee; and Rep. Harrell and others (CS/CS/SB 1228 by Military Affairs, Space, and Domestic Security Committee; Health Regulation Committee; and Senators Altman and Evers)

The bill authorizes the Department of Health (DOH) to issue a temporary license to a healthcare practitioner whose spouse is stationed in Florida on active duty with the Armed Forces if the applicant meets the eligibility requirements for a full license and is qualified to take the licensure examination. The healthcare practitioner is required to meet certain criteria to obtain the 12-month non-renewable, temporary license. The bill requires the applicable board, or the DOH if there is no board, to deny applications under certain circumstances. The bill requires the applicant for a temporary license to pay the cost for fingerprint processing for a criminal history check, and an application fee.

The bill names the temporary certificates for practice in areas of critical need under ss. 458.315 and 459.0076, F.S., the “Rear Admiral LeRoy Collins, Jr., Temporary Certificate for Practice in Areas of Critical Need.”

The bill generally expands the scope and area of practice of dental hygienists by authorizing dental hygienists to perform certain duties unsupervised in health access settings, which includes school-based prevention programs and accredited dental hygiene programs. The bill allows dental hygienists to apply fluorides, instruct on the oral hygiene of a patient, and supervise the oral hygiene of a patient, without the supervision of a dentist. The bill requires dental hygienists, who perform remediable tasks without supervision, to provide a dental referral in compliance with federal and state patient referral, anti-kickback, and patient brokering laws; encourages the establishment of a dental home; and requires the dental hygienists to maintain a certain amount of professional malpractice insurance coverage.

The bill clarifies that the authorization for dental hygienists to perform some duties does not prevent a program operated by one of the health access settings or a nonprofit organization from billing and obtaining reimbursement for the services provided by a dental hygienist.

The bill replaces the current dental exam, administered through the DOH, with a national exam, the American Dental Licensing Examination (ADLEX). The bill provides that if an individual who is relocating to Florida took the ADLEX exam more than a year ago, he or she must meet additional criteria for licensure, including engaging in the full-time practice of dentistry in the 5 years preceding the date of application to practice dentistry in Florida or since initial licensure, if he or she has practiced less than 5 years. However, this provision only applies to individuals who took the ADLEX exam after October 1, 2011. Additionally, the bill provides that an individual who is relocating to Florida to practice dentistry must engage in the full-time practice of dentistry within one year of receiving a dental license. The bill requires the Board of Dentistry to develop rules for the full-time dentistry requirements, and recoup costs for verification of full-

time practice. The bill provides for the expiration of licenses if the full-time practice requirements are not fulfilled and requires the Board of Dentistry to provide notice of the impending expiration of the license. The bill makes it a third degree felony to use or attempt to use a license that is expired or has been revoked.

The bill amends statutory requirements related to athletic trainers. It defines “Board of Certification” and requires members of the Board of Athletic Training to be certified by the Board of Certification. The bill includes colleges, universities, and education programs recognized by the Board of Certification in the qualifying colleges, universities, and programs for licensure as an athletic trainer. The bill also requires athletic trainers to be certified in the use of automated external defibrillators (AED’s), and meet additional continuing education requirements in the use of AED’s. The bill deletes the requirement that each licensee must complete a continuing education course on human immunodeficiency virus and acquired immune deficiency syndrome as part of biennial relicensure.

The bill also includes a severability clause.

If approved by the Governor, these provisions take effect upon becoming law or as otherwise specifically provided for in the act.

*Vote: Senate 39-0; House 116-0*



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**CS/HB 1463 — Crisis Stabilization Units**

by Health and Human Services Committee and Reps. Hudson and Workman (SB 1052, 1st Engrossed by Senator Altman)

The bill amends s. 394.875, F.S., by directing the Department of Children and Families (DCF) to implement a demonstration project in Circuit 18, which includes Brevard and Seminole Counties. The DCF is directed to authorize the existing public and private crisis stabilization units in Circuit 18 to expand to up to 50 beds. The pilot project is to determine the impact this expansion would have on the availability of crisis stabilization services to clients.

If approved by the Governor, these provisions take effect July 1, 2011.

*Vote: Senate 39-0; House 112-0*

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**CS/HB 1473 — Public Records/Florida Health Choices Program**

by Government Operations Subcommittee and Rep. Corcoran (CS/CS/SB 1456 by Governmental Oversight and Accountability Committee; Children, Families, and Elder Affairs Committee; and Senator Garcia)

The bill creates exemptions from the state's public records requirements for specified types of information relating to enrollment or participation in the Florida Health Choices program.

The Florida Health Choices program is a single, centralized marketplace for the sale and purchase of health care coverage, including, but not limited to, health insurance plans, health maintenance organization (HMO) plans, prepaid health services, and flexible spending accounts. Policies sold under the program are exempt from regulation under the Florida Insurance Code and laws governing HMOs. Current law specifies entities eligible to purchase products through, and participate in, the program; vendors eligible to participate in the program; and individuals eligible to enroll in the program.

The bill creates a public record exemption for the following information held by the program:

- Personal identifying information of an enrollee or participant who has applied for or participates in the program;
- Client lists and customer lists of a buyer's representative; and
- Proprietary confidential business information.

The bill provides for retroactive application of the public record exemptions to cover information held by the program before, on, or after the effective date of the exemptions. It provides exceptions to the exemptions and provides criminal penalties for violation of the public record exemptions.

The bill provides for repeal of the exemptions on October 2, 2016, unless reviewed and saved from repeal by the Legislature. It also provides a statement of public necessity as required by the State Constitution.

If approved by the Governor, these provisions take effect October 1, 2011.

*Vote: Senate 38-1; House 114-0*

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**CS/SB 1676 — Sovereign Immunity**

by Judiciary Committee and Senators Thrasher and Oelrich

The bill establishes legislative findings that nonprofit independent private colleges and universities located and chartered in Florida, which own or operate medical schools, and which permit their employees or agents to provide patient services in teaching hospitals pursuant to an affiliation agreement or other contract, should be afforded sovereign immunity protections under s. 768.28, F.S. Additionally, the Legislature declares that there is an overwhelming public necessity for extending the state's sovereign immunity to such entities and that there is no alternative method of meeting such public necessity.

Under the bill, any nonprofit independent college or university located and chartered in Florida, which owns or operates an accredited medical school, or any of its employees or agents, and which has agreed by affiliation agreement or other contract to provide, or to permit its employees or agents to provide, patient services as agents of a teaching hospital, is considered an agent of the teaching hospital while acting within the scope of and pursuant to guidelines established in the contract.

The contract must provide for the indemnification of the teaching hospital, up to certain limits, by the agent for any liability incurred which was caused by the negligence of the college or university or its employees or agents. The contract must also provide that those limited portions of the college, university, or medical school which are directly providing services pursuant to the contract and which are considered an agent of the teaching hospital, are deemed to be acting on behalf of a public agency for purposes of public records laws.

Notice must be provided to each patient, or the patient's legal representative, that the exclusive remedy for injury or damage suffered as the result of any act or omission of the teaching hospital, the college or university, or the employees or agents of the college or university, while acting within the scope of duties pursuant to the contract with the teaching hospital, is by commencement of an action under the state's limited waiver of sovereign immunity pursuant to s. 768.28, F.S. This notice requirement may be met by posting the notice in a place conspicuous to all persons.

The bill does not designate any employee providing contracted patient services in a teaching hospital as an employee or agent of the state for purposes of workers' compensation insurance.

If approved by the Governor, these provisions take effect upon becoming law and apply to all claims accruing on or after that date.

*Vote: Senate 38-0; House 109-8*

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**HB 4027 — Obsolete Health Care Provisions**

by Rep. Horner (SB 548 by Senator Hays)

The bill repeals Florida Statutes relating to the designation of separate restrooms and separate dressing rooms for males and females, the Florida Healthy People 2010 program, and the MedAccess program.

***Separate Restrooms and Separate Dressing Rooms for Males and Females***

In 1977 the Legislature provided that any business may designate separate restrooms and separate dressing rooms for males and females and may prohibit the use of such designated restrooms or dressing rooms by persons of the opposite gender. In buildings or facilities owned or operated by the state or any political subdivision of the state that contain more than one restroom, the restrooms for males must be separate from those for females and each restroom that has capacity for more than one occupant must be designated by appropriate signage as a restroom for males or for females. All these statutory provisions are eliminated under the bill.

***Florida Healthy People 2010***

In 2004 the Legislature created the Florida Healthy People 2010 program. Under the program, the Department of Health (DOH) is directed to monitor and report Florida's status regarding the federal Healthy People 2010 program's goals and objectives that were being tracked and were available to the DOH on July 1, 2004. The goals and objectives of the federal program are described in Florida Statutes as being designed to measure and help improve the health of all Americans by increasing the quality and years of healthy life and eliminating health disparities among different segments of the population. In December 2010, the federal government replaced the Healthy People 2010 program with the Healthy People 2020 program, the new purpose of which is for health promotion and disease prevention. This bill repeals statutory provisions for the creation and administration of the Florida Healthy People 2010 program.

***MedAccess***

In 1993 the Legislature created the MedAccess program, designed for the state to provide certain health care benefits to uninsured Floridians with a gross family income equal to or less than 250 percent of the federal poverty level who also meet other eligibility requirements. The state is authorized to pay health care providers under the program at the same reimbursement rates and fees as those under the Medicaid program. Despite being statutorily authorized, the MedAccess program has never been funded and therefore has never been implemented. This bill repeals statutory provisions for the creation and administration of the MedAccess program.

If approved by the Governor, these provisions take effect July 1, 2011.

*Vote: Senate 39-0; House 117-0*

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**HB 4121 — Clove Cigarettes**

by Rep. Artiles (SB 1778 by Senator Bogdanoff)

The bill repeals the statutory prohibition against the sale, use, possession, transfer, or otherwise disposing of clove cigarettes or similar products, which was enacted in 1985.

Despite a 1985 judicial injunction prohibiting the enforcement of the clove cigarette ban, the statute was never amended or repealed. This bill repeals the ban and aligns Florida Statutes with the injunction prohibiting enforcement of the ban.

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

*Vote: Senate 34-4; House 114-3*

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**HB 7079 — OGSR/Florida Center for Brain Tumor Research**

by Government Operations Subcommittee and Rep. Bileca (SB 420 by Health Regulation Committee)

This bill modifies and reenacts the public records exemption for the Florida Center for Brain Tumor Research under s. 381.8531, F.S. The public records exemption is modified by making confidential and exempt from s. 119.07(1), F.S., and s. 24, Art. I of the Florida Constitution all personal identifying information of a donor to the central repository for brain tumor biopsies or the brain tumor registry. The bill authorizes the disclosure of such personal identifying information for bona fide research purposes, if the researcher submits a research plan that has been approved by an institutional review board, signs a confidentiality agreement, maintains the confidentiality of the information received, and destroys the confidential information after the research has concluded.

This bill extends the repeal date from October 2, 2011, to October 2, 2016, and provides a public necessity statement.

If approved by the Governor, these provisions take effect July 1, 2011.

*Vote: Senate 39-0; House 113-1*

THE FLORIDA SENATE  
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**CS/CS/HB 7095 — Prescription Drugs**

by Appropriations Committee; Judiciary Committee; Health and Human Services Committee; and Rep. Schenck (CS/CS/SB 818 by Criminal Justice Committee; Health Regulation Committee; and Senators Fasano, Lynn, and Margolis)

This bill provides a more comprehensive approach to address the epidemic of prescription drug abuse and the untimely deaths that result from such abuse in this state. The approach includes the regulation of activities by physicians, pain management clinics, pharmacies, and wholesale drug distributors. The bill also provides minor revisions to the prescription drug monitoring program.

***Physicians Generally***

On July 1, 2011, practitioners will no longer be authorized to dispense controlled substances. However, there are exceptions. These include dispensing:

- Complimentary or sample controlled substances.
- In the health care system of the Department of Corrections.
- In connection with certain surgical procedures within certain timeframes.
- Pursuant to participation in an approved clinical trial.
- Methadone in a licensed treatment program.
- For hospice patients.

On July 1, 2011, when this law goes into effect, the State Health Officer will declare a public health emergency concerning the possession of controlled substances for dispensing by practitioners who are no longer authorized to dispense controlled substances. Any controlled substance inventory that was acquired for dispensing that is still in the possession of a practitioner who will no longer be authorized to dispense controlled substances once this act goes into effect, must be disposed of by July 11, 2011. The drugs can be disposed of by returning them to the wholesale distributor or turning the inventory in to a local law enforcement agency and abandoning them. If this does not happen by August 2, the controlled substances are deemed contraband and are subject to seizure by law enforcement agencies.

Wholesale distributors are required to buy back the inventory of controlled substances listed in Schedule II or Schedule III which are in the manufacturer's original packaging, unopened, and in date, in accordance with the established policies of the wholesale distributor or the contractual terms between the wholesale distributor and the physician concerning returns.

In addition, using actual purchasing records from wholesalers and other information, the Department of Health (department) will identify those practitioners who pose the greatest threat to the public health and risk that the controlled substances may not be disposed of in accordance with this act. Beginning on the 3<sup>rd</sup> day after this act goes into effect, law enforcement agencies will enter the business premises of the identified dispensing practitioners and quarantine the inventory on site. A \$3 million appropriation is available for law enforcement for this effort, to

maintain the security of the quarantined inventory until final disposition, and to investigate and prosecute crimes related to prescribed controlled substances.

Effective January 1, 2012, each medical physician, osteopathic physician, podiatrist, or dentist who prescribes controlled substances for the treatment of chronic nonmalignant pain must designate on his or her practitioner profile that he or she is a controlled substance prescribing practitioner.

The standards of practice for a controlled substance prescribing practitioner are spelled out in the law. These standards of practice do not supersede the level of care, skill, and treatment recognized in general law. The standards of practice in this bill include, among other things:

- A complete medical history and physical examination, the exact components of the exam are left to the judgment of the clinician;
- Development of a written individualized treatment plan for each patient, with objectives for treatment success and other treatment modalities;
- Discussion with the patient concerning the risks and benefits of the use of controlled substances;
- A written controlled substance agreement between the physician and the patient that includes reasons for which drug therapy may be discontinued and that controlled substances shall be prescribed by a single treating physician, unless otherwise authorized and documented in the medical record;
- Regular follow-up appointments at least every 3 months to assess the efficacy and appropriateness of treatment;
- Referrals to specialists when indicated; and
- Maintenance of accurate and complete records on each patient.

Certain specialists and surgeons are exempted from these standards of practice.

Additional disciplinary or criminal sanctions are established for physicians who violate the controlled substances laws, including:

- Failing to comply with the controlled substance prescribing and dispensing requirements.
- If a physician violates the standard of practice for prescribing or dispensing a controlled substance as set forth in the bill, then the physician will be suspended for at least 6 months and pay a fine of at least \$10,000. Repeat offenses result in increased penalties.

The department will approve vendors of counterfeit-proof prescription pads. The approved vendors will report monthly to the department on the number of pads sold and the purchasers of the pads. The counterfeit-resistant prescription blanks must be used by practitioners for the purpose of prescribing any controlled substance.

### ***Pain Management Clinics***

The bill revises the criteria for required registration as a pain management clinic. Registration is required if the clinic advertises in any medium for any type of pain management services or



where, in any month, a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain (pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual period or more than 90 days after surgery). The bill includes additional exemptions from registration.

Physicians practicing in pain management clinics must:

- Notify the applicable board within 10 days after beginning or ending practice at a pain management clinic.
- Ensure compliance with facility and physical operations of the clinic, infection control requirements, and health and safety requirements.

The designated physician is also responsible for certain additional functions, including quality assurance requirements to evaluate the quality and appropriateness of patient care and reporting aggregated patient statistics.

Provisions and requirements under the regulation of pain management clinics do not supersede the level of care, skill, and treatment recognized in general law related to healthcare licensure.

The amendment authorizes a physician assistant or advanced registered nurse practitioner under both the medical practice act and the osteopathic practice act to perform the physician examination of a patient in a pain management clinic.

The amendment strikes the requirement that passed last year requiring physicians practicing in pain management clinics after July 1, 2012 to meet certain training and education requirements.

The laws pertaining to the regulation of pain management clinics are set to expire on January 1, 2016.

A pain management clinic which has been used on more than two occasions within a 6-month period as a site in which certain criminal violations occur may be declared a public nuisance.

### ***Pharmacies / Pharmacists***

Community pharmacies must be re-licensed under the provisions of this act and rules adopted thereunder by July 1, 2012. Additional licensure requirements are intended to prevent felons and other nefarious persons from owning or operating pharmacies. In addition, pharmacies will be required to develop policies and procedures to minimize dispensing based on fraudulent representations or invalid practitioner-patient relationships.

A pharmacist must report to a local law enforcement officer any person who obtains or attempts to obtain a controlled substance through fraudulent methods or representations. The failure to report is a misdemeanor of the first degree.

Principals associated with a pharmacy must undergo annual criminal background screening. The department must forward the results to wholesale distributors permitted under ch. 499, F.S., for purposes of complying with the requirements related to due diligence of purchasers.

The amendment includes additional requirements and disciplinary action related to activities in pharmacies and by pharmacists.

### ***Drug Wholesalers***

Licensed drug wholesalers are required to:

- Credential and understand the normal business transactions of their customers who purchase certain controlled substances.
- Report to the department on wholesale distributions of unusual quantities of controlled substances. Unusual purchasing levels for the purchasing entity's clinical needs will be investigated by law enforcement.
- Abstain from distributing controlled substances to an entity if any person associated with that entity meets certain disqualifying conditions in the criminal history record check.

The department is required to identify the national average of distributions per pharmacy of certain controlled substances and report to the Governor and Legislature by November 1, 2012.

The amendment provides for stiffer criminal penalties and administrative sanctions for unlawfully distributing controlled substances or submitting false reports pertaining to controlled substance distributions.

### ***Prescription Drug Monitoring Program***

The bill reduces the timeframe for dispensers to report to the prescription drug monitoring program database from 15 days to 7 days. The bill also requires persons who have access to the database to submit fingerprints for background screening. Department staff are prohibited from having direct access to information in the database.

Funds provided by prescription drug manufacturers may not be used to implement the prescription drug monitoring program. References to the department and State Surgeon General are substituted for the Office of Drug Control and the director of the Office of Drug Control.

### ***Other Provisions***

The bill specifies that law enforcement officers may obtain access to or copy records that are required to be maintained under ch. 893, F.S., without a subpoena, court order, or search warrant.

Upon the discovery of the theft or significant loss of controlled substances, a manufacturer, importer, distributor, or dispenser must report the theft or significant loss to a law enforcement officer. The failure to report is a misdemeanor.

Fraudulently obtaining, attempting to obtain, or providing a prescription for a controlled substance by concealment of a material fact (the existence of another prescription for a controlled substance for the same time period) when the controlled substance is not medically necessary for the patient is a third degree felony.

The bill enhances criminal offenses relating to theft and burglary involving controlled substances.

If approved by the Governor, these provisions take effect on July 1, 2011.

*Vote: Senate 39-0; House 118-0*

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**CS/HB 7107 — Medicaid Managed Care**

by Appropriations Committee; Health and Human Services Committee; and Rep. Schenck (CS/CS/CS/SB 1972 by Budget Committee; Budget Subcommittee on Health and Human Services Appropriations; Health Regulation Committee; and Senators Negron, Gaetz, Garcia, and Hays)

The bill establishes the Medicaid program as a statewide, integrated managed care program for all covered services, including long-term care services. The Agency for Health Care Administration (AHCA) is directed to apply for and implement amendments to the Medicaid state plan or waivers of applicable federal laws and regulations by August 1, 2011, necessary to implement the program. The AHCA is directed to provide public notice and seek public comment before applying for such waivers and is required to include public feedback in waiver applications.

The new Medicaid program consists of two components:

- **Managed Medical Assistance**  
Provides medically-necessary primary and acute health care services such as doctor's visits, hospitalization, pregnancy care, prescription drugs, etc.
- **Managed Long-Term Care**  
Provides individuals who are aged and/or disabled, and who meet additional acuity levels, with additional services beyond routine health care needs such as adult day care, home delivered meals, personal care, case management, etc.

All Medicaid recipients will be enrolled in managed care plans unless specifically exempt. Recipients who are exempted include persons with limited eligibility or benefits and persons with developmental disabilities.

A variety of managed care plans may participate in the program. A recipient has a choice of plans and plan types that are contracted by the AHCA in the recipient's region of residence. Recipients may choose between insurers, exclusive provider organizations, health maintenance organizations (HMOs), and other managed care plans run by health care providers or groups of providers, such as provider service networks (PSNs) or accountable care organizations (ACOs). Recipients may also choose specialty plans with expertise in specific medical conditions.

Plans will compete for Medicaid contracts via an invitation-to-negotiate process based on specified qualifications, such as price, provider network adequacy, accreditation, community partnerships, additional benefit offerings, and performance history.

- Specific factors are identified for the AHCA to use in selecting bidders to participate in negotiations. Critical factors include:
  - Accreditation and experience
  - Sufficient primary and specialty physicians in the network
  - Community partnerships
  - Commitment to quality improvement

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- Coverage of additional benefits including dental care and disease management
- Evidence of established relationships with providers
- Input from providers
- Documentation of policies to prevent fraud and abuse
- Plans must reveal their business relationships so that one company cannot dominate a region and prevent Medicaid recipients from having a real choice among plans.
- Preference will be given to plans that demonstrate:
  - Signed contracts with primary and specialty physicians and with essential providers;
  - Well-defined programs for recognizing patient-centered medical homes and accountable care organizations;
  - Ability to produce a greater economic benefit by being headquartered in Florida and employing Floridians to meet contract terms;
  - Provider networks in which over 10 percent of providers use electronic health records;
  - A contract with AHCA to provide managed long-term care services in the same region;
  - Contracts or other arrangements for cancer disease management programs;
  - Contracts or other arrangements for diabetes disease management programs;
  - A process for prompt payment of claims.

There will be a limited number of plans in each of eleven regions to promote plan stability but also provide choices to recipients.

Insurers and HMOs will be prepaid on a full-risk basis via a monthly capitated rate designed to represent the costs needed to provide all medically necessary services in the aggregate during any month-long period. Capitation rates will be risk-adjusted based on patient encounter data. Risk-adjusted rates will ensure plans are paid more for sicker patients in order to allocate resources appropriately.

Provider service networks will have the option of assuming risk immediately or being paid on a fee-for-service basis for the first 2 years of operation, after which a PSN that initially opted to be paid via fee-for-service must convert to a full-risk capitation payment.

During the first year of the first contract term, managed care plans, including prepaid plans and PSNs paid via fee-for-service, must guarantee a savings of at least 5 percent from the amount they would have been paid in the previous year based on service area and population.

Managed care plans will be held accountable:

- Payment to physicians must be equal to or exceed Medicare rates after 2 years of continuous plan operation.
- Prescription drug formularies or preferred drug lists must be accessible on the plan's website.
- Prior authorization requests must be accepted electronically.
- Provider networks must meet specific adequacy standards, and plans must maintain an online database of network providers that can be used by consumers and the AHCA.

This summary is provided for information only and does not represent the opinion of any Senator, Senate Officer, or Senate Office.
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- Valid encounter data must be submitted on time.
- Plans must provide quality data measures on their websites to allow recipients to compare plans.
- Plans must be accredited by a nationally recognized accrediting body or seek accreditation by such a body within one year of plan operation.
- Performance must continuously improve based on specific standards that are raised over the term of the contract.
- Active systems must be used to reduce the incidence of fraud and abuse.
- All recipients must have access to a grievance process.
- Financial penalties will be imposed and contracts will be terminated for reducing enrollment or withdrawing prior to the end of a contract term.
- Financial penalties will be imposed on plans that fail to comply with encounter data reporting requirements. If the plan does not comply within 90 days, its contract will be terminated.

Limits will be placed on how much profit can be earned by managed care plans to ensure that plans are not overspending on administration or earning profit at the expense of patient care. This system of “achieved savings rebates” will require plans that exceed an appropriate profit threshold to pay dollars back to the state, thereby eliminating an incentive to withhold appropriate spending on health care services:

- Administrative fees are restricted to actuarially appropriate levels.
- Effective management of care will achieve savings that will be shared with the state.
- Plans may retain a reasonable profit of up to a 5 percent margin. Plans must pay back a portion of profits above that threshold and must pay back all profits above a 10 percent margin.
- Plans can earn an additional one percent profit if they demonstrate exceptional performance.
- Plans will be required to perform and submit detailed audits to verify the achieved savings rebates.

#### Intergovernmental Transfer Process:

- Local funding sources may contribute funds to the state Medicaid program.
- Specific conditions apply to the local contributions.
- The Low Income Pool is restructured to function within a managed care environment.
- The Access to Care Partnership is created as a single organization representing all providers designated by local funding sources as eligible to receive support through the Low Income Pool.
- Any additional resources generated by the local contributions may be used to enhance hospital payment rates through a specific formula for hospitals classified in three tiers. All hospitals will receive some benefit from tiered rate increases.

Medicaid recipients will have an opportunity to choose among plans in their region. Those who do not choose a plan will be automatically enrolled, with a preference for enrollment in specialty

plans if there is one available to serve their particular condition. This will ensure recipients are served by plans with expertise in their specific disease states.

The AHCA is directed to develop a process to enable a recipient with access to employer-sponsored coverage to opt-out of all Medicaid managed care plans and use Medicaid financial assistance to pay the recipient's share of the cost for the employer-sponsored coverage, and the AHCA is directed to seek federal approval to require such recipients to opt-out of Medicaid managed care in favor of their employer-sponsored coverage. The AHCA is also directed to seek federal approval to enable recipients with access to other insurance or related products that provide access to health care services, including products available under the Florida Health Choices program or any health exchange, to opt-out. The amount of financial assistance provided for any such recipient may not exceed the amount the Medicaid program would have paid to a Medicaid managed care plan for that recipient.

Participation in the Medicaid managed care medical assistance component by the Children's Medical Services Network will be under a single, statewide contract with the AHCA that is not subject to the program's procurement process or the regional limitation on the number of plans. However, the Children's Medical Services Network must meet all other plan requirements for the managed medical assistance component.

### ***Managed Medical Assistance***

The bill creates the managed medical assistance component for primary and acute care services. Implementation of the medical assistance component begins January 1, 2013, and is scheduled to be fully implemented by October 1, 2014. All mandatory and optional primary and acute care services are covered in the program, and plans can offer additional benefits.

Plans contracted for the medical assistance component must:

- Maintain adequate provider networks
- Monitor quality and performance standards of their providers
- Contract with Healthy Start Coalitions to improve outcomes for pregnant women and infants.
- Ensure at least 80 percent of their enrolled children receive their well-child screening by the end of the second year in pursuit of proper preventive care and treatment.

The bill requires medical assistance plans to contract with certain "essential providers," which include:

- Federally qualified health centers;
- Statutory teaching hospitals;
- Hospitals that are trauma centers;
- Hospitals located at least 25 miles from any other hospital with similar services;
- Faculty plans of Florida medical schools;
- Regional perinatal intensive care centers;
- Specialty children's hospitals;

- Accredited and integrated systems serving medically complex children that comprise separately licensed, but commonly owned, health care providers delivering at least the following services: medical group home, in-home and outpatient nursing care and therapies, pharmacy services, durable medical equipment, and prescribed pediatric extended care.

The bill sets reimbursement mandates for plans that are unable to contract with essential providers.

The bill brings the Medically Needy population into managed care under certain conditions that are contingent on federal approval. After being deemed eligible for the Medically Needy program, recipients will be enrolled in managed care plans and pay a portion of the managed care plan premium, based on their income and share of cost as determined by the Department of Children and Families. The state will pay the remaining portion of the premium to the managed care plan.

### ***Managed Long-term Care***

The bill creates the managed long-term care component for Medicaid recipients eligible for long-term care services. Implementation of the long-term care component will begin July 1, 2012, and is scheduled to be fully implemented in all regions by October 1, 2013.

The managed long-term care component covers:

- Medicaid recipients who are age 65 or older, or age 18 or older and eligible for Medicaid by reason of a disability; and
- Determined by the Comprehensive Assessment Review and Evaluation for Long-term Care Services (CARES) program to require nursing facility care.

Medicaid recipients who, on the date long-term care plans become available in their region, reside in a nursing home facility or are enrolled in certain long-term care Medicaid waiver programs, are eligible to participate in the long-term care component for up to 12 months without being reevaluated for their need for nursing facility care.

There will be two types of long-term care plans:

- Comprehensive long-term care plans that combine medical assistance and long-term care services
- Long-term care plans that provide only long-term care services

Selection preference will be given to comprehensive plans so seniors can receive all services from one plan. Plans will provide residential care in nursing facilities or assisting living facilities. The plans also must offer a comprehensive range of home and community based services for the care of seniors or the disabled who need assistance but not round-the-clock nursing care. Eligible plans must have specialized staffing with experience in serving elders and the disabled.



Long-term care plans must provide a complete range of services throughout their regions and must have needed providers such as nursing homes, assisting living facilities, and hospices in their networks.

A long-term care plan's network must include all of the following:

- Adult Day Center Centers
- Adult Family Care Homes
- Assisted Living Facilities
- Health Care Services Pools
- Home Health Agencies
- Homemaker and Companion Services
- Hospices
- Lead Agencies
- Nurse Registries
- Nursing Homes

Long-term care recipients who are referred to nursing homes or assisted living facilities will be informed of facilities within the plans that are associated with specific religious or cultural affiliations, and a reasonable effort must be made to place the recipient in the facility of their choice.

The bill provides an additional choice for hospice patients. When a senior is referred for hospice services, the senior will have a 30-day period in which to change plans if a preferred hospice provider is only available through another plan.

When a recipient does not choose a long-term care plan, auto-assignment will be based on the quality measures of plans in the region. Members of certain Medicare Advantage plans who are also Medicaid-eligible and who do not choose a Medicaid plan will be assigned to their Medicare Advantage plan for applicable Medicaid services if their Medicare Advantage plan has contracted with the AHCA for the Medicaid long-term care component.

Medicare Advantage plans that serve only individuals who are dually eligible (qualify for both Medicare and Medicaid) may enter into a contract with the AHCA and will not be subject to the procurement requirements contained in the bill. All other Medicare plans will be subject to competitive procurement.

Program for All Inclusive Care for the Elderly (PACE) plans are eligible plans and are not subject to the procurement process or region limits. They may continue to serve recipients at the enrollment caps set by the Legislature.

The bill focuses on keeping seniors in their homes as long as possible. Home and community based care is both required and rewarded. Payment rates for long-term care plans will be adjusted to create incentives for keeping individuals out of nursing homes when in-home accommodations and care can be arranged instead of nursing home care.

Long-term care plans are required to pay nursing homes and hospices at payment levels established by the AHCA.

If approved by the Governor, these provisions take effect July 1, 2011.

*Vote: Senate 28-11; House 79-39*

THE FLORIDA SENATE  
2011 SUMMARY OF LEGISLATION PASSED  
**Committee on Health Regulation**

**CS/HB 7109 — Medicaid**

by Appropriations Committee; Health and Human Services Committee; and Rep. Schenck (CS/CS/CS/SB 1972 by Budget Committee; Budget Subcommittee on Health and Human Services Appropriations; Health Regulation Committee; and Senators Negron, Gaetz, Garcia, and Hays)

The bill is designed to conform certain provisions of existing Medicaid law to CS/HB 7107 and authorizes a number of immediate changes to the Medicaid program. The bill also repeals numerous provisions on future dates to conform general Medicaid provisions to the full implementation of the Medicaid managed care program. The bill becomes effective only if CS/HB 7107 is enacted.

**Persons with Developmental Disabilities**

- The bill expands eligibility for the home and community-based waiver program for persons with developmental disabilities to include individuals diagnosed with Down Syndrome.
- If the Agency for Persons with Disabilities continues a deficit during fiscal year 2012-2013, the agency must submit a plan to the Legislature for a redesigned waiver program as an alternative to current waiver models. The new program model must include specific elements (e.g., budget predictability and redesigned support coordination services) and be approved by the Legislature before implementation on July 1, 2014.

**Medicaid Program**

- The bill expands the disqualification for receiving Medicaid benefits from 5 to 10 years for a person found to have committed Medicaid fraud.
- The Agency for Health Care Administration (AHCA) is directed to request federal approval to develop a system to require parents with household incomes greater than 100 percent of the federal poverty level to pay premiums or other cost sharing methods for home and community-based services for their developmentally disabled children.
- The AHCA is directed to request federal approval to require Medicaid recipients to pay \$100 co-payments for nonemergency services provided in a hospital emergency department.
- The bill provides that Medicaid shall not pay for psychotropic medications for a child unless specifically authorized by the parent or guardian.
- The AHCA is directed to develop a process to enable a recipient with access to employer-sponsored coverage to opt-out of all Medicaid managed care plans and use Medicaid financial assistance to pay the recipient's share of the cost for the employer-sponsored coverage. The AHCA is also directed to seek federal approval to enable recipients with access to other insurance or related products that provide access to health care services, including products available under the Florida Health Choices program or any health exchange, to opt-out. The amount of financial assistance provided for any such recipient

may not exceed the amount the Medicaid program would have paid to a Medicaid managed care plan for that recipient.

### **Medicaid Managed Care**

- The AHCA is required to develop uniform accounting and reporting requirements for Medicaid managed care plans. The plans must begin reporting their medical and non-medical costs to the AHCA. This information must be made public will help ensure that plans are providing adequately managed, patient-centered care.
- Plans will be given advance notice and an opportunity to comment on any potential rate adjustments. The AHCA will perform a simulated rate-setting exercise prior to making rate adjustments, the results of which must be posted on the AHCA's website for 45 days.
- The current option for Medicaid recipients in one of the five Medicaid Reform pilot counties to use their Medicaid premium to purchase employer-sponsored insurance is permitted statewide. This option is further expanded (subject to federal approval) by allowing recipients to use their Medicaid dollars to pay for other insurance or products that may be available to them.
- The AHCA is authorized to exempt recipients from managed care on a case-by-case basis for specialized or unique, time-limited, and ongoing care that patients may be receiving at the time they enroll in Medicaid.
- The AHCA is required to contract with prepaid dental plans until Medicaid managed care is fully implemented in all regions under CS/HB 7107.

### **Hospital Rates**

- The AHCA is directed to implement a methodology for establishing Medicaid reimbursement rates for each hospital based on allowable costs. The rates will be set once annually and the reconciliation period is limited. This process is designed to provide budgetary certainty and administrative simplification.
- The AHCA is directed to develop a plan to convert inpatient hospital rates to a prospective payment system that uses diagnosis related groups (DRG) and assigns a payment weight.
- The AHCA must submit the Medicaid DGR plan to the Governor and Legislature by January 1, 2013.

### **Provider Service Networks**

- The same payment requirements applicable to provider service networks (PSNs) in the five Medicaid Reform pilot counties are applied to all PSNs statewide in order to prepare them for expansion of managed care under CS/HB 7107.
- PSNs may still be fee-for-service for a period of time, but specific requirements are established for shared savings and guidelines are defined for a reconciliation process that determines shared savings.
- A prepaid PSN that applies for and obtains a health care provider certificate from the AHCA, meets the surplus requirements for health maintenance organizations (HMOs) under the Insurance Code, and meets all other applicable requirements relating to the

regulation of health maintenance organizations (HMOs), may obtain a certificate of authority under the Insurance Code relating to HMOs. A certified PSN is granted the same rights and responsibilities as a certified HMO. The bill creates an exception in the Insurance Code's solvency requirements for PSNs to specify that a PSN seeking a certificate of authority must meet the bill's surplus requirements instead of those under existing law.

## **MediPass**

AHCA is directed to contract with a single PSN to function as a third party administrator and managing entity for the MediPass program in all counties with fewer than two prepaid plans. The contract will expire when the managed care program is fully implemented under the provisions of CS/HB 7107.

## **Medically Needy Program**

- The AHCA is directed to immediately contract with a PSN to coordinate and manage the care of the Medically Needy. Such recipients will be continuously enrolled for a period of 6 months. The enrollees will pay their share of costs as a monthly premium and enrollees will be given a 90 day grace period for late payments of their share of costs.
- The Medically Needy contract with the PSN will expire when the managed medical assistance program is effective statewide under CS/SB 7107.
- Additionally the AHCA is directed to develop a plan for transitioning Medically Needy recipients into the managed medical assistance program. The AHCA is to immediately seek any federal authorization needed for the implementation.

## **Tort Reform**

- To encourage greater participation by medical practitioners in the Medicaid program, the bill creates limitations on noneconomic damages for negligence of a practitioner providing services and care to a Medicaid recipient.
- Noneconomic damages may not exceed \$300,000 per claimant unless the claimant pleads and proves, by clear and convincing evidence, that the practitioner acted in a wrongful manner, defined as acting in bad faith or with malicious purpose or in a manner exhibiting wanton and willful disregard of human rights, safety, or property.
- An individual practitioner is not liable for more than \$200,000 in noneconomic damages, regardless of the number of claimants, unless a claimant pleads and proves, by clear and convincing evidence, that the practitioner acted in a wrongful manner.
- For the bill's limitations on noneconomic damages, the term "practitioner," in addition to practitioners included in the definition under s. 766.118(1), F.S., includes hospitals, ambulatory surgical centers, and mobile surgical facilities.

## **The Department of Elder Affairs**

- The Department of Elder Affairs (DOEA), which currently manages waivers related to elder care, will no longer manage the waiver programs once managed care is

implemented statewide under CS/HB 7107. However, the DOEA will still play key roles in transitioning their clients to managed care plans as the plans are available in each region.

- This bill recognizes that continued support of the DOEA is important to the Medicaid program and will still play a role in assessing or assisting recipients. CARES staff at the DOEA will continue to assist with initial assessments of an enrollee's level of care and will be responsible for assisting clients to interact with plans.
- Aging Resource Centers (ARCs) will provide enrollment and coverage information about the Medicaid managed care long-term care program under CS/HB 7107.
- ARCs can assist elders with information about services and long-term care managed care; help recipients resolve complaints; and make initial assessments about elders' needs.

### **Nursing Home Certificate of Need**

- The bill extends the moratorium on certificates of need (CONs) for additional nursing home beds until the Medicaid managed care program under CS/HB 7107, is implemented statewide or October 1, 2016, whichever is earlier.
- Effective July 1, 2012, the bill prohibits the AHCA from imposing a sanction on a nursing home for failure to meet the Medicaid patient-day utilization conditions for that nursing home.

### **AHCA Reorganization**

- The AHCA is directed to develop a reorganization plan for realignment of administrative resources of the Medicaid program to respond to changes in functional responsibilities and priorities necessary for implementation of CS/HB 7107.
- The reorganization plan must assess the AHCA's current capabilities, identify shifts in staffing and other resources necessary to strengthen procurement and contract monitoring functions, and establish an implementation timeline.
- The plan must be submitted to the Governor, the Speaker of the House of Representatives, and the President of the Senate by August 1, 2011.

If approved by the Governor, these provisions take effect July 1, 2011.

*Vote: Senate 26-12; House 80-39*