



Health Care Regulation Policy Committee

**Monday, March 1, 2010
3:15 PM – 6:00 PM
Morris Hall (17 HOB)**

MEETING PACKET

**Larry Cretul
Speaker**

**Nick Thompson
Chair**



The Florida House of Representatives

Health Care Regulation Policy Committee

A G E N D A

**March 1, 2010
3:15 PM - 6:00 PM
Morris Hall (17 HOB)**

- I. Opening Remarks by Chair Thompson**
- II. Consideration of the following bill(s):**
 - HB 45 Use of Prescribed Pancreatic Enzyme Supplements by Rep. Renuart**
 - PCS for HB 225 Controlled Substances**
 - HB 573 Physician Assistants by Rep. Kreegel**
- III. Consideration of the following proposed committee bill(s):**
 - PCB HCR 10-01 Relating to Obsolote Health Care Provisions**
- IV. Closing Remarks by Chair**
- V. Adjournment**

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 45
SPONSOR(S): Renuart
TIED BILLS:

Use of Prescribed Pancreatic Enzyme Supplements

IDEN./SIM. BILLS: SB 166

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) PreK-12 Policy Committee	10 Y, 0 N	Duncan	Ahearn
2) Health Care Regulation Policy Committee		Holt <i>HA</i>	Calamas <i>CC</i>
3) Education Policy Council			
4)			
5)			

SUMMARY ANALYSIS

House Bill 45 authorizes K-12 students at risk for pancreatic insufficiency or who have been diagnosed as having cystic fibrosis to use a prescribed pancreatic enzyme supplement while in school, participating in school-sponsored activities, or in transit to or from school or school-sponsored activities.

In addition, the bill provides that parents of a student who uses a prescribed pancreatic enzyme supplement must indemnify certain entities from all liability related to the use of the supplements.

This bill does not appear to have a fiscal impact on state or local government revenues or expenditures.

The bill takes effect July 1, 2010.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background:

Administering Medication in Schools

Current law authorizes school personnel to assist students in the administration of prescription medication when designated personnel¹ have received training from a registered nurse, licensed practical nurse, physician, or physician's assistant.² The district school board must adopt policies and procedures governing the administration of prescription medication by school personnel. Included in the policies and procedures must be a requirement that:³

- With each prescribed medication, parents provide the principal a written statement granting the principal or the principal's designee, permission to assist in the administration of their child's medication and explain why the medication has to be provided during the school day⁴;
- Any prescribed medication that is to be administered by school personnel must be received, counted, and stored in its original container; and
- When the medication is not in use, it must be stored under lock and key in a location designated by the school principal.

There is no liability for civil damages as a result of the administration of the medication when the designated person acts as an ordinarily reasonably prudent person would have acted under the same or similar circumstances.⁵

Asthmatic and Severely Allergic Students

Under current law, asthmatic students are permitted to carry a metered dose inhaler while in school, if the students' parent and physician provide a copy of their approval to the principal.⁶ A severely allergic

¹ Individuals are designated by the school principal.

² Section 1006.062(1)(a), F.S.

³ Section 1006.062(1)(b), F.S.

⁴ This also includes any occasion when the student is away from school grounds on official school business. See s.1006.062 (1)(b), F.S.

⁵ Section 1006.062(2), F.S.

⁶ Section 1002.20(3)(h), F.S.

student is also permitted to carry and self-administer epinephrine⁷ auto-injector⁸ while in school, participating in school-sponsored activities or in transit to or from school, if, the school has been provided parental and physician authorization.⁹ The parent must indemnify the school district, county health department, public-private partner, and their employees and volunteers from any and all liability related to the use of the epinephrine auto-injector.¹⁰

Cystic Fibrosis

Cystic Fibrosis (CF) is a chronic, inherited disease that affects the lungs and digestive system of about 30,000 children and adults in the United States.¹¹ A defective gene and its protein product cause the body to produce unusually thick, sticky mucus that clogs the lungs and leads to life-threatening lung infections and obstructs the pancreas and stops natural enzymes from helping the body break down and absorb food.¹² This mucous can also prevent pancreatic enzymes from reaching the intestines to digest food and absorb food which results in malnutrition, slow growth, and poor weight gain.¹³

To treat CF, oral pancreatic enzyme medication is taken with all meals and snacks that contain fat, protein, and/or complex carbohydrates.¹⁴ Pancreatic enzyme replacements come in capsule form.¹⁵ Inside each capsule are many small "beads" that contain digestive enzymes.¹⁶ The digestive enzymes are released in the small intestine to help digest food.¹⁷ According to the Cystic Fibrosis Foundation, more than 90% of people who have CF take pancreatic enzyme replacements. Oral pancreatic enzymes are not addictive and will not change the child's behavior.¹⁸ Pancreatic enzymes do not cause a problem if taken by another child.¹⁹

Effect of Proposed Changes:

The bill authorizes K-12 students at risk for pancreatic insufficiency or who have been diagnosed as having cystic fibrosis to use a prescribed pancreatic enzyme supplement while in school, participating in school-sponsored activities, or in transit to or from school or school-sponsored activities, if the school has been provided with parental and prescribing practitioner approval.

The parents of students authorized to use a prescribed pancreatic enzyme supplement must indemnify the school district, county health department, public-private partner, and their employees and volunteers from any and all liability related to the use of the prescribed pancreatic enzyme supplements.

The bill provides the State Board of Education (SBE), in cooperation with the Department of Health (DOH), the authority to promulgate rules that include provisions to protect the safety of all students from the misuse or abuse of pancreatic enzyme supplements.

⁷ A form of adrenaline medication used to treat severe allergic reactions, such as anaphylactic shock or insect stings.

⁸ A medical device designed to deliver a single dose of a particular (typically life-saving) drug.

⁹ Section 1002.20(3)(i), F.S.

¹⁰ *Ibid.*

¹¹ Cystic Fibrosis Foundation, About Cystic Fibrosis: What you need to know, available at: <http://www.cff.org/AboutCF/> (last viewed February 23, 2010).

¹² Cystic Fibrosis Foundation, About Cystic Fibrosis: Frequently Asked Questions, available at: <http://www.cff.org/AboutCF/Faqs/> (last viewed February 23, 2010).

¹³ *Ibid.*

¹⁴ *Ibid.*

¹⁵ Cystic Fibrosis Foundation, Living with CF, Staying Healthy: Pancreatic Enzyme Supplements, available at: <http://www.cff.org/LivingWithCF/StayingHealthy/> (last viewed February 23, 2010).

¹⁶ *Ibid.*

¹⁷ *Ibid.*

¹⁸ Cystic Fibrosis Foundation, Living with CF, At School: School, Enzymes, and Sports for the Child with Cystic Fibrosis, available at: <http://www.cff.org/LivingWithCF/AtSchool/SchoolEnzymes/> (last viewed February 23, 2010).

¹⁹ *Ibid.*

B. SECTION DIRECTORY:

Section 1. Amends s. 1002.20(3), F.S., relating to K-12 student and parent rights.

Section 2. Provides an effective date of July 1, 2010.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

This bill does not appear to have a fiscal impact on state government revenues.

2. Expenditures:

This bill does not appear to have a fiscal impact on state government expenditures.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

This bill does not appear to have a fiscal impact on local government revenues.

2. Expenditures:

This bill does not appear to have a fiscal impact on local government expenditures.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None identified.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The bill does not appear to require a city or county to expend funds or take any action requiring the expenditure of funds. The bill does not appear to reduce the authority that municipalities or counties have to raise revenues in the aggregate. The bill does not appear to reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides the SBE, in cooperation with the DOH, sufficient rule-making authority to adopt rules for the use of prescribed pancreatic enzyme supplements.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The indemnity provision does not prohibit a person from filing a lawsuit. This provision merely provides that the school district, county health department, public-private partner, and their employees or volunteers may recover from the parent of the student authorized to carry the prescribed pancreatic

enzyme supplements.

According to the Department of Education, "there is some question of whether the proposal, which creates a statutory right, is necessary given the authority to administer medication under s. 1006.062. Further, there is a potential for liability on the district's or school's part, given that immunity is limited in scope to the student's use."²⁰

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

None.

²⁰ Department of Education, Analysis of House Bill 45, November 16, 2009.

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1 A bill to be entitled
 2 An act relating to the use of prescribed pancreatic enzyme
 3 supplements; amending s. 1002.20, F.S.; authorizing
 4 certain K-12 students to use prescribed pancreatic enzyme
 5 supplements under certain circumstances; requiring the
 6 State Board of Education to adopt rules; providing for
 7 indemnification; providing an effective date.

8
 9 Be It Enacted by the Legislature of the State of Florida:

10
 11 Section 1. Paragraph (j) is added to subsection (3) of
 12 section 1002.20, Florida Statutes, to read:

13 1002.20 K-12 student and parent rights.--Parents of public
 14 school students must receive accurate and timely information
 15 regarding their child's academic progress and must be informed
 16 of ways they can help their child to succeed in school. K-12
 17 students and their parents are afforded numerous statutory
 18 rights including, but not limited to, the following:

19 (3) HEALTH ISSUES.--

20 (j) Use of prescribed pancreatic enzyme supplements.--A
 21 student who has experienced or is at risk for pancreatic
 22 insufficiency or who has been diagnosed as having cystic
 23 fibrosis may carry and self-administer a prescribed pancreatic
 24 enzyme supplement while in school, participating in school-
 25 sponsored activities, or in transit to or from school or school-
 26 sponsored activities if the school has been provided with
 27 authorization from the student's parent and prescribing
 28 practitioner. The State Board of Education, in cooperation with

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29 the Department of Health, shall adopt rules for the use of
30 prescribed pancreatic enzyme supplements which shall include
31 provisions to protect the safety of all students from the misuse
32 or abuse of the supplements. A school district, county health
33 department, public-private partner, and their employees and
34 volunteers shall be indemnified by the parent of a student
35 authorized to use prescribed pancreatic enzyme supplements for
36 any and all liability with respect to the student's use of the
37 supplements under this paragraph.

38 Section 2. This act shall take effect July 1, 2010.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCS for HB 225 Controlled Substances
SPONSOR(S): Health Care Regulation Policy Committee
TIED BILLS: **IDEN./SIM. BILLS:**

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.:	Health Care Regulation Policy Committee		Calamas	Calamas <i>CC</i>
1)				
2)				
3)				
4)				
5)				

SUMMARY ANALYSIS

The Proposed Committee Substitute (PCS) for House Bill 225 increases regulation and provides for public-private partnerships to address prescription drug abuse.

The PCS requires pharmacies to participate in a multi-state electronic prescribing network, and requires pharmacies to transmit dispensing information for controlled substances through the network. The PCS makes these provisions effective July 1, 2012, and January 1, 2013, for new and existing pharmacies, respectively. The PCS requires the Agency for Health Care administration to negotiate access for law enforcement and state regulatory entities to controlled substance information through a multi-state electronic prescribing network.

The PCS adds new requirements for pain clinic registration by prohibiting the Department of Health from registering pain clinics owned by non-physicians, pain clinics employing or contracting with a physician against whom regulatory action has been taken related to drug or alcohol abuse, and pain clinics with owners who have certain felony drug convictions. The PCS also amends the definition of "clinics" to make it applicable to entities that are primarily engaged in the treatment pain by prescribing or dispensing controlled substances, as opposed to other methods of pain treatment.

The PCS to adds practitioner regulations and penalties. It makes physician advertising of controlled substances and practicing medicine in an unregistered clinic which is required to be registered grounds for licensure action. It prohibits dispensing practitioners from dispensing more than a 72-hour supply of controlled substances listed in Schedules II and III. Certain medication samples are exempt from the dispensing limit, and the PCS does not prohibit physicians from prescribing controlled substances in any way. Under the bill's provisions, patients who receive prescriptions for controlled substances would fill them at pharmacies, rather than in physician offices or clinics. The PCS makes violation of the dispensing limit a third degree felony.

The bill appears to have no fiscal impact on state or local government. The Agency for Health Care Administration is authorized to seek private grants and donations to establish state access to the private multi-state electronic prescribing network data.

The bill provides an effective date of July 1, 2010.

HOUSE PRINCIPLES

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FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Controlled Substance Dispensing

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act.¹ Controlled substances are classified into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid. Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds.

Pharmacists and Pharmacies

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice to dispense controlled substances upon a written or oral prescription under specified conditions:

- An oral prescription must be promptly reduced to writing by the pharmacist;
- The written prescription must be dated and signed by the prescribing practitioner on the date issued; and
- The face of the prescription or written record for the controlled substance must include:
 - The full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed;
 - The full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number;
 - If the prescription is for an animal, the species of animal for which the controlled substance is prescribed;

¹ See, also, the federal Controlled Substances Act, 21 U.S.C. 812.

- The name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof;
- The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filed; and
- The initials of the pharmacist filling the prescription and the date filled.

Section 893.04(1)(d), F.S., requires the pharmacy in which a prescription for controlled substances is filled to retain the prescription on file for a period of 2 years. The original container in which a controlled substance is dispensed must bear a label with the following information:

- The name and address of the pharmacy from which the controlled substance was dispensed;
- The date on which the prescription for the controlled substance was filled;
- The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled;
- The name of the prescribing practitioner;
- The name of the patient for whom, or of the owner and species of the animal for which, the controlled substance is prescribed;
- The directions for the use of the controlled substance prescribed in the prescription; and
- A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

Chapter 893, F.S., imposes other limitations on controlled substance prescriptions. A prescription for a Schedule II controlled substance may be dispensed only upon a written prescription of a practitioner, except in an emergency situation, as defined by rule of the department. No prescription for a Schedule II controlled substance may be refilled.² No prescription for a controlled substance listed in Schedules III, IV, or V may be filled or refilled more than five times within a period of 6 months after the date on which the prescription was written unless the prescription is renewed by a practitioner.³ A pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of a prescribed medication, except for those listed in Schedule II.⁴

In addition to these requirements for dispensing controlled substances, pharmacies must comply with regulations that apply to all dispensing. A pharmacy cannot dispense a medication if the prescription is not based on a "valid practitioner-patient relationship". Such a relationship includes "a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed".⁵ Department of Health rules apply this standard to controlled substances:⁶

The following criteria shall cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose:

- (a) Frequent loss of controlled substance medications,
- (b) Only controlled substance medications are prescribed for a patient,
- (c) One person presents controlled substance prescriptions with different patient names,
- (d) Same or similar controlled substance medication is prescribed by two or more prescribers at same time,
- (e) Patient always pays cash and always insists on brand name product.

If any of those criteria are met the pharmacy must copy the patient's photo identification for its records, and confirm the prescription with the physician. The Department of Health inspects pharmacies at least once a year to ensure compliance with statutory and regulatory requirements.⁷

² s. 893.04(1)(f), F.S.

³ s. 893.04(1)(g), F.S.

⁴ See 21 C.F.R. 1306.11(d)(1), which provides that in an emergency situation, a pharmacist may dispense a Schedule II controlled substance upon receiving oral authorization of a prescribing practitioner if the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.

⁵ S. 465.023(1)(h), F.S.

⁶ Rule 64B16-27.831, F.A.C.

⁷ Rule 64B16-28.101, F.A.C.

Physicians

Section 893.05, F.S., allows a practitioner, in good faith and in the course of professional practice only, to prescribe, administer, dispense, mix, or otherwise prepare a controlled substance. "Practitioner" means a licensed medical physician, a licensed dentist, a licensed veterinarian, a licensed osteopathic physician, a licensed naturopathic physician, or a licensed podiatrist, if such practitioner holds a valid federal controlled substance registry number.⁸ Physician dispensing is regulated by the relevant medical boards within the Department of Health.

In order to dispense medications, rather than just prescribe them, physicians must register with the Department and pay a fee of \$100.⁹ Physicians who only dispense complimentary medications, and who receive no direct or indirect payment or remuneration for the medications, are not required to register.¹⁰ There are 7,108 registered dispensing practitioners in Florida.¹¹

The Department must inspect any facility in which a physician dispenses medication, such as a physician office or medical clinic, with the same frequency as it inspects pharmacies, that is, at least once a year (see above).¹² Dispensing physicians are required to comply with all state and federal laws and regulations applicable to pharmacists and pharmacies (see above).¹³ For example, a pharmacy is not permitted to dispense a drug if the prescription is not based on a valid practitioner-patient relationship, which requires a patient history and a physical examination adequate to establish the diagnosis. This requirement applies to dispensing physicians as well.

Dispensing Prohibitions

Currently, Florida law allows registered physicians to dispense any prescribed drug. Other states have varying degrees of regulation. Twenty states allow dispensing and require some form of dispensing license.¹⁴ Twenty-three states allow dispensing do not require any license. One state allows dispensing but requires a license to dispense controlled substances.

Some states prohibit physician dispensing entirely.¹⁵ Montana, Texas and Utah prohibit all physician dispensing; Massachusetts allows physicians to dispense only a 72-hour supply for emergencies. These states do not distinguish between controlled substances and other medications; all are included in the prohibition.

Electronic Prescribing

Electronic prescribing is the electronic generation and transmission of a patient's prescription by a health care practitioner at the point of care. It includes two major functions: Two-way electronic communication between physicians and pharmacies regarding new prescriptions, refills, change requests, prescription cancellations, and patient compliance; and communication with other health care partners, like payers, related to eligibility, formularies and medication history.¹⁶

Electronic prescribing involves a secure, electronic connection between the physician and the pharmacy. In addition, electronic prescribing software generally allows a healthcare practitioner to not only securely

⁸ S. 893.02, F.S.

⁹ S. 465.0276(2)(a), F.S.; Rule 64B8-3.006, F.A.C.

¹⁰ S. 465.0276(5), F.S.

¹¹ Provided by the Department of Health via email to committee staff, dated February 1, 2010, on file with the committee. This number includes 935 advanced registered nurse practitioners, 230 dentists, 4,925 medical doctors, 855 osteopathic physicians, 119 podiatric physicians, and 44 optometrists,

¹² S. 465.0276(3), F.S.

¹³ S. 465.0276(2)(a), F.S.

¹⁴ Dispensing Regulations by State, American Academy of Urgent Care Medicine, see <http://aaucm.org/Professionals/MedicalClinicalNews/DispensingRegulations/default.aspx> (last viewed January 30, 2010).

¹⁵ *Id.*

¹⁶ Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, 2, see <http://www.fhin.net/eprescribe/Index.shtml> (last viewed February 23, 2010).

access the patient's health plan formulary, but also the patient's medication history, all at the point of care. Medication history is generally available in an 11- to 24-month rolling window, and it generally includes both written and electronically transmitted prescriptions. Numerous software companies offer stand-alone electronic prescribing products. While the cost of the product varies, some products are available at no cost to the healthcare practitioner.¹⁷

Section 408.0611, created in 2007, requires AHCA to work with private-sector initiatives and relevant stakeholders to create a "clearinghouse" of information on electronic prescribing for healthcare practitioners, facilities, and pharmacies. AHCA developed a website that provides information on the process and advantages of electronic prescribing, the availability of electronic prescribing software, including no-cost and low-cost software, and state and federal electronic prescribing incentive programs.¹⁸ AHCA also reports annually to the Governor and Legislature on the implementation of electronic prescribing by health care practitioners, facilities and pharmacies.

According to AHCA and the Institute of Medicine, electronic prescribing offers numerous benefits, including:¹⁹

- Reduced health care and legal costs by preventing medication prescription errors caused by events such as illegible hand writing, look-alike or sound-alike drugs, drug-to-drug interactions, incorrect dosing, drug allergy reactions, duplication of drugs, etc.;
- Real-time communications between doctors, pharmacies and patients;
- Provision of drug pricing, payer coverage and preferred drug information;
- Improved clinical outcomes by creating complete patient medication history and providing critical drug alerts and patient specific information at the health care professionals' fingertips; and
- Reduction of fraud and crime by increasing the security of prescriptions.

According to AHCA's most recent report, E-prescribing improved prescription security by providing a complete audit trail of each transaction, from the prescribing physician's office to the dispensing pharmacy, to the patient picking up the prescription. E-prescribing requires a secure log-in process for prescribing practitioners and pharmacies, which must be credentialed and approved before they can participate.^{20,21} E-prescribing provides an additional back-up for prescription records, which makes it useful in situations of natural disaster when paper records may be destroyed.²²

The use of e-prescribing is rising. Of the 6,157 pharmacies in Florida in 2008, 71.33 percent were activated to receive electronic prescriptions, an increase from 63 percent in 2007.²³ Similarly, in 2007 the highest monthly total of e-prescribing healthcare professionals was 2,331. The highest monthly total of e-prescribing physicians in 2008 was 4,492, an increase of 92.75 percent.²⁴ Among e-prescribers, the number of e-prescriptions issued per month rose 72 percent between 2007 and 2008.²⁵

¹⁷ See e.g., <http://www.nationalerx.com/> and <http://www.iscribe.com/> (offering free web-based electronic prescribing software) (last viewed February 23, 2010); Florida ePrescribe Clearinghouse, Products and Services, see <http://www.fhin.net/eprescribe/Technology/products.shtml> (last viewed February 23, 2010).

¹⁸ Florida E-Prescribe Clearinghouse, see <http://www.fhin.net/eprescribe/Index.shtml> (last viewed February 23, 2010); Agency for Health Care Administration, see <http://ahca.myflorida.com/dhit/ElectronicPrescribing/ePrescribeIndex.shtml> (last viewed February 23, 2010).

¹⁹ Agency for Health Care Administration, Advantages of ePrescribing, see <http://www.fhin.net/eprescribe/Benefits/Benefits.shtml> (last viewed February 23, 2010), citing Institute of Medicine, Committee on Identifying and Preventing Medication Errors, "Preventing Medication Errors: Quality Chasm Series" (2006).

²⁰ Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, see <http://www.fhin.net/eprescribe/Index.shtml> (last viewed February 23, 2010): "Secure access is possible using a virtual private network (VPN) connection over the Internet, which creates a protected electronic channel for the safe transmission of encrypted medication information. Infrastructure technology partners, vendors and others are bound through strong contracts to ensure the authentication of users, the integrity of prescriptions, and the privacy and security of personal health information that passes through the secure networks. Unwarranted prescription activity can be identified much more readily in the electronic system through the use of embedded auditing features."

²¹ *Id.* at 7.

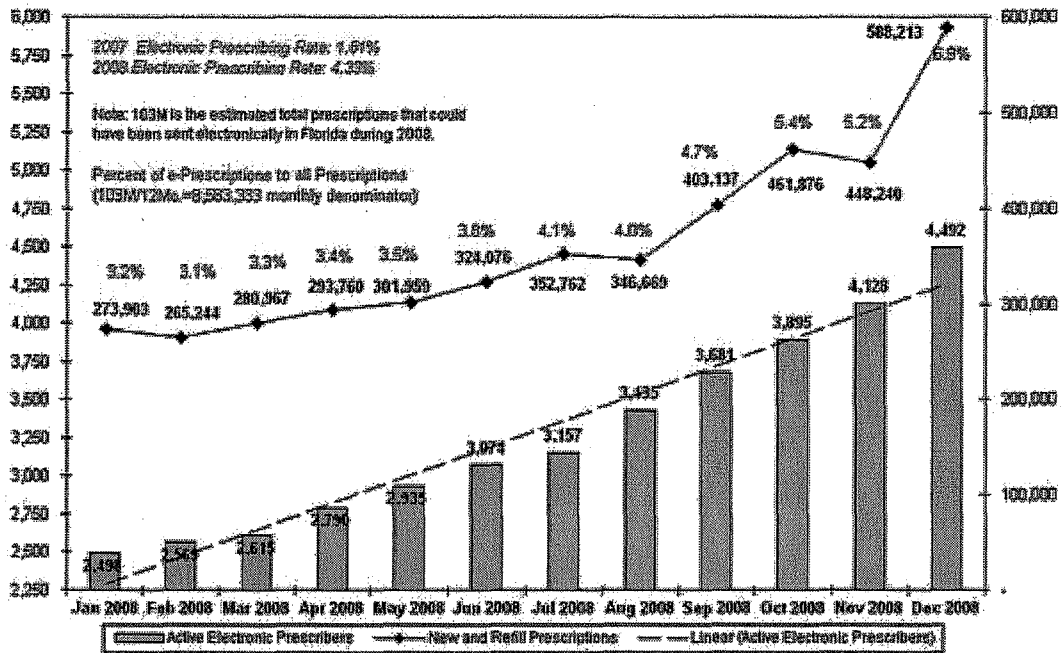
²² *Id.*

²³ Agency for Health Care Administration, ePrescribing Clearinghouse, ePrescribing Dashboard 2008 Metrics, see <http://www.fhin.net/eprescribe/Dashboard/FLmetrics.shtml> (last viewed February 23, 2010).

²⁴ *Id.*

²⁵ *Id.*

**Electronic Prescriptions and Electronic Prescribing Healthcare Providers,
January to December 2008**



Source: SureScripts-RxHub, cited in, Agency for Health Care Administration, ePrescribing Clearinghouse, ePrescribing Dashboard 2008 Metrics.

Controlled Substance E-Prescribing

The Drug Enforcement Administration (DEA) requires every person who dispenses controlled substances to register with the DEA and obtain a unique registration number.²⁶ All prescriptions for controlled substances must include the DEA registration number of the prescribing practitioner.²⁷ The DEA prohibits the use of electronic prescribing for controlled substances.²⁸ On June 27, 2008 the DEA proposed rules that would allow practitioners to issue electronic prescriptions for controlled substances.²⁹ The proposed rules delineate system requirements for prescribing practitioners e-prescribing vendors, pharmacies, pharmacists, and others. Public comments on the proposed rules were due September 25, 2008, and the DEA received more than 500 comments.³⁰

Federal Incentives and Penalties

The 2008 Medicare Improvements for Patients and Providers Act created a Medicare program to encourage physicians to adopt e-prescribing systems.³¹ From 2009 through 2014, Medicare will provide incentive payments to eligible health care practitioners who demonstrate “meaningful use” of electronic prescribing: Practitioners will receive a 2 percent incentive payment in 2009 and 2010; a 1 percent incentive payment in 2011 and 2012; and a .5 percent incentive payment in 2013.

Beginning in 2012, Medicare health care practitioners not using electronic prescribing will receive reduced payments for Medicare-covered services: Reimbursements will be reduced 1 percent in 2012, 1.5 percent

²⁶ 21 C.F.R. 1301.11 (2010).

²⁷ 21 C.F.R. 1306.05 (2010).

²⁸ 21 C.F.R. 1306.05 (2010).

²⁹ Electronic Prescriptions for Controlled Substances, 73 Fed. Reg. 125 (June 27, 2008), (to be codified at 21 C.F.R. pts. 1300, 1304, 1306, 1311), see <http://www.gpoaccess.gov/fr/index.html>, last viewed February 23, 2010.

³⁰ Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, see <http://www.fhin.net/eprescribe/Index.shtml> (last viewed February 23, 2010).

³¹ Pub. L. No. 110-275 (2008).

in 2013, and 2 percent in 2014 and ongoing.³² Exemptions may be awarded on a case-by-case basis if it is determined that compliance would result in significant hardship for the practitioner.³³

The 2009 American Recovery and Investment Act (ARRA)³⁴ authorized approximately \$19 billion for additional Medicare and Medicaid incentives to assist providers in adopting health information technology, and for state loan programs. The incentives will be available for five years, starting in 2011.

Electronic Prescribing Networks

To manage health care costs, private sector health care entities established secure internet-based networks for electronically connecting prescribers, dispensers, payers, and pharmacy benefits managers across the country. These e-prescribing networks use private contracting mechanisms to ensure that their technology partners and other affiliates properly authenticate users, maintain prescription integrity, and protect the privacy and security of the health information transmitted through the network. E-prescribing networks use national standards to certify e-prescribing software for use by physicians and pharmacies to participate in the networks.³⁵

Until 2008, the two largest e-prescribing networks were RxHub and Surescripts. Both companies were established in 2001. RxHub was founded by three pharmacy benefits management companies, CVS Caremark Corporation, Express Scripts, Inc., and Medco Health Solutions.³⁶ RxHub focused on providing services related to the delivery of medication information to e-prescribing physicians.³⁷ Surescripts was created by the National Association of Chain Drug Stores and the National Community Pharmacists Association.³⁸ SureScripts focused on the provision of services related to electronic communication of prescription information between physicians and pharmacies.³⁹ In 2008 the two companies merged under the name Surescripts-RxHub, later Surescripts, and became the single largest e-prescribing network, nationally.

According to AHCA, Surescripts does not develop or endorse specific e-prescribing software. Rather, it works with vendors that supply electronic health record and e-prescribing applications to connect their applications to the network.⁴⁰ Both stand-alone e-prescribing systems and full electronic medical records systems can be used to connect to the network. There are over 30 Surescripts-certified technology partners available in Florida.⁴¹

According to 2009 Surescripts' data, the network has access to 27 payer sources, 49 states have patient accessibility rates of 50 percent or more, and the network accesses over 220 million patient records annually.⁴² Nationally, the network includes major chain pharmacies like Walgreens, CVS, and Wal-Mart, and over 10,000 independent pharmacies.⁴³ In Florida, over 8,000 physicians have access to the network, as do the majority of pharmacies. By agreement with AHCA, Florida Medicaid prescription drug data will be added this year.⁴⁴ According to Surescripts, the network now includes cash and paper transactions, rather than just electronic and third-party-paid transactions, if the prescribing or dispensing entity uses the network for that purpose.

³² *Id.*

³³ Agency for Health Care Administration, ePrescribing Clearinghouse, ePrescribing Initiatives and Incentive Programs, see <http://www.fhin.net/eprescribe/ePrescribingInitiatives/NationalIncentivePrograms.shtml> (last viewed February 23, 2010).

³⁴ Public Law 111-05 (2009).

³⁵ Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, 7, see <http://www.fhin.net/eprescribe/Index.shtml> (last viewed February 23, 2010).

³⁶ See, <http://www.surescripts.com/the-company.html>.

³⁷ Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, 24 see <http://www.fhin.net/eprescribe/Index.shtml> (last viewed February 23, 2010).

³⁸ See, <http://www.surescripts.com/the-company.html>.

³⁹ Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, 24 see <http://www.fhin.net/eprescribe/Index.shtml> (last viewed February 23, 2010).

⁴⁰ *Id.* at 2.

⁴¹ Presentation by Tom Groom, Senior Vice President, Surescripts, to the Health Regulation Policy Committee, March 25, 2009.

⁴² Presentation by Tom Groom, Senior Vice President, Surescripts, to the Health Regulation Policy Committee, March 25, 2009.

⁴³ See, <http://www.surescripts.com/the-company.html>; <http://www.surescripts.com/connected-pharmacies.html>.

⁴⁴ Presentation by Tom Groom, Senior Vice President, Surescripts, to the Health Regulation Policy Committee, March 25, 2009.

Prescription Drug Diversion and Abuse

According to the Substance Abuse and Mental Health Services Administration, more than 6.3 million Americans reported using prescription drugs for nonmedical reasons in 2003.⁴⁵ Most people who take prescription medications take them responsibly; however, the nonmedical use or abuse of prescription drugs remains a serious public health concern in the United States. Certain prescription drugs – opioid substances, central nervous system depressants, and stimulants – when abused can alter the brain's activity and lead to dependence and possible addiction.

Prescription drug abuse also occurs when a person illegally obtains a legal prescription drug for nonmedical use. People obtain these drugs in a variety of ways, including "doctor shopping," in which the person continually switches physicians so that they can obtain enough of the drug to feed their addiction. By frequently switching physicians, the doctors are unaware that the patient has already been prescribed the same drug and may be abusing it. Some physicians prescribe and dispense medically unjustifiable amounts of controlled substances, and are aware of their patients' abuse.⁴⁶

Use of prescription pain relievers without a doctor's prescription or only for the experience or feeling they cause ("nonmedical" use) is, after marijuana use, the second most common form of illicit drug use in the United States.⁴⁷ According to the Drug Abuse Warning Network (DAWN), approximately 324,000 emergency department visits in 2006 involved the nonmedical use of pain relievers (including both prescription and over-the-counter pain medications).⁴⁸

According to research by the National Institute on Drug Abuse⁴⁹, the three most abused classes of prescription drugs are:

- Opioids, used to treat pain. Examples include codeine (Schedules II, III, V), oxycodone (OxyContin, Percocet – Schedule II), and morphine (Kadian, Avinza -Schedule II);
- Central nervous system depressants, used to treat anxiety and sleep disorders. Examples include barbiturates (Mebaral, Nembutal) and benzodiazepines (Valium, Xanax) (all in Schedule IV); and
- Stimulants, used to treat ADHD, narcolepsy, and obesity. Examples include dextroamphetamine (Dexedrine, Adderall) and methylphenidate (Ritalin, Concerta) (all in Schedule II).

⁴⁵ Overview of Findings from the 2003 National Survey on Drug Use and Health, see <http://oas.samhsa.gov/nhsda/2k3nsduh/2k3Overview.htm> (last viewed January 30, 2010).

⁴⁶ See, Press Release, U.S. Att'y No. Dist. Fla., Destin Physician Sentenced to Life Imprisonment for Illegal Distribution of Controlled Substances, see <http://www.justice.gov/usao/fln/press%20releases/2010/jan/webb.html> (last viewed January 30, 2010); The Oxycontin Express (Vanguard, 2009) see <http://www.hulu.com/watch/100279/vanguard-the-oxycontin-express> (last viewed January 30, 2010).

⁴⁷ Substance Abuse and Mental Health Services Administration, Office of Applied Studies, Results from the 2007 National Survey on Drug Use and Health: National findings (DHHS Publication No. SMA 08-4343, NSDUH Series H-34) (2008), see <http://oas.samhsa.gov/p0000016.htm> (last viewed January 30, 2010); cited in, The NSDUH Report, Trends in Nonmedical Use of Prescription Pain Relievers: 2002 to 2007, Feb. 5, 2009, see <http://www.oas.samhsa.gov/2k9/painRelievers/nonmedicalTrends.cfm> (last viewed January 30, 2010).

⁴⁸ Substance Abuse and Mental Health Services Administration, Office of Applied Studies, Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits, (August 2008), see <http://dawninfo.samhsa.gov/files/ED2006/DAWN2K6ED.pdf> (last viewed January 30, 2010), cited in, The NSDUH Report, Trends in Nonmedical Use of Prescription Pain Relievers: 2002 to 2007, Feb. 5, 2009, see <http://www.oas.samhsa.gov/2k9/painRelievers/nonmedicalTrends.cfm> (last viewed January 30, 2010).

⁴⁹ National Institutes of Health, National Institute on Drug Abuse, see, <http://www.drugabuse.gov/Researchreports/Prescription/prescription2.html>.

The most commonly abused drugs (highlighted below) are found in all four prescribable controlled substance Schedules.⁵⁰

Substance	Other Names
Schedule II - high potential for abuse; severely restricted medical use	
1-Phenylcyclohexylamine	Precursor of PCP
1-Piperidinocyclohexanecarbonitrile	PCC, precursor of PCP
Alfentanil	Alfenta
Alphaprodine	Nisentil
Amobarbital	Amytal, Tuinal
Amphetamine	Dexedrine, Biphetamine
Anileridine	Leritine
Benzoylcegonine	Cocaine metabolite
Bezitramide	Burgodin
Carfentanil	Wildnil
Coca Leaves	
Cocaine	Methyl benzoylcegonine, Crack
Codeine	Morphine methyl ester, methyl morphine
Dextropropoxyphene, bulk (non-dosage forms)	Propoxyphene
Dihydrocodeine	Didrate, Parzone
Diphenoxylate	
Diprenorphine	M50-50
Ecgonine	Cocaine precursor, in Coca leaves
Ethylmorphine	Dionin
Etorphine HCl	M 99
Fentanyl	Innovar, Sublimaze, Duragesic
Glutethimide	Doriden, Dorimide
Hydrocodone	dihydrocodeinone
Hydromorphone	Dilaudid, dihydromorphinone
Isomethadone	Isoamidone
Levo-alphaacetylmethadol	LAAM, long acting methadone, levomethadyl acetate
Levomethorphan	
Levorphanol	Levo-Dromoran
Meperidine	Demerol, Mepergan, pethidine
Meperidine intermediate-A	Meperidine precursor
Meperidine intermediate-B	Meperidine precursor
Meperidine intermediate-C	Meperidine precursor
Metazocine	
Methadone	Dolophine, Methadose, Amidone
Methadone intermediate	Methadone precursor
Methamphetamine	Desoxyn, D-desoxyephedrine, ICE, Crank, Speed
Methylphenidate	Ritalin
Metopon	
Moramide-intermediate	
Morphine	MS Contin, Roxanol, Duramorph, RMS, MSIR
Nabilone	Cesamet
Opium extracts	

⁵⁰ National Institutes of Health, National Institute on Drug Abuse, see, <http://www.drugabuse.gov/DrugPages/DrugsOfAbuse.html> (last viewed January 30, 2010); U.S. Drug Enforcement Administration, see, <http://www.justice.gov/dea/pubs/scheduling.html> (last viewed January 30, 2010). This is a very basic list which describes the parent chemicals, not the salts, isomers and salts of isomers, esters, ethers and derivatives which may also be controlled substances.

Opium fluid extract	
Opium poppy	Papaver somniferum
Opium tincture	Laudanum
Opium, granulated	Granulated opium
Opium, powdered	Powdered Opium
Opium, raw	Raw opium, gum opium
Oxycodone	OxyContin, Percocet, Tylox, Roxicodone, Roxicet
Oxymorphone	Numorphan
Pentobarbital	Nembutal
Phenazocine	Narphen, Prinadol
Phencyclidine	PCP, Sernylan
Phenmetrazine	Preludin
Phenylacetone	P2P, phenyl-2-propanone, benzyl methyl ketone
Piminodine	
Poppy Straw	Opium poppy capsules, poppy heads
Poppy Straw Concentrate	Concentrate of Poppy Straw, CPS
Racemethorphan	
Racemorphan	Dromoran
Remifentanil	Ultiva
Secobarbital	Seconal, Tuinal
Sufentanil	Sufenta
Thebaine	Precursor of many narcotics
Schedule III - (less potential for abuse than Schedules I or II substances; some accepted medical use)	
Amobarbital & noncontrolled active ingred.	Amobarbital/ephedrine capsules
Amobarbital suppository dosage form	
Anabolic steroids	"Body Building" drugs
Aprobarbital	Alurate
Barbituric acid derivative	Barbiturates not specifically listed
Benzphetamine	Didrex, Inapetyl
Boldenone	Equipoise, Parenabol, Vebonol, dehydrotestosterone
Buprenorphine	Buprenex, Temgesic
Butabarbital	Butisol, Butibel
Butalbital	Fiorinal, Butalbital with aspirin
Chlorhexadol	Mechloral, Mecoral, Medodorm, Chloralodol
Chlorotestosterone (same as clostebol)	if 4-chlorotestosterone then clostebol
Chlorphentermine	Pre-Sate, Lucofen, Apsedon, Desopimon
Clortermine	Voranil
Clostebol	Alfa-Trofodermin, Clostene, 4-chlorotestosterone
Codeine & isoquinoline alkaloid 90 mg/du	Codeine with papaverine or noscapine
Codeine combination product 90 mg/du	Empirin, Fiorinal, Tylenol, ASA or APAP w/codeine
Dehydrochlormethyltestosterone	Oral-Turinabol
Dihydrocodeine combination product 90 mg/du	Synalgos-DC, Compal
Dihydrotestosterone (same as stanolone)	see stanolone
Dronabinol in sesame oil in soft gelatin capsule	Marinol, synthetic THC in sesame oil/soft gelatin
Drostanolone	Drolban, Masterid, Permastril
Ethylestrenol	Maxibolin, Orabolin, Durabolin-O, Duraboral
Ethylmorphine combination product 15 mg/du	
Fluoxymesterone	Anadroid-F, Halotestin, Ora-Testryl
Formebolone (incorrect spelling in law)	Esiclene, Hubernol
Hydrocodone & isoquinoline alkaloid 15 mg/du	Dihydrocodeinone+papaverine or noscapine
Hydrocodone combination product 15 mg/du	Tussionex, Tussend, Lortab, Vicodin, Hycodan, Anexsia ++

Ketamine	Ketaset, Ketalar, Special K, K
Lysergic acid	LSD precursor
Lysergic acid amide	LSD precursor
Mesterolone	Proviron
Methandienone (see Methandrostenolone)	
Methandranone	
Methandriol	Sinesex, Stenediol, Troformone
Methandrostenolone	Dianabol, Metabolina, Nerobol, Perbolin
Methenolone	Primobolan, Primobolan Depot, Primobolan S
Methyltestosterone	Android, Oreton, Testred, Virilon
Methypylon	Noludar
Mibolerone	Cheque
Morphine combination product/50 mg/100 ml or gm	
Nalorphine	Nalline
Nandrolone	Deca-Durabolin, Durabolin, Durabolin-50
Norethandrolone	Nilevar, Solevar
Opium combination product 25 mg/du	Paregoric, other combination products
Oxandrolone	Anavar, Lonavar, Provitar, Vasorome
Oxymesterone	Anamidol, Balnimax, Oranabol, Oranabol 10
Oxymetholone	Anadrol-50, Adroyd, Anapolon, Anasteron, Pardroyd
Pentobarbital & noncontrolled active ingred.	FP-3
Pentobarbital suppository dosage form	WANS
Phendimetrazine	Plegine, Prelu-2, Bontril, Melfiat, Statabex
Secobarbital & noncontrolled active ingred	various
Secobarbital suppository dosage form	various
Stanolone	Anabolex, Andractim, Pesomax, dihydrotestosterone
Stanozolol	Winstrol, Winstrol-V
Stimulant compounds previously excepted	Mediatric
Sulfondiethylmethane	
Sulfonethylmethane	
Sulfonmethane	
Talbutal	Lotusate
Testolactone	Teslac
Testosterone	Android-T, Androlan, Depotest, Delatestryl
Thiamylal	Surital
Thiopental	Pentothal
Tiletamine & Zolazepam Combination Product	Telazol
Trenbolone	Finaplix-S, Finajet, Parabolan
Vinbarbital	Delvinal, vinbarbitone
Schedule IV - (less potential for abuse than Schedules I, II, or III substances; some accepted medical use)	
Alprazolam	Xanax
Barbital	Veronal, Plexonal, barbitone
Bromazepam	Lexotan, Lexatin, Lexotanil
Butorphanol	Stadol, Stadol NS, Torbugesic, Torbutrol
Camazepam	Albego, Limpidon, Paxor
Cathine	Constituent of "Khat" plant
Chloral betaine	Beta Chlor
Chloral hydrate	Noctec
Chlordiazepoxide	Librium, Libritabs, Limbitrol, SK-Lygen
Clobazam	Urbadan, Urbanyl
Clonazepam	Klonopin, Clonopin
Clorazepate	Tranxene

Clotiazepam	Trecalmo, Rize
Cloxazolam	Enadel, Sepazon, Tolestan
Delorazepam	
Dexfenfluramine	Redux
Dextropropoxyphene dosage forms	Darvon, propoxyphene, Darvocet, Dolene, Propacet
Diazepam	Valium, Valrelease
Dichloralphenazone	Midrin, dichloralantipyrine
Diethylpropion	Tenuate, Tepanil
Difenoxin 1 mg/25 ug AtSO4/du	Motofen
Estazolam	ProSom, Domnamid, Eurodin, Nuctalon
Ethchlorvynol	Placidyl
Ethinamate	Valmid, Valamin
Ethyl loflazepate	
Fencamfamin	Reactivan
Fenfluramine	Pondimin, Ponderal
Fenproporex	Gacilin, Solvolip
Fludiazepam	
Flunitrazepam	Rohypnol, Narcozep, Darkene, Roipnol
Flurazepam	Dalmane
Halazepam	Paxipam
Haloxazolam	
Ketazolam	Anxon, Loftran, Solatran, Contamex
Loprazolam	
Lorazepam	Ativan
Lormetazepam	Noctamid
Mazindol	Sanorex, Mazanor
Mebutamate	Capla
Medazepam	Nobrium
Mefenorex	Anorexic, Amexate, Doracil, Pondinil
Meprobamate	Miltown, Equanil, Deprol, Equagesic, Meprospan
Methohexital	Brevital
Methylphenobarbital (mephobarbital)	Mebaral, mephobarbital
Midazolam	Versed
Modafinil	Provigil
Nimetazepam	Erimin
Nitrazepam	Mogadon
Nordiazepam	Nordazepam, Demadar, Madar
Oxazepam	Serax, Serenid-D
Oxazolam	Serenal, Convertal
Paraldehyde	Paral
Pemoline	Cylert
Pentazocine	Talwin, Talwin NX, Talacen, Talwin Compound
Petrichloral	Pentaerythritol chloral, Periclor
Phenobarbital	Luminal, Donnatal, Bellerгал-S
Phentermine	Ionamin, Fastin, Adipex-P, Obe-Nix, Zantryl
Pinazepam	Domar
Pipradrol	Detaril, Stimolag Fortis
Prazepam	Centrax
Quazepam	Doral, Dormalin
Sibutramine	Meridia
SPA	1-dimethylamino-1,2-diphenylethane, Lefetamine
Temazepam	Restoril

Tetrazepam	
Triazolam	Halcion
Zaleplon	Sonata
Zolpidem	Ambien, Stilnoct, Ivadal
Schedule V - (low potential for abuse compared to Schedule IV substances; some accepted medical use)	
Codeine preparations - 200 mg/100 ml or 100 gm	Cosanyl, Robitussin A-C, Cheracol, Cerose, Pediacof
Difenoxin preparations - 0.5 mg/25 ug AtSO4/du	Motofen
Dihydrocodeine preparations 10 mg/100 ml or 100 gm	Cophene-S, various others
Diphenoxylate preparations 2.5 mg/25 ug AtSO4	Lomotil, Logen
Ethylmorphine preparations 100 mg/100 ml or 100 gm	
Opium preparations - 100 mg/100 ml or gm	Parepectolin, Kapectolin PG, Kaolin Pectin P.G.
Pyrovalerone	Centroton, Thymergix

The Substance Abuse and Mental Health Services Administration (SAMHSA) sponsors an annual national survey on drug use and health. The most recent survey⁵¹ indicates there are 7.0 million (2.8 percent) persons aged 12 or older who used prescription-type psychotherapeutic drugs nonmedically in the past month. Of these, 5.2 million used pain relievers, an increase from 4.7 million in 2005.

Of those 7 million people who used pain relievers nonmedically in a 12-month period, 55.7 percent reported they received the drug from a friend or relative for free. Another 9.3 percent bought the drugs from a friend or family member. Another 19.1 percent reported they obtained the drug through just one doctor. Only 3.9 percent got the pain relievers from a drug dealer or other stranger, and only 0.1 percent reported buying the drug on the Internet. Among those who reported getting the pain reliever from a friend or relative for free, 80.7 percent reported in a follow-up question that the friend or relative had obtained the drugs from just one doctor, while only 1.6 percent reported that the friend or relative had bought the drug from a drug dealer or other stranger.⁵²

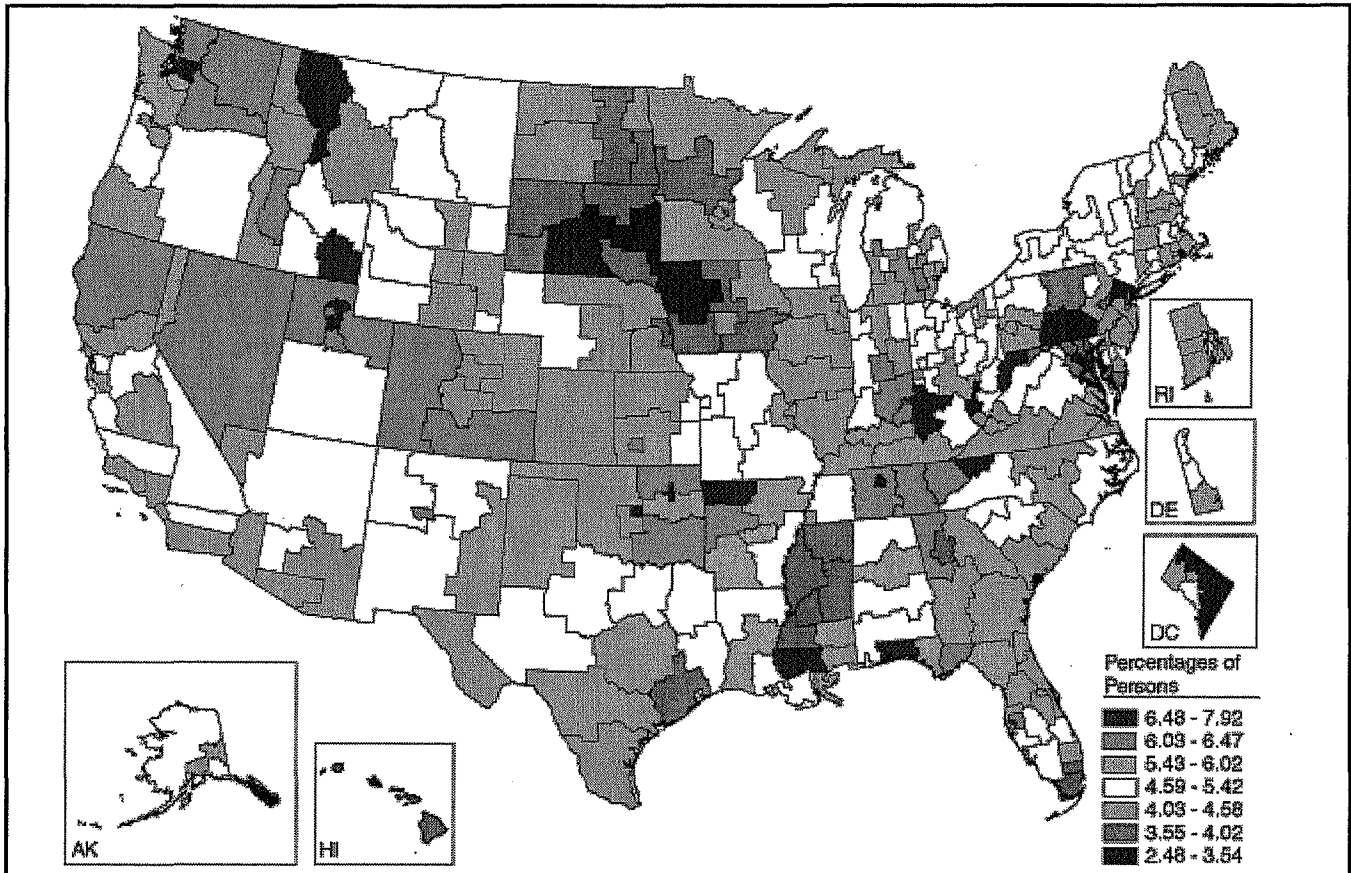
National data indicate that the percent of the population using prescription pain relievers for nonmedical purposes in the past year ranged from a low of 2.48 percent in area of the District of Columbia to a high of 7.92 percent in northwest Florida. In Florida, for example: Palm Beach County measured 4.53 percent; Broward County measured 3.82 percent; Miami-Dade and Monroe Counties measured 3.59 percent; and Escambia, Okaloosa, Santa Rosa and Walton Counties combined measured 7.92 percent.⁵³

⁵¹ 2006 National Survey on Drug Use and Health, U.S. Substance Abuse and Mental Health Services Administration, see <http://www.oas.samhsa.gov/nsduh/2k6nsduh/2k6Results.cfm#High> (last viewed January 30, 2010).

⁵² *Id.*

⁵³ Substance Abuse and Mental Health Services Administration, Office of Applied Studies, The NSDUH Report: Nonmedical Use of Pain Relievers in Substate Regions: 2004 to 2006, June 19, 2008, see <http://www.oas.samhsa.gov/2k8/pain/substate.cfm> (last viewed January 30, 2010).

Figure 1. Nonmedical Use of Pain Relievers in the Past Year among Persons Aged 12 or Older, by Substate Region*: Percentages, Annual Averages Based on 2004, 2005, and 2006 NSDUHs



Source: Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (June 19, 2008). The NSDUH Report: Nonmedical Use of Pain Relievers in Substate Regions: 2004 to 2006.

The Florida Medical Examiners Commission reports on drug-related deaths in Florida, and specifically tracks deaths caused by abuse of prescriptions drugs⁵⁴. According to the Commission, prescription drugs are found in deceased persons in lethal amounts more often than illicit drugs.⁵⁵ According to the Commission's data, 1,157 deaths in Florida from January 2009 through June 2009 were caused by prescription drugs, or about 6.3 deaths per day.⁵⁶

According to recent U.S. DEA statistics, the top 25 pain management clinics for dispensing of time release opioids and other pain relievers are all located in Florida.⁵⁷ The U.S. Drug Enforcement Administration identified the 50 practitioners who dispense the most Oxycodone in the country. All 50 top-dispensing practitioners are in Florida, and 33 are in Broward County.⁵⁸

⁵⁴ Florida Department of Law Enforcement, Medical Examiners Commission, Drugs Identified in Deceased Persons Interim Report, November 2009, see <http://www.fdle.state.fl.us/content/getdoc/036671bc-4148-4749-a891-7e3932e0a483/Publications.aspx> (last viewed January 30, 2010).

⁵⁵ *Id.*

⁵⁶ *Id.*

⁵⁷ Data drawn from the Automation of Reports and Consolidated Orders System, U.S. Department of Justice Drug Enforcement Administration, provided by the Florida Office of Drug Control via email March 22, 2009, on file with the Health Regulation Policy Committee, see <http://www.dea diversion.usdoj.gov/arcos/index.html> (last viewed January 30, 2010).

⁵⁸ Data drawn from the Automation of Reports and Consolidated Orders System, July-December 2008, U.S. Department of Justice Drug Enforcement Administration, provided by the Florida Office of Drug Control via email March 22, 2009, on file with the Health Regulation Policy Committee, see <http://www.dea diversion.usdoj.gov/arcos/index.html> (last viewed January 30, 2010)

Physician Dispensing of Oxycodone, by County⁵⁹

County	Units Oxycodone
Broward	6,584,200
Palm Beach	1,809,400
Miami-Dade	450,000
Pinellas	308,400
Hillsborough	277,300
Lake	220,400
Orange	111,200
Seminole	109,760

Physician Dispensing of Oxycodone in Palm Beach, Broward, Miami-Dade Counties, by Zip Code⁶⁰

Zip Code	Units Oxycodone
33311	1,235,700
33309	775,400
33334	727,600
33407	575,100
33313	442,800
33324	436,600
33009	396,000
33312	340,900
33020	329,000
33162	314,800
33301	285,900
33463	277,500
33417	241,700
33431	227,600
33325	198,800
33483	193,600
33323	186,800
33021	153,600
33487	151,200
33321	143,200
33445	142,700
33016	135,200
33024	130,200
33069	126,600
33023	122,800
33063	118,000
33073	111,900
33317	109,100
33308	107,000
33064	106,300

In 2009, the State Attorney for the 17th Judicial Circuit (Broward County) empanelled a grand jury to consider the proliferation of pain clinics in Broward County and their effect on the community, and to make recommendations on what can be done to protect the public from the dangers of pain clinics. The grand jury interim report found that physicians in pain clinics dispense controlled substances directly to patients, rather than the patient going to a pharmacy to fill the prescription. Among other things, the grand jury recommended the state prohibit dispensing prescription drugs in pain clinics.⁶¹

Prescription Drug Monitoring Program and Pain Clinic Regulation

In the 2009 regular legislative session, the Legislature passed Senate bill 462 (Ch. 2009-198, Laws of Florida) to address the problem of prescription drug abuse. The bill:

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ The Proliferation of Pain Clinics in South Florida, Interim Report of the Broward County Grand Jury, Circuit Court of the Seventeenth Judicial Circuit, November 19, 2009.

- Required the Department of Health to establish a database of controlled substances dispensed to all patients in Florida;
- Required all pharmacies and all dispensing physicians are required to report all controlled substance dispensing to the Department within 15 days of dispensing;
- Required the Department to load the reported dispensing information into the database, and make it available to practitioners, regulators, and criminal justice entities upon their request;
- Required all pain clinics, defined as entities that advertise for pain management services or employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substances, to register with the Department;
- Required the medical boards to adopt rules for the standards of medical practice in pain clinics;
- Created a task force within the Executive Office of the Governor, chaired by the Office of Drug Control, to monitor and report on the implementation of the database; and
- Authorized the Office of Drug Control within the Executive Office of the Governor to establish a direct support organization to solicit public and private funding for the database.

As of January, 2010, the Department has implemented the clinic registration requirement, and the boards have begun rulemaking on the standards of practice.⁶² The Office of Drug Control has established the direct support organization. To date, \$400,000 has been generated to fund the database, via a grant from the U.S. Department of Justice awarded to the Department of Children and Families prior to the passage of the bill. Current cost projections for the program are \$449,665 in non-recurring first year costs, and \$480,486 in recurring annual costs.⁶³

Effect of Proposed Changes

The Proposed Committee Substitute (PCS) for House Bill 225 makes several regulatory changes to address the problem of prescription drug abuse, related to pharmacies, physicians, pain clinics, and access to controlled substance dispensing information.

The PCS amends sections 465.018 and 465.023, F.S., to require pharmacies to participate in a multi-state electronic prescribing network, and require pharmacies to transmit dispensing information for controlled substances through the network. The bill also makes failure to so transmit controlled substance dispensing information grounds for pharmacy permit disciplinary action. The bill makes these provisions effective July 1, 2012, for new pharmacies and January 1, 2013, for existing pharmacies.

The bill creates s. 408.0513, F.S., which requires the Agency for Health Care Administration to negotiate access to controlled substance information through a multi-state electronic prescribing network for law enforcement and state regulatory entities. Access to the information available in the network is limited to criminal justice agencies, as defined in s. 119.011, engaged in an active investigation involving a specific violation of law, and the department or relevant regulatory board involved in a specific investigation involving a regulated person. Section 119.011 defines "criminal justice agency" as:

- Any law enforcement agency, court, or prosecutor;
- Any other agency charged by law with criminal law enforcement duties;
- Any agency having custody of criminal intelligence information or criminal investigative information for the purpose of assisting law enforcement agencies in the conduct of certain investigations; and
- The Department of Corrections.

The PCS amends sections 458.309 and 459.005, F.S., to add pain clinic registration requirements. It prohibits the Department of Health from registering pain clinics owned by non-physicians, pain clinics employing or contracting with a physician against whom regulatory action has been taken related to drug or alcohol abuse, and pain clinics with owners who have certain felony drug convictions. The PCS also amends the definition of "clinics" to make it applicable only to entities that are primarily engaged in the

⁶² See, Rules 64B8-9.0131, 64B8-9.0132, 64B8-9.0133, F.A.C., under development.

⁶³ PL2009-198 Implementation of the Prescription Drug Monitoring Program & Pain Clinic Registration Florida Department of Health, Florida Department of Health, presentation to the House Health Regulation Policy Committee, January 12, 2010; Prescription Drug Monitoring Program PL2009 – 198 Implementation Status Plan, Florida Office of Drug Control, Executive Office of the Governor, presentation to the House Health Regulation Policy Committee, January 12, 2010.

treatment pain by prescribing or dispensing controlled substances, as opposed to other methods of pain treatment.

The PCS amends sections 458.331, 459.015 and 465.0276, F.S., to add practitioner regulations and penalties. It makes advertising controlled substances and practicing medicine in an unregistered clinic which is required to be registered grounds for physician licensure action. It prohibits dispensing practitioners from dispensing more than a 72-hour supply of controlled substances listed in Schedules II and III. The PCS exempts medication samples from the dispensing limit, if they are provided with no direct or indirect remuneration. The PCS does not prohibit physicians from prescribing controlled substances in any way. Under the bill's provisions, patients who receive prescriptions for controlled substances would fill them at pharmacies, rather than in physician offices or clinics. The PCS makes violation of the dispensing limit a third degree felony.⁶⁴

The PCS authorizes the Agency for Health Care Administration to adopt rules to implement s. 408.0513, F.S.

The bill appears to have no fiscal impact on state or local government. The Agency for Health Care Administration is authorized to seek private grants and donations to implement s. 408.0513, F.S.

The bill provides an effective date of July 1, 2010.

B. SECTION DIRECTORY:

Section 1. Creates s. 408.0513 related to access to prescription drug medication history.

Section 2. Amends s. 458.309, F.S., related to rulemaking authority.

Section 2. Amends s. 458.331, F.S., related to grounds for disciplinary action and action by the board and department.

Section 3. Amends s. 459.005, F.S., related to rulemaking authority.

Section 4. Amends s. 459.015, F.S., related to grounds for disciplinary action and action by the board and department.

Section 5. Amends s. 465.018, F.S., related to community pharmacies and permits.

Section 6. Amends s. 465.023, F.S., related to pharmacy permittees and disciplinary action.

Section 7. Amends s. 465.0276, F.S., related to dispensing practitioners.

Section 8. Provides an effective date of July 1, 2010.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See Fiscal Comments. According to the Department of Health, which regulates dispensing practitioners, the dispensing limit provisions of the bill have no fiscal impact on the Department.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

⁶⁴ Third degree felonies are punishable by up to 5 years in prison and/or up to a \$5,000 fine. SS. 775.082, 775.083, F.S.

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The PCS requires pharmacies to participate in, and transmit controlled substance dispensing information through, a multi-state electronic prescribing network as a condition of permitting. According to the Agency for Health Care Administration, over 70 percent of pharmacies in Florida are activated to receive electronic prescriptions. Such pharmacies may incur transmission transaction costs if they do not currently use these systems for controlled substance prescriptions. The approximately 30 percent of pharmacies in Florida which are not activated to participate in a multi-state e-prescribing network will incur activation costs, which may include computer upgrades, software purchases, licensing agreements, and the above-mentioned transaction costs. These costs will vary with each pharmacy.

D. FISCAL COMMENTS:

The costs of access to information contained in an existing multi-state network are unknown, and are subject to negotiation by the Agency for Health Care Administration. The agency is authorized to seek private grants and donations to implement this provision.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is required to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

1 A bill to be entitled
 2 An act relating to controlled substances; creating s.
 3 408.0512; requiring the Agency for Health Care
 4 Administration to enter into a contract with a multi-state
 5 electronic prescribing network to provide access to
 6 certain information on certain controlled substances;
 7 providing for access to controlled substance information
 8 in the network by a criminal justice agency and the
 9 Department of Health or relevant regulatory board;
 10 requiring the agency to seek grants and donations to
 11 implement the act; amending s. 458.309, F.S.; limiting
 12 ownership of pain management clinics; amending s. 458.331,
 13 F.S.; making the practice of medicine in an unregistered
 14 pain management clinic grounds for licensure disciplinary
 15 action; making advertising the use, sale, or dispensing of
 16 controlled substances grounds for physician licensure
 17 disciplinary action; amending s. 459.005, F.S.; limiting
 18 ownership of pain management clinics; amending s. 459.015,
 19 F.S.; making the practice of osteopathic medicine in an
 20 unregistered pain management clinic grounds for
 21 osteopathic physician licensure disciplinary action;
 22 making advertising the use, sale, or dispensing of
 23 controlled substances grounds for licensure disciplinary
 24 action; amending s. 465.018, F.S.; requiring community
 25 pharmacy permit applicants to demonstrate ability to
 26 participate in and transmit dispensing information through
 27 a multi-state electronic prescribing network; requiring
 28 community pharmacies to transmit dispensing information on

29 certain controlled substance prescriptions through a
 30 multi-state electronic prescribing network; providing
 31 effective dates; amending 465.023, F.S.; making failure to
 32 transmit certain dispensing information through a multi-
 33 state electronic prescribing network grounds for community
 34 pharmacy permit disciplinary action; amending s. 465.0276,
 35 F.S.; prohibiting registered dispensing practitioners from
 36 dispensing more than a specified amount of certain
 37 controlled substances; providing penalties; providing
 38 exceptions; providing an effective date.

39

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

41

42 Section 1. Section 408.0513, Florida Statutes, is
 43 created to read:

44 408.0513 Access to prescription drug medication history.-

45 (1) The agency shall, by December 1, 2010, contract with
 46 an entity that operates a multi-state electronic prescribing
 47 network to provide access to Schedule II and III controlled
 48 substance information available on the network to:

49 (a) A criminal justice agency, as defined in s. 119.011,
 50 which enforces the laws of this state or the United States and
 51 which has initiated an active investigation involving a specific
 52 violation of law.

53 (b) The Department of Health or the relevant health
 54 regulatory board responsible for the licensure, regulation, or
 55 discipline of practitioners, pharmacists, or other persons who
 56 are authorized to prescribe, administer, or dispense controlled

57 | substances and who are involved in a specific investigation
 58 | involving a designated person.

59 | (2) The agency shall adopt rules under ss. 120.536(1) and
 60 | 120.54 to administer the provisions of this section, including
 61 | the method and terms of access to the information provided under
 62 | subsection (1).

63 | (3) The agency shall seek federal grants and donations
 64 | from private entities to implement this section.

65 | Section 2. Subsection (4) of section 458.309, Florida
 66 | Statutes, is amended to read:

67 | 458.309 Rulemaking authority.—

68 | (4) All privately owned pain-management clinics,
 69 | facilities, or offices, hereinafter referred to as "clinics,"
 70 | primarily engaged in the treatment of pain by prescribing or
 71 | dispensing controlled substances, and which advertise in any
 72 | medium for any type of pain-management services, or employ a
 73 | physician who is primarily engaged in the treatment of pain by
 74 | prescribing or dispensing controlled substance medications, must
 75 | register with the department by January 4, 2010, unless that
 76 | clinic is licensed as a facility pursuant to chapter 395. The
 77 | department shall deny registration to any clinic not fully owned
 78 | by a physician or group of physicians. The department shall deny
 79 | registration to any clinic owned by or with any contractual or
 80 | employment relationship with a physician whose Drug Enforcement
 81 | Administration number has ever been suspended or revoked, or
 82 | against whom the board has taken final administrative action
 83 | related to the physician's impairment due to the misuse or abuse
 84 | of alcohol or drugs. The department shall deny registration to

85 any clinic in which ownership or any controlling interest is
 86 held by any person who was convicted of, or entered a plea of
 87 guilty or nolo contendere to, regardless of adjudication, a
 88 felony under chapter 893. A physician may not practice medicine
 89 in a pain-management clinic that is required to but has not
 90 registered with the department. Each clinic location shall be
 91 registered separately regardless of whether the clinic is
 92 operated under the same business name or management as another
 93 clinic. If the clinic is licensed as a health care clinic under
 94 chapter 400, the medical director is responsible for registering
 95 the facility with the department. If the clinic is not
 96 registered pursuant to chapter 395 or chapter 400, the clinic
 97 shall, upon registration with the department, designate a
 98 physician who is responsible for complying with all requirements
 99 related to registration of the clinic. The designated physician
 100 shall be licensed under this chapter or chapter 459 and shall
 101 practice at the office location for which the physician has
 102 assumed responsibility. The department shall inspect the clinic
 103 annually to ensure that it complies with rules of the Board of
 104 Medicine adopted pursuant to this subsection and subsection (5)
 105 unless the office is accredited by a nationally recognized
 106 accrediting agency approved by the Board of Medicine. The actual
 107 costs for registration and inspection or accreditation shall be
 108 paid by the physician seeking to register the clinic.

109 Section 2. Paragraph (nn) of subsection (1) of section
 110 458.331, Florida Statutes, is amended to read:

111 458.331 Grounds for disciplinary action; action by the
 112 board and department.—

113 (1) The following acts constitute grounds for denial of a
 114 license or disciplinary action, as specified in s. 456.072(2):

115 (nn) Practicing medicine in a clinic that is required to
 116 but has not registered with the department pursuant to s.
 117 458.309.

118 (oo) Using any communication media to promote or advertise
 119 the use, sale, or dispensing of any controlled substance
 120 appearing in any schedule in chapter 893.

121 (pp) Violating any provision of this chapter or chapter
 122 456, or any rules adopted pursuant thereto.

123 Section 3. Subsection (3) of section 459.005, Florida
 124 Statutes, is amended to read:

125 459.005 Rulemaking authority.—

126 (3) All privately owned pain-management clinics,
 127 facilities, or offices, hereinafter referred to as "clinics,"
 128 primarily engaged in the treatment of pain by prescribing or
 129 dispensing controlled substances, and which advertise in any
 130 medium for any type of pain-management services, or employ a
 131 physician who is licensed under this chapter and who is
 132 primarily engaged in the treatment of pain by prescribing or
 133 dispensing controlled substance medications, must register with
 134 the department by January 4, 2010, unless that clinic is
 135 licensed as a facility under chapter 395. The department shall
 136 deny registration to any clinic not fully owned by a physician
 137 or group of physicians. The department shall deny registration
 138 to any clinic owned by or with any contractual or employment
 139 relationship with a physician whose Drug Enforcement
 140 Administration number has ever been suspended or revoked, or

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141 against whom the board has taken final administrative action
142 related to the physician's impairment due to the misuse or abuse
143 of alcohol or drugs. The department shall deny registration to
144 any clinic in which ownership or any controlling interest is
145 held by any person who was convicted of, or entered a plea of
146 guilty or nolo contendere to, regardless of adjudication, a
147 felony under chapter 893. A physician may not practice
148 osteopathic medicine in a pain-management clinic that is
149 required to but has not registered with the department. Each
150 clinic location shall be registered separately regardless of
151 whether the clinic is operated under the same business name or
152 management as another clinic. If the clinic is licensed as a
153 health care clinic under chapter 400, the medical director is
154 responsible for registering the facility with the department. If
155 the clinic is not registered under chapter 395 or chapter 400,
156 the clinic shall, upon registration with the department,
157 designate a physician who is responsible for complying with all
158 requirements related to registration of the clinic. The
159 designated physician shall be licensed under chapter 458 or this
160 chapter and shall practice at the office location for which the
161 physician has assumed responsibility. The department shall
162 inspect the clinic annually to ensure that it complies with
163 rules of the Board of Osteopathic Medicine adopted pursuant to
164 this subsection and subsection (4) unless the office is
165 accredited by a nationally recognized accrediting agency
166 approved by the Board of Osteopathic Medicine. The actual costs
167 for registration and inspection or accreditation shall be paid
168 by the physician seeking to register the clinic.

169 Section 4. Paragraph (pp) of subsection (1) of section
 170 459.015, Florida Statutes, is amended to read:

171 459.015 Grounds for disciplinary action; action by the
 172 board and department.—

173 (1) The following acts constitute grounds for denial of a
 174 license or disciplinary action, as specified in s. 456.072(2):

175 (pp) Practicing osteopathic medicine in a clinic that is
 176 required to but has not registered with the department pursuant
 177 to s. 458.309.

178 (qq) Using any communication media to promote or advertise
 179 the use, sale, or dispensing of any controlled substance
 180 appearing in any schedule in chapter 893.

181 (rr) Violating any provision of this chapter or chapter
 182 456, or any rules adopted pursuant thereto.

183 Section 5. Section 465.018, Florida Statutes, is amended
 184 to read:

185 465.018 Community pharmacies; permits.—Any person desiring
 186 a permit to operate a community pharmacy shall apply to the
 187 department. If the board office certifies that the application
 188 complies with the laws of the state and the rules of the board
 189 governing pharmacies, the department shall issue the permit. No
 190 permit shall be issued unless a licensed pharmacist is
 191 designated as the prescription department manager responsible
 192 for maintaining all drug records, providing for the security of
 193 the prescription department, and following such other rules as
 194 relate to the practice of the profession of pharmacy. The
 195 permittee and the newly designated prescription department
 196 manager shall notify the department within 10 days of any change

197 in prescription department manager. Effective July 1, 2012, no
 198 permit shall be issued unless the applicant demonstrates ability
 199 to participate in and transmit dispensing information through a
 200 multi-state electronic prescribing network. Effective January
 201 1, 2013, all permittees shall transmit dispensing information
 202 for all Schedule II and III controlled substance prescriptions
 203 through a multi-state electronic prescribing network.

204 Section 6. Subsection (1) of section 465.023, Florida
 205 Statutes, is amended to read:

206 465.023 Pharmacy permittee; disciplinary action.—

207 (1) The department or the board may revoke or suspend the
 208 permit of any pharmacy permittee, and may fine, place on
 209 probation, or otherwise discipline any pharmacy permittee if the
 210 permittee, or any affiliated person, partner, officer, director,
 211 or agent of the permittee, including a person fingerprinted
 212 under s. 465.022(3), has:

213 (a) Obtained a permit by misrepresentation or fraud or
 214 through an error of the department or the board;

215 (b) Attempted to procure, or has procured, a permit for
 216 any other person by making, or causing to be made, any false
 217 representation;

218 (c) Violated any of the requirements of this chapter or
 219 any of the rules of the Board of Pharmacy; of chapter 499, known
 220 as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-
 221 392, known as the "Federal Food, Drug, and Cosmetic Act"; of 21
 222 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse
 223 Prevention and Control Act; or of chapter 893;

224 (d) Been convicted or found guilty, regardless of

225 adjudication, of a felony or any other crime involving moral
 226 turpitude in any of the courts of this state, of any other
 227 state, or of the United States;

228 (e) Been convicted or disciplined by a regulatory agency
 229 of the Federal Government or a regulatory agency of another
 230 state for any offense that would constitute a violation of this
 231 chapter;

232 (f) Been convicted of, or entered a plea of guilty or nolo
 233 contendere to, regardless of adjudication, a crime in any
 234 jurisdiction which relates to the practice of, or the ability to
 235 practice, the profession of pharmacy;

236 (g) Been convicted of, or entered a plea of guilty or nolo
 237 contendere to, regardless of adjudication, a crime in any
 238 jurisdiction which relates to health care fraud; ~~or~~

239 (h) Dispensed any medicinal drug based upon a
 240 communication that purports to be a prescription as defined by
 241 s. 465.003(14) or s. 893.02 when the pharmacist knows or has
 242 reason to believe that the purported prescription is not based
 243 upon a valid practitioner-patient relationship that includes a
 244 documented patient evaluation, including history and a physical
 245 examination adequate to establish the diagnosis for which any
 246 drug is prescribed and any other requirement established by
 247 board rule under chapter 458, chapter 459, chapter 461, chapter
 248 463, chapter 464, or chapter 466; ~~or~~ or

249 (i) Failed to transmit dispensing information for all
 250 Schedule II and III controlled substance prescriptions through a
 251 multi-state electronic prescribing network pursuant to s.
 252 465.018.

253 Section 7. Subsection (1) of section 465.0276, Florida
 254 Statutes, is amended to read:

255 465.0276 Dispensing practitioner.—

256 (1) (a) A person may not dispense medicinal drugs unless
 257 licensed as a pharmacist or otherwise authorized under this
 258 chapter to do so, except that a practitioner authorized by law
 259 to prescribe drugs may dispense such drugs to her or his
 260 patients in the regular course of her or his practice in
 261 compliance with this section.

262 (b) A practitioner registered under this section may not
 263 dispense more than a 72-hour supply of a controlled substance
 264 listed in Schedule II or Schedule III as provided in s. 893.03.
 265 It is unlawful for a practitioner registered under this section
 266 to dispense more than a 72-hour supply of a controlled substance
 267 listed in Schedule II or Schedule III as provided in s. 893.03.
 268 A practitioner who violates this provision commits a felony of
 269 the third degree, punishable as provided in s. 775.082 or s
 270 775.083. This paragraph does not apply to the dispensing of
 271 complimentary packages of medicinal drugs to the practitioner's
 272 own patients in the regular course of her or his practice,
 273 without the payment of fee or remuneration of any kind, whether
 274 direct or indirect, and in conformity with the requirements of
 275 subsection (5). This paragraph does not apply to controlled
 276 substances dispensed in the health care system of the Department
 277 of Corrections.

278 Section 8. This act shall take effect July 1, 2010.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 573

Physician Assistants

SPONSOR(S): Kreegel

TIED BILLS:

IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Policy Committee		Guy <i>[Signature]</i>	Calamas <i>[Signature]</i>
2) Health Care Appropriations Committee			
3) Health & Family Services Policy Council			
4)			
5)			

SUMMARY ANALYSIS

House Bill 573 requires physician assistants to undergo state and federal criminal background checks prior to licensure by the Florida Department of Health (DOH).

The bill deletes the requirement that a physician assistant have at least three months of clinical experience in the specialty of the supervising physician. A licensed physician assistant will be allowed to practice and prescribe medication immediately upon the establishment of a supervisory relationship with a physician.

The bill authorizes DOH to accept physician assistant licensure applications and supporting documentation electronically.

The bill appears to have no fiscal impact to state or local government.

House Bill 573 provides an effective date of July 1, 2010.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Sections 458.347(7), and 459.022(7), F.S., govern the licensure of physician assistants (PAs) in Florida. Physician assistants are licensed by the Department of Health (DOH) and are regulated by the Florida Council on Physician Assistants (Council) and either the Florida Board of Medicine (Board) for PAs licensed under Chapter 458, F.S., or the Florida Board of Osteopathic Medicine (Board) for PAs, licensed under Chapter 459, F.S. Currently there are a total of 4,966 licensed physician assistants in Florida: 3,656 with prescribing authority and 1,310 non-prescribing physician assistants.¹

Physician assistants may only practice under the direct or indirect supervision of a medical doctor or doctor of osteopathic medicine with whom they have a clinical relationship. A supervising physician may only delegate tasks and procedures to the physician assistant that are within the supervising physician's scope of practice.² The supervising physician is responsible and liable for any and all acts of the PA and may only supervise up to four PAs at any time.³

PAs are regulated through the physician practice acts.⁴ Each of the medical practice acts has a corresponding board (i.e., the Board of Medicine and the Board of Osteopathic Medicine). The duty of the Boards and its members is to participate in probable cause panels and make disciplinary decisions concerning whether a doctor or PA was practicing medicine within the confines of their practice act.

The Florida Council on Physician Assistants (Council) was created in 1995 to recommend the licensure requirements (including educational and training requirements) for PAs, establish a list of formulary drugs that a PA may not prescribe, and develop rules for the use of PAs by doctors to ensure that the continuity of supervision is maintained in each practice setting throughout the state.⁵ The Council is composed of five members: three physicians who are members of the Board of Medicine; one physician who is a member of the Board of Osteopathic Medicine; and one licensed PA.⁶ Two physician members of the Council must supervise physician assistants.⁷ The Council and the medical

¹ Teleconference with Department of Health staff, February 24, 2010 (notes on file with the Committee).

² Rule 64B8-30.012(1), F.A.C., and Rule 64B15-6.010(1), F.A.C.

³ S. 458.347(3), F.S., and s. 459.022(3), F.S.

⁴ S. 458.347, F.S., and s. 459.002, F.S.

⁵ S. 458.347(9), F.S., and s. 459.002(9), F.S.

⁶ *Id.*

⁷ *Id.*

boards both have regulatory functions related to PAs: The Council is responsible for licensing PAs; and the boards are responsible for disciplining PAs licensees.

Licensure

To become licensed as a PA in Florida, an applicant must demonstrate to the Council:⁸

- Passage of the National Commission on Certification of Physician Assistant exam;
- Completion of the application, the format of which is approved by the Council, which includes:
 - certificate of completion of a PA training program;
 - sworn, notarized statement of felony convictions; and
 - sworn statement of denial or revocation of licensure in any state.
- Two letters of recommendation from physicians;⁹
- Payment of a licensure fee; and
- Completion of a two hour course on the prevention of medical errors, error reduction and prevention, and patient safety.¹⁰

The Council does not currently accept initial licensure and renewal applications electronically. However, DOH is implementing the infrastructure to do so and the Council is scheduled to have this capability by the end of 2010.¹¹

Licensure renewal occurs biennially.¹² At the time of renewal, a PA must submit a sworn statement that he or she has had no felony convictions in the previous two years.¹³ All PAs are required to complete 100 hours of continuing medical education (CME) biennially.¹⁴ Renewal is subject to specific CME subject matter requirements prescribed in Rules 64B8-30.005, and 64B15-6.0035, F.A.C.

Section 458.347, F.S., provides for two alternative methods of licensure of a physician assistant for:

- An unlicensed medical doctor and foreign medical school graduate who has been certified by the Board of Medicine as having met the requirements for licensure as a medical doctor with certain exceptions; and
- A graduate of the now-closed Florida College of Physician Assistants.

Supervision

A supervising doctor may only delegate tasks and procedures to PA that are within the supervising doctor's scope of practice.¹⁵ The physician may provide direct or indirect supervision. All tasks and procedures performed by the PA must be documented in the appropriate medical record. It is the responsibility of the supervising doctor to ensure that the PA is knowledgeable and skilled in performing the tasks and procedures assigned. The supervising physician is responsible and liable for any and all acts of the PA.

Prescribing and Non-prescribing Physician Assistants

The Council licenses two types of PAs: non-prescribing and prescribing. Prescribing PAs have the authority to prescribe and dispense medications used in the supervising physician's practice, subject to exclusion by the PA formulary.¹⁶ A prescribing PA is not allowed to prescribe controlled substances.¹⁷

⁸ S. 458.347(7), F.S., and s. 459.022(7), F.S.

⁹ Rule 64B8-30.003(1), F.A.C., and Rule 64B15-6.003(1), F.A.C.

¹⁰ Rule 64B8-30.003(3), F.A.C., and Rule 64B15-6.003(4), F.A.C.

¹¹ Teleconference with Department of Health staff, February 24, 2010 (notes on file with the Committee).

¹² S. 458.347(7)(c), F.S. Rule 64B8-30.019, F.A.C., establishes the initial licensure and renewal fee schedule. s. 459.022(7)(b), F.S. Rule 64B15-6.013, F.A.C., establishes the initial licensure and renewal fee schedule.

¹³ S. 458.347(7)(c)2, F.S., and s. 459.022(7)(b)2, F.S.

¹⁴ S. 458.347(7)(d), F.S., and s. 459.022(7)(c), F.S.

¹⁵ Rule 64B8-30.012(1), F.A.C., and Rule 64B15-6.010(1), F.A.C.

¹⁶ S. 458.347(4)(e), F.S., and s. 459.022(4)(e), F.S.

¹⁷ S. 458.347(4)(f)1, F.S.

Prescribing PAs are required to demonstrate three months of clinical experience in the specialty area of their supervising physician prior to being authorized to prescribe or dispense medication.¹⁸ Prior to licensure, prescribing PAs must complete a Board-approved three hour prescriptive practice course¹⁹ and they must file for licensure jointly with their supervising physician.²⁰ For licensure renewal, prescribing PAs must complete an additional 10 hours in the specialty area in which the PA practices.²¹

Each supervising doctor and prescribing PA must keep a written agreement (or protocol) that outlines the intent to delegate prescribing authority and which non-controlled substances the PA is authorized to prescribe. The agreement must be signed and dated by all parties and maintained on file for at least five years and a copy must be provided to the respective board or council upon request. The PA is restricted to prescribing drugs that are used in the supervising doctor's practice.²²

Criminal Background Checks

Four of the 40 health care professions regulated by DOH are required under their respective practice acts to undergo state and federal criminal background checks prior to licensure and renewal.^{23 24} The process by which DOH conducts criminal background checks for these professions differs from criminal background checks conducted for non-health care professions. By way of example, medical doctors licensed pursuant to Chapter 458, F.S., are statutorily-required to undergo a criminal background check,²⁵ and the Board of Medicine has the authority to make licensure determinations based on the results.²⁶ DOH is unable to accept fingerprints submitted in an electronic format.²⁷

According to the Board, the criminal background check for physicians consists of a fingerprint-based search of the Florida Department of Law Enforcement (FDLE) and the Federal Bureau of Investigations (FBI) databases for state and national criminal arrest records, respectively. The Board determines criminal history criteria for which the applicant would be required to submit additional information to the Board for consideration.²⁸ The Board may, based on the criminal background check results and any application addendums, approve the application, reject the application, or approve the application with restrictions on practice.²⁹

Currently, an applicant to be licensed as a physician assistant submits a sworn statement with his or her application attesting to any criminal history to DOH and is required to update his or her criminal history upon biennial licensure renewal. However, no formal criminal background check is required for licensure as a physician assistant.

Effect of Proposed Changes

House Bill 573 deletes the requirement that a physician assistant have at least three months of clinical experience in the specialty of the supervising physician. The practical effect of this provision is to allow

¹⁸ S. 458.347(4)(e)4, F.S., and s. 459.022(4)(e)4, F.S. Generally, Rule 64B8-30.003(5), F.A.C., and Rule 64B15-6.003(5), F.A.C., direct the licensure of prescribing physician assistants.

¹⁹ Rule 64B8-30.003(5)(b), F.A.C., and Rule 64B15-6.033(5)(b), F.A.C.

²⁰ Rule 64B8-30.003(5)(a), F.A.C., and Rule 64B15-6.003(5)(a), F.A.C.

²¹ S. 458.347(4)(e)5, F.S., and s. 459.022, (4)(e)5, F.S.

²² S. 458.347(4)(e), F.S., and s. 459.022(4)(e), F.S.

²³ Generally, authority for criminal background screening is provided to the Department of Health in s. 456.039(4), F.S. Specific practice act authority is provided for: allopathic physicians (s. 458.311(1)(g), F.S.); osteopathic physicians (s. 459.055(1)(i), F.S.); chiropractors (s. 460.406(1)(g), F.S.); and podiatrists (s. 461.007(1)(e), F.S.).

²⁴ Unlike other provisions of law which require criminal background checks for employees that work with vulnerable persons, Chapter 456, F.S., does not provide for offenses that would disqualify an applicant from licensure by DOH. Chapter 435, F.S., outlines the process by which Level 1 and Level 2 criminal background checks are conducted for employees who work with vulnerable populations and provides for offenses that would lead to disqualification from employment.

²⁵ S. 458.311(1)(g), F.S., which states, "Has submitted to the department a set of fingerprints on a form and under procedures specified by the department, along with a payment in an amount equal to the costs incurred by the Department of Health for the criminal background check of the applicant."

²⁶ Teleconference with Board of Medicine staff, February 25, 2010 (notes on file with the Committee).

²⁷ Teleconference with Department of Health staff, February 24, 2010 (notes on file with the Committee).

²⁸ *Id.*

²⁹ *Id.*

a prescribing PA to prescribe medication immediately upon the establishment of a supervisory relationship with a physician.

The bill requires the Department of Health to develop the licensure application for physician assistants. Currently, the application is developed by the Council and the Board of Medicine.

The bill requires state and federal criminal background checks for all PA applicants for initial licensure. The bill prescribes the process by which criminal background checks will be conducted for physician assistant applicants for initial licensure. The bill requires an applicant to submit his or her fingerprints electronically to DOH and provides authority to DOH to contract with private vendors for the collection of electronic fingerprints from applicants. The bill requires DOH to submit an applicant's fingerprints to FDLE to conduct a statewide criminal history check. The bill requires FDLE to forward the applicant's fingerprints to the FBI to conduct a national criminal history check. Any cost of the criminal background check shall be borne by the applicant. The background check requirement only applies to initial licensure; not licensure renewal.

The bill requires DOH to review the results of the criminal background check and issue a physician assistant license to any applicant that has no criminal history, provided that all other licensure criteria have been met by the applicant. In the case of an applicant with a criminal history, the bill provides the Boards of Medicine and Osteopathic Medicine the authority to make a determination of whether the applicant should be licensed. The bill provides the Boards the authority to grant conditional licensure to any applicant with a criminal history.

The bill gives DOH the authority to accept physician assistant licensure applications and supporting documentation electronically.

B. SECTION DIRECTORY:

Section 1: Amending s. 458.347, F.S., relating to physician assistants.

Section 2: Amending s. 458.348, F.S., relating to formal supervisory relationships, standing orders, and established protocols; notice; standards.

Section 3: Amending s. 459.022, F.S., relating to physician assistants.

Section 4: Amending s. 459.025, F.S., relating to formal supervisory relationships, standing orders, and established protocols; notice; standards.

Section 5: Providing an effective date of July 1, 2010.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

According to the Florida Department of Law Enforcement, there is a cost per applicant of \$24 for the statewide criminal history record check and \$19.25 for the national criminal history record check. FDLE retains the \$24 fee in the FDLE Operating Trust Fund and forwards the \$19.25 fee to the FBI.

According to the Department of Health, there is \$1.25 fee per applicant to scan the fingerprint cards into the system to begin the criminal background check process. There is no estimated cost to DOH to evaluate the criminal background checks that will be generated by requirements of House Bill 573.³⁰

For estimation purposes, DOH processed 481 applications for initial licensure as a physician assistant during FY 2008-2009. Assuming the same number of initial licensure applicants in future years, the cost to process criminal background checks will be:

³⁰ Teleconference with Department of Health staff, February 24, 2010 (notes on file with the Committee).

\$24.00 (FDLE fee) + \$19.25 (FBI fee) + \$1.25 (DOH fee) = \$44.50/applicant

\$44.50 X 481 initial applicants =

TOTAL: \$21,404.50/year

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Section 216.0236, F.S., requires the cost of professional regulation to be borne by those subject to the regulation. House Bill 573 provides the department with the authority to pass the cost for physician assistant criminal background checks to the applicant. There will be a cost to the applicant of \$44.50 in addition to the licensure fee for physician assistant licensure.

D. FISCAL COMMENTS:

According to the Department of Health, there may be an unanticipated cost associated with implementation of electronic fingerprint submission.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

The bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Health has sufficient rule-making authority to implement provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill appears to confer authority over an aspect of licensing, the discretion to license applicants with a criminal history, to the Board of Medicine and the Board of Osteopathic Medicine. Authority to make licensing determinations is currently exercised by the Florida Council on Physician Assistants.

The bill requires initial licensees to undergo state and federal criminal background checks. Applicants for licensure renewal are not required to undergo background checks. The four DOH practice acts which currently require criminal background checks impose the requirement on renewals as well as initial licensure. Physician assistants would be the only profession regulated by DOH to be subject to background checks only upon initial licensure.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

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1 A bill to be entitled

2 An act relating to physician assistants; amending ss.
3 458.347 and 459.022, F.S.; deleting requirements that
4 physician assistants file evidence of certain clinical
5 experience before prescribing or dispensing medication;
6 requiring applicants for licensure as physician assistants
7 to remit applications in a specified format, submit
8 fingerprints, and undergo statewide and national criminal
9 history checks; requiring the Department of Health to
10 allow the electronic submission of fingerprints;
11 authorizing the department to contract for electronic
12 fingerprint collection and imaging; requiring that
13 applicants pay the cost of the criminal history checks;
14 requiring the department to refer physician assistant
15 license applicants with criminal histories to the Board of
16 Medicine or the Board of Osteopathic Medicine for
17 licensure determination; authorizing the electronic
18 submission of applications and other required
19 documentation; amending ss. 458.348 and 459.025, F.S.;
20 conforming cross-references; providing an effective date.

21
22 Be It Enacted by the Legislature of the State of Florida:

23
24 Section 1. Paragraph (e) of subsection (4) and paragraphs
25 (a) and (b) of subsection (7) of section 458.347, Florida
26 Statutes, are amended, and paragraph (h) is added to subsection
27 (7) of that section, to read:

28 458.347 Physician assistants.—

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CODING: Words ~~stricken~~ are deletions; words underlined are additions.

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29 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

30 (e) A supervisory physician may delegate to a fully
 31 licensed physician assistant the authority to prescribe or
 32 dispense any medication used in the supervisory physician's
 33 practice unless such medication is listed on the formulary
 34 created pursuant to paragraph (f). A fully licensed physician
 35 assistant may only prescribe or dispense such medication under
 36 the following circumstances:

37 1. A physician assistant must clearly identify to the
 38 patient that he or she is a physician assistant. Furthermore,
 39 the physician assistant must inform the patient that the patient
 40 has the right to see the physician prior to any prescription
 41 being prescribed or dispensed by the physician assistant.

42 2. The supervisory physician must notify the department of
 43 his or her intent to delegate, on a department-approved form,
 44 before delegating such authority and notify the department of
 45 any change in prescriptive privileges of the physician
 46 assistant. Authority to dispense may be delegated only by a
 47 supervising physician who is registered as a dispensing
 48 practitioner in compliance with s. 465.0276.

49 3. The physician assistant must file with the department,
 50 before commencing to prescribe or dispense, evidence that he or
 51 she has completed a continuing medical education course of at
 52 least 3 classroom hours in prescriptive practice, conducted by
 53 an accredited program approved by the boards, which course
 54 covers the limitations, responsibilities, and privileges
 55 involved in prescribing medicinal drugs, or evidence that he or
 56 she has received education comparable to the continuing

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57 education course as part of an accredited physician assistant
58 training program.

59 ~~4. The physician assistant must file with the department,~~
60 ~~before commencing to prescribe or dispense, evidence that the~~
61 ~~physician assistant has a minimum of 3 months of clinical~~
62 ~~experience in the specialty area of the supervising physician.~~

63 4.5. The physician assistant must file with the department
64 a signed affidavit that he or she has completed a minimum of 10
65 continuing medical education hours in the specialty practice in
66 which the physician assistant has prescriptive privileges with
67 each licensure renewal application.

68 5.6. The department shall issue a license and a prescriber
69 number to the physician assistant granting authority for the
70 prescribing of medicinal drugs authorized within this paragraph
71 upon completion of the foregoing requirements. The physician
72 assistant shall not be required to independently register
73 pursuant to s. 465.0276.

74 6.7. The prescription must be written in a form that
75 complies with chapter 499 and must contain, in addition to the
76 supervisory physician's name, address, and telephone number, the
77 physician assistant's prescriber number. Unless it is a drug or
78 drug sample dispensed by the physician assistant, the
79 prescription must be filled in a pharmacy permitted under
80 chapter 465 and must be dispensed in that pharmacy by a
81 pharmacist licensed under chapter 465. The appearance of the
82 prescriber number creates a presumption that the physician
83 assistant is authorized to prescribe the medicinal drug and the
84 prescription is valid.

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85 ~~7.8.~~ The physician assistant must note the prescription or
 86 dispensing of medication in the appropriate medical record.

87 ~~8.9.~~ This paragraph does not prohibit a supervisory
 88 physician from delegating to a physician assistant the authority
 89 to order medication for a hospitalized patient of the
 90 supervisory physician.

91
 92 This paragraph does not apply to facilities licensed pursuant to
 93 chapter 395.

94 (7) PHYSICIAN ASSISTANT LICENSURE.—

95 (a) Any person desiring to be licensed as a physician
 96 assistant must apply to the department. The department shall
 97 issue a license to any person certified by the council as having
 98 met the following requirements:

99 1. Is at least 18 years of age.

100 2. Has satisfactorily passed a proficiency examination by
 101 an acceptable score established by the National Commission on
 102 Certification of Physician Assistants. If an applicant does not
 103 hold a current certificate issued by the National Commission on
 104 Certification of Physician Assistants and has not actively
 105 practiced as a physician assistant within the immediately
 106 preceding 4 years, the applicant must retake and successfully
 107 complete the entry-level examination of the National Commission
 108 on Certification of Physician Assistants to be eligible for
 109 licensure.

110 3. Has completed an the application in the format
 111 prescribed by the department form and remitted an application
 112 fee not to exceed \$300 as set by the boards. An application for

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113 licensure made by a physician assistant must include:

114 a. A certificate of completion of a physician assistant
115 training program specified in subsection (6).

116 b. A sworn statement of any prior felony convictions.

117 c. A sworn statement of any previous revocation or denial
118 of licensure or certification in any state.

119 d. Two letters of recommendation.

120 4. Has submitted to the department a complete set of
121 fingerprints in the format and under the procedures prescribed
122 by the department. The department shall allow an applicant to
123 submit his or her fingerprints electronically and may contract
124 with private vendors or enter into interagency agreements for
125 the collection and imaging of electronically submitted
126 fingerprints. The department shall submit an applicant's
127 fingerprints to the Department of Law Enforcement for a
128 statewide criminal history check, and the Department of Law
129 Enforcement shall forward the fingerprints to the Federal Bureau
130 of Investigation for a national criminal history check. The cost
131 of the criminal history checks shall be borne by the applicant.
132 The department shall review the results of the criminal history
133 checks, shall issue a license to an applicant who meets all
134 requirements for licensure and does not have a criminal history,
135 and shall refer an applicant with a criminal history to the
136 board for a determination of whether and under what conditions a
137 license should be issued.

138 (b)1. Notwithstanding subparagraph (a)2. and sub-
139 subparagraph (a)3.a., the department shall examine each
140 applicant who the Board of Medicine certifies:

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141 a. Has completed an ~~the~~ application in the format
142 prescribed by the department ~~form~~ and remitted a nonrefundable
143 application fee not to exceed \$500 and an examination fee not to
144 exceed \$300, plus the actual cost to the department to provide
145 the examination. The examination fee is refundable if the
146 applicant is found to be ineligible to take the examination. The
147 department shall not require the applicant to pass a separate
148 practical component of the examination. For examinations given
149 after July 1, 1998, competencies measured through practical
150 examinations shall be incorporated into the written examination
151 through a multiple-choice format. The department shall translate
152 the examination into the native language of any applicant who
153 requests and agrees to pay all costs of such translation,
154 provided that the translation request is filed with the board
155 office no later than 9 months before the scheduled examination
156 and the applicant remits translation fees as specified by the
157 department no later than 6 months before the scheduled
158 examination, and provided that the applicant demonstrates to the
159 department the ability to communicate orally in basic English.
160 If the applicant is unable to pay translation costs, the
161 applicant may take the next available examination in English if
162 the applicant submits a request in writing by the application
163 deadline and if the applicant is otherwise eligible under this
164 section. To demonstrate the ability to communicate orally in
165 basic English, a passing score or grade is required, as
166 determined by the department or organization that developed it,
167 on the test for spoken English (TSE) by the Educational Testing
168 Service (ETS), the test of English as a foreign language (TOEFL)

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169 by ETS, a high school or college level English course, or the
 170 English examination for citizenship, Bureau of Citizenship and
 171 Immigration Services. A notarized copy of an Educational
 172 Commission for Foreign Medical Graduates (ECFMG) certificate may
 173 also be used to demonstrate the ability to communicate in basic
 174 English; and

175 b.(I) Is an unlicensed physician who graduated from a
 176 foreign medical school listed with the World Health Organization
 177 who has not previously taken and failed the examination of the
 178 National Commission on Certification of Physician Assistants and
 179 who has been certified by the Board of Medicine as having met
 180 the requirements for licensure as a medical doctor by
 181 examination as set forth in s. 458.311(1), (3), (4), and (5),
 182 with the exception that the applicant is not required to have
 183 completed an approved residency of at least 1 year and the
 184 applicant is not required to have passed the licensing
 185 examination specified under s. 458.311 or hold a valid, active
 186 certificate issued by the Educational Commission for Foreign
 187 Medical Graduates; was eligible and made initial application for
 188 certification as a physician assistant in this state between
 189 July 1, 1990, and June 30, 1991; and was a resident of this
 190 state on July 1, 1990, or was licensed or certified in any state
 191 in the United States as a physician assistant on July 1, 1990;
 192 or

193 (II) Completed all coursework requirements of the Master
 194 of Medical Science Physician Assistant Program offered through
 195 the Florida College of Physician's Assistants prior to its
 196 closure in August of 1996. Prior to taking the examination, such

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197 applicant must successfully complete any clinical rotations that
198 were not completed under such program prior to its termination
199 and any additional clinical rotations with an appropriate
200 physician assistant preceptor, not to exceed 6 months, that are
201 determined necessary by the council. The boards shall determine,
202 based on recommendations from the council, the facilities under
203 which such incomplete or additional clinical rotations may be
204 completed and shall also determine what constitutes successful
205 completion thereof, provided such requirements are comparable to
206 those established by accredited physician assistant programs.
207 This sub-sub-subparagraph is repealed July 1, 2001.

208 2. The department may grant temporary licensure to an
209 applicant who meets the requirements of subparagraph 1. Between
210 meetings of the council, the department may grant temporary
211 licensure to practice based on the completion of all temporary
212 licensure requirements. All such administratively issued
213 licenses shall be reviewed and acted on at the next regular
214 meeting of the council. A temporary license expires 30 days
215 after receipt and notice of scores to the licenseholder from the
216 first available examination specified in subparagraph 1.
217 following licensure by the department. An applicant who fails
218 the proficiency examination is no longer temporarily licensed,
219 but may apply for a one-time extension of temporary licensure
220 after reapplying for the next available examination. Extended
221 licensure shall expire upon failure of the licenseholder to sit
222 for the next available examination or upon receipt and notice of
223 scores to the licenseholder from such examination.

224 3. Notwithstanding any other provision of law, the

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225 examination specified pursuant to subparagraph 1. shall be
 226 administered by the department only five times. Applicants
 227 certified by the board for examination shall receive at least 6
 228 months' notice of eligibility prior to the administration of the
 229 initial examination. Subsequent examinations shall be
 230 administered at 1-year intervals following the reporting of the
 231 scores of the first and subsequent examinations. For the
 232 purposes of this paragraph, the department may develop, contract
 233 for the development of, purchase, or approve an examination that
 234 adequately measures an applicant's ability to practice with
 235 reasonable skill and safety. The minimum passing score on the
 236 examination shall be established by the department, with the
 237 advice of the board. Those applicants failing to pass that
 238 examination or any subsequent examination shall receive notice
 239 of the administration of the next examination with the notice of
 240 scores following such examination. Any applicant who passes the
 241 examination and meets the requirements of this section shall be
 242 licensed as a physician assistant with all rights defined
 243 thereby.

244 (h) An application or other documentation required to be
 245 submitted to the department under this subsection may be
 246 submitted electronically.

247 Section 2. Paragraph (c) of subsection (4) of section
 248 458.348, Florida Statutes, is amended to read:

249 458.348 Formal supervisory relationships, standing orders,
 250 and established protocols; notice; standards.—

251 (4) SUPERVISORY RELATIONSHIPS IN MEDICAL OFFICE SETTINGS.—
 252 A physician who supervises an advanced registered nurse

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253 practitioner or physician assistant at a medical office other
 254 than the physician's primary practice location, where the
 255 advanced registered nurse practitioner or physician assistant is
 256 not under the onsite supervision of a supervising physician,
 257 must comply with the standards set forth in this subsection. For
 258 the purpose of this subsection, a physician's "primary practice
 259 location" means the address reflected on the physician's profile
 260 published pursuant to s. 456.041.

261 (c) A physician who supervises an advanced registered
 262 nurse practitioner or physician assistant at a medical office
 263 other than the physician's primary practice location, where the
 264 advanced registered nurse practitioner or physician assistant is
 265 not under the onsite supervision of a supervising physician and
 266 the services offered at the office are primarily dermatologic or
 267 skin care services, which include aesthetic skin care services
 268 other than plastic surgery, must comply with the standards
 269 listed in subparagraphs 1.-4. Notwithstanding s.

270 458.347(4)(e)~~7.8~~, a physician supervising a physician assistant
 271 pursuant to this paragraph may not be required to review and
 272 cosign charts or medical records prepared by such physician
 273 assistant.

274 1. The physician shall submit to the board the addresses
 275 of all offices where he or she is supervising an advanced
 276 registered nurse practitioner or a physician's assistant which
 277 are not the physician's primary practice location.

278 2. The physician must be board certified or board eligible
 279 in dermatology or plastic surgery as recognized by the board
 280 pursuant to s. 458.3312.

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281 3. All such offices that are not the physician's primary
 282 place of practice must be within 25 miles of the physician's
 283 primary place of practice or in a county that is contiguous to
 284 the county of the physician's primary place of practice.
 285 However, the distance between any of the offices may not exceed
 286 75 miles.

287 4. The physician may supervise only one office other than
 288 the physician's primary place of practice except that until July
 289 1, 2011, the physician may supervise up to two medical offices
 290 other than the physician's primary place of practice if the
 291 addresses of the offices are submitted to the board before July
 292 1, 2006. Effective July 1, 2011, the physician may supervise
 293 only one office other than the physician's primary place of
 294 practice, regardless of when the addresses of the offices were
 295 submitted to the board.

296 Section 3. Paragraph (e) of subsection (4) and paragraph
 297 (a) of subsection (7) of section 459.022, Florida Statutes, are
 298 amended, and paragraph (g) is added to subsection (7) of that
 299 section, to read:

300 459.022 Physician assistants.—

301 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

302 (e) A supervisory physician may delegate to a fully
 303 licensed physician assistant the authority to prescribe or
 304 dispense any medication used in the supervisory physician's
 305 practice unless such medication is listed on the formulary
 306 created pursuant to s. 458.347. A fully licensed physician
 307 assistant may only prescribe or dispense such medication under
 308 the following circumstances:

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309 1. A physician assistant must clearly identify to the
 310 patient that she or he is a physician assistant. Furthermore,
 311 the physician assistant must inform the patient that the patient
 312 has the right to see the physician prior to any prescription
 313 being prescribed or dispensed by the physician assistant.

314 2. The supervisory physician must notify the department of
 315 her or his intent to delegate, on a department-approved form,
 316 before delegating such authority and notify the department of
 317 any change in prescriptive privileges of the physician
 318 assistant. Authority to dispense may be delegated only by a
 319 supervisory physician who is registered as a dispensing
 320 practitioner in compliance with s. 465.0276.

321 3. The physician assistant must file with the department,
 322 before commencing to prescribe or dispense, evidence that she or
 323 he has completed a continuing medical education course of at
 324 least 3 classroom hours in prescriptive practice, conducted by
 325 an accredited program approved by the boards, which course
 326 covers the limitations, responsibilities, and privileges
 327 involved in prescribing medicinal drugs, or evidence that she or
 328 he has received education comparable to the continuing education
 329 course as part of an accredited physician assistant training
 330 program.

331 ~~4. The physician assistant must file with the department,~~
 332 ~~before commencing to prescribe or dispense, evidence that the~~
 333 ~~physician assistant has a minimum of 3 months of clinical~~
 334 ~~experience in the specialty area of the supervising physician.~~

335 4.5. The physician assistant must file with the department
 336 a signed affidavit that she or he has completed a minimum of 10

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337 continuing medical education hours in the specialty practice in
 338 which the physician assistant has prescriptive privileges with
 339 each licensure renewal application.

340 ~~5.6.~~ The department shall issue a license and a prescriber
 341 number to the physician assistant granting authority for the
 342 prescribing of medicinal drugs authorized within this paragraph
 343 upon completion of the foregoing requirements. The physician
 344 assistant shall not be required to independently register
 345 pursuant to s. 465.0276.

346 ~~6.7.~~ The prescription must be written in a form that
 347 complies with chapter 499 and must contain, in addition to the
 348 supervisory physician's name, address, and telephone number, the
 349 physician assistant's prescriber number. Unless it is a drug or
 350 drug sample dispensed by the physician assistant, the
 351 prescription must be filled in a pharmacy permitted under
 352 chapter 465, and must be dispensed in that pharmacy by a
 353 pharmacist licensed under chapter 465. The appearance of the
 354 prescriber number creates a presumption that the physician
 355 assistant is authorized to prescribe the medicinal drug and the
 356 prescription is valid.

357 ~~7.8.~~ The physician assistant must note the prescription or
 358 dispensing of medication in the appropriate medical record.

359 ~~8.9.~~ This paragraph does not prohibit a supervisory
 360 physician from delegating to a physician assistant the authority
 361 to order medication for a hospitalized patient of the
 362 supervisory physician.

363

364 This paragraph does not apply to facilities licensed pursuant to

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365 chapter 395.

366 (7) PHYSICIAN ASSISTANT LICENSURE.—

367 (a) Any person desiring to be licensed as a physician
 368 assistant must apply to the department. The department shall
 369 issue a license to any person certified by the council as having
 370 met the following requirements:

371 1. Is at least 18 years of age.

372 2. Has satisfactorily passed a proficiency examination by
 373 an acceptable score established by the National Commission on
 374 Certification of Physician Assistants. If an applicant does not
 375 hold a current certificate issued by the National Commission on
 376 Certification of Physician Assistants and has not actively
 377 practiced as a physician assistant within the immediately
 378 preceding 4 years, the applicant must retake and successfully
 379 complete the entry-level examination of the National Commission
 380 on Certification of Physician Assistants to be eligible for
 381 licensure.

382 3. Has completed an ~~the~~ application in the format
 383 prescribed by the department ~~form~~ and remitted an application
 384 fee not to exceed \$300 as set by the boards. An application for
 385 licensure made by a physician assistant must include:

386 a. A certificate of completion of a physician assistant
 387 training program specified in subsection (6).

388 b. A sworn statement of any prior felony convictions.

389 c. A sworn statement of any previous revocation or denial
 390 of licensure or certification in any state.

391 d. Two letters of recommendation.

392 4. Has submitted to the department a complete set of

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393 fingerprints in the format and under the procedures prescribed
394 by the department. The department shall allow an applicant to
395 submit his or her fingerprints electronically and may contract
396 with private vendors or enter into interagency agreements for
397 the collection and imaging of electronically submitted
398 fingerprints. The department shall submit an applicant's
399 fingerprints to the Department of Law Enforcement for a
400 statewide criminal history check, and the Department of Law
401 Enforcement shall forward the fingerprints to the Federal Bureau
402 of Investigation for a national criminal history check. The cost
403 of the criminal history checks shall be borne by the applicant.
404 The department shall review the results of the criminal history
405 checks, shall issue a license to an applicant who meets all
406 requirements for licensure and does not have a criminal history,
407 and shall refer an applicant with a criminal history to the
408 board for a determination of whether and under what conditions a
409 license should be issued.

410 (g) An application or other documentation required to be
411 submitted to the department under this subsection may be
412 submitted electronically.

413 Section 4. Paragraph (c) of subsection (3) of section
414 459.025, Florida Statutes, is amended to read:

415 459.025 Formal supervisory relationships, standing orders,
416 and established protocols; notice; standards.—

417 (3) SUPERVISORY RELATIONSHIPS IN MEDICAL OFFICE SETTINGS.—
418 An osteopathic physician who supervises an advanced registered
419 nurse practitioner or physician assistant at a medical office
420 other than the osteopathic physician's primary practice

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421 location, where the advanced registered nurse practitioner or
422 physician assistant is not under the onsite supervision of a
423 supervising osteopathic physician, must comply with the
424 standards set forth in this subsection. For the purpose of this
425 subsection, an osteopathic physician's "primary practice
426 location" means the address reflected on the physician's profile
427 published pursuant to s. 456.041.

428 (c) An osteopathic physician who supervises an advanced
429 registered nurse practitioner or physician assistant at a
430 medical office other than the osteopathic physician's primary
431 practice location, where the advanced registered nurse
432 practitioner or physician assistant is not under the onsite
433 supervision of a supervising osteopathic physician and the
434 services offered at the office are primarily dermatologic or
435 skin care services, which include aesthetic skin care services
436 other than plastic surgery, must comply with the standards
437 listed in subparagraphs 1.-4. Notwithstanding s.
438 459.022(4)(e)~~7.8~~, an osteopathic physician supervising a
439 physician assistant pursuant to this paragraph may not be
440 required to review and cosign charts or medical records prepared
441 by such physician assistant.

442 1. The osteopathic physician shall submit to the Board of
443 Osteopathic Medicine the addresses of all offices where he or
444 she is supervising or has a protocol with an advanced registered
445 nurse practitioner or a physician's assistant which are not the
446 osteopathic physician's primary practice location.

447 2. The osteopathic physician must be board certified or
448 board eligible in dermatology or plastic surgery as recognized

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449 | by the Board of Osteopathic Medicine pursuant to s. 459.0152.

450 | 3. All such offices that are not the osteopathic
 451 | physician's primary place of practice must be within 25 miles of
 452 | the osteopathic physician's primary place of practice or in a
 453 | county that is contiguous to the county of the osteopathic
 454 | physician's primary place of practice. However, the distance
 455 | between any of the offices may not exceed 75 miles.

456 | 4. The osteopathic physician may supervise only one office
 457 | other than the osteopathic physician's primary place of practice
 458 | except that until July 1, 2011, the osteopathic physician may
 459 | supervise up to two medical offices other than the osteopathic
 460 | physician's primary place of practice if the addresses of the
 461 | offices are submitted to the Board of Osteopathic Medicine
 462 | before July 1, 2006. Effective July 1, 2011, the osteopathic
 463 | physician may supervise only one office other than the
 464 | osteopathic physician's primary place of practice, regardless of
 465 | when the addresses of the offices were submitted to the Board of
 466 | Osteopathic Medicine.

467 | Section 5. This act shall take effect July 1, 2010.

COUNCIL/COMMITTEE AMENDMENT

Bill No. HB 573 (2010)

Amendment No.

COUNCIL/COMMITTEE ACTION

ADOPTED ___ (Y/N)
ADOPTED AS AMENDED ___ (Y/N)
ADOPTED W/O OBJECTION ___ (Y/N)
FAILED TO ADOPT ___ (Y/N)
WITHDRAWN ___ (Y/N)
OTHER _____

1 Council/Committee hearing bill: Health Care Regulation Policy
2 Committee
3 Representative Kreegel offered the following:

Amendment (with title amendment)

6 Remove everything after the enacting clause and insert:
7 Section 1. Paragraph (e) of subsection (4) of section
8 458.347, Florida Statutes, is amended, and paragraph (h) is
9 added to subsection (7) of that section, to read:

10 458.347 Physician assistants.—

11 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

12 (e) A supervisory physician may delegate to a fully
13 licensed physician assistant the authority to prescribe or
14 dispense any medication used in the supervisory physician's
15 practice unless such medication is listed on the formulary
16 created pursuant to paragraph (f). A fully licensed physician
17 assistant may only prescribe or dispense such medication under
18 the following circumstances:

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19 1. A physician assistant must clearly identify to the
20 patient that he or she is a physician assistant. Furthermore,
21 the physician assistant must inform the patient that the patient
22 has the right to see the physician prior to any prescription
23 being prescribed or dispensed by the physician assistant.

24 2. The supervisory physician must notify the department of
25 his or her intent to delegate, on a department-approved form,
26 before delegating such authority and notify the department of
27 any change in prescriptive privileges of the physician
28 assistant. Authority to dispense may be delegated only by a
29 supervising physician who is registered as a dispensing
30 practitioner in compliance with s. 465.0276.

31 3. The physician assistant must file with the department,
32 before commencing to prescribe or dispense, evidence that he or
33 she has completed a continuing medical education course of at
34 least 3 classroom hours in prescriptive practice, conducted by
35 an accredited program approved by the boards, which course
36 covers the limitations, responsibilities, and privileges
37 involved in prescribing medicinal drugs, or evidence that he or
38 she has received education comparable to the continuing
39 education course as part of an accredited physician assistant
40 training program.

41 ~~4. The physician assistant must file with the department,~~
42 ~~before commencing to prescribe or dispense, evidence that the~~
43 ~~physician assistant has a minimum of 3 months of clinical~~
44 ~~experience in the specialty area of the supervising physician.~~

45 4.5. The physician assistant must file with the department
46 a signed affidavit that he or she has completed a minimum of 10

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47 continuing medical education hours in the specialty practice in
48 which the physician assistant has prescriptive privileges with
49 each licensure renewal application.

50 ~~5.6.~~ The department shall issue a license and a prescriber
51 number to the physician assistant granting authority for the
52 prescribing of medicinal drugs authorized within this paragraph
53 upon completion of the foregoing requirements. The physician
54 assistant shall not be required to independently register
55 pursuant to s. 465.0276.

56 ~~6.7.~~ The prescription must be written in a form that
57 complies with chapter 499 and must contain, in addition to the
58 supervisory physician's name, address, and telephone number, the
59 physician assistant's prescriber number. Unless it is a drug or
60 drug sample dispensed by the physician assistant, the
61 prescription must be filled in a pharmacy permitted under
62 chapter 465 and must be dispensed in that pharmacy by a
63 pharmacist licensed under chapter 465. The appearance of the
64 prescriber number creates a presumption that the physician
65 assistant is authorized to prescribe the medicinal drug and the
66 prescription is valid.

67 ~~7.8.~~ The physician assistant must note the prescription or
68 dispensing of medication in the appropriate medical record.

69 ~~8.9.~~ This paragraph does not prohibit a supervisory
70 physician from delegating to a physician assistant the authority
71 to order medication for a hospitalized patient of the
72 supervisory physician.

73

COUNCIL/COMMITTEE AMENDMENT

Bill No. HB 573 (2010)

Amendment No.

74 This paragraph does not apply to facilities licensed pursuant to
75 chapter 395.

76 (7) PHYSICIAN ASSISTANT LICENSURE.—

77 (h) An application or other documentation required to be
78 submitted to the department under this subsection may be
79 submitted electronically.

80 Section 2. Paragraph (c) of subsection (4) of section
81 458.348, Florida Statutes, is amended to read:

82 458.348 Formal supervisory relationships, standing orders,
83 and established protocols; notice; standards.—

84 (4) SUPERVISORY RELATIONSHIPS IN MEDICAL OFFICE SETTINGS.—

85 A physician who supervises an advanced registered nurse
86 practitioner or physician assistant at a medical office other
87 than the physician's primary practice location, where the
88 advanced registered nurse practitioner or physician assistant is
89 not under the onsite supervision of a supervising physician,
90 must comply with the standards set forth in this subsection. For
91 the purpose of this subsection, a physician's "primary practice
92 location" means the address reflected on the physician's profile
93 published pursuant to s. 456.041.

94 (c) A physician who supervises an advanced registered
95 nurse practitioner or physician assistant at a medical office
96 other than the physician's primary practice location, where the
97 advanced registered nurse practitioner or physician assistant is
98 not under the onsite supervision of a supervising physician and
99 the services offered at the office are primarily dermatologic or
100 skin care services, which include aesthetic skin care services
101 other than plastic surgery, must comply with the standards

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Amendment No.

102 listed in subparagraphs 1.-4. Notwithstanding s.
103 458.347(4)(e)~~7.8.~~, a physician supervising a physician assistant
104 pursuant to this paragraph may not be required to review and
105 cosign charts or medical records prepared by such physician
106 assistant.

107 1. The physician shall submit to the board the addresses
108 of all offices where he or she is supervising an advanced
109 registered nurse practitioner or a physician's assistant which
110 are not the physician's primary practice location.

111 2. The physician must be board certified or board eligible
112 in dermatology or plastic surgery as recognized by the board
113 pursuant to s. 458.3312.

114 3. All such offices that are not the physician's primary
115 place of practice must be within 25 miles of the physician's
116 primary place of practice or in a county that is contiguous to
117 the county of the physician's primary place of practice.
118 However, the distance between any of the offices may not exceed
119 75 miles.

120 4. The physician may supervise only one office other than
121 the physician's primary place of practice except that until July
122 1, 2011, the physician may supervise up to two medical offices
123 other than the physician's primary place of practice if the
124 addresses of the offices are submitted to the board before July
125 1, 2006. Effective July 1, 2011, the physician may supervise
126 only one office other than the physician's primary place of
127 practice, regardless of when the addresses of the offices were
128 submitted to the board.

Amendment No.

129 Section 3. Paragraph (e) of subsection (4) of section
130 459.022, Florida Statutes, is amended, and paragraph (g) is
131 added to subsection (7) of that section, to read:

132 459.022 Physician assistants.—

133 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

134 (e) A supervisory physician may delegate to a fully
135 licensed physician assistant the authority to prescribe or
136 dispense any medication used in the supervisory physician's
137 practice unless such medication is listed on the formulary
138 created pursuant to s. 458.347. A fully licensed physician
139 assistant may only prescribe or dispense such medication under
140 the following circumstances:

141 1. A physician assistant must clearly identify to the
142 patient that she or he is a physician assistant. Furthermore,
143 the physician assistant must inform the patient that the patient
144 has the right to see the physician prior to any prescription
145 being prescribed or dispensed by the physician assistant.

146 2. The supervisory physician must notify the department of
147 her or his intent to delegate, on a department-approved form,
148 before delegating such authority and notify the department of
149 any change in prescriptive privileges of the physician
150 assistant. Authority to dispense may be delegated only by a
151 supervisory physician who is registered as a dispensing
152 practitioner in compliance with s. 465.0276.

153 3. The physician assistant must file with the department,
154 before commencing to prescribe or dispense, evidence that she or
155 he has completed a continuing medical education course of at
156 least 3 classroom hours in prescriptive practice, conducted by

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Bill No. HB 573 (2010)

Amendment No.

157 an accredited program approved by the boards, which course
158 covers the limitations, responsibilities, and privileges
159 involved in prescribing medicinal drugs, or evidence that she or
160 he has received education comparable to the continuing education
161 course as part of an accredited physician assistant training
162 program.

163 ~~4. The physician assistant must file with the department,~~
164 ~~before commencing to prescribe or dispense, evidence that the~~
165 ~~physician assistant has a minimum of 3 months of clinical~~
166 ~~experience in the specialty area of the supervising physician.~~

167 4.5. The physician assistant must file with the department
168 a signed affidavit that she or he has completed a minimum of 10
169 continuing medical education hours in the specialty practice in
170 which the physician assistant has prescriptive privileges with
171 each licensure renewal application.

172 5.6. The department shall issue a license and a prescriber
173 number to the physician assistant granting authority for the
174 prescribing of medicinal drugs authorized within this paragraph
175 upon completion of the foregoing requirements. The physician
176 assistant shall not be required to independently register
177 pursuant to s. 465.0276.

178 6.7. The prescription must be written in a form that
179 complies with chapter 499 and must contain, in addition to the
180 supervisory physician's name, address, and telephone number, the
181 physician assistant's prescriber number. Unless it is a drug or
182 drug sample dispensed by the physician assistant, the
183 prescription must be filled in a pharmacy permitted under
184 chapter 465, and must be dispensed in that pharmacy by a

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Amendment No.

185 pharmacist licensed under chapter 465. The appearance of the
186 prescriber number creates a presumption that the physician
187 assistant is authorized to prescribe the medicinal drug and the
188 prescription is valid.

189 ~~7.8.~~ The physician assistant must note the prescription or
190 dispensing of medication in the appropriate medical record.

191 ~~8.9.~~ This paragraph does not prohibit a supervisory
192 physician from delegating to a physician assistant the authority
193 to order medication for a hospitalized patient of the
194 supervisory physician.

195

196 This paragraph does not apply to facilities licensed pursuant to
197 chapter 395.

198 (7) PHYSICIAN ASSISTANT LICENSURE.—

199 (g) An application or other documentation required to be
200 submitted to the department under this subsection may be
201 submitted electronically.

202 Section 4. Paragraph (c) of subsection (3) of section
203 459.025, Florida Statutes, is amended to read:

204 459.025 Formal supervisory relationships, standing orders,
205 and established protocols; notice; standards.—

206 (3) SUPERVISORY RELATIONSHIPS IN MEDICAL OFFICE SETTINGS.—

207 An osteopathic physician who supervises an advanced registered
208 nurse practitioner or physician assistant at a medical office
209 other than the osteopathic physician's primary practice
210 location, where the advanced registered nurse practitioner or
211 physician assistant is not under the onsite supervision of a
212 supervising osteopathic physician, must comply with the

Amendment No.

213 standards set forth in this subsection. For the purpose of this
214 subsection, an osteopathic physician's "primary practice
215 location" means the address reflected on the physician's profile
216 published pursuant to s. 456.041.

217 (c) An osteopathic physician who supervises an advanced
218 registered nurse practitioner or physician assistant at a
219 medical office other than the osteopathic physician's primary
220 practice location, where the advanced registered nurse
221 practitioner or physician assistant is not under the onsite
222 supervision of a supervising osteopathic physician and the
223 services offered at the office are primarily dermatologic or
224 skin care services, which include aesthetic skin care services
225 other than plastic surgery, must comply with the standards
226 listed in subparagraphs 1.-4. Notwithstanding s.
227 459.022(4)(e)~~7.8~~, an osteopathic physician supervising a
228 physician assistant pursuant to this paragraph may not be
229 required to review and cosign charts or medical records prepared
230 by such physician assistant.

231 1. The osteopathic physician shall submit to the Board of
232 Osteopathic Medicine the addresses of all offices where he or
233 she is supervising or has a protocol with an advanced registered
234 nurse practitioner or a physician's assistant which are not the
235 osteopathic physician's primary practice location.

236 2. The osteopathic physician must be board certified or
237 board eligible in dermatology or plastic surgery as recognized
238 by the Board of Osteopathic Medicine pursuant to s. 459.0152.

239 3. All such offices that are not the osteopathic
240 physician's primary place of practice must be within 25 miles of

Amendment No.

241 the osteopathic physician's primary place of practice or in a
242 county that is contiguous to the county of the osteopathic
243 physician's primary place of practice. However, the distance
244 between any of the offices may not exceed 75 miles.

245 4. The osteopathic physician may supervise only one office
246 other than the osteopathic physician's primary place of practice
247 except that until July 1, 2011, the osteopathic physician may
248 supervise up to two medical offices other than the osteopathic
249 physician's primary place of practice if the addresses of the
250 offices are submitted to the Board of Osteopathic Medicine
251 before July 1, 2006. Effective July 1, 2011, the osteopathic
252 physician may supervise only one office other than the
253 osteopathic physician's primary place of practice, regardless of
254 when the addresses of the offices were submitted to the Board of
255 Osteopathic Medicine.

256 Section 5. This act shall take effect July 1, 2010.

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T I T L E A M E N D M E N T

Remove the entire title and insert:

A bill to be entitled

An act relating to physician assistants; amending ss.
458.347 and 459.022, F.S.; deleting requirements that
physician assistants file evidence of certain clinical
experience before prescribing or dispensing medication;
authorizing the electronic submission of physician
assistant license applications and other required

COUNCIL/COMMITTEE AMENDMENT

Bill No. HB 573 (2010)

Amendment No.

269 | documentation; amending ss. 458.348 and 459.025, F.S.;

270 | conforming cross-references; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HCR 10-01 Obsolete Health Care Provisions
SPONSOR(S): Health Care Regulation Policy Committee
TIED BILLS: **IDEN./SIM. BILLS:**

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.:	Health Care Regulation Policy Committee		Holt <i>RA</i>	Calamas <i>CC</i>
1)				
2)				
3)				
4)				
5)				

SUMMARY ANALYSIS

This proposed committee bill deletes outdated or obsolete provisions:

- Separate restrooms and separate dressing rooms for males and females;
- Florida Healthy People 2010 Program; and
- MedAccess Program

The bill will not affect the funding to any existing programs.

The bill appears to have no fiscal impact on state or local government.

The bill takes effect July 1, 2010.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

The effect of this bill is of a technical, non-substantive nature. This bill deletes outdated or obsolete language relating to various health care provisions as follows:

Separate Male and Female Restrooms

Created in 1977, section 381.0091, F.S., authorizes private businesses to designate separate restroom and separate dressing room for males and females, and to prohibit any female from using a restroom or dressing room designated for males and likewise for females. In addition, if more than one restroom is provided that has occupant capacity for more than one person in any building or facility operated by the state, the restrooms must be separate for males and females and designated as such by appropriate signage. In 1991, this section was amended to transfer and renumber s. 381.523, F.S., to s. 381.0091, F.S., when the Department of Health and Rehabilitative Services was created.

The provision related to private businesses is merely permissive and appears to have little effect. The provision related to government buildings and facilities is outdated and no longer appears to be necessary. In addition, the section does not provide any enforcement provision nor inspection requirements for the Department of Health ("department"). Currently, the department does not inspect entities for compliance with this provision.¹

The bill repeals s. 381.0091, F.S. The repeal will have no impact on the ability of private businesses and government buildings to designate separate male and female restrooms or dressing rooms.

Florida Healthy People 2010 Program

Section 381.736, F.S., requires the department, within existing resources, to monitor and report Florida's status on the Healthy People 2010 goals and objectives currently tracked and available to the Department of Health. The department is required to submit an annual report to the Legislature on the status of health disparities among minorities and non-minorities, using health indicators consistent with those identified by Healthy People 2010. Furthermore, the provision directs the department to work with minority physician networks² to develop programs to educate health care professionals about the

¹ Per telephone conversation with Department of Health staff on February 22, 2010.

² A "minority physician network" is a network of primary care physicians with experience managing Medicaid or Medicare recipients that is predominantly owned by minorities as defined in s. 288.703, F.S., which may have a collaborative partnership with a public college or university and a tax-exempt charitable corporation. See s. 409.901, F.S.

importance of culture in health status.³ Moreover, the provision directs the department to promote research on methods to reduce disparities by encouraging local minority students enrolled at colleges and universities⁴ to pursue professions in health care.

Healthy People 2010 is a set of federal health core public health indicators used for priority-setting and decision-making that reflect major health concerns and that provide guidance to help states, local governments and private organizations improve the health status of their communities. The Healthy People 2010 program has two major program goals: increase quality and years of healthy life; and eliminate health disparities.⁵ There are 28 different focus areas in the 2010 program that include:⁶

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|---------------------------------------------------------|----------------------------------------|
| 1. Access to Quality Health Services | 15. Injury and Violence Prevention |
| 2. Arthritis, Osteoporosis, and Chronic Back Conditions | 16. Maternal, Infant, and Child Health |
| 3. Cancer | 17. Medical Product Safety |
| 4. Chronic Kidney Disease | 18. Mental Health and Mental Disorders |
| 5. Diabetes | 19. Nutrition and Overweight |
| 6. Disability and Secondary Conditions | 20. Occupational Safety and Health |
| 7. Educational and Community-Based Programs | 21. Oral Health |
| 8. Environmental Health | 22. Physical Activity and Fitness |
| 9. Family Planning | 23. Public Health Infrastructure |
| 10. Food Safety | 24. Respiratory Diseases |
| 11. Health Communication | 25. Sexually Transmitted Diseases |
| 12. Heart Disease and Stroke | 26. Substance Abuse |
| 13. HIV | 27. Tobacco Use |
| 14. Immunization and Infectious Diseases | 28. Vision and Hearing |

The Healthy People program goals and objectives are updated every 10 years, thus the existing 2010 goals are obsolete. In 2009, the U.S. Department of Health and Human Services and the Centers for Disease Control and Prevention launched the Healthy People 2020 framework.⁷ The Healthy People 2020 objectives will be released in 2010 along with guidance for achieving the new 10-year targets.⁸

Currently, the Florida Healthy People 2010 program duplicates other department programs and is not treated as a separate program. Therefore, the intent is being achieved through other statutory directives. This program is not specifically funded. The last annual report was published in December 2008.⁹ The department complies with the reporting requirements of this section by reporting on other programs that receive funding.¹⁰

For example, a Healthy People 2010 goal is to eliminate health disparities. The department's Office of Minority Health ("office") addresses health disparities through the Reducing Racial and Ethnic Health Disparities, Closing the Gap Program that disperses funding for community-based initiatives that focus on seven priority areas that include: maternal and infant mortality; cancer; cardiovascular disease; diabetes; adult and child immunizations; oral health; and HIV/AIDS. In addition, the office has developed statewide recommendations for a culturally competent curriculum for department staff and employees, plus training in health disparity education, health literacy, and culturally and linguistically

³ Minority physician networks will not be impacted by repealing this section of law. The Agency for Health Care Administration oversees services provided by the Minority Physician Networks. According to the 2008 Healthy People 2010 Annual Report, minority physician networks serve a small subset of Florida's Medicaid population and are not expected to significantly impact disparate health outcomes at the state level.

⁴ The statute references colleges and universities that have historically large minority enrollments to include centers of excellence that are identified by the National Center on Minority Health and Disparities.

⁵ Section 381.736, F.S.

⁶ In addition, these focus areas are broken down into 467 specific objectives.

⁷ Centers for Disease Control and Prevention, CDC Helps Launch Healthy People 2020 Collaboration, available at: <http://www.cdc.gov/news/2008/03/HealthyPeople2020.html> (last viewed February 21, 2010).

⁸ *Ibid.*

⁹ Department of Health, Office of Minority Health, Florida Healthy People 2010, Reports, available at: <http://www.doh.state.fl.us/Minority/HealthyPeople.htm> (last viewed February 22, 2010).

¹⁰ Per telephone call with Department of Health staff on February 22, 2010.

appropriate services.¹¹ Similarly, the department's Bureau of Chronic Disease Prevention and Health Promotion, address health disparities through the following funded programs: Heart Disease and Stroke Prevention program; Breast and Cervical Cancer Early Detection program; Comprehensive Cancer Control program; Diabetes Prevention and Control program; Arthritis Prevention and Education program; and the Epilepsy program.¹² None of these programs were created pursuant to the Healthy People 2010 goals contained in s. 381.736, F.S. These are just a few examples, and are not a complete compilation of all funded programs within the department that may address the Healthy People 2010 goals.

The bill repeals s. 381.736, F.S., the Florida Healthy People 2010 goals and reporting. Repealing this provision will only affect the requirement for submitting the annual report to the Legislature, and information available in the annual report will still be collected by the department and made available thru other programs. No funding to any existing programs will be affected.

MedAccess Program

Sections 408.90-408.908, F.S., create the MedAccess program.¹³ MedAccess was intended to be a state-subsidized program to provide certain health care services to low-income uninsured Floridians who are ineligible for Medicaid or Medicare. The program excludes coverage for preexisting conditions under certain circumstances. The Agency for Health Care Administration ("agency") is the fiscal agent for the program, and is required to develop the provider network, collect premiums and deductibles from enrollees, and make claims payments at Medicaid rates to providers. The program is not subject to state insurance regulation.

The MedAccess program encompasses nine statutory provisions that provide: Legislative findings and intent; definitions; program creation and title; eligibility; benefits; limitations and exclusions; collection of premiums; and administration. The program was created in 1993 and only the benefits provision¹⁴ was amended since adoption. In 2000, the amount of hospital outpatient services provided to a member was increased from \$1000 to \$1,500 per calendar year per member and an obsolete cross-reference to licensed abuse treatment centers was deleted.¹⁵

According to the agency, the program was never funded or implemented. The bill repeals ss. 408.90-408.908, F.S., the MedAccess Program.

B. SECTION DIRECTORY:

- Section 1. Repeals s. 381.0091, F.S., relating to separate restrooms and separate dressing rooms for males and females.
- Section 2. Repeals s. 381.736, F.S., relating to the Florida Healthy People 2010 Program.
- Section 3. Repeals s. 408.90, F.S., relating to legislative findings and intent.
- Section 4. Repeals s. 408.901, F.S., relating to definitions.
- Section 5. Repeals s. 408.902, F.S., relating to MedAccess program creation and title.
- Section 6. Repeals s. 408.903, F.S., relating to eligibility.
- Section 7. Repeals s. 408.904, F.S., relating to benefits.
- Section 8. Repeals s. 408.905, F.S., relating to limitations and exclusions.
- Section 9. Repeals s. 408.906, F.S., relating to payment of claims.
- Section 10. Repeals s. 408.907, F.S., relating to collection of premiums.
- Section 11. Repeals s. 408.908, F.S., relating to administration.
- Section 12. Provides an effective date of July 1, 2010.

¹¹ Office of Minority Health, Florida Healthy People 2010 Program Annual Report, December 2008, available at: <http://www.doh.state.fl.us/Minority/HealthyPeople.htm> (last viewed February 22, 2010).

¹² Florida Department of Health, Resource Manual, A Compilation of the Department of Health's Offices and Programs for State Fiscal Year 2007-2008 (January 2008).

¹³ 1993-129, L.O.F.

¹⁴ Section 408.904, F.S.

¹⁵ 2000-256, L.O.F. and 2000-153, L.O.F.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Not applicable.

2. Expenditures:

Not applicable.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

Not applicable.

2. Expenditures:

Not applicable.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Not applicable.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to: require counties or municipalities to spend funds or take an action requiring the expenditure of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of a state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No rule-making authority is provided in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES

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A bill to be entitled

An act relating to obsolete health care provisions; repealing s. 381.0091, F.S., relating to separate restrooms and separate dressing rooms for males and females; repealing s. 381.736, F.S., relating to Florida Healthy People 2010 Program; repealing s. 408.90, F.S., relating to Legislative findings and intent; repealing s. 408.901, F.S., relating to definitions; repealing s. 408.902, F.S., relating to MedAccess program creation and title; repealing s. 408.903, F.S., relating to eligibility; repealing s. 408.904, F.S., relating to benefits; repealing s. 408.905, F.S., relating to limitations and exclusions; repealing s. 408.906, F.S., relating to payment of claims; repealing s. 408.907, F.S., relating to collection of premiums; repealing s. 408.908, F.S., relating to administration; providing an effective date.

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

- Section 1. Section 381.0091, Florida Statutes, is repealed.
- Section 2. Section 381.736, Florida Statutes, is repealed.
- Section 3. Section 408.90, Florida Statutes, is repealed.
- Section 4. Section 408.901, Florida Statutes, is repealed.
- Section 5. Section 408.902, Florida Statutes, is repealed.
- Section 6. Section 408.903, Florida Statutes, is repealed.
- Section 7. Section 408.904, Florida Statutes, is repealed.

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 CODING: Words ~~stricken~~ are deletions; words underlined are additions.

PCB HCR 10-01

ORIGINAL

2010

- 29 Section 8. Section 408.905, Florida Statutes, is repealed.
- 30 Section 9. Section 408.906, Florida Statutes, is repealed.
- 31 Section 10. Section 408.907, Florida Statutes, is
- 32 repealed.
- 33 Section 11. Section 408.908, Florida Statutes, is
- 34 repealed.
- 35 Section 12. This act shall take effect July 1, 2010.