

## **Appropriations Committee**

# **Action Packet**

Tuesday, April 12, 2011 9:00 AM – 12:00 PM 212 Knott Building

#### **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)

Summary:

**Appropriations Committee** 

Tuesday April 12, 2011 09:00 am

CS/CS/CS/HJR 381 Not Considered

CS/HB 567 Favorable

Yeas: 23 Nays: 0

CS/HB 1125 Not Considered

CS/HB 1163 Not Considered

CS/HB 1231 Favorable

Yeas: 23 Nays: 0

CS/HB 1277 Not Considered

CS/HB 7095 Favorable With Committee Substitute

Yeas: 24 Nays: 0

Amendment 1 Adopted

Amendment 1a Withdrawn

Amd 1 to Amd 1

Amendment 2a Adopted

Amd 2 to Amd 1

Amendment 3a Failed to Adopt Yeas: 5 Nays: 19

Amd 3 to Amd 1

HB 7215 Not Considered

Print Date: 4/12/2011 2:57 pm

HJR 7221 Favorable

Yeas: 14 Nays: 10

## **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)

Print Date: 4/12/2011 2:57 pm

#### Attendance:

	Present	Absent	Excused
Denise Grimsley (Chair)	X		
Leonard Bembry	X		
Charles Chestnut IV	X		······································
Marti Coley	X		
Joseph Gibbons	X		
Richard Glorioso	X		
Ed Hooper	X		
Mike Horner	X		
Matt Hudson	X		
Dorothy Hukill	X		
Mia Jones	X		
Martin Kiar	X		
Paige Kreegel	×	· · · · · · · · · · · · · · · · · · ·	
John Legg	×		
Carlos Lopez-Cantera	×		
Seth McKeel	X		
H. Marlene O'Toole	×		
William Proctor	X		
Darryl Rouson	×		
Franklin Sands	X		
Ron Saunders	×		
Robert Schenck	×		
William Snyder	X		
Trudi Williams	X		
Totals:	24	0	0

## **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)

CS/CS/CS/HJR 381: Property Assessment, Homestead and Specified Nonhomestead Value Decline; Nonhomestead Increase Limitation Reduction; Additional Homestead Exemption;

**Scheduled Repeal Deletion** 

Not Considered

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#### **Appropriations Committee**

4/12/2011 9:00:00AM

**Location:** Webster Hall (212 Knott) **CS/HB 567: Judgment Interest** 

X Favorable

	Yea	Nay	No Vote	Absentee Yea	Absentee Nay
Leonard Bembry	X				
Charles Chestnut IV	X				
Marti Coley	X				
Joseph Gibbons	X				
Richard Glorioso	X				
Ed Hooper	X				
Mike Horner	X				
Matt Hudson	X				
Dorothy Hukill				X	
Mia Jones	X				
Martin Kiar	X				
Paige Kreegel	X				
John Legg	X				
Carlos Lopez-Cantera	X				
Seth McKeel	X				
H. Marlene O'Toole	X				
William Proctor	X				
Darryl Rouson	X				
Franklin Sands	X				
Ron Saunders	X				
Robert Schenck	X				
William Snyder	X				
Trudi Williams	X				
Denise Grimsley (Chair)	X				
	Total Yeas: 23	Total Nays: (	)		

## **Appearances:**

CS/HB 567 Sanford, Paul (Lobbyist) - Waive In Support JM Family Enterprises, Inc 106 S Monroe St Tallahassee Florida 32301 Phone: (850)222-7200

CS/HB 567

Adams, Leticia M (Lobbyist) - Waive In Support Florida Chamber of Commerce 136 South Bronough Street Tallahassee Florida 32301

Phone: 850-521-1279

Print Date: 4/12/2011 2:57 pm

#### **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)

CS/HB 567

Perdue, Tammy (Lobbyist) - Waive In Support

Associated Industries of Florida

516 N Adams St

Tallahassee Florida 32301 Phone: 850-224-7173

## **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)

CS/HB 1125 : Florida Health Choices Program

X Not Considered

Print Date: 4/12/2011 2:57 pm

## **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)
CS/HB 1163 : Ad Valorem Taxation

X Not Considered

## **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)
CS/HB 1231: Telecommunications

X Favorable

	Ýea	Nay	No Vote	Absentee Yea	Absentee Nay
Leonard Bembry	X				
Charles Chestnut IV	X				
Marti Coley	X				
Joseph Gibbons	X				
Richard Glorioso	X				
Ed Hooper	X				
Mike Horner	X				
Matt Hudson	X				
Dorothy Hukill				X	
Mia Jones	X				
Martin Kiar	X				
Paige Kreegel	X				
John Legg	X				
Carlos Lopez-Cantera	X				
Seth McKeel	X				
H. Marlene O'Toole	x				
William Proctor	X				
Darryl Rouson	X				
Franklin Sands	X				
Ron Saunders	X				
Robert Schenck	X				
William Snyder	X				
Trudi Williams	X				
Denise Grimsley (Chair)	X				
	Total Yeas: 23	Total Nays: 0	)		

#### **Appearances:**

CS/HB 1231

Johnson, Christina (Lobbyist) - Waive In Support

Citizens for a Digital Future 200 W. College Ave. Suite 210

Tallahassee FL 32301

Phone: (850)391-5040

CS/HB 1231

Perry, Gail Marie (General Public) - Opponent

Communications Workers of America/Council of Florida

PO Box 1766

Pompano FL 33061

Phone: (954)850-4055

CS/HB 1231

Haverlah, Mark Allen (General Public) - Opponent

3435 Treaty Oak Trail Tallahassee FL 32312

Phone: (850)509-4137

#### **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)

CS/HB 1231

McRay, Jack (Lobbyist) - Opponent

AARP

200 W College Ave Ste 304

Tallahassee FL 32301

Phone: (850)577-5187

CS/HB 1231

Adams, Leticia (Lobbyist) - Waive In Support

Florida Chamber of Commerce

136 S. Bronough St.

Tallahassee FL 32301

Phone: (850) 521-1279

CS/HB 1231

Landry, Dale (General Public) - Proponent

Tallahassee Branch NAACP

Tallahassee FL

Phone: (850)459-3460

CS/HB 1231

Watkins, Roosevelt (Lobbyist) - Proponent

Ministerial Allicance Against Digital Divide

9231 S. Cottage Dr.

Chicago Illinois 60619

Phone: (773)569-8282

CS/HB 1231

Perdue, Tammy (Lobbyist) - Waive In Support

Associated Industries of Florida

516 N. Adams St.

Tallahassee FL 32301

Phone: (850)224-7173

CS/HB 1231

Robinson, Michelle (Lobbyist) - Waive In Support

Verizon

PO Box 110 MC: FLTP0195

Tampa FL 33601

Phone: (813)483-1285

CS/HB 1231

Kandrach, Matthew (General Public) - Proponent

60 PLYS Association

515 King St. Suite 315

Alexandria VA 22314

Phone: (703)807-2070

Print Date: 4/12/2011 2:57 pm

## **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)

CS/HB 1277 : Sexual Offenders and Predators

X Not Considered

## **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)
CS/HB 7095 : Controlled Substances

X Favorable With Committee Substitute

	Yea	Nay	No Vote	Absentee Yea	Absentee Nay
Leonard Bembry	X				
Charles Chestnut IV	X				
Marti Coley	X				
Joseph Gibbons	X				
Richard Glorioso	X				
Ed Hooper	X				
Mike Horner	X				
Matt Hudson	X				
Dorothy Hukill	X				
Mia Jones	X				
Martin Kiar	X				
Paige Kreegel	X				
John Legg	X				
Carlos Lopez-Cantera	X				
Seth McKeel	X				
H. Mariene O'Toole	X				
William Proctor	X				
Darryl Rouson	X				
Franklin Sands	X				
Ron Saunders	X				
Robert Schenck	X				
William Snyder	X				
Trudi Williams	X				
Denise Grimsley (Chair)	X				
	Total Yeas: 24	Total Nays: (	)		

#### **CS/HB 7095 Amendments**

Ame	ndment	1
X	Adopted	1

Amendment 1a - Amd 1 to Amd 1

X Withdrawn

Amendment 2a - Amd 2 to Amd 1

X Adopted

#### **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)

Amendment 3a - Amd 3 to Amd 1

X Failed to Adopt

	Yea	Nay	No Vote	Absentee Yea	Absentee Nay
Leonard Bembry	X				
Charles Chestnut IV	X				
Marti Coley		X			
Joseph Gibbons	X				
Richard Glorioso		X			
Ed Hooper		x			
Mike Horner		х			
Matt Hudson		X			
Dorothy Hukill		Х			
Mia Jones		X			
Martin Kiar		X			
Paige Kreegel		Х			
John Legg		X			
Carlos Lopez-Cantera		х			
Seth McKeel		X			
H. Marlene O'Toole		X			
William Proctor		Х			
Darryl Rouson	X				
Franklin Sands		X			
Ron Saunders	X				
Robert Schenck		Х			
William Snyder		Х			
Trudi Williams		X			
Denise Grimsley (Chair)		X			
	Total Yays: 5	Total Nays	s: 19		

#### Appearances:

CS/HB 7095
Bondi, Pam (State Employee) - Proponent
Attorney General
PL 01, The Capitol
Tallahassee FL 32399
Phone: (850) 245-0184

Print Date: 4/12/2011 2:57 pm

#### **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)
CS/HB 7095 Strike - All Amendment
Driscoll, Jim - Waive In Opposition
Independent Pharmacy Cooperation
1550 Columbus St
Sun Prairie Wisconsin
Phone: 608-469-9913

CS/HB 7095 Strike - All Amendment Large, Toni (Lobbyist) - Proponent Florida Orthopaedic Society 519 E Park Ave Tallahassee FL 32308 Phone: (850)201-0888

CS/HB 7095 Strike - All Amendment West, Sally (Lobbyist) - Information Only Florida Retail Federation PO Box 10024 Tallahassee FL 32302-2024 Phone: (850)222-4082

CS/HB 7095 Strike - All Amendment Jackson, Michael (Lobbyist) - Opponent Florida Pharmacy Association 610 N Adams St Tallahassee FL 32301 Phone: (850)222-2400

CS/HB 7095 Strike - All Amendment Winn, Stephen (Lobbyist) - Waive In Opposition Florida Osteopathic Medical Association 2007 Apalachee Pky Tallahassee FL 32301 Phone: (850)878-7463

CS/HB 7095 Strike - All Amendment LaGamba, William - Opponent APS PHcy 5421 Karlsburg Place Palm Harbor Florida 34685 Phone: 727-480-0094

CS/HB 7095 Strike - All Amendment Abbott, Shane - Opponent 1337 US Hwy 90 West Defuniak Springs Florida 32433 Phone: 850-892-6898

CS/HB 7095 Strike - All Amendment Scott, Jeffery - Opponent Florida Pharmacist 1500 Ohio Ave S Live Oak Florida 32064 Phone: 386-362-2591

Committee meeting was reported out: Tuesday, April 12, 2011 2:57:09PM

Print Date: 4/12/2011 2:57 pm Leagis ® Page 13 of 21

#### **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott) CS/HB 7095 Strike - All Amendment Mincy, Bill - Information Only 1,200 Independent Pharmacies 2648 Bantry Bay Drive Tallahassee Florida 32309 Phone: 850-322-7740

CS/HB 7095 Strike - All Amendment Powers, Jim - Opponent **Independent Pharmacies** 1349 Old Village Road

Tallahassee Florida 32312 Phone: 850-422-0079

CS/HB 7095 Strike - All Amendment Adams, N. Lois - Opponent

FIPN - Independent Pharmacy Freedom & Cystic Fibrosis Pharmacy

3901 E. Colonial Dr Orlando Florida 32803 Phone: 407-898-4427

CS/HB 7095 Strike - All Amendment Biszick, Meryl - Waive In Opposition Florida Pharmacy 3901 E Colonial Drive Orlando Florida 32803

Phone: 407-898-4427

CS/HB 7095 Strike - All Amendment

Zoobi, Omar - Opponent Metropharmacy, LLC 2238 Kettle Drive Orlando Florida 32835 Phone: 321-438-6145

CS/HB 7095 Strike - All Amendment

Zoobi, Omar - Opponent Metropharmacy, LLC 2238 Kettle Drive Orlando Florida 32835 Phone: 321-438-6145

CS/HB 7095 Strike - All Amendment Fisher-Bezick, Linda (At Request Of Chair) - Opponent All North Florida Pharmacies 683 NW Garefowl St Greenville Florida 32331

Phone: 850-464-7049

Print Date: 4/12/2011 2:57 pm

## **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)
CS/HB 7095 Strike - All Amendment
Pratt, Kenneth (Lobbyist) - Waive In Support
Florida League of Cities
301 S Bronough St Suite 300
Tallahassee FL 32301
Phone: (850)701-3676

Print Date: 4/12/2011 2:57 pm Leagis ® Page 15 of 21

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COMMITTEE/SUBCOMM	ITTEE ACTION	Martegl
ADOPTED	(Y/N)	Adopted 4-12-11
ADOPTED AS AMENDED	(Y/N)	-, , -
ADOPTED W/O OBJECTION	(Y/N)	
FAILED TO ADOPT	(Y/N)	•
WITHDRAWN	(Y/N)	•
OTHER	transmission and the Assertance and	
Committee/Subcommittee Representative(s) Sche	_	Appropriations Committee following:

#### Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Paragraph (mm) is added to subsection (1) of section 456.072, Florida Statutes, and subsection (7) is amended, and subsection (8) is created, to read:

456.072 Grounds for discipline; penalties; enforcement.-

- (1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:
- (mm) Failure to comply with controlled substance prescribing requirements of s. 456.44.
- (7) Any licensee who has been found to over-prescribe or inappropriately prescribe controlled substances in violation of ss. 456.44, 458.331(1)(t) or (q), 459.015(t) or (x), 461.013(1)(o) or (s), or 466.028(1)(p) or (x), shall be

(2011)

Amendment No. 1

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suspended for a period of no less than six months and pay a fine of no less than \$10,000.00 per count. Repeated violations shall result in increased penalties.

(8) The purpose of this section is to facilitate uniform discipline for those actions made punishable under this section and, to this end, a reference to this section constitutes a general reference under the doctrine of incorporation by reference.

Section 2. Section 456.42, Florida Statutes, is amended to read:

456.42 Written prescriptions for medicinal drugs.-

A written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed, and the directions for use of the drug; must be dated; and must be signed by the prescribing practitioner on the day when issued. A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats and must be dated with the abbreviated month written out on the face of the prescription. However, a prescription that is electronically generated and transmitted must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical format, and the directions for use of the drug and must be dated

and signed by the prescribing practitioner only on the day issued, which signature may be in an electronic format as defined in s. 668.003(4).

- (2) A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats and must be dated with the abbreviated month written out on the face of the prescription, and must be either written on a standardized counterfeit-proof prescription pad produced by a vendor approved by the department, or electronically prescribed, as that term is used in s. 408.0611. As a condition of being an approved vendor, prescription pad vendors must submit a report monthly to the department which, at a minimum, documents the number of prescription pads sold and identifies the purchasers. The department may require reporting of additional information by rule.
- Section 3. Section 456.44, Florida Statutes, is created to read:
  - 456.44 Controlled Substance Prescribing.-
  - (1) Definitions.
- (a) "Adverse incident" means any incident set forth in s. 458.351(4)(a)-(e), or s. 459.026(4)(a)-(e).
- (b) "Board-certified pain management physician" means a physician who possesses board certification by a specialty board recognized by the American Board of Medical Specialties and holds a sub-specialty certification in pain medicine, or who possesses board certification in pain medicine by the American Board of Pain Medicine.

- (c) "Addiction medicine specialist" means a boardcertified psychiatrist with a sub-specialty certification in
  addiction medicine or who is eligible for such subspecialty
  certification in addiction medicine or an addiction medicine
  physician certified or eligible for certification by the
  American Society of Addiction Medicine.
- (d) "Mental health addiction facility" means a facility licensed pursuant to chapters 394 or 397.
- (2) Registration. Effective January 1, 2012, a physician licensed under chapters 458, 459, 461 or 466, who prescribes any controlled substance, as defined in s. 893.03, for the treatment of chronic, non-cancer pain, must:
- (a) Register with her or his professional licensing board as a controlled substance prescribing practitioner and pay a fee of \$100 at the time of such registration and upon each renewal of her or his license.
- (b) Comply with the requirements of this section and applicable board rules.
- (3) Standards of Practice. The standards of practice as set forth in this section shall not be construed to supersede the level of care, skill, and treatment recognized in general law related to healthcare licensure.
- (a) Evaluation of Patient and Medical Diagnosis. A complete medical history and a physical examination must be conducted prior to commencement of any treatment and documented in the medical record. The exact components of the physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to

the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of prior medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing.

Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis, in accordance with the plan.

(b) Treatment Plan. Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

- (c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks and benefits of the use of controlled substances including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The physician shall employ the use of a written controlled substance agreement between physician and patient outlining patient responsibilities, including, but not limited to:
- 1. Number and frequency of controlled substance prescriptions and refills;
- 2. Patient compliance and reasons for which drug therapy may be discontinued (e.g., violation of agreement); and
- 3. Agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating physician unless otherwise authorized by the treating physician and documented in the medical record.
- (d) Periodic Review. The patient shall be seen by the physician at regular intervals, not to exceed three months, to assess the efficacy of treatment, assure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects and review the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage,

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related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of three-month intervals.

- (e) Consultation. The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and requires consultation with or referral to an addictionologist or psychiatrist.
  - (f) Patient Medical Records. A physician registered under this section must maintain accurate, current and complete records which are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:
  - 1. The complete medical history and a physical examination, including history of drug abuse or dependence;
    - 2. Diagnostic, therapeutic, and laboratory results;
    - 3. Evaluations and consultations;
      - 4. Treatment objectives;
    - 5. Discussion of risks and benefits;
    - Treatments;
- 7. Medications (including date, type, dosage, and quantity prescribed);

(2011)

Bill No. CS/HB 7095

#### Amendment No. 1

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- 187 8. Instructions and agreements;
  - 9. Periodic reviews;
  - 10. Results of any drug testing;
- 11. A photocopy of the patient's government-issued photo 191 identification; and
  - 12. If a written prescription for a controlled substance is given to the patient, a duplicate of said prescription;
  - 13. The physician's full name presented in a legible manner.
  - (q) Prescription Loq. Registrants must maintain a current and accurate log of all prescriptions for controlled substances. The log must must not contain patient identifiable information, but must distinguish unduplicated patients. Registrants must make the log available to the department and law enforcement agencies upon request.
  - (h) Denial or Termination of Controlled Substance Therapy. Patients with signs or symptoms of substance abuse, shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period of time prior to receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to assure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician will incorporate the

consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy and the patient shall be discharged and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

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This subsection does not apply to a board-certified physician who has completed a fellowship in pain medicine approved by the American Accreditation Council for Graduate Medical Education or who is board-certified in pain medicine by a board approved by the American Board of Medical Specialties and performs interventional pain procedures of the type routinely billed using surgical codes.

231 Section 4. Section 458.3265, Florida Statutes, is amended 232 to read:

458.3265 Pain-management clinics.

- (1) REGISTRATION.-
- "Clinic", means a publicly or privately owned facility where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol, for the treatment of chronic nonmalignant pain. "Chronic nonmalignant pain is pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery. All

7	a	~+	NTO	7
Amen	amei	10	NO.	

- privately owned pain management clinics, facilities, or offices, hereinafter referred to as "clinics," which advertise in any medium for any type of pain management services, or employ a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, All pain-management clinics must register with the department unless:
- 1. That clinic is licensed as a facility pursuant to chapter 395;
- 2. The majority of the physicians who provide services in the clinic primarily provide surgical services;
- 3. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the overthe-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded \$50 million;
- 4. The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
- 5. The clinic does not prescribe <del>or dispense</del> controlled substances for the treatment of pain; <del>or</del>
- 6. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3); or-
- 7. The clinic is wholly owned and operated by a board-certified anesthesiologist, physiatrist, neurologist, or another medical specialist who has completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or who is board certified in pain medicine by a board approved by the American Board of Medical Specialties,

- and that medical specialist performs interventional pain procedures of the type routinely billed using surgical codes, or is wholly owned and operated by a group of such specialists.
- (b) Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic.
- (c) As a part of registration, a clinic must designate a physician who is responsible for complying with all requirements related to registration and operation of the clinic in compliance with this section. Within 10 days after termination of a designated physician, the clinic must notify the department of the identity of another designated physician for that clinic. The designated physician shall have a full, active, and unencumbered license under this chapter or chapter 459 and shall practice at the clinic location for which the physician has assumed responsibility. Failing to have a licensed designated physician practicing at the location of the registered clinic may be the basis for a summary suspension of the clinic registration certificate as described in s. 456.073(8) for a license or s. 120.60(6).
- (d) The department shall deny registration to any clinic that is not fully owned by a physician licensed under this chapter or chapter 459 or a group of physicians, each of whom is licensed under this chapter or chapter 459; or that is not a health care clinic licensed under part X of chapter 400.
- (e) The department shall deny registration to any painmanagement clinic owned by or with any contractual or employment relationship with a physician:

- 1. Whose Drug Enforcement Administration number has ever been revoked.
- 2. Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction.
- 3. Who has been convicted of or pleaded guilty or nolo contendere to, regardless of adjudication, an offense that constitutes a felony for receipt of illicit and diverted drugs, including a controlled substance listed in Schedule I, Schedule II, Schedule IV, or Schedule V of s. 893.03, in this state, any other state, or the United States.
- (f) If the department finds that a pain-management clinic does not meet the requirement of paragraph (d) or is owned, directly or indirectly, by a person meeting any criteria listed in paragraph (e), the department shall revoke the certificate of registration previously issued by the department. As determined by rule, the department may grant an exemption to denying a registration or revoking a previously issued registration if more than 10 years have elapsed since adjudication. As used in this subsection, the term "convicted" includes an adjudication of guilt following a plea of guilty or nolo contendere or the forfeiture of a bond when charged with a crime.
- (g) The department may revoke the clinic's certificate of registration and prohibit all physicians associated with that pain-management clinic from practicing at that clinic location based upon an annual inspection and evaluation of the factors described in subsection (3).

- (h) If the registration of a pain-management clinic is revoked or suspended, the designated physician of the pain-management clinic, the owner or lessor of the pain-management clinic property, the manager, and the proprietor shall cease to operate the facility as a pain-management clinic as of the effective date of the suspension or revocation.
- (i) If a pain-management clinic registration is revoked or suspended, the designated physician of the pain-management clinic, the owner or lessor of the clinic property, the manager, or the proprietor is responsible for removing all signs and symbols identifying the premises as a pain-management clinic.
- (j) Upon the effective date of the suspension or revocation, the designated physician of the pain-management clinic shall advise the department of the disposition of the medicinal drugs located on the premises. The disposition is subject to the supervision and approval of the department.

  Medicinal drugs that are purchased or held by a pain-management clinic that is not registered may be deemed adulterated pursuant to s. 499.006.
- (k) If the clinic's registration is revoked, any person named in the registration documents of the pain-management clinic, including persons owning or operating the pain-management clinic, may not, as an individual or as a part of a group, apply to operate a pain-management clinic for 5 years after the date the registration is revoked.
- (1) The period of suspension for the registration of a pain-management clinic shall be prescribed by the department, but may not exceed 1 year.

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- (m) A change of ownership of a registered pain-management clinic requires submission of a new registration application.
- (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).
- (a) A physician may not practice medicine in a painmanagement clinic, as described in subsection (4), if:
- 1. The pain-management clinic is not registered with the department as required by this section; or
- 2. Effective July 1, 2012, the physician has not successfully completed a pain-medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education or a pain-medicine residency that is accredited by the Accreditation Council for Graduate Medical Education or, prior to July 1, 2012, does not comply with rules adopted by the board.

Any physician who qualifies to practice medicine in a painmanagement clinic pursuant to rules adopted by the Board of Medicine as of July 1, 2012, may continue to practice medicine in a pain-management clinic as long as the physician continues to meet the qualifications set forth in the board rules. A physician who violates this paragraph is subject to disciplinary action by his or her appropriate medical regulatory board.

(b) A person may not dispense any medication, including a controlled substance, on the premises of a registered pain-

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management clinic unless he or she is a physician licensed under this chapter or chapter 459.

- (c) A physician must perform a physical examination of a patient on the same day that he or she dispenses or prescribes a controlled substance to a patient at a pain-management clinic. If the physician prescribes or dispenses more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the physician must document in the patient's record the reason for prescribing or dispensing that quantity.
- (d) A physician authorized to prescribe controlled substances who practices at a pain-management clinic is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing controlled substance pain medication. The physician shall comply with the requirements for counterfeit-resistant prescription blanks in s. 893.065 and the rules adopted pursuant to that section. The physician shall notify, in writing, the department within 24 hours following any theft or loss of a prescription blank or breach of any other method for prescribing pain medication.
- (e) The designated physician of a pain-management clinic shall notify the applicable board in writing of the date of termination of employment within 10 days after terminating his or her employment with a pain-management clinic that is required to be registered under subsection (1). All physicians practicing in pain-management clinics shall advise the Board of Medicine in writing, within 10 calendar days of beginning or ending his or her practice at a pain-management clinic.

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- (i) Each physician practicing in a pain management clinic

  is responsible for ensuring compliance with the following

  facility and physical operations requirements.
  - 1. A pain management clinic shall be located and operated at a publicly accessible fixed location and shall contain the following:
  - a. A sign that can be viewed by the public that contains the clinic name, hours of operations, and a street address;
  - b. A publicly listed telephone number and a dedicated phone number to send and receive faxes with a fax machine that shall be operational twenty-four hours per day;
    - c. Emergency lighting and communications;
    - d. Reception and waiting area;
    - e. Restroom;
  - f. Administrative area including room for storage of medical records, supplies and equipment;
    - g. Private patient examination room(s);
- h. Treatment room(s) if treatment is being provided to the patient;
  - i. A printed sign located in a conspicuous place in the waiting room viewable by the public disclosing the name and contact information of the clinic designated physician, and the names of all physicians practicing in the clinic;
- j. Clinics that store and dispense prescription drugs shall comply with ss. 499.0121 and 893.07.
- 2. Nothing in this section shall excuse a physician from providing any treatment or performing any medical duty without the proper equipment and materials as required by the standard

	Amendment No. 1
437	of care. This section shall not be construed to supersede the
438	level of care, skill, and treatment recognized in general law
439	related to healthcare licensure.
440	(j) Each physician practicing in a pain management clinic
441	is responsible for ensuring compliance with the following
442	infection control requirements.
443	1. The clinic shall maintain equipment and supplies to
444	support infection prevention and control activities.
445	2. The clinic shall identify infection risks based on the
446	following:
447	a. Geographic location, community, and population served;
448	b. The care, treatment and services it provides; and
449	c. An analysis of its infection surveillance and control
150	data.
451	3. The clinic shall maintain written infection prevention
452	policies and procedures that address the following:
453	a. Prioritized risks;
454	b. Limiting unprotected exposure to pathogen;
455	c. Limiting the transmission of infections associated with
456	procedures performed in the clinic; and
457	d. Limiting the transmission of infections associated with
458	the clinic's use of medical equipment, devices, and supplies.
459	(k) Each physician practicing in a pain management clinic
460	is responsible for ensuring compliance with the following health

1. The clinic, including its grounds, buildings, furniture,

appliances and equipment shall be structurally sound, in good

repair, clean, and free from health and safety hazards.

and safety requirements.

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- 2. The clinic shall have evacuation procedures in the event of an emergency which shall include provisions for the evacuation of disabled patients and employees.
- 3. The clinic shall have a written facility-specific disaster plan which sets forth actions that will be taken in the event of clinic closure due to unforeseen disasters which shall include provisions for the protection of medical records and any controlled substances.
- 4. Each clinic shall have at least one employee on the premises during patient care hours that is certified in Basic Life Support and is trained in reacting to accidents and medical emergencies until emergency medical personnel arrive.
- (1) The designated physician is responsible for ensuring compliance with the following quality assurance requirements. Each pain management clinic shall have an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the facility, alerts the designated physician to identify and resolve recurring problems, and provides for opportunities to improve the facility's performance and to enhance and improve the quality of care provided to the public. The designated physician shall establish a quality assurance program that includes the following components:
- 1. The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients,
  - 2. The identification of trends or patterns of incidents,

(2011)

Bill No. CS/HB 7095

#### Amendment No. 1

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- 3. The development of measures to correct, reduce,
  minimize, or eliminate the risk of adverse incidents to
  patients, and
  - 4. The documentation of these functions and periodic review no less than quarterly of such information by the designated physician.
  - (m) The designated physician is responsible for ensuring compliance with the following data collection and reporting requirements.
  - 1. The designated physician for each pain-management clinic shall report all adverse incidents to the department as set forth in s. 458.351.
  - 2. The designated physician shall also report to the Board of Medicine, in writing, on a quarterly basis the following data:
  - a. Number of new and repeat patients seen and treated at the clinic who are prescribed controlled substance medications for the treatment of chronic, non-malignant pain.
    - b. The number of patients discharged due to drug abuse.
    - c. The number of patients discharged due to drug diversion.
  - d. The number of patients treated at the pain clinic whose domicile is located somewhere other than in Florida. A patient's domicile is the patient's fixed or permanent home to which he intends to return even though he may temporarily reside elsewhere.
    - (4) RULEMAKING.-
- 518 (a) The department shall adopt rules necessary to 519 administer the registration and inspection of pain-management

Amendment No. 1 clinics which establish the specific requirements, procedures, forms, and fees.

- (b) The department shall adopt a rule defining what constitutes practice by a designated physician at the clinic location for which the physician has assumed responsibility, as set forth in subsection (1). When adopting the rule, the department shall consider the number of clinic employees, the location of the pain management clinic, the clinic's hours of operation, and the amount of controlled substances being prescribed, dispensed, or administered at the pain management clinic.
- (c) The Board of Medicine shall adopt a rule establishing the maximum number of prescriptions for Schedule II or Schedule III controlled substances or the controlled substance Alprazolam which may be written at any one registered pain management clinic during any 24 hour period.
- (d) The Board of Medicine shall adopt rules setting forth standards of practice for physicians practicing in privately owned pain management clinics that primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications. Such rules shall address, but need not be limited to:
  - 1. Facility operations;
  - 2. Physical operations;
  - 3. Infection control requirements;
- 545 4. Health and safety requirements;
- 5. Quality assurance requirements;
- 547 6. Patient records;

- 7. <u>Ttraining</u> requirements for all facility health care practitioners who are not regulated by another board.
  - 8. Inspections; and
  - 9. Data collection and reporting requirements.

A physician is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications when the majority of the patients seen are prescribed or dispensed controlled substance medications for the treatment of chronic nonmalignant pain. Chronic nonmalignant pain is pain unrelated to cancer which persists beyond the usual course of the disease or the injury that is the cause of the pain or more than 90 days after surgery.

(6) This section expires January 1, 2016.

Section 5. Paragraph (f) of subsection (1) of section 458.327, Florida Statutes, is created to read:

458.327 Penalty for violations.—

- (1) Each of the following acts constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084:
- (f) Dispensing a controlled substance listed in Schedule II or Schedule III in violation of s. 465.0276.

Section 6. Paragraph (rr) of subsection (1) of section 458.331, Florida Statutes, is created to read:

- 458.331 Grounds for disciplinary action; action by the board and department.—
- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(2011)

Bill No. CS/HB 7095

#### Amendment No. 1

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(rr) Dispensing a controlled substance listed in Schedule II or Schedule III in violation of s. 465.0276.

Section 7. Section 459.0137, Florida Statutes, is amended to read:

459.0137 Pain-management clinics.

- (1) REGISTRATION.—
- "Pain-management clinic", hereinafter referred to as (a) "clinic", means a publicly or privately owned facility where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol, for the treatment of chronic nonmalignant pain. "Chronic nonmalignant pain is pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery. All privately owned pain management clinics, facilities, or offices, hereinafter referred to as "clinics," which advertise in any medium for any type of pain management services, or employ an osteopathic physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, All pain-management clinics must register with the department unless:
- That clinic is licensed as a facility pursuant to chapter 395;
- 2. The majority of the physicians who provide services in the clinic primarily provide surgical services;
- 3. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-

the-counter market and whose total assets at the end of the corporation's most recent fiscal quarter exceeded \$50 million;

- 4. The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows:
- 5. The clinic does not prescribe <del>or dispense</del> controlled substances for the treatment of pain; <del>or</del>
- 6. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3);
- 7. The clinic is wholly owned and operated by a boardcertified anesthesiologist, physiatrist, neurologist, or another
  medical specialist who has completed a fellowship in pain
  medicine approved by the Accreditation Council for Graduate
  Medical Education or who is board certified in pain medicine by
  a board approved by the American Board of Medical Specialties,
  and that medical specialist performs interventional pain
  procedures of the type routinely billed using surgical codes, or
  is wholly owned and operated by a group of such specialists.
- (b) Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic.
- (c) As a part of registration, a clinic must designate an osteopathic physician who is responsible for complying with all requirements related to registration and operation of the clinic in compliance with this section. Within 10 days after termination of a designated osteopathic physician, the clinic must notify the department of the identity of another designated physician for that clinic. The designated physician shall have a

- full, active, and unencumbered license under chapter 458 or this chapter and shall practice at the clinic location for which the physician has assumed responsibility. Failing to have a licensed designated osteopathic physician practicing at the location of the registered clinic may be the basis for a summary suspension of the clinic registration certificate as described in s. 456.073(8) for a license or s. 120.60(6).
- (d) The department shall deny registration to any clinic that is not fully owned by a physician licensed under chapter 458 or this chapter or a group of physicians, each of whom is licensed under chapter 458 or this chapter; or that is not a health care clinic licensed under part X of chapter 400.
- (e) The department shall deny registration to any painmanagement clinic owned by or with any contractual or employment relationship with a physician:
- 1. Whose Drug Enforcement Administration number has ever been revoked.
- 2. Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction.
- 3. Who has been convicted of or pleaded guilty or nolo contendere to, regardless of adjudication, an offense that constitutes a felony for receipt of illicit and diverted drugs, including a controlled substance listed in Schedule I, Schedule II, Schedule IV, or Schedule V of s. 893.03, in this state, any other state, or the United States.
- (f) If the department finds that a pain-management clinic does not meet the requirement of paragraph (d) or is owned,

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directly or indirectly, by a person meeting any criteria listed in paragraph (e), the department shall revoke the certificate of registration previously issued by the department. As determined by rule, the department may grant an exemption to denying a registration or revoking a previously issued registration if more than 10 years have elapsed since adjudication. As used in this subsection, the term "convicted" includes an adjudication of quilt following a plea of quilty or nolo contendere or the forfeiture of a bond when charged with a crime.

- The department may revoke the clinic's certificate of (q) registration and prohibit all physicians associated with that pain-management clinic from practicing at that clinic location based upon an annual inspection and evaluation of the factors described in subsection (3).
- If the registration of a pain-management clinic is revoked or suspended, the designated physician of the painmanagement clinic, the owner or lessor of the pain-management clinic property, the manager, and the proprietor shall cease to operate the facility as a pain-management clinic as of the effective date of the suspension or revocation.
- If a pain-management clinic registration is revoked or suspended, the designated physician of the pain-management clinic, the owner or lessor of the clinic property, the manager, or the proprietor is responsible for removing all signs and symbols identifying the premises as a pain-management clinic.
- Upon the effective date of the suspension or revocation, the designated physician of the pain-management clinic shall advise the department of the disposition of the

medicinal drugs located on the premises. The disposition is subject to the supervision and approval of the department. Medicinal drugs that are purchased or held by a pain-management clinic that is not registered may be deemed adulterated pursuant to s. 499.006.

- (k) If the clinic's registration is revoked, any person named in the registration documents of the pain-management clinic, including persons owning or operating the pain-management clinic, may not, as an individual or as a part of a group, make application for a permit to operate a pain-management clinic for 5 years after the date the registration is revoked.
- (1) The period of suspension for the registration of a pain-management clinic shall be prescribed by the department, but may not exceed 1 year.
- (m) A change of ownership of a registered pain-management clinic requires submission of a new registration application.
- (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any osteopathic physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).
- (a) An osteopathic physician may not practice medicine in a pain-management clinic, as described in subsection (4), if:
- 1. The pain-management clinic is not registered with the department as required by this section; or
- 2. Effective July 1, 2012, the physician has not successfully completed a pain-medicine fellowship that is accredited by the Accreditation Council for Graduate Medical

Education or the American Osteopathic Association or a painmedicine residency that is accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association or, prior to July 1, 2012, does not comply with rules adopted by the board.

Any physician who qualifies to practice medicine in a pain-management clinic pursuant to rules adopted by the Board of Osteopathic Medicine as of July 1, 2012, may continue to practice medicine in a pain-management clinic as long as the physician continues to meet the qualifications set forth in the board rules. An osteopathic physician who violates this paragraph is subject to disciplinary action by his or her appropriate medical regulatory board.

- (b) A person may not dispense any medication, including a controlled substance, on the premises of a registered pain-management clinic unless he or she is a physician licensed under this chapter or chapter 458.
- examination of a patient on the same day that he or she dispenses or prescribes a controlled substance to a patient at a pain-management clinic. If the osteopathic physician prescribes or dispenses more than a 72-hour dose of controlled substances for the treatment of chronic nonmalignant pain, the osteopathic physician must document in the patient's record the reason for prescribing or dispensing that quantity.
- (d) An osteopathic physician authorized to prescribe controlled substances who practices at a pain-management clinic

- is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing controlled substance pain medication. The osteopathic physician shall comply with the requirements for counterfeit-resistant prescription blanks in s. 893.065 and the rules adopted pursuant to that section. The osteopathic physician shall notify, in writing, the department within 24 hours following any theft or loss of a prescription blank or breach of any other method for prescribing pain medication.
- (e) The designated osteopathic physician of a pain-management clinic shall notify the applicable board in writing of the date of termination of employment within 10 days after terminating his or her employment with a pain-management clinic that is required to be registered under subsection (1). All physicians practicing in pain-management clinics shall advise the Board of Medicine in writing, within 10 calendar days of beginning or ending his or her practice at a pain-management clinic.
- (f) Each physician practicing in a pain management clinic is responsible for ensuring compliance with the following facility and physical operations requirements.
- 1. A pain management clinic shall be located and operated at a publicly accessible fixed location and shall contain the following:
- a. A sign that can be viewed by the public that contains the clinic name, hours of operations, and a street address;

- b. A publicly listed telephone number and a dedicated phone number to send and receive faxes with a fax machine that shall be operational twenty-four hours per day;
  - c. Emergency lighting and communications;
  - d. Reception and waiting area;
  - e. Restroom;
- f. Administrative area including room for storage of
  medical records, supplies and equipment;
  - g. Private patient examination room(s);
- h. Treatment room(s) if treatment is being provided to the patient;
- i. A printed sign located in a conspicuous place in the waiting room viewable by the public disclosing the name and contact information of the clinic designated physician, and the names of all physicians practicing in the clinic;
- j. Clinics that store and dispense prescription drug shall comply with ss. 499.0121 and 893.07.
- 2. Nothing in this section shall excuse a physician from providing any treatment or performing any medical duty without the proper equipment and materials as required by the standard of care. This section shall not be construed to supersede the level of care, skill, and treatment recognized in general law related to healthcare licensure.
- (g) Each physician practicing in a pain management clinic is responsible for ensuring compliance with the following infection control requirements.
- 1. The clinic shall maintain equipment and supplies to support infection prevention and control activities.

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- 797 <u>2. The clinic shall identify infection risks based on the</u> 798 following:
  - a. Geographic location, community, and population served;
  - b. The care, treatment and services it provides; and
  - c. An analysis of its infection surveillance and control data.
  - 3. The clinic shall maintain written infection prevention policies and procedures that address the following:
    - a. Prioritized risks;
    - b. Limiting unprotected exposure to pathogen;
  - c. Limiting the transmission of infections associated with procedures performed in the clinic; and
  - d. Limiting the transmission of infections associated with the clinic's use of medical equipment, devices, and supplies.
  - (h) Each physician practicing in a pain management clinic is responsible for ensuring compliance with the following health and safety requirements.
  - 1. The clinic, including its grounds, buildings, furniture, appliances and equipment shall be structurally sound, in good repair, clean, and free from health and safety hazards.
  - 2. The clinic shall have evacuation procedures in the event of an emergency which shall include provisions for the evacuation of disabled patients and employees.
  - 3. The clinic shall have a written facility-specific disaster plan which sets forth actions that will be taken in the event of clinic closure due to unforeseen disasters which shall include provisions for the protection of medical records and any controlled substances.

- 4. Each clinic shall have at least one employee on the premises during patient care hours that is certified in Basic

  Life Support and is trained in reacting to accidents and medical emergencies until emergency medical personnel arrive.
- (i) The designated physician is responsible for ensuring compliance with the following quality assurance requirements.

  Each pain management clinic shall have an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the facility, alerts the designated physician to identify and resolve recurring problems, and provides for opportunities to improve the facility's performance and to enhance and improve the quality of care provided to the public. The designated physician shall establish a quality assurance program that includes the following components:
- 1. The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients,
  - 2. The identification of trends or patterns of incidents,
- 3. The development of measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients, and
- 4. The documentation of these functions and periodic review no less than quarterly of such information by the designated physician.
- (j) The designated physician is responsible for ensuring compliance with the following data collection and reporting requirements.

- 1. Reporting of adverse incidents. The designated physician for each pain-management clinic shall report all adverse incidents to the Department of Health as set forth in Section 459.026, F.S.
- 2. The designated physician shall also report to the Board of Osteopathic Medicine, in writing, on a quarterly basis the following data:
- a. Number of new and repeat patients seen and treated at the clinic who are prescribed controlled substance medications for the treatment of chronic, non-malignant pain;
  - b. The number of patients discharged due to drug abuse;
- c. The number of patients discharged due to drug diversion; and
- d. The number of patients treated at the pain clinic whose domicile is located somewhere other than in Florida. A patient's domicile is the patient's fixed or permanent home to which he intends to return even though he may temporarily reside elsewhere.
  - (4) RULEMAKING.-
- (a) The department shall adopt rules necessary to administer the registration and inspection of pain-management clinics which establish the specific requirements, procedures, forms, and fees.
- (b) The department shall adopt a rule defining what constitutes practice by a designated osteopathic physician at the clinic location for which the physician has assumed responsibility, as set forth in subsection (1). When adopting the rule, the department shall consider the number of clinic

Amendment No. 1 881 employees, the location of the pain-management clinic, the 882 clinic's hours of operation, and the amount of controlled substances being prescribed, dispensed, or administered at the 883 884 pain-management clinic. 885 (c) The Board of Osteopathic Medicine shall adopt a rule 886 establishing the maximum number of prescriptions for Schedule II 887 or Schedule III controlled substances or the controlled 888 substance Alprazolam which may be written at any one registered 889 pain-management-clinic-during any 24 hour period. 890 (d) The Board of Osteopathic Medicine shall adopt rules 891 setting forth standards of practice for osteopathic physicians 892 practicing in privately owned pain-management-clinics that 893 primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications. Such rules shall 994 895 address, but need not be limited to: 1. Facility operations; 896 897 2. Physical operations; 898 3. Infection control requirements; 4. Health and safety requirements; 899 900 5. Quality assurance requirements; 901 Patient records; 7. Ttraining requirements for all facility health care 902 903 practitioners who are not regulated by another board. + 904 8. Inspections; and 905 9. Data collection and reporting requirements. 906 An osteopathic physician is primarily engaged in the treatment 907

of pain by prescribing or dispensing controlled substance

	Amendment No. 1
909	medications when the majority of the patients seen are
910	prescribed or dispensed controlled substance medications for the
911	treatment of chronic nonmalignant pain. Chronic nonmalignant
912	pain is pain unrelated to cancer which persists beyond the usual
913	course of the disease or the injury that is the cause of the
914	pain or more than 90 days after surgery.
915	(6) This section expires January 1, 2016.
916	Section 8. Paragraph (f) of subsection (1) of section
917	459.013, Florida Statutes, is created to read:
918	459.013 Penalty for violations.—
919	(1) Each of the following acts constitutes a felony of the
920	third degree, punishable as provided in s. 775.082, s. 775.083,
921	or s. 775.084:
922	(f) Dispensing a controlled substance listed in Schedule
923	II or Schedule III in violation of s. 465.0276.
924	Section 9. Paragraph (tt) of subsection (1) of section
925	459.015, Florida Statutes, is created to read:
926	459.015 Grounds for disciplinary action; action by the
927	board and department.—
928	(1) The following acts constitute grounds for denial of a
929	license or disciplinary action, as specified in s. 456.072(2):
930	(tt) Dispensing a controlled substance listed in Schedule
931	II or Schedule III in violation of s. 465.0276.
932	Section 10. Subsections (3) and (4) of section 465.015,
933	Florida Statutes, are renumbered as subsections (4) and (5),
934	respectively, a new subsection (3) is added to that section, and
035	present subsection (4) of that section is amended to read.

465.015 Violations and penalties.-

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It is unlawful for any pharmacist to fail to report to the sheriff of the county where the pharmacy is located within 24 hours after learning of any instance in which a person obtained or attempted to obtain a controlled substance, as defined in s. 893.02, that the pharmacist knew or reasonably should have known was obtained or attempted to be obtained from the pharmacy though fraudulent methods or representations. Any pharmacist who fails to make such a report within 24 hours after learning of the fraud or attempted fraud commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. A sufficient report of the fraudulent obtaining of controlled substances under this subsection shall contain, at a minimum, a copy of the prescription used or presented and a narrative, including all information available to the pharmacy concerning the transaction, such as the name and telephone number of the prescribing physician; the name, description, and any personal identification information pertaining to the person who presented the prescription; and all other material information, such as photographic or video surveillance of the transaction.

(5)(4) Any person who violates any provision of subsection (1) or subsection (4) (3) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. Any person who violates any provision of subsection (2) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In any warrant, information, or indictment, it shall not be necessary to negative any

964	Amendment No. 1 exceptions, and the burden of any exception shall be upon the
965	defendant.
966	Section 11. Paragraph (t) is added to subsection (1) of
967	section 465.016, Florida Statutes, to read:
968	465.016 Disciplinary actions.—
969	(1) The following acts constitute grounds for denial of a
970	license or disciplinary action, as specified in s. 456.072(2):
971	(t) Committing an error or omission during the performance
97Ż	of a specific function of prescription drug processing which
973	includes for purposes of this provision:
974	1. Receiving, interpreting, or clarifying a prescription;
975	2. Entering prescription data into the pharmacy's record;
976	3. Verifying or validating a prescription;
977	4. Performing pharmaceutical calculations;
978	5. Performing prospective drug review as defined by the
979	board;
980	6. Obtaining refill and substitution authorizations;
981	7. Interpreting or acting on clinical data;
982	8. Performing therapeutic interventions;
983	9. Providing drug information concerning a patient's
984	prescription;
985	10. Providing patient counseling.
986	Section 12. Section 465.018, Florida Statutes, is amended
987	to read:
988	465.018 Community pharmacies; permits.—
989	(1) Any person desiring a permit to operate a community
990	pharmacy shall apply to the department.

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- (2) If the board office certifies that the application complies with the laws of the state and the rules of the board governing pharmacies, the department shall issue the permit. No permit shall be issued unless a licensed pharmacist is designated as the prescription department manager. responsible for maintaining all drug records, providing for the security of the prescription department, and following such other rules as relate to the practice of the profession of pharmacy. The permittee and the newly designated prescription department manager shall notify the department within 10 days of any change in prescription department manager.
- (3) The board may suspend or revoke the permit of, or may refuse to issue a permit to:
- (a) Any person which has been disciplined, abandoned, or has become null and void after written notice that disciplinary proceedings had been or would be brought against the permit; or
- (b) Any person who is an officer, director, or person interested directly or indirectly in the person or business entity has had her or his permit disciplined, abandoned, or has become null and void after written notice that disciplinary proceedings had been or would be brought against her or his permit; or
- (c) Any person who is or has been an officer of a business entity, or who was interested directly or indirectly in a business entity, the permit of which has been disciplined, abandoned or has become null and void after written notice that disciplinary proceedings had been or would be brought against the license.

- (4) In addition to any other remedies provided by law, the board may deny each application or suspend or revoke each license, registration, or certificate of entities regulated or licensed by it if the applicant, licensee, registrant, or license holder, or, in the case of a corporation, partnership, or other business entity, if any officer, director, agent, or managing employee of that business entity or any affiliated person, partner, or shareholder having an ownership interest equal to 5 percent or greater in that business entity, has failed to pay all outstanding fines, liens, or overpayments assessed by final order of the department, unless a repayment plan is approved by the department; or for failure to comply with any repayment plan.
- (5) In reviewing any application requesting a change of ownership, or change of licensee or registrant, the transferor shall, prior to board approval of the change, repay or make arrangements to repay any amounts owed to the department. Should the transferor fail to repay or make arrangements to repay the amounts owed to the department, the license or registration shall not be issued to the transferee until repayment or until arrangements for repayment are made.
- (6) Passing an onsite inspection is a prerequisite of issuing an initial permit or a permit for a change of location.

  The department must make the inspection within ninety days prior to issuance of the permit.
- (7) Effective January 1, 2012, a pharmacy permitted under this section may not dispense a controlled substance listed in

	Amendment No. 1
1046	Schedule II or Schedule III as provided in s. 893.03 unless the
1047	pharmacy:
1048	(a) Is wholly owned by a corporation whose shares are
1049	publicly traded on a recognized stock exchange; or
1050	(b) Is wholly owned by a corporation having more than \$100
1051	million of business taxable assets in this state;
1052	(c) Is wholly owned or operated by a licensed hospice,
1053	hospital or nursing facility, or provides services exclusively
1054	to patients of a licensed hospice, hospital or nursing facility;
1055	<u>or</u>
1056	(d) Has been continuously permitted for at least 10 years;
1057	<u>or</u>
1058	(e) Received or renewed a permit pursuant to the
י59	requirements of this section. ; ex
1060	
1061	Community pharmacies which dispense controlled substances must
1062	maintain a record of all controlled substance dispensing
1063	consistent with the requirements of s. 893.07, and must make the
1064	record available to the department and law enforcement agencies
1065	upon request.
1066	Section 13. Section 465.022, Florida Statutes, is amended

465.022 Pharmacies; general requirements; fees.-

and 120.54 to implement the provisions of this chapter. Such

rules shall include, but shall not be limited to, rules relating

The board shall adopt rules pursuant to ss. 120.536(1)

(a) General drug safety measures.

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to read:

to:

- (b) Minimum standards for the physical facilities of pharmacies.
  - (c) Safe storage of floor-stock drugs.
- (d) Functions of a pharmacist in an institutional pharmacy, consistent with the size and scope of the pharmacy.
- (e) Procedures for the safe storage and handling of radioactive drugs.
- (f) Procedures for the distribution and disposition of medicinal drugs distributed pursuant to s. 499.028.
- (g) Procedures for transfer of prescription files and medicinal drugs upon the change of ownership or closing of a pharmacy.
- (h) Minimum equipment which a pharmacy shall at all times possess to fill prescriptions properly.
- (i) Procedures for dispensing of controlled substances to minimize dispensing based on fraudulent representations or invalid practitioner-patient relationships.
- person who is at least 18 years of age, or to a partnership comprised of at least one natural person and whose partners are all at least 18 years of age, or to a business entity that is properly registered with the Florida Secretary of State, if required by law, and has been issued a federal employer tax identification number; or to a government agency corporation that is registered pursuant to chapter 607 or chapter 617 whose officers, directors, and shareholders are at least 18 years of age. Permits issued to business entities shall be issued only to entities whose affiliated persons, members, partners, officers,

directors, agents, including persons required to be

fingerprinted under s. 465.022(3), are not less than 18 years of age.

- (3) Any person, or business entity, partnership, or corporation before engaging in the operation of a pharmacy shall file with the board a sworn application on forms provided by the department. For purposes of this section any person required to provide fingerprints under this subsection is an affiliated person within the meaning of s. 465.023(1).
- (a) An application for a pharmacy permit must include a set of fingerprints from each person having an ownership interest of 5 percent or greater and from any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant, including officers and members of the board of directors of an applicant that is a corporation. The applicant must provide payment in the application for the cost of state and national criminal history records checks.
- 1. For corporations having more than \$100 million of business taxable assets in this state, in lieu of these fingerprint requirements, the department shall require the prescription department manager or consultant pharmacist of record who will be directly involved in the management and operation of the pharmacy to submit a set of fingerprints.
- 2. A representative of a corporation described in subparagraph 1. satisfies the requirement to submit a set of his or her fingerprints if the fingerprints are on file with the department or the Agency for Health Care Administration, meet

the fingerprint specifications for submission by the Department of Law Enforcement, and are available to the department.

- (b) The department shall submit the fingerprints provided by the applicant to the Department of Law Enforcement for a state criminal history records check. The Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history records check.
- (c) In addition to those documents required by the department or board, each applicant with any financial or ownership interest greater than five percent in the subject of the application shall submit a signed affidavit disclosing any financial or ownership interest greater than five percent in any pharmacy permitted in the past five years, which pharmacy has closed voluntarily or involuntarily; has filed a voluntary relinquishment of its permit; has had its permit suspended or revoked; or has had an injunction issued against it by a regulatory agency. The affidavit must disclose the reason such entity was closed whether, voluntary or involuntary.
- (4) An application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships.

  The board must review the policies and procedures and may deny a permit if the policies and procedures are insufficient to reasonably prevent such dispensing.
- (5)(4) The department or board shall deny an application for a pharmacy permit if the applicant or an affiliated person,

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- partner, officer, director, or prescription department manager or consultant pharmacist of record, of the applicant has:
  - Obtained a permit by misrepresentation or fraud; (a)
- Attempted to procure, or has procured, a permit for (b) any other person by making, or causing to be made, any false representation;
- Been convicted of, or entered a plea of quilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy;
- Been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud;
- Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under: chapter 409, chapter 817, chapter 893, or a similar felony offense committed in another state or jurisdiction since July 1, 2009. Been terminated for cause, pursuant to the appeals procedures established by the state or Federal Government, from any state Medicaid program or the federal Medicare program, unless the applicant has been in good standing with a state Medicaid program or the federal Medicare program for the most recent 5 years and the termination occurred at least 20 years ago; or
- Has been convicted of, or entered a plea of quilty or (f) nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396 since July 1,2009.

- (g) Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5 years.
- (h) Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state

  Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5 years and the termination occurred at least 20 years before the date of the application.
- (i) Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.
- (j) For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall not approve or deny the application for a renewal of a license, certificate, or registration until the final resolution of the case.
- (k) Dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by

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board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

- (1) Has violated or failed to comply with any provision of this chapter; chapter 499, known as the "Florida Drug and Cosmetic Act"; chapter 893; 21 U.S.C. ss. 301-392, known as the "Federal Food Drug and Cosmetic Act"; 21 U.S.C. ss. 821 et seq, known as the Comprehensive Drug Abuse Prevention and Control Act; or any rules or regulations promulgated under any of them.
- (6)(5) After the application has been filed with the board and the permit fee provided in this section has been received, the board shall cause the application to be fully investigated, both as to the qualifications of the applicant and the prescription department manager or consultant pharmacist designated to be in charge and as to the premises and location described in the application.
- (7)(6) The Board of Pharmacy shall have the authority to determine whether a bona fide transfer of ownership is present and that the sale of a pharmacy is not being accomplished for the purpose of avoiding an administrative prosecution.
- (8) (7) Upon the completion of the investigation of an application, the board shall approve or <u>denydisapprove</u> the application. If approved, the permit shall be issued by the department.
- (9) (8) Permits issued by the department are not transferable. The permittee shall notify the department, on a form approved by the board, within 10 days of any change in prescription department manager or consultant pharmacist of record.

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- (10) (9) Permittees shall notify the department of the identity of the prescription department manager within 10 days of employment. The prescription department manager comply with the following requirements.
- (a) The prescription department manager must obtain and maintain all drug records required by any state or federal law to be obtained by a pharmacy, including but not limited to records required by or under chapters 465, 499, or 893. The prescription department manager must ensure the permittee's compliance with all rules promulgated thereunder as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.
- (c) The prescription department manager must ensure the security of the prescription department. The prescription department manager shall notify the board of any theft or significant loss of any controlled substances within one business day of discovery.
- (d) A registered pharmacist shall not serve as the prescription department manager in more than one location unless approved by the board.
- 1259 The board shall set the fees for the following:
  - (a) Initial permit fee not to exceed \$250.
- 1261 (b) Biennial permit renewal not to exceed \$250.
- 1262 (c) Delinquent fee not to exceed \$100.
  - (d) Change of location fee not to exceed \$100.
- 1264 (11) The board shall adopt rules that require keeping of

  1265 such records of prescription drugs as are necessary for the
- 1266 protection of public health, safety, and welfare.

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- (a) All required records documenting prescription drug distributions shall be readily available or immediately retrievable during an inspection by the department
- (b) The records must be maintained four (4) years from the creation or receipt of the record which ever date is later.
- (12) Permits issued by the department are not transferable.
  - (13) The board shall set the fees for the following:
  - (a) Initial permit fee not to exceed \$250.
  - (b) Biennial permit renewal not to exceed \$250.
  - (c) Delinquent fee not to exceed \$100.
- (d) Change of location or change of ownership fee not to exceed \$250.

Section 14. Paragraph (b) of subsection (1) of section 465.0276, Florida Statutes, is amended to read:

465.0276 Dispensing practitioner.-

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dispense a controlled substance listed in Schedule II or
Schedule III as provided in s. 893.03. A practitioner registered under this section may not dispense more than a 72 hour supply of a controlled substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03 for any patient who pays for the medication by cash, check, or credit card in a clinic registered under s. 458.3265 or s. 459.0137. A practitioner who violates this paragraph commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. This paragraph does not apply to:

- 1. A practitioner who dispenses medication to a workers compensation patient pursuant to chapter 440.
- 2. A practitioner who dispenses medication to an insured patient who pays by cash, check, or credit card to cover any applicable copayment or deductible.
- 1.3. The dispensing of complimentary packages of medicinal drugs to the practitioner's own patients in the regular course of her or his practice without the payment of a fee or remuneration of any kind, whether direct or indirect, as provided in subsection (5).
- 2. The dispensing of controlled substances in the health care system of the Department of Corrections.
- Section 15. Subsections (16) and (17) are added to section 499.0051, Florida Statutes, to read:
  - 499.0051 Criminal acts.-
- (16) FALSE REPORT.— Any person who submits a report required by s. 499.0121(14) knowing that such report contains a false statement shall be guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.
- distributor who distributes controlled substances in violation of s. 499.0121(14) this provision shall be guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In addition to any other fine that may be imposed, a wholesale distributor convicted of violating this provision may be sentenced to pay a fine that does not exceed three times the gross monetary value gained from such violation,

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- plus court costs and the costs of investigation and prosecution, reasonably incurred.
- Section 16. Paragraph (o) is added to subsection (8) of section 499.012, Florida Statutes, to read:
  - 499.012 Permit application requirements.
- (8) An application for a permit or to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor submitted to the department must include:
- (o) Documentation of the credentialing policies and procedures required by s. 499.0121(14).
- Section 17. Subsections (14) and (15) are added to section 499.0121, Florida Statutes, to read:
- 499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.
- (14) DISTRIBUTION REPORTING.—Each wholesale distributor shall submit a report to the department of its receipts and distributions of controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V as provided in s. 893.03. Wholesale distributor facilities located within this state shall report all transactions involving controlled substances and wholesale distributor facilities located outside this state shall report all distributions to entities located in

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L350	Amendment No. 1 this state. If the wholesale distributor did not have any
L351	controlled substance distributions for the month, a report shall
L352	be sent indicating no distributions occurred in the period. The
L353	report shall be submitted monthly by the 20th of the next month,
1354	in the electronic format used for controlled substance reporting
1355	to the Automation of Reports and Consolidated Orders System
1356	division of the federal Drug Enforcement Administration.
1357	Submission of electronic data must be made in a secured web
1358	environment that allows for manual or automated transmission.
1359	Upon successful transmission, an acknowledgement page must be
1360	displayed to confirm receipt. The report must contain the
1361	following information:
1362	(a) The federal Drug Enforcement Administration
1363	registration number of the wholesale distributing location.
1364	(b) The federal Drug Enforcement Administration
1365	registration number of the entity to which the drugs are
1366	distributed or from which the drugs are received.
1367	(c) The transaction code that indicates the type of
1368	transaction.
1369	(d) The National Drug Code identifier of the product and
1370	the quantity distributed or received.
1371	(e) The Drug Enforcement Administration Form 222 number or
1372	Controlled Substance Ordering System Identifier on all schedule
1373	II transactions.
1374	(f) The date of the transaction.
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1376	The department must share the reported data with the Department

of Law Enforcement and local law enforcement agencies upon

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request, and must monitor purchasing to identify purchasing levels that are inconsistent with the purchasing entity's clinical needs. The Department of Law Enforcement shall investigate purchases at levels that are inconsistent with the purchasing entity's clinical needs to determine whether violations of chapter 893 have occurred.

# (15) DUE DILIGENCE OF PURCHASERS.-

- (a) Each wholesale distributor must establish and maintain policies and procedures to credential physicians licensed under chapter 459, chapter 459, chapter 461, or chapter 466 and pharmacies that would purchase or otherwise receive from the wholesale distributor controlled substances listed in Schedule III or Schedule III as provided in s. 893.03. The wholesale distributor shall maintain records of such credentialing and make the records available to the department upon request. Such credentialing must, at a minimum, include:
- 1. A determination of the clinical nature of the receiving entity, including any specialty practice area.
- 2. A review of the receiving entity's history of Schedule
  II and Schedule III controlled substance purchasing from the
  wholesale distributor.
- 3. A determination that the receiving entity's Schedule II and Schedule III controlled substance purchasing history, if any, is consistent with and reasonable for that entity's clinical business needs.
- 4. Documentation of a level 2 background screening
  pursuant to chapter 435 through the department on any person who
  owns a controlling interest in or, directly or indirectly,

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manages, oversees, or controls the operation of the entity, including officers and members of the board of directors of an entity that is a corporation. This requirement does not apply to publicly traded entities or entities having more than \$100 million of business taxable assets in this state. For such entities, wholesale distributors must require current documentation of all state and federal licenses and permits.

Wholesale distributors must take reasonable measures (b) to identify their customers, understand the normal and expected transactions conducted by those customers, and identify thos transactions which are suspicious in nature. Wholesale distributors must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. Wholesale distributors must assess orders for greater than 5,000 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. In making such assessments, wholesale distributors may consider the purchasing entity's clinical business needs, location and population served, in addition to other factors established in their policies and procedures. Wholesale distributors must report to the department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. For each reported transaction which is completed, wholesale distributors must document the basis for determining the transaction was reasonable.

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- (c) Wholesale distributors may not distribute controlled substances to an entity if any criminal history record check for any person associated with that entity shows the person has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction related to controlled substances, the practice of pharmacy, or the dispensing of medicinal drugs.
- (d) Wholesale distributors may not distribute more than 5,000 unit doses each of hydrocodone, morphine, oxycodone, methadone, or any one benzodiazepine, or any derivative, precursor or component of these drugs, to a retail pharmacy in any given month.

Section 18. Paragraphs (o) and (p) are added to subsection (1) of section 499.05, Florida Statutes, to read:

499.05 Rules.-

- (1) The department shall adopt rules to implement and enforce this part with respect to:
- (o) Wholesale distributor reporting requirements of s. 499.0121(14).
  - (p) Wholesale distributor credentialing and distribution requirements of s. 499.0121(15).
- Section 19. Subsections (8) and (9) are added to section 499.067, Florida Statutes, to read:
- 1457 499.067 Denial, suspension, or revocation of permit, 1458 certification, or registration.—
- 1459 (8) The department shall deny, suspend, or revoke a permit

  1460 if it finds the permittee has not complied with the

  1461 credentialing requirements of s. 499.0121(15).

 (9) The department shall deny, suspend, or revoke a permit if it finds the permittee has not complied with the reporting requirements of, or knowingly made a false statement in a report required by, s. 499.0121(14).

Section 20. Paragraph (f) is added to subsection (3) of section 810.02, Florida Statutes, to read:

810.02 Burglary.-

- (3) Burglary is a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if, in the course of committing the offense, the offender does not make an assault or battery and is not and does not become armed with a dangerous weapon or explosive, and the offender enters or remains in a:
- (f) Structure or conveyance when the offense intended to be committed therein is theft of a controlled substance as defined in s. 893.02. Notwithstanding any other law, separate judgments and sentences for burglary with the intent to commit theft of a controlled substance under this paragraph and for any applicable possession of controlled substance offense under s. 893.13 or trafficking in controlled substance offense under s. 893.135 may be imposed when all such offenses involve the same amount or amounts of a controlled substance.

However, if the burglary is committed within a county that is subject to a state of emergency declared by the Governor under chapter 252 after the declaration of emergency is made and the perpetration of the burglary is facilitated by conditions arising from the emergency, the burglary is a felony of the

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first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. As used in this subsection, the term "conditions arising from the emergency" means civil unrest, power outages, curfews, voluntary or mandatory evacuations, or a reduction in the presence of or response time for first responders or homeland security personnel. A person arrested for committing a burglary within a county that is subject to such a state of emergency may not be released until the person appears before a committing magistrate at a first appearance hearing. For purposes of sentencing under chapter 921, a felony offense that is reclassified under this subsection is ranked one level above the ranking under s. 921.0022 or s. 921.0023 of the offense committed.

Section 21. Paragraph (c) of subsection (2) of section 812.014, Florida Statutes, is amended to read:

812.014 Theft.-

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- (c) It is grand theft of the third degree and a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if the property stolen is:
  - 1. Valued at \$300 or more, but less than \$5,000.
  - 2. Valued at \$5,000 or more, but less than \$10,000.
  - 3. Valued at \$10,000 or more, but less than \$20,000.
  - 4. A will, codicil, or other testamentary instrument.
  - A firearm.
  - 6. A motor vehicle, except as provided in paragraph (a).
- 7. Any commercially farmed animal, including any animal of the equine, bovine, or swine class, or other grazing animal, and

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including aquaculture species raised at a certified aquaculture facility. If the property stolen is aquaculture species raised at a certified aquaculture facility, then a \$10,000 fine shall be imposed.

- 8. Any fire extinguisher.
- 9. Any amount of citrus fruit consisting of 2,000 or more individual/pieces of fruit.
- 10. Taken from a designated construction site identified by the posting of a sign as provided for in s. 810.09(2)(d).
  - 11. Any stop sign.
  - 12. Anhydrous ammonia.
- 13. Any amount of a controlled substance as defined in s. 893.02. Notwithstanding any other law, separate judgments and sentences for theft of a controlled substance under this subparagraph and for any applicable possession of controlled substance offense under s. 893.13 or trafficking in controlled substance offense under s. 893.135 may be imposed when all such offenses involve the same amount or amounts of a controlled substance.

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However, if the property is stolen within a county that is subject to a state of emergency declared by the Governor under chapter 252, the property is stolen after the declaration of emergency is made, and the perpetration of the theft is facilitated by conditions arising from the emergency, the offender commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if the property is valued at \$5,000 or more, but less than \$10,000, as

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provided under subparagraph 2., or if the property is valued at \$10,000 or more, but less than \$20,000, as provided under subparagraph 3. As used in this paragraph, the term "conditions arising from the emergency" means civil unrest, power outages, curfews, voluntary or mandatory evacuations, or a reduction in the presence of or the response time for first responders or homeland security personnel. For purposes of sentencing under chapter 921, a felony offense that is reclassified under this paragraph is ranked one level above the ranking under s. 921.0022 or s. 921.0023 of the offense committed.

Section 22. Section 893.055, Florida Statutes, is amended to read:

893.055 Prescription drug monitoring program.-

(2) (a) By December 1, 2010, tThe department shall design and establish a comprehensive electronic database system that has controlled substance prescriptions provided to it and that provides prescription information to a patient's health care practitioner and pharmacist who inform the department that they wish the patient advisory report provided to them. Otherwise, the patient advisory report will not be sent to the practitioner, pharmacy, or pharmacist. The system shall be designed to provide information regarding dispensed prescriptions of controlled substances and shall not infringe upon the legitimate prescribing or dispensing of a controlled substance by a prescriber or dispenser acting in good faith and in the course of professional practice. The system shall be consistent with standards of the American Society for Automation in Pharmacy (ASAP). The electronic system shall also comply with

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the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to protected health information (PHI), electronic protected health information (EPHI), and all other relevant state and federal privacy and security laws and regulations. The department shall establish policies and procedures as appropriate regarding the reporting, accessing the database, evaluation, management, development, implementation, operation, storage, and security of information within the system. The reporting of prescribed controlled substances shall include a dispensing transaction with a dispenser pursuant to chapter 465 or through a dispensing transaction to an individual or address in this state with a pharmacy that is not located in this state but that is otherwise subject to the jurisdiction of this state as to that dispensing transaction. The reporting of patient advisory reports refers only to reports to patients, pharmacies, and practitioners. Separate reports that contain patient prescription history information and that are not patient advisory reports are provided to persons and entities as authorized in paragraphs (7)(b) and (c) and s. 893.0551.

(b) The department, when the direct support organization receives at least \$20,000 in nonstate moneys or the state receives at least \$20,000 in federal grants for the prescription drug monitoring program, and in consultation with the Office of Drug Control, shall adopt rules as necessary concerning the reporting, accessing the database, evaluation, management, development, implementation, operation, security, and storage of information within the system, including rules for when patient advisory reports are provided to pharmacies and prescribers. The

patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The department shall work with the professional health care licensure boards, such as the Board of Medicine, the Board of Osteopathic Medicine, and the Board of Pharmacy; other appropriate organizations, such as the Florida Pharmacy Association, the Office of Drug Control, the Florida Medical Association, the Florida Retail Federation, and the Florida Osteopathic Medical Association, including those relating to pain management; and the Attorney General, the Department of Law Enforcement, and the Agency for Health Care Administration to develop rules appropriate for the prescription drug monitoring program.

- (c) All dispensers and prescribers subject to these reporting requirements shall be notified by the department of the implementation date for such reporting requirements.
- (d) The program manager shall work with professional health care licensure boards and the stakeholders listed in paragraph (b) to develop rules appropriate for identifying indicators of controlled substance abuse.
- (3) The pharmacy dispensing the controlled substance and each prescriber who directly dispenses a controlled substance shall submit to the electronic system, by a procedure and in a format established by the department and consistent with an ASAP-approved format, the following information for inclusion in the database:
- (a) The name of the prescribing practitioner, the practitioner's federal Drug Enforcement Administration registration number, the practitioner's National Provider

Identification (NPI) or other appropriate identifier, and the date of the prescription.

- (b) The date the prescription was filled and the method of payment, such as cash by an individual, insurance coverage through a third party, or Medicaid payment. This paragraph does not authorize the department to include individual credit card numbers or other account numbers in the database.
- (c) The full name, address, and date of birth of the person for whom the prescription was written.
- (d) The name, national drug code, quantity, and strength of the controlled substance dispensed.
- (e) The full name, federal Drug Enforcement Administration registration number, and address of the pharmacy or other location from which the controlled substance was dispensed. If the controlled substance was dispensed by a practitioner other than a pharmacist, the practitioner's full name, federal Drug Enforcement Administration registration number, and address.
- (f) The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's National Provider Identification (NPI).
- (g) Other appropriate identifying information as determined by department rule.
- (4) Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but not more than <u>715</u> days after the date the controlled substance is dispensed unless an extension is approved by the department for cause as determined by rule. A dispenser must

meet the reporting requirements of this section by providing the required information concerning each controlled substance that it dispensed in a department-approved, secure methodology and format. Such approved formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail.

- (5) When the following acts of dispensing or administering occur, the following are exempt from reporting under this section for that specific act of dispensing or administration:
- (a) A health care practitioner when administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.
- (b) A pharmacist or health care practitioner when administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.
- (c) A practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections.
- (d) A practitioner when administering a controlled substance in the emergency room of a licensed hospital.
- (e) A health care practitioner when administering or dispensing a controlled substance to a person under the age of 16.

- (f) A pharmacist or a dispensing practitioner when dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient.
- (6) The department may establish when to suspend and when to resume reporting information during a state-declared or nationally declared disaster.
- (7) (a) A practitioner or pharmacist who dispenses a controlled substance must submit the information required by this section in an electronic or other method in an ASAP format approved by rule of the department unless otherwise provided in this section. The cost to the dispenser in submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, electronic media, regular electronic mail, and facsimile charges.
- (b) A pharmacy, prescriber, or dispenser shall have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. Other access to the program's database shall be limited to the program's manager and to the designated program and support staff, who may act only at the direction of the program manager or, in the absence of the program manager, as authorized. Access by the program manager or such designated staff is for prescription drug program management only or for management of the program's database and

- its system in support of the requirements of this section and in furtherance of the prescription drug monitoring program.

  Confidential and exempt information in the database shall be released only as provided in paragraph (c) and s. 893.0551.
- (c) The following entities shall not be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that is confidential and exempt under s. 893.0551. Prior to release, the request shall be verified as authentic and authorized with the requesting organization by the program manager, the program manager's program and support staff, or as determined in rules by the department as being authentic and as having been authorized by the requesting entity:
- 1. The department or its relevant health care regulatory boards responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances and who are involved in a specific controlled substance investigation involving a designated person for one or more prescribed controlled substances.
- 2. The Attorney General for Medicaid fraud cases involving prescribed controlled substances.
- 3. A law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances.

4. A patient or the legal guardian or designated health care surrogate of an incapacitated patient as described in s. 893.0551 who, for the purpose of verifying the accuracy of the database information, submits a written and notarized request that includes the patient's full name, address, and date of birth, and includes the same information if the legal guardian or health care surrogate submits the request. The request shall be validated by the department to verify the identity of the patient and the legal guardian or health care surrogate, if the patient's legal guardian or health care surrogate is the requestor. Such verification is also required for any request to change a patient's prescription history or other information related to his or her information in the electronic database.

Information in the database for the electronic prescription drug monitoring system is not discoverable or admissible in any civil or administrative action, except in an investigation and disciplinary proceeding by the department or the appropriate regulatory board.

(d) Department staff The following entities shall not be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that contains no identifying information of any patient, physician, health care practitioner, prescriber, or dispenser and that is not confidential and exempt, ÷

- 1. Department staff for the purpose of calculating performance measures pursuant to subsection (8).
- 2. The Program Implementation and Oversight Task Force for its reporting to the Governor, the President of the Senate, and the Speaker of the House of Representatives regarding the prescription drug monitoring program. This subparagraph expires July 1, 2012.
- (e) All transmissions of data required by this section must comply with relevant state and federal privacy and security laws and regulations. However, any authorized agency or person under s. 893.0551 receiving such information as allowed by s. 893.0551 may maintain the information received for up to 24 months before purging it from his or her records or maintain it for longer than 24 months if the information is pertinent to ongoing health care or an active law enforcement investigation or prosecution.
- (f) The program manager, upon determining a pattern consistent with the rules established under paragraph (2)(d) and having cause to believe a violation of s. 893.13(7)(a)8., (8)(a), or (8)(b) has occurred, may provide relevant information to the applicable law enforcement agency.
- (8) To assist in fulfilling program responsibilities, performance measures shall be reported annually to the Governor, the President of the Senate, and the Speaker of the House of Representatives by the department each December 1, beginning in 2011. Data that does not contain patient, physician, health care practitioner, prescriber, or dispenser identifying information may be requested during the year by department employees so that

the department may undertake public health care and safety initiatives that take advantage of observed trends. Performance measures may include, but are not limited to, efforts to achieve the following outcomes:

- (a) Reduction of the rate of inappropriate use of prescription drugs through department education and safety efforts.
- (b) Reduction of the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit.
- (c) Increased coordination among partners participating in the prescription drug monitoring program.
- (d) Involvement of stakeholders in achieving improved patient health care and safety and reduction of prescription drug abuse and prescription drug diversion.
- (9) Any person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.
- (10) All costs incurred by the department in administering the prescription drug monitoring program shall be funded through federal grants or private funding applied for or received by the state. The department may not commit funds for the monitoring program without ensuring funding is available. The prescription drug monitoring program and the implementation thereof are contingent upon receipt of the nonstate funding. The department and state government shall cooperate with the direct-support organization established pursuant to subsection (11) in seeking

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federal grant funds, other nonstate grant funds, gifts, donations, or other private moneys for the department so long as the costs of doing so are not considered material. Nonmaterial costs for this purpose include, but are not limited to, the costs of mailing and personnel assigned to research or apply for a grant. Notwithstanding the exemptions to competitive-solicitation requirements under s. 287.057(3)(f), the department shall comply with the competitive-solicitation requirements under s. 287.057 for the procurement of any goods or services required by this section. Funds provided, directly or indirectly, by prescription drug manufacturers may not be used to implement the program.

- (11) The Office of Drug Control, in coordination with the department, may establish a direct-support organization that has a board consisting of at least five members to provide assistance, funding, and promotional support for the activities authorized for the prescription drug monitoring program.
- (a) As used in this subsection, the term "direct-support organization" means an organization that is:
- 1. A Florida corporation not for profit incorporated under chapter 617, exempted from filing fees, and approved by the Department of State.
- 2. Organized and operated to conduct programs and activities; raise funds; request and receive grants, gifts, and bequests of money; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or provide funding to or for the direct or indirect benefit of the

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- department in the furtherance of the prescription drug monitoring program.
- The direct-support organization is not considered a lobbying firm within the meaning of s. 11.045.
- The state surgeon general director of the Office of Drug Control shall appoint a board of directors for the directsupport organization. The director may designate employees of the Office of Drug Control, state employees other than state employees from the department, and any other nonstate employees as appropriate, to serve on the board. Members of the board shall serve at the pleasure of the director of the state surgeon generalOffice of Drug Control. The state surgeon generaldirector shall provide quidance to members of the board to ensure that moneys received by the direct-support organization are not received from inappropriate sources. Inappropriate sources include, but are not limited to, donors, grantors, persons, or organizations that may monetarily or substantively benefit from the purchase of goods or services by the department in furtherance of the prescription drug monitoring program.
- The direct-support organization shall operate under written contract with the departmentOffice of Drug Control. The contract must, at a minimum, provide for:
- Approval of the articles of incorporation and bylaws of the direct-support organization by the departmentOffice of Drug Control.
- Submission of an annual budget for the approval of the 2. departmentOffice of Drug Control.

- 3. Certification by the <u>departmentOffice of Drug Control</u> in consultation with the department that the direct-support organization is complying with the terms of the contract in a manner consistent with and in furtherance of the goals and purposes of the prescription drug monitoring program and in the best interests of the state. Such certification must be made annually and reported in the official minutes of a meeting of the direct-support organization.
- 4. The reversion, without penalty, to the Office of Drug Control, or to the state if the Office of Drug Control ceases to exist, of all moneys and property held in trust by the direct-support organization for the benefit of the prescription drug monitoring program if the direct-support organization ceases to exist or if the contract is terminated.
- 5. The fiscal year of the direct-support organization, which must begin July 1 of each year and end June 30 of the following year.
- 6. The disclosure of the material provisions of the contract to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising publications, and an explanation to such donors of the distinction between the <u>departmentOffice of Drug Control</u> and the direct-support organization.
- 7. The direct-support organization's collecting, expending, and providing of funds to the department for the development, implementation, and operation of the prescription drug monitoring program as described in this section and s. 2, chapter 2009-198, Laws of Florida, as long as the task force is

authorized. The direct-support organization may collect and expend funds to be used for the functions of the direct-support organization's board of directors, as necessary and approved by the department director of the Office of Drug Control. In addition, the direct-support organization may collect and provide funding to the department in furtherance of the prescription drug monitoring program by:

- a. Establishing and administering the prescription drug monitoring program's electronic database, including hardware and software.
- b. Conducting studies on the efficiency and effectiveness of the program to include feasibility studies as described in subsection (13).
- c. Providing funds for future enhancements of the program within the intent of this section.
- d. Providing user training of the prescription drug monitoring program, including distribution of materials to promote public awareness and education and conducting workshops or other meetings, for health care practitioners, pharmacists, and others as appropriate.
  - e. Providing funds for travel expenses.
- f. Providing funds for administrative costs, including personnel, audits, facilities, and equipment.
- g. Fulfilling all other requirements necessary to implement and operate the program as outlined in this section.
- (e) The activities of the direct-support organization must be consistent with the goals and mission of the <u>departmentOffice</u> of <u>Drug Control</u>, as determined by the <u>office in consultation</u>

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with the department, and in the best interests of the state. The direct-support organization must obtain a written approval from the <u>department director of the Office of Drug Control</u> for any activities in support of the prescription drug monitoring program before undertaking those activities.

- (f) The Office of Drug Control, in consultation with the department, may permit, without charge, appropriate use of administrative services, property, and facilities of the Office of Drug Control and the department by the direct-support organization, subject to this section. The use must be directly in keeping with the approved purposes of the direct-support organization and may not be made at times or places that would unreasonably interfere with opportunities for the public to use such facilities for established purposes. Any moneys received from rentals of facilities and properties managed by the Office of Drug Control and the department may be held by the Office of Drug Control or in a separate depository account in the name of the direct-support organization and subject to the provisions of the letter of agreement with the departmentOffice of Drug Control. The letter of agreement must provide that any funds held in the separate depository account in the name of the direct-support organization must revert to the departmentOffice of Drug Control if the direct-support organization is no longer approved by the departmentOffice of Drug Control to operate in the best interests of the state.
- (g) The Office of Drug Control, in consultation with the department, may adopt rules under s. 120.54 to govern the use of

 administrative services, property, or facilities of the department or office by the direct-support organization.

- (h) The <u>departmentOffice of Drug Control</u> may not permit the use of any administrative services, property, or facilities of the state by a direct-support organization if that organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, gender, age, or national origin.
- (i) The direct-support organization shall provide for an independent annual financial audit in accordance with s.

  215.981. Copies of the audit shall be provided to the departmentOffice of Drug Control and the Office of Policy and Budget in the Executive Office of the Governor.
- (j) The direct-support organization may not exercise any power under s. 617.0302(12) or (16).
- (12) A prescriber or dispenser may have access to the information under this section which relates to a patient of that prescriber or dispenser as needed for the purpose of reviewing the patient's controlled drug prescription history. A prescriber or dispenser acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug monitoring program. This subsection does not create a private cause of action, and a person may not recover damages against a prescriber or dispenser authorized to access information under this subsection for accessing or failing to access such information.

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- To the extent that funding is provided for such purpose through federal or private grants or gifts and other types of available moneys, the department, in collaboration with the Office of Drug Control, shall study the feasibility of enhancing the prescription drug monitoring program for the purposes of public health initiatives and statistical reporting that respects the privacy of the patient, the prescriber, and the dispenser. Such a study shall be conducted in order to further improve the quality of health care services and safety by improving the prescribing and dispensing practices for prescription drugs, taking advantage of advances in technology, reducing duplicative prescriptions and the overprescribing of prescription drugs, and reducing drug abuse. The requirements of the National All Schedules Prescription Electronic Reporting (NASPER) Act are authorized in order to apply for federal NASPER funding. In addition, the direct-support organization shall provide funding for the department, in collaboration with the Office of Drug Control, to conduct training for health care practitioners and other appropriate persons in using the monitoring program to support the program enhancements.
- (14) A pharmacist, pharmacy, or dispensing health care practitioner or his or her agent, before releasing a controlled substance to any person not known to such dispenser, shall require the person purchasing, receiving, or otherwise acquiring the controlled substance to present valid photographic identification or other verification of his or her identity to the dispenser. If the person does not have proper identification, the dispenser may verify the validity of the

prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system will be considered to be proper identification. This subsection does not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted. As used in this subsection, the term "proper identification" means an identification that is issued by a state or the Federal Government containing the person's photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

- (15) The Agency for Health Care Administration shall continue the promotion of electronic prescribing by health care practitioners, health care facilities, and pharmacies under s. 408.0611.
- (16) By October 1, 2010, the department shall adopt rules pursuant to ss. 120.536(1) and 120.54 to administer the provisions of this section, which shall include as necessary the reporting, accessing, evaluation, management, development, implementation, operation, and storage of information within the monitoring program's system.
- Section 23. Section 893.065, Florida Statutes, is amended to read:
  - 893.065 Counterfeit-resistant prescription blanks for controlled substances listed in Schedule II, Schedule III, or Schedule IV.—The Department of Health shall develop and adopt by rule the form and content for a counterfeit-resistant

prescription blank which <u>mustmay</u> be used by practitioners for the purpose of prescribing a controlled substance listed in Schedule II, Schedule III, <u>or</u> Schedule IV <u>or Schedule V pursuant to s. 456.42</u>. The Department of Health may require the prescription blanks to be printed on distinctive, watermarked paper and to bear the preprinted name, address, and category of professional licensure of the practitioner and that practitioner's federal registry number for controlled substances. The prescription blanks may not be transferred.

Section 24. Subsections (4) and (5) of section 893.07, Florida Statutes, are amended to read:

893.07 Records.-

- (4) Every inventory or record required by this chapter, including prescription records, shall be maintained:
- (a) Separately from all other records of the registrant, or
- (b) Alternatively, in the case of Schedule III, IV, or V controlled substances, in such form that information required by this chapter is readily retrievable from the ordinary business records of the registrant.

In either case, the records described in this subsection shall be kept and made available for a period of at least 2 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled substances. Law enforcement officers are not required to obtain a subpoena, court order, or search warrant in order to obtain access to or copies of such records.

- (5) Each person described in subsection (1) shall:
- (a) Maintain a record which shall contain a detailed list of controlled substances lost, destroyed, or stolen, if any; the kind and quantity of such controlled substances; and the date of the discovering of such loss, destruction, or theft.
- (b) In the event of the discovery of the theft or loss of controlled substances, report such theft or loss to the sheriff of that county within 24 hours after its discovery. A person who fails to report a theft or loss of a substance listed in s.

  893.03(3), (4), or (5) within 24 hours after discovery as required in this paragraph commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. A person who fails to report a theft or loss of a substance listed in s. 893.03(2) within 24 hours after discovery as required in this paragraph commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

Section 25. Section 2 of chapter 2009-198, Laws of Florida, is repealed.

Section 26.

- (1) BUY-BACK PROGRAM.—Within 10 days after the effective date of this act, each physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466, Florida Statutes, shall ensure that undispensed inventory of controlled substances listed in Schedule II or Schedule III as provided in s. 893.03, Florida Statutes, purchased under the physician's Drug Enforcement Administration number for dispensing is:
- (a) Returned to the wholesale distributor, as defined in s. 499.003, Florida Statutes, which distributed them; or

(b) Turned in to local law enforcement agencies and abandoned.

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- Wholesale distributors shall buy back the undispensed inventory of controlled substances listed in Schedule II or Schedule III as provided in s. 893.03, Florida Statutes, at the purchase price paid by the physician, physician practice, clinic, or other paying entity. Each wholesale distributor shall submit a report of its activities under this section to the Department of Health by August 1, 2011. The report shall include the following information:
  - 1. The name and address of the returning entity.
- 2. The Florida license, registration, or permit number and Drug Enforcement Administration number of the entity that originally ordered the drugs.
  - 3. The drug name and number of unit doses returned.
  - 4. The date of return.
  - (2) PUBLIC HEALTH EMERGENCY.-
  - (a) The Legislature finds that:
- 1. Prescription drug overdose has been declared a public health epidemic by the United States Centers for Disease Control and Prevention.
- 2. Prescription drug abuse results in an average of 7 deaths in this state each day.
- 3. Physicians in this state purchased over 85 percent of the oxycodone purchased by all practitioners in the United States in 2006.

(2011)

## Amendment No. 1

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- Physicians in this state purchased over 93 percent of the methadone purchased by all practitioners in the United States in 2006.
- 5. Some physicians in this state dispense medically unjustifiable amounts of controlled substances to addicts and people who intend to illegally sell the drugs.
- 6. Physicians in this state who have purchased large quantities of controlled substances may have significant inventory on the effective date of this act.
- 7. On the effective date of this act, the only legal method for a dispensing practitioner to sell or otherwise transfer controlled substances listed in Schedule II or Schedule III as provided in s. 893.03, Florida Statutes, purchased for dispensing is through the buy-back procedure or abandonment procedures of subsection (1).
- It is likely that the same physicians who purchase and 8. dispense medically unjustifiable amounts of drugs will not legally dispose of remaining inventory.
- 9. The actions of such dispensing practitioners may result in substantial injury to the public health.
- Immediately on the effective date of this act, the State Health Officer shall declare a public health emergency pursuant to s. 381.00315, Florida Statutes. Pursuant to that declaration, the Department of Health, the Attorney General, the Department of Law Enforcement, and local law enforcement agencies shall take the following actions:
- Within 2 days after the effective date of this act, in consultation with wholesale distributors as defined in s.

# Bill No. CS/HB 7095 (2011)

	Amendment No. 1
2155	499.003, Florida Statutes, the Department of Health shall
2156	identify dispensing practitioners that purchased more than an
2157	average of 2,000 unit doses of controlled substances listed in
2158	Schedule II or Schedule III as provided in s. 893.03, Florida
2159	Statutes, per month in the previous 6 months, and shall identify
2160	the dispensing practitioners in that group who pose the greatest
2161	threat to the public health based on an assessment of:

- a. The risk of noncompliance with subsection (1).
- b. Purchase amounts.
- c. Manner of medical practice.
- d. Any other factor set by the State Health Officer.

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- The Attorney General shall consult and coordinate with federal law enforcement agencies. The Department of Law Enforcement shall coordinate the efforts of local law enforcement agencies.
- 2. On the 3rd day after the effective date of this act, the Department of Law Enforcement or local law enforcement agencies shall enter the business premises of the dispensing practitioners identified as posing the greatest threat to public health and quarantine the inventory of controlled substances listed in Schedule II or Schedule III as provided in s. 893.03, Florida Statutes, of such dispensing practitioners on site.
- 3. The Department of Law Enforcement or local law enforcement agencies shall ensure the security of such inventory 24 hours a day through the 10th day after the effective date of this act or until the inventory is validly transferred pursuant to subsection (1), whichever is earlier.

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- 4. On the 11th day after the effective date of this act, any remaining inventory of controlled substances listed in Schedule II or Schedule III as provided in s. 893.03, Florida Statutes, purchased for dispensing by practitioners is deemed contraband under s. 893.12, Florida Statutes. The Department of Law Enforcement or local law enforcement agencies shall seize the inventory and comply with the provisions of s. 893.12, Florida Statutes, to destroy it.
- (c) In order to implement the provisions of this section, the sum of \$3 million of nonrecurring funds from the General Revenue Fund is appropriated to the Department of Law Enforcement for the 2010-2011 fiscal year. The Department of Law Enforcement shall expend the appropriation by reimbursing local law enforcement agencies for the overtime-hour costs associated with securing the quarantined controlled substance inventory as provided in paragraph (b) and activities related to investigation and prosecution of crimes related to prescribed controlled substances. If requests for reimbursement exceed the amount appropriated, the reimbursements shall be provated by the hours of overtime per requesting agency at a maximum of one law enforcement officer per quarantine site.
  - (3) This section is repealed January 1, 2013.

Section 27. Except as otherwise expressly provided in this act, this act shall take effect July 1, 2011.

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### TITLE AMENDMENT

Remove the entire title and insert: amending s. 456.072, F.S.; making failure to comply with the requirements of s. 456.44 grounds for disciplinary action; providing mandatory administrative penalties for certain violations related to prescribing; amending s. 456.42, F.S.; requiring prescriptions for controlled substances to be written on a counterfeit-resistant pad produced by an approved vendor or electronically prescribed; creating s. 456.44, F.S. related to controlled substance prescribing; creating definitions; requiring certain physicians to register with the appropriate board to prescribe controlled substances for the treatment of chronic, non-cancer pain; providing an effective date; requiring a fee; requiring registered physicians to meet certain standards of practice; requiring a physical exam; requiring a written protocol; requiring an assessment of risk for aberrant behavior; requiring a treatment plan; requiring specified informed consent; requiring consultation and referral in certain circumstances; requiring medical records meeting certain criteria; requiring a prescription log; providing an exemption for physicians meeting certain criteria; amending s. 458.3265, F.S., relating to regulation of pain-management clinics and medical doctors; amending the definition of a pain-management clinic; providing an exemption from registration for clinics owned and operated by physicians meeting certain criteria; requiring physicians in pain-management clinics to ensure compliance with certain requirements; imposing facility and physical operations requirements; imposing infection control

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Amendment No. 1 requirements; imposing health and safety requirements; imposing quality assurance requirements; imposing data collection and reporting requirements; amending rulemaking authority; making conforming changes; providing for expiration of the section on January 1, 2016; amending s. 458.327, F.S.; providing that dispensing certain controlled substances in violation of specified provisions is a third-degree felony; amending s. 458.331, F.S.; providing that dispensing certain controlled substances in violation of specified provisions is grounds for disciplinary action; amending s. 459.0137, F.S., relating to regulation of pain-management clinics and osteopathic physicians; amending the definition of a pain-management clinic; providing an exemption from registration for clinics owned and operated by physicians meeting certain criteria; requiring physicians in pain-management clinics to ensure compliance with certain requirements; imposing facility and physical operations requirements; imposing infection control requirements; imposing health and safety requirements; imposing quality assurance requirements; imposing data collection and reporting requirements; amending rulemaking authority; making conforming changes; providing for expiration of the section on January 1, 2016; amending s. 459.013, F.S., relating to penalties for violations; providing that dispensing certain controlled substances in violation of specified provisions is a thirddegree felony; amending s. 459.015, F.S.; providing that dispensing certain controlled substances in violation of specified provisions is ground for disciplinary action; amending s. 465.015, F.S.; requiring a pharmacist to report to the

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sheriff within a specified period any instance in which a person fraudulently obtained or attempted to fraudulently obtain a controlled substance; providing criminal penalties; providing requirements for reports; amending s. 456.016, F.S.; providing additional grounds for denial of or disciplinary action against a pharmacist license; amending s. 465.018, F.S.; providing grounds for permit denial or discipline; requiring applicants to pay or make arrangements to pay amounts owed to the Department of Health; requiring an inspection; limiting the community pharmacies that may dispense controlled substances; providing an effective date; providing exemptions; providing an effective date; requiring permittees to maintain certain records; amending s. 465.022, F.S.; requiring the Department of Health to adopt rules related to procedures for dispensing controlled substances; providing requirements for the issuance of a pharmacy permit; requiring disclosure of financial interests; requiring submission of policies and procedures and providing for grounds for permit denial based on them; requiring the Department of Health to deny a permit to applicants under certain circumstances; requiring permittees to provide notice of certain management changes; requiring prescription department managers to meet certain criteria; imposing duties on prescription department managers; limiting the number of locations a prescription department manager may manage; requiring the board to adopt rules related to record-keeping; amending s. 465.0276, F.S.; prohibiting registered dispensing practitioners from dispensing certain controlled substances; providing an exception; repealing a 72-hour supply limit on

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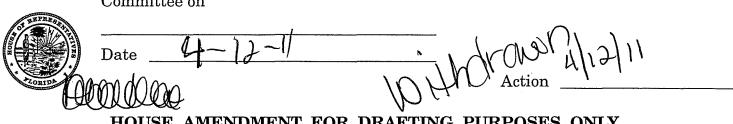
dispensing certain controlled substances to certain patients in registered pain-management clinics; providing an exception for dispensing controlled substances in the health care system of the Department of Corrections; amending s. 499.0051, F.S.; creating two third degree felonies for violations of certain provisions of s. 499.0121; amending s. 499.012, F.S.; requiring wholesale distributor permit applicants to submit documentation of credentialing policies; amending s. 499.0121, F.S.; providing reporting requirements for wholesale distributors of certain controlled substances; requiring the Department of Health to share the reported data with law enforcement agencies; requiring the Department of Law Enforcement to make investigations based on the reported data; providing credentialing requirements for distribution of controlled substances to certain entities by wholesale distributors; requiring distributors to identify suspicious transactions; requiring distributors to determine the reasonableness of orders for controlled substances over certain amounts; requiring distributors to report certain transactions to the Department of Health; prohibiting distribution to entities with certain criminal histories; limiting monthly distribution amounts of certain controlled substances to retail pharmacies; prohibiting distribution to entities with certain criminal backgrounds; amending s. 499.05, F.S.; authorizing rulemaking concerning specified controlled substance wholesale distributor reporting requirements and credentialing requirements; amending s. 499.067, F.S.; requiring the Department of Health to take disciplinary action against wholesale distributors failing to comply with specified

Amendment No. 1 credentialing requirements; amending s. 810.02, F.S.; 2322 2323 authorizing separate judgments and sentences for burglary with the intent to commit theft of a controlled substance under 2324 specified provisions and for any applicable possession of 2325 2326 controlled substance offense under specified provisions in certain circumstances; amending s. 812.014, F.S.; authorizing 2327 2328 separate judgments and sentences for theft of a controlled substance under specified provisions and for any applicable 2329 2330 possession of controlled substance offense under specified provisions in certain circumstances; amending s. 893.055, F.S.; 2331 deleting obsolete dates; deleting references to the Office of 2332 Drug Control; making conforming changes; requiring the state 2333 surgeon general to appoint a board of directors for a direct-2334 335 support organization; requiring reports to the prescription drug ∠336 monitoring system to be made in 7 days; amending s. 893.065, F.S.; conforming to changes made to s. 456.42; amending s. 2337 893.07, F.S.; providing that law enforcement officers are not 2338 2339 required to obtain a subpoena, court order, or search warrant in 2340 order to obtain access to or copies of specified controlled substance inventory records; requiring reporting discovery of 2341 2342 the theft or loss of controlled substances to the sheriff within a specified period; providing criminal penalties; repealing s. 2 2343 2344 of chapter 2009-198, Laws of Florida, relating to Program Implementation and Oversight Task Force in the Executive Office 2345 of the Governor concerning the electronic system established for 2346 the prescription drug monitoring program; providing a buyback 2347 program for undispensed controlled substance inventory held by 2348 2349 specified licensed physicians; requiring reports of program;

# COMMITTEE/SUBCOMMITTEE AMENDMENT Bill No. CS/HB 7095 (2011)

	Amendment No. 1
2350	providing for a declaration of a public health emergency;
2351	requiring certain actions relating to dispensing practitioners
2352	identified as posing the greatest threat to public health;
2353	providing an appropriation; providing for future repeal of
2354	program provisions; providing an effective date.

Committee on



# HOUSE AMENDMENT FOR DRAFTING PURPOSES ONLY

(may be used in Committee, but not on House Floor)

Amendment No.	1 to Strikeal	U	Bill No.	
(For filin	ng with the Clerk, Commi	ittee and Member Amendm	ents must be prepared on con	ıputer)
			:	
		the Strike all am		
Amendment				
on page	, line	7		
:	Remove	Lines	88-91	
	ine 92	change (B.	(A)	
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Committee on
Appropriations

Date 4/12/11

Aclopt-Cl 4-12-11

Action	

		, -		ommittee, bi		louse Floor)	
Amendment No.	10	_(an2	to S	reileau	)	Bill No	7095
(For fili	ng with t	the Clerk, Co	ommittee a	and Member A	nendments n	nust be prepared or	n computer)
Representative(s)/	_						<u> </u>
offered the followi	ng ame	endment:	to the	strikeal	amene	lment:	
Amendment							
on page	4	, line	39	-91	,		
Remove	Lin	es 99-	91 au	nd inser	+;		
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Committee on  Fauled to adopt  4-12-11  Action
HOUSE AMENDMENT FOR DRAFTING PURPOSES ONLY  (may be used in Committee, but not on House Floor)  Bill No. 1095
(For filing with the Clerk, Committee and Member Amendments must be prepared on computer)  Representative(s)/The Committee on  Little Struckers  offered the following amendment: to the Strike all amendment
Amendment  on page, line,
Remove Lines 88-91
Line 92 change (B) -> (A)

## **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)

HB 7215 : Department of Agriculture and Consumer Services

X Not Considered

## **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)

HJR 7221: State Revenue Limitation

X Favorable

	Yea	Nay	No Vote	Absentee Yea	Absentee Nay
Leonard Bembry		X			
Charles Chestnut IV		X			
Marti Coley	X				
Joseph Gibbons		X			
Richard Glorioso	X				
Ed Hooper	Х				
Mike Horner	X				
Matt Hudson	X				
Dorothy Hukill	X				
Mia Jones		X			
Martin Kiar		X			
Paige Kreegel		X			
John Legg	X				
Carlos Lopez-Cantera	X				
Seth McKeel	X				·
H. Marlene O'Toole	X				
William Proctor	X				
Darryl Rouson		X			
Franklin Sands		X			
Ron Saunders		X			
Robert Schenck	X				
William Snyder	X				
Trudi Williams		X			
Denise Grimsley (Chair)	X				
	Total Yeas: 14	Total Nays: 1	0		

## **Appearances:**

HJR 7221

Jarnett, Ray A. (General Public) - Opponent

FOPE Business Rep. 1744 NW 83rd Ave Coral Springs FL 33071

Phone: (954)684-6220

HJR 7221

Harris, Shea (General Public) - Waive In Opposition

1456 Cane Road Tallahassee FL 32305

HJR 7221

McRay, Jack (Lobbyist) - Opponent

AARP

200 W College Ave Ste 304

Tallahassee FL 32301

Phone: (850)577-5187

Print Date: 4/12/2011 2:57 pm

## **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)

HJR 7221

Steward, Dawn (General Public) - Waive In Opposition

2130 Blossom Lane Winter Park FL 32789 Phone: (407)645-0273

HJR 7221

Wilcox, Benjamin (Lobbyist) - Opponent League of Women Voters of Florida 540 Beverly Ct Tallahassee FL 32301

Phone: (850)544-4448

HJR 7221

Hunte, Sidney R. (General Public) - Opponent 8250 Sands Point Blvd. E 110 Tamarac FL 33321

Phone: (754)381-3653

HJR 7221

Templin, Rich (Lobbyist) - Opponent Florida AFL-CIO 135 S. Monroe Tallahassee FL 32301

Phone: 850-224-6926

HJR 7221

Taylor, Maryann (General Public) - Opponent 10730 Windsor Place Orlando FL 32821 Phone: (407)748-0849

HJR 7221

Steckroat, William (General Public) - Waive In Opposition 626 SE 11th Place Cape Coral FL 33990

HJR 7221

Greenwell, Lora - Waive In Opposition 621 SW 29th St Cape Coral FL 33914

Phone: (239)872-2872

HJR 7221

Meiners, H. (Lobbyist) - Waive In Support Associated Industries of Florida 516 N Adams St Tallahassee FL 32301

Phone: (850)591-0177

Print Date: 4/12/2011 2:57 pm

## **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)

HJR 7221

Harbisen, Jacki (General Public) - Opponent

1029 NE 35th Ave. Cape Coral FL 33909 Phone: (239)770-2577

HJR 7221

Bryant, David (General Public) - Waive In Opposition

8853 Atter Lane Jacksonville FL 32216 Phone: (904)233-4040

HJR 7221

Cole, Anna (General Public) - Waive In Opposition

261 Kettle Court Casselberry FL 32707 Phone: (407)446-4431

HJR 7221

Perry, Gail Marie (General Public) - Opponent

Communications Workers of America/Council of Florida

PO Box 1766 Pompano FL 33061 Phone: (954)850-4055

HJR 7221

Clark, Bart (General Public) - Waive In Opposition

2071 Cynthia Drive Tallahassee FL 32303 Phone: (850)559-4348

HJR 7221

Woodall, Karen (Lobbyist) - Opponent

Florida Center for Fiscal & Economic Policy

545 E. Tennessee Street Tallahassee FL 32308 Phone: 850-321-9386

HJR 7221

Reeder, Glynn (General Public) - Opponent

2847 SE 113th Way Starke FL 32091 Phone: (904)449-4770

HJR 7221

Pruett, Brett (State Employee) - Waive In Opposition

6415 Ashburough Court Apt. D

Print Date: 4/12/2011 2:57 pm

Milton FL 32570 Phone: (850)313-6682

## **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)

HJR 7221

Schlipf, Maureen (State Employee) - Waive In Opposition

6671 SW CR 791 Lake Butler FL 32054 Phone: (386)466-9004

HJR 7221

Schlipf, Kevin (State Employee) - Waive In Opposition

6671 SW CR 791 Lake Butler FL 32054 Phone: (386)466-9880

HJR 7221

Stepanovich, Stacy (General Public) - Waive In Opposition

3610 Cardinal Blvd.

Daytona Beach Shores FL 32118

Phone: (386)235-5751

HJR 7221

Reeder, Penny (State Employee) - Opponent

2847 SE 113th Way Starke FL 32091 Phone: (904)364-6340

HJR 7221

Williams, Ken (General Public) - Waive In Opposition

7411 Meadow Drive Tampa FL 33634 Phone: (813)886-1753

HJR 7221

Jenkins, Tiffany (General Public) - Waive In Opposition

4804 Jacobs Glenn Drive

Tampa FL

Phone: (813)506-4193

HJR 7221

Cephus, Vanessa (General Public) - Opponent

421 Big Cedar Way Apt. B

Brandon Fl 33510 Phone: (813)495-7190

HJR 7221

Dupree, Larry (General Public) - Waive In Opposition

8301 N River Highlands Pl.

Tampa FL 33617 Phone: (813)984-8828

HJR 7221

Murray, Leo (General Public) - Waive In Opposition

6418 10 St. North St. Petersburg FL 33702

Phone: (727)460-0029

Print Date: 4/12/2011 2:57 pm

## **Appropriations Committee**

4/12/2011 9:00:00AM

Location: Webster Hall (212 Knott)

HJR 7221

DelGuercio, Vincent (General Public) - Opponent

1474 Admiral Nimitz Ave. Daytona Beach FL 32124

Print Date: 4/12/2011 2:57 pm Leagis ® Page 21 of 21