

**IN THE CIRCUIT COURT OF THE SEVENTEENTH JUDICIAL CIRCUIT
IN AND FOR BROWARD COUNTY, FLORIDA**

**INTERIM REPORT
OF THE
BROWARD COUNTY GRAND JURY**

**THE PROLIFERATION OF
PAIN CLINICS IN SOUTH FLORIDA**

SPRING TERM A.D. 2009



MICHAEL J. SATZ
State Attorney

NOVEMBER 19, 2009

I. INTRODUCTION

Pill Mills are afflicting the health and welfare of the citizens of our community. Here in Broward County, Florida, Pill Mills have proliferated at an alarming rate.

Your Grand Jury was empanelled to investigate and review why Pill Mills are proliferating in South Florida, what effect they are having on the community, how Broward County has become a major source of Oxycodone and what can be done to protect the public from the dangers that may be caused by Pill Mills.

Your Grand Jury heard testimony from doctors who specialize in pain medicine, prescription drug abusers, addicts and their family members, local law enforcement personnel, state and federal law enforcement personnel from neighboring states including members of the Federal High Intensity Drug Trafficking Area (HIDTA) Task Force and investigators on the Appalachia High Intensity Drug Trafficking Area (HIDTA) Initiative for the South Florida-Kentucky Prescription Fraud Task Force, a representative of the Florida Department of Health's Office of Drug Control responsible for coordinating the State's Prescription Drug Monitoring Program, an elected representative of the Florida State House of Representatives responsible for the State's Prescription Drug Monitoring Program, local officials responsible for initiating local ordinances to regulate pain clinics, a physician appointed to the Florida Board of Medicine, a veteran prosecutor in charge of a Drug Trafficking Unit that specializes in the prosecution of drug trafficking cases by prescription drugs, a member of the judiciary in charge of drug court from the State of Florida's Seventeenth Judicial Circuit, an elected public defender, an epidemiologist with the Center for the Study and Prevention of Substance Abuse at Nova Southeastern University, and a Lieutenant Governor of a neighboring state.

II. BACKGROUND

After the tragedy of 9-11 in 2001, the United States of America secured its ports; the increased security effectively reduced the quantity of illegal drugs imported into the United States. According to law enforcement who testified before your Grand Jury, as a result of the dwindling supply and inaccessibility of illegal drugs entering the United States through South Florida, many traffickers, dealers and users shifted their efforts from acquiring illegal drugs to the diversion of legal prescription drugs to illegal uses.

Beginning in 2002, and continuing for the next seven years, the Florida Legislature failed, in spite of repeated bills brought before it, to enact legislation to implement a Prescription Drug Monitoring Program (PDMP). A Prescription Drug Monitoring Program provides an electronic database from which doctors, pharmacists and law enforcement officers can track the dispensation of prescription drugs to patients. In early 2009, thirty eight (38) states had enacted legislation implementing a Prescription Drug Monitoring Program in their states. Thirty two (32) of the states' Prescription Drug Monitoring Programs were in effect, while six were waiting to go online. Florida was the largest state without a Prescription Drug Monitoring Program and became a destination for traffickers, dealers and users seeking to illegally acquire prescription drugs.

Without a Prescription Drug Monitoring Program in place, drug traffickers, dealers and users easily engage in illegal doctor shopping to acquire prescription drugs. They travel to multiple doctors several times a day, week or month in search of physicians who willingly prescribe and supply them prescription drugs. If ethical and conscientious doctors refuse to sell them drugs, they travel from pain clinic to pain clinic attempting to find an unscrupulous physician willing to supply them drugs.

Pain clinics that “treat patients for pain” by dispensing large quantities of controlled substance medication for non-medical purposes are referred to as Pill Mills. Not all pain clinics are Pill Mills; however, Pill Mills can be a doctor’s office, pain clinic or health care facility. They differ from legitimate pain clinics that are associated with hospital facilities and legitimate pain medicine practices. Typically, they are rogue clinics putting pills out for cash.

Patients seeking drugs, who go to pain clinics, engage in the “dance” with the doctor. The patients fake illnesses and complain of nonexistent pain. They produce altered MRI’s or MRI’s that do not show any injuries. Some clinic doctors will take cash for the initial visit, spend a few minutes with the patient for an “exam” and then prescribe a 30 day cocktail of various narcotics to the patient. Your Grand Jury heard testimony from law enforcement officials and addicts that the cocktail usually includes: 1) 150 to 240 30 milligram Roxicodone pills, which are Oxycodone; 2) 90 to 100 10 milligram Percocet pills which contain Oxycodone and Tylenol and is administered for breakthrough pain between the Roxicodone doses; 3) 350 milligram tablets of Soma, which is Carisoprodol and is a muscle relaxant; and 4) 2 milligram pills of Xanax, which is Alprazolam and is an anti-anxiety medication given to help patients with sleep disturbances. Through some doctors, the pain clinics dispense the cocktail or Oxycodone on site to the patient, for cash only. The patient then travels to another clinic to repeat the “dance.” This routine allows traffickers, dealers and users to easily obtain enormous quantities of prescription drugs and allows some doctors, and some clinics that dispense drugs on site, to profit handsomely while plausibly denying any wrongdoing.

The number of pain clinics has skyrocketed in South Florida. From August 2008 to November 2009, a new pain clinic opened in Broward and Palm Beach counties on average every 3 days. Finally, in July 2009 Florida enacted legislation to implement a Prescription Drug Monitoring Program. The Prescription Drug Monitoring Program is to be operational beginning in December 2010. While supporters of the Prescription Drug Monitoring Program jubilantly hailed the long overdue enactment of the legislation, many questions are being raised as to whether the Program will ever be properly funded or effective as a deterrent to doctor shopping, as the legislation is presently written. Opponents of the legislation still raise questions regarding the constitutionality of the legislation; they claim that the legislation jeopardizes the privacy rights of innocent citizens.¹ See recommendations on pages 40-43 of this report that address these concerns.

¹ Some opponents to the legislation object to the very idea that a database will be kept that contains their prescription drug history (although others point out that pharmacies already have that information in a database). If a patient takes his prescription to a pharmacy and submits the prescription to them for a drug, the information goes to a clearing house and if you are on Medicaid the information goes into a database.

Other opponents object to the legislation because it allows law enforcement to have access to the database when law enforcement is conducting an active criminal investigation and requests the information from the manager of the database. They contend that law enforcement should have to establish the standard of probable cause (i.e., that they articulate that there is a reasonable suspicion of criminal activity) before being allowed access to the database of someone's prescription drug history.

III. THE RISE OF THE PAIN CLINICS AND THEIR EFFECTS

A. The Proliferation of Pain Clinics

In 2007 there were 4 pain clinics operating in Broward County. From those 4 pain clinics in Broward County the number swelled to 66 pain clinics operating in South Florida in 2008. From August 2008 to November 2009 the number of pain clinics opening and operating in South Florida exploded in number from 66 to 176, and the number of pain clinics opening and operating in Broward County increased from 47 to 115.² Pain clinics, which dispense prescription drugs on site, dispensed almost 9 million dose units of Oxycodone in South Florida during the last six months of 2008. 6.5 million Dose units of the 9 million dose units were dispensed in Broward County alone.³

B. Broward County: the Source of Oxycodone

During the first six months of 2008, the top 25 dispensing doctors of Oxycodone in the nation were located in the State of Florida; 22 of the top 25 dispensing doctors of Oxycodone were in South Florida; and, 18 of the top 25 dispensing doctors of Oxycodone were located in Broward County, Florida.⁴

² Information regarding the number of Pain Clinics provided by Law Enforcement Officers of the Broward Sheriff's Office Pharmaceutical Drug Diversion Unit.

³ Information regarding Dispensing Practitioners of Oxycodone obtained from Automation of Reports and Consolidated Orders System (ARCOS) by US Drug Enforcement Administration through the Broward Sheriff's Office and the Center for the Study and Prevention of Substance Abuse at Nova Southeastern University

⁴ Information regarding Dispensing Practitioners of Oxycodone obtained from Automation of Reports and Consolidated Orders System (ARCOS) by US Drug Enforcement Administration through the Broward Sheriff's Office and the Center for the Study and Prevention of Substance Abuse at Nova Southeastern University

Of the more than 1 million dispensing doctors registered with the Drug Enforcement Administration (DEA) almost 60,000 dispensing doctors (or 6%) are registered in the State of Florida.⁵ During the last six months of 2008, all 50 of the top 50

Oxycodone Units Dispensed January 2008 – June 2008 by top 25 dispensing doctors:

3,383,200	Broward
852,800	Palm Beach
393,900	Miami-Dade
126,990	Hillsborough
116,800	Manatee

⁵ Florida Statute 465.0276 provides the authority for practitioners to dispense drugs. It reads as follows:

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

(2) A practitioner who dispenses medicinal drugs for human consumption for fee or remuneration of any kind, whether direct or indirect, must:

(a) Register with her or his professional licensing board as a dispensing practitioner and pay a fee not to exceed \$100 at the time of such registration and upon each renewal of her or his license. Each appropriate board shall establish such fee by rule.

(b) Comply with and be subject to all laws and rules applicable to pharmacists and pharmacies, including, but not limited to, this chapter and chapters 499 and 893 and all federal laws and federal regulations.

(c) Before dispensing any drug, give the patient a written prescription and orally or in writing advise the patient that the prescription may be filled in the practitioner's office or at any pharmacy.

(3) The department shall inspect any facility where a practitioner dispenses medicinal drugs pursuant to subsection (2) in the same manner and with the same frequency as it inspects pharmacies for the purpose of determining whether the practitioner is in compliance with all statutes and rules applicable to her or his dispensing practice.

(4) The registration of any practitioner who has been found by her or his respective board to have dispensed medicinal drugs in violation of this chapter shall be subject to suspension or revocation.

(5) A practitioner who confines her or his activities to 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 fee or remuneration of any kind, whether direct or indirect, and who herself or himself dispenses such drugs is not required to register pursuant to this section. The practitioner must dispense such drugs in the manufacturer's labeled package with the practitioner's name, patient's name, and date dispensed, or, if such drugs are not dispensed in the manufacturer's labeled package, they must be dispensed in a container which bears the following information:

(a) Practitioner's name;

dispensing doctors of Oxycodone in the nation were in the State of Florida; 45 of the top 50 dispensing doctors of Oxycodone were located in South Florida; and, 33 of the top 50 dispensing doctors of Oxycodone were located in Broward County, Florida.⁶

The most recent data available for the top 50 doctors dispensing Oxycodone reveals that from October 1, 2008 through March 31, 2009, 49 of the top 50 dispensing doctors of Oxycodone in the United States were in the State of Florida, 43 of the top 50 dispensing doctors of Oxycodone were in South Florida and 25 of the top dispensing doctors of Oxycodone were located in Broward County.⁷

-
- (b) Patient's name;
 - (c) Date dispensed;
 - (d) Name and strength of drug; and
 - (e) Directions for use.

⁶Information regarding Dispensing Practitioners of Oxycodone obtained from Automation of Reports and Consolidated Orders System (ARCOS) by US Drug Enforcement Administration through the Broward Sheriff's Office and the Center for the Study and Prevention of Substance Abuse at Nova Southeastern University

Oxycodone Units Dispensed July 2008 – December 2008 by top 50 dispensing doctors:

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

⁷ Information regarding Dispensing Practitioners of Oxycodone obtained from Automation of Reports and Consolidated Orders System (ARCOS) by US Drug Enforcement Administration through the Broward Sheriff's Office and the Center for the Study and Prevention of Substance Abuse at Nova Southeastern University

Oxycodone Units Dispensed October 2008 –March 2009 by top 50 dispensing doctors:

5,233,785	Broward
2,368,430	Palm Beach
646,500	Miami-Dade
192,400	Pinellas
184,330	Hillsborough
169,200	Lake

The most recent data available for the top 100 doctors dispensing Oxycodone reveals that from October 1, 2008 through March 31, 2009, 48 of the top 100 dispensing doctors of Oxycodone in the United States were located in Broward County, Florida. Those 48 doctors dispensed 7,174,885 dose units during that six month period, or 53.8% of the total Oxycodone dose units dispensed by the top 100 dispensing doctors in the United States.

The data for the most recent period from April 2009 to September 2009 has not yet been released and is not yet available.

C. The Effects of prescription drugs and Oxycodone throughout Florida and Broward County

1. Deaths from prescription drugs and Oxycodone

The Florida Medical Examiners Commission reported that in 2006 there were 2,780 lethal dose reports of prescription drugs detected in deceased persons in the State of Florida or an average of more than 7 reported deaths per day.

In 2007 the Florida Medical Examiners Commission reported that there were 3,317 lethal dose reports of prescription drugs detected in deceased persons in the State of Florida or an average of more than 9 reported deaths per day.

In 2008 the Florida Medical Examiners Commission reported that there were 3,750 lethal dose reports of prescription drugs detected in deceased persons in the State of Florida or an average of more than 10 reported deaths per day. In 2008 there were an additional 6,286 reports where prescription drugs were detected in deceased persons that

164,686	Seminole
133,800	Orange
108,600	Lee

were not considered to be at a lethal dose level but may have been found in combination with other substances. The total of 10,036 prescription drugs detected was related to 4,924 deaths or an average of nearly 13 ½ deaths per day in Florida during 2008.

Oxycodone alone was detected in 1,574 deceased persons in Florida during 2008 and was determined to be a lethal dose level by medical examiners who considered it to be the cause of death in 942 of those cases. Across Florida, the number of reports detected among deceased persons for Oxycodone increased 26 percent in 2008. Reports related to the category of prescription opioids detected among deceased persons increased 8 percent in Florida in 2008 and increased 23 percent in Broward County in 2008.

2. Increases in crime and the costs of enforcing the laws.

Your Grand Jury heard testimony from law enforcement officials that burglaries and robberies in the areas where the pain clinics are located have increased; drug trafficking in prescription drugs and street level sales of prescription drugs have increased; and, identity theft and organized criminal activities have increased.

Your Grand Jury heard testimony from law enforcement officials how criminals rob pharmacists of Oxycodone and then ignore and leave cash behind; your Grand Jury also heard testimony where an addict described how offenders broke into his house and violently robbed him and his family at gunpoint to get his Oxycodone.

The costs incurred by law enforcement to combat the crimes, the costs incurred by the judicial system to process the offenders, and the costs incurred by the Department of Corrections and the County to house the offenders have all increased. Testimony was presented to your Grand Jury, that drug trafficking in prescription drugs in Broward

County increased greatly. Testimony was presented to your Grand Jury, by the Circuit Court Judge in charge of the drug court for the Seventeenth Judicial Circuit that fifty percent (50%) of the 1600 active cases in Drug Court are individuals who are charged with the illegal possession of prescription drugs.

3. Increases in the use of prescription drugs, addictions and the costs of treating patients.

Several witnesses, including an epidemiologist with the Center for the Study and Prevention of Substance Abuse at Nova Southeastern University, testified to your Grand Jury that prescription drug abuse is an epidemic spreading across the nation, particularly in Florida, and more specifically in Broward County. As the use of cocaine has recently declined the non-medical illegal use of prescription opioids has dramatically increased. Reports show that drug use today is more dangerous, more addictive and more deadly than it was even just a decade ago. Prescription drug abuse leads to polysubstance abuse (people using more than one drug) and an increase in the consequences of deaths, medical emergencies and addiction treatments.

The National Survey on Drug Use and Health conducted annually by the Substance Abuse Mental Health Services Administration estimates that in the last 30 days over 5 million Americans used non-medical prescription opioids or narcotic analgesics or pain relievers. In 2005, 11,300,000 Americans age 12 and above had used prescription pain medication in a non-medical use. In 2007, the number increased almost 50% to 16,280,000 Americans. One of the age groups that have shown the highest levels of prescription non-medical use has been young adults age 18 to 25. In 2007, 2,147,000

Americans were first time non-medical users of prescription pain medication. You can only be a first time user once in your life and those first time non-medical users of prescription pain medication numbered more than those first time users of marihuana (2,090,000), prescription tranquilizers (1,232,000), cocaine (906,000), Ecstasy, inhalants, and prescription stimulants (642,000).

The DAWN system tracks reports of incidents of hospital emergency departments. According to the DAWN tracking system Broward County has the highest proportion of prescription drug and prescription opioid visits among 20 metropolitan areas in the country. Compared to Miami-Dade County, which has the highest reports for cocaine, Broward County has a much higher proportion of prescription medication reports from emergency departments for prescription opioids. In Broward County, 20% of the opioid emergency department reports were related to heroin while 80% were related to prescription opioids. In Miami-Dade County 73% of the opioid emergency department reports were for heroin and 27% were among the prescription opioids. This reverse pattern between two neighboring counties illustrates the difference that we have with the prescription drug problem even within South Florida.

In tracking Florida Primary Treatment Admissions, prescription drugs have been the fastest rising number of treatment admissions in Florida, with a 150% increase between 2004 and 2008.

The costs of treating the drug abusers' and drug addicts' addictions have increased. There are not enough government programs, treatment facilities and beds to handle the growing number of patients who need treatment for their addictions. In the past 5 years there has been a 30% decrease in the availability of community based

residential treatment facilities and programs in Broward County. This loss of residential programs is having an effect on the entire criminal justice system. The prognosis only gets bleaker as funding shrinks with the budget cuts imposed upon all government agencies.

4. Decreases in the quality of life

With the increase in the number of pain clinics has come an increase in the number of overdose deaths involving the illegal use of prescription medications. And, with the increase in the number of pain clinics has come a decrease in the quality of life for the person who becomes addicted and for an ever increasing number of Floridians and Americans who lives are affected by a loved one who becomes addicted to prescription medication due to the ease of access provided by some pain clinics.

IV. THE OPERATIONS OF PAIN CLINICS

A. Dispensing Controlled Substances

Authority to prescribe and dispense controlled substances by a practitioner is found in Florida Statute 893.05(1). It states: “A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may cause the same to be administered by a licensed nurse or an intern practitioner under his or her direction and supervision only.”

To administer is to provide a single dose treatment of a drug to a patient, such as an injection or oral dose. To prescribe is to author or write a prescription for a patient. The prescription is usually for an extended treatment (from days to a month). To dispense is to sell medications to a patient/customer such as a pharmacy does or a doctor licensed to dispense medications.

At some pain clinics, doctors dispense drugs directly to patients without using a pharmacist. Pursuant to Florida Statute 467.0276(2)(3), the doctor need only pay the state a fee of \$100 and agree to submit to the same annual inspections required of pharmacists. However, pain clinics that dispense drugs on site are not held to the same standards of practice as pharmacies.⁸ Pharmacies are required to maintain their records for two years

⁸ Chapter 64B16-27 of the Florida Department of Health’s regulations establishes Standards of Practice for Pharmacies dispensing Controlled Substances for the Treatment of Pain:

(1) An order purporting to be a prescription that is not issued for a legitimate medical purpose is not a prescription and the pharmacist knowingly filling such a purported prescription shall be subject to penalties for violations of the law.

for inspection and copying by law enforcement officers.⁹ Pain Clinics are supposed to

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

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

⁹ Florida Statute 893.07 regarding Records states:

(1) Every person who engages in the manufacture, compounding, mixing, cultivating, growing, or by any other process producing or preparing, or in the dispensing, importation, or, as a wholesaler, distribution, of controlled substances shall:

(a) On January 1, 1974, or as soon thereafter as any person first engages in such activity, and every second year thereafter, make a complete and accurate record of all stocks of controlled substances on hand. The inventory may be prepared on the regular physical inventory date which is nearest to, and does not vary by more than 6 months from, the biennial date that would otherwise apply. As additional substances are designated for control under this chapter, they shall be inventoried as provided for in this subsection.

(b) On and after January 1, 1974, maintain, on a current basis, a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of by him or her, except that this subsection shall not require the maintenance of a perpetual inventory.

Compliance with the provisions of federal law pertaining to the keeping of records of controlled substances shall be deemed a compliance with the requirements of this subsection.

(2) The record of controlled substances received shall in every case show:

- (a) The date of receipt.
- (b) The name and address of the person from whom received.
- (c) The kind and quantity of controlled substances received.

(3) The record of all controlled substances sold, administered, dispensed, or otherwise disposed of shall show:

- (a) The date of selling, administering, or dispensing.
- (b) The correct name and address of the person to whom or for whose use, or the owner and species of animal for which, sold, administered, or dispensed.
- (c) The kind and quantity of controlled substances sold, administered, or dispensed.

also. Pharmacies are not allowed to advertise that they distribute narcotics.¹⁰ Pain clinics do advertise that they dispense narcotics.¹¹ Many clinics are not owned by doctors. The

(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, records 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.

(5) Each person shall 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.

¹⁰Florida Statute 465.024 prohibits promoting the sale of certain drugs. It states:

(1) It is declared that the unrestricted use of certain controlled substances, causing abnormal reactions that may interfere with the user's physical reflexes and judgments, may create hazardous circumstances which may cause accidents to the user and to others, thereby affecting the public health, safety, and welfare. It is further declared to be in the public interest to limit the means of promoting the sale and use of these drugs. All provisions of this section shall be liberally construed to carry out these objectives and purposes.

(2) No pharmacist, owner, or employee of a retail drug establishment shall use any communication media to promote or advertise the use or sale of any controlled substance appearing in any schedule in chapter 893.

(3) This section shall not prohibit the advertising of any medicinal drugs, other than those controlled substances specified in chapter 893, or any patent or proprietary preparation, provided the advertising is not false, misleading, or deceptive.

¹¹ Florida Statute 465.015 states:

(3)(c) It is unlawful for a person, firm, or corporation that is not licensed or registered under this chapter to:

1. Use in a trade name, sign, letter, or advertisement any term, including "drug," "pharmacy," "prescription drugs," "Rx," or "apothecary," which implies that the person, firm, or corporation is licensed or registered to practice pharmacy in this state.

2. Hold himself or herself out to others as a person, firm, or corporation licensed or registered to practice pharmacy in this state.

(d) It is unlawful for a person who is not registered as a pharmacy technician under this chapter or who is not otherwise exempt from the requirement to register as a pharmacy technician, to perform the functions

doctors work as contractors for the owners. The owners may have little or no medical background. If the pain clinic is not physician owned, then it is unregulated by any state agency. There is no requirement that owners and employees undergo a criminal background check. The clinic is not regulated through the Florida Department of Health or the Florida Board of Medicine. The Department of Health regulates healthcare professionals and not facilities. The dispensing doctor's activity at the clinic can be regulated by the Board of Medicine, but the pain clinic is independent and not under scrutiny. The Agency for Health Care Administration oversees only the clinics that accept insurance. Therefore, nearly all Pill Mills take cash only.

of a registered pharmacy technician, or hold himself or herself out to others as a person who is registered to perform the functions of a registered pharmacy technician in this state.

4) Any person who violates any provision of subsection (1) or subsection (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.

V. PAIN MEDICINE

A. Background

Your Grand Jury heard testimony regarding the advent of the treatment of pain by specialists. Doctors testified that our bodies need to have pain. If we did not experience pain then our bodies would not know that there was something wrong with them. If we hurt our back or our leg and did not feel pain, then we would keep on hurting our back or leg. Pain is a symptom. Throughout our lives we experience pain and then we heal. In some people's lives they experience illness or injury that gives them pain, and even though they try to treat that illness or that problem, the pain does not go away. Someone who has an injury and has experienced multiple back surgeries because of the injury but still has pain has a chronic pain or intractable pain. People with an intractable pain have a disease. Pain medicine or pain management is the management of the disease process, either with medication, with physical modalities, with psychological or psychiatric modalities, with interventional management, with acupuncture or other modalities. A pain specialist treats someone with severe, chronic, unrelenting pain.

B. Board Certification of Pain Specialists

In 1993 the American Board of Anesthesiology created a specialty in pain medicine by creating a Certificate of Added Qualifications in Pain Management. The American Board of Physical Medicine and Rehabilitation and the American Board of Psychiatry and Neurology also accept that Board. To become board certified with a Certificate of Added Qualifications in Pain Management, you first have to be board certified in your specialty.

The American Board of Pain Medicine was then created. It is more interdisciplinary and bestows upon the successful specialist in pain medicine a Diplomate of American Board of Pain Management. Both of these Boards are recognized in the State of Florida by the Florida Board of Medicine. Prior to the establishment of the Boards the treatment of pain medicine was often haphazard and accomplished through a variety of doctors, neurologists, family physicians, and internists.

C. The Treatment of Pain

There are many legitimate pain medicine specialists who caringly treat patients who suffer from chronic pain. A pain medicine specialist described to your Grand Jury the typical treatment of a patient suffering from chronic pain. First, the doctor would examine the patient to ensure there were no neurological injuries. If a patient injured his neck in an automobile accident and had an acute injury, he was in pain because his neck got banged up in an automobile accident and it was in a spasm. That would be a symptom and it would be appropriate to give an opioid or pain killer to treat that symptom. However, a doctor would also want to treat the underlying problem. He would ask, "Why does the patient have this pain?" The patient's muscles may have gotten stretched or torn, or the ligament may have been pulled, or the patient may have a herniated disc. The doctor would want to diagnose the problem and prescribe the appropriate medication: an inflammatory medicine would be prescribed if the muscles or disc were inflamed or muscle relaxers would be given to treat a spasm when the muscle locked down. Also modalities such as heat, physical therapy, and stretching would be used.

If a patient had chronic intractable pain and other numerous ways of dealing with it had failed, then in an effort to make the person functional, the doctor would discuss therapy involving opioids. The patient would sign an informed consent form acknowledging the risks and pitfalls. The doctor would also ensure that the patient understood that the patient would probably develop physical dependence on the drug and experience side effects.

D. Respected Specialists in Pain Medicine v. Pill Mills

Respected specialists in pain medicine also administer opioids to patients; however, they never administer opioids in the manner Pill Mills do. They have usually attempted other treatments and have carefully discussed with the patient the ramifications of using opioids. They also continue to treat their patients and monitor their patients' prognoses. Respected and legitimate pain medicine specialists abhor the Pill Mills that taint their profession and sully their reputations. At Pill Mills doctors write prescriptions and dispense controlled substances allegedly treating pain; however, Pill Mills treat all patients who say that they have pain the same, whether they have pain or not, by prescribing and selling opioids to the patients. They do not treat pain or the symptom of pain. They are lucrative businesses accepting cash only. They do not require extensive screening and do not treat patients nor conduct follow-up examinations of the patients. They do not follow the authorized treatment for intractable pain outlined in the Florida Statutes.¹²

¹² Florida Statute 458.326 Intractable pain; authorized treatment.

E. The user

The average user of prescription drugs has changed in the last few years. Your Grand Jury heard testimony from law enforcement officials that a few years ago the mean demographic of the user was a white upper middleclass person from their late 30s to early 40s to their late 50s. The drug seeker started out with a legitimate medical injury that developed into a dependence upon and a tolerance to the drugs. Eventually, the user's original injury healed and when his physician refused to supply him additional drugs the user sought them anyway he could.

Today, the average user is a white upper middleclass person, age 18-25. Typically today, the drug seeker started out seeking the drugs for recreational purposes as opposed to easing the pain of a legitimate medical injury. There are still many, many patients seeking drugs who developed dependence because they sought comfort from the pain of an injury. Anyone can become addicted to prescription drugs and Oxycodone, in particular. A patient with a nagging injury who suffers legitimate pain can become addicted to the drug as easily as a person who is just seeking a drug to obtain a high. Oxycodone is a powerful drug and does not discriminate against which user becomes an

(1) For the purposes of this section, the term "intractable pain" means pain for which, in the generally accepted course of medical practice, the cause cannot be removed and otherwise treated.

(2) Intractable pain must be diagnosed by a physician licensed under this chapter and qualified by experience to render such diagnosis.

(3) Notwithstanding any other provision of law, a physician may prescribe or administer any controlled substance under Schedules II-V, as provided for in s. 893.03, to a person for the treatment of intractable pain, provided the physician does so in accordance with that level of care, skill, and treatment recognized by a reasonably prudent physician under similar conditions and circumstances.

(4) Nothing in this section shall be construed to condone, authorize, or approve mercy killing or euthanasia, and no treatment authorized by this section may be used for such purpose.

addict. Narcotic pain medicines taken long enough and in high enough strengths, not only stop working, while escalating physical dependence, but make the user's pain worse. Hyperalgesia occurs when a user experiences extreme sensitivity to pain. Experts tell us that the treatment is to detoxify the user. However, as users and other experts testified, if the user is not willing to stop using the drugs then any treatment is doomed to failure.

VI. OXYCODONE

A. Background

Opium is a natural plant. From opium we get three major drugs: morphine, codeine and thebaine, all naturally occurring opiates. Opioids are synthetic and not naturally occurring. Oxycodone is an opioid. The drug works in the brain and spinal cord to reduce pain, create pain relief and analgesia. It also produces side effects, respiratory depression, sedation and constipation. It is a reward enhancing substance that has the potential for addiction.

Drug manufacturer's brand name drugs Percodan, Percocet, Oxycontin and Roxicodone contain Oxycodone. Oxycodone is a schedule II controlled substance in the federal schedule registry, which means it has a high potential for abuse and a currently accepted but severely restricted medical use in treatment in the United States. It is not an illegal drug and can be prescribed by a physician; however, abuse of the substance may lead to severe psychological or physical dependence.¹³

¹³ One addict testified to the effect of Oxycodone upon him, "It just made me feel more relaxed. I wasn't hyper and wound up and I feel, I felt that I could function on that drug more so than cocaine." He then described the withdrawals he experienced from Oxycodone to your Grand Jury, "You get terrible pains in your legs, and hot and cold flashes, really bad diarrhea, throwing up. You can't eat at all even though you're feeling better, 'cause you just don't have an appetite at all. It's really bad."

Another addict testified, "I could not function without it [Oxycodone]. I had to have it every day." He then described the withdrawals:

The first part of it would be you would start to get ill as in your stomach would hurt, you couldn't eat, you couldn't hold food down. You'd try to sleep at night, or I should say you would get cold sweats. It didn't matter what the temperature is, you feel like its 20 degrees outside and you're sweating bullets. And then from there you couldn't sleep at night. And that would go on for, different areas of those symptoms would go on for about a week or two. And then from there, I think a month after that, within the month, that first month of detox, I couldn't get a full night's worth of sleep. Your legs would kind of kick and flex and twit. I mean twitch around.

He then described the side effects from the drugs upon him:

It's a synthetic Heroin, so it would have the same effects that Heroin would have on you, things, you can use it all the same way as you can use Heroin, it has on it. You know. It would horribly

B. Types of Drugs

There are three types of drugs: controlled substances, non-controlled substances and over the counter drugs. Controlled substances are regulated by the Drug Enforcement Administration (DEA) and fall into 5 schedules. They are enumerated in Florida Statute 893.03.¹⁴

constipate you for weeks, it would make you not be able to sleep fully. Those were some of the effects. After that, you know, the long term effects, I know I never had to wear glasses before, but you know I came to thinking about it, and after I had detoxed and I had gotten out of jail, I find later that my vision seemed to be awful bad. I don't know if it has any correlation to it, but I mean I go to think about it and, you know, my eyes are, you know, dilated every single day for two years, it can't be good for you, from taking the medication. So there after that I had to get glasses. And my memory had gone and it slowly seems to be coming back. I mean I can remember, I can stay awake through a movie or anything like that. I couldn't do that before. Fall asleep, have a cigarette in my hand, burn holes in my pants. It was horrible. I'd just nod off. Driving trying to rub my eyes to stay awake even though it's in the middle of the day.

¹⁴ Florida Statute 893.03, Standards and Controlled Substances.

a. Schedule I: A substance in Schedule I has a high potential for abuse and has no currently accepted medical use in treatment in the United States and in its use under medical supervision does not meet accepted safety standards. Examples of Schedule I controlled substances include Heroin and LSD.

b. Schedule II: A substance in Schedule II has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States, and abuse of the substance may lead to severe psychological or physical dependence. Examples of Schedule II controlled substances include Raw opium, codeine, hydrocodone, hydromorphone, morphine, and cocaine. As we previously mentioned, Oxycodone is a Schedule II controlled substance.

c. Schedule III: A substance in Schedule III has a potential for abuse less than the substances contained in Schedules I and II and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to moderate to low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. Examples of Schedule III controlled substances include diet drugs, barbituric acid, lysergic acid and anabolic steroids.

d. Schedule IV: A substance in Schedule IV has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III. Examples of Schedule IV controlled substances include Benzodiazepines such as Xanax and Valium, alprazolam, diazepam, prazepam, and Phenobarbital.

e. Schedule V: A substance, compound, mixture, or preparation of a substance in Schedule V has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States, and abuse of such compound, mixture, or preparation may lead to limited physical or psychological dependence relative to the substances in Schedule IV.

Non-Controlled substances require a prescription to obtain but are not controlled. Examples of non-controlled substances include antibiotics, cholesterol medication, and Viagra. No prescription is needed for over-the-counter medications. Examples include Robitussin, Tylenol and Sudafed.

C. Doctor Shopping

Florida Statute 893.13(6)(a) makes it “unlawful for any person to be in actual or constructive possession of a controlled substance unless such controlled substance was lawfully obtained from a practitioner or pursuant to a valid prescription or order of a practitioner while acting in the course of his or her professional practice or to be in actual or constructive possession of a controlled substance except as otherwise authorized by this chapter. Any person who violates this provision commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.”

Florida Statute 893.13(7)(a)8 is referred to as the “doctor shopping” statute and governs the conduct of those seeking to obtain prescription drugs from multiple pain clinics multiple times. Violating it is a third degree felony. It states: “It is unlawful for any person ...[t]o withhold information from a practitioner from whom the person seeks to obtain a controlled substance or a prescription for a controlled substance that the person making the request has received a controlled substance or a prescription for a controlled substance of like therapeutic use from another practitioner within the previous 30 days.”

Florida Statute 893.13(8)(a) governs the conduct of the doctors who dispense controlled substances in Florida.¹⁵ It prohibits prescribing physicians from assisting patients to obtain controlled substances through deceptive or fraudulent representations, knowingly writing a prescription for a controlled substance for a fictitious person, or writing a prescription for a controlled substance for a patient if the sole purpose for the prescription is to provide a monetary benefit for the prescribing physician.

D. Diversion

Diversion is the illegal movement and illegal use of legal drugs. Law Enforcement is faced with thousands of traffickers, dealers and abusers seeking to illegally obtain legal prescription drugs and divert them to illegal uses. These individuals are local residents and travelers from out of state. They come to South Florida from

¹⁵ Florida Statute 893.13(8) states:

(a) Notwithstanding subsection (9), a prescribing practitioner may not:

1. Knowingly assist a patient, other person, or the owner of an animal in obtaining a controlled substance through deceptive, untrue, or fraudulent representations in or related to the practice of the prescribing practitioner's professional practice;

2. Employ a trick or scheme in the practice of the prescribing practitioner's professional practice to assist a patient, other person, or the owner of an animal in obtaining a controlled substance;

3. Knowingly write a prescription for a controlled substance for a fictitious person; or

4. Write a prescription for a controlled substance for a patient, other person or an animal ***if the sole purpose*** of writing such prescription is to provide a monetary benefit to, or obtain a monetary benefit for, the prescribing practitioner. (Emphasis added).

(b) If the prescribing practitioner wrote a prescription or multiple prescriptions for a controlled substance for the patient, other person, or animal for which there was no medical necessity, or which was in excess of what was medically necessary to treat the patient, other person, or animal, that fact does not give rise to any presumption that the prescribing practitioner violated subparagraph (a)1., but may be considered with other competent evidence in determining whether the prescribing practitioner knowingly assisted a patient, other person, or the owner of an animal to obtain a controlled substance in violation of subparagraph (a)1.

(c) A person who violates paragraph (a) commits felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Kentucky, illegally and legally obtaining Florida Identification cards, presenting fraudulent MRI records to doctors, faking injuries, lying about their symptoms and “doctor shopping” multiple times at rogue clinics that are willing to prescribe, dispense and sell them prescription drugs for cash. The patients then either sell their prescription drugs on the street to obtain cash to buy more prescription drugs, travel back to Kentucky to sell the prescription drugs on the streets there for a handsome profit or use their 30 day supply within a couple of days and then seek to obtain more drugs illegally.

Enforcing the criminal statutes involving diversion trafficking and doctor shopping can be very difficult. The investigations involving doctor shopping are very labor and paper intensive and often take several weeks or months to investigate. There is usually not an immediate arrest as the investigations are time consuming and involve diligently obtaining prescriptions and documents from pharmacies or dispensing practitioners. However, the number of prescription drug trafficking cases being prosecuted in the Seventeenth Judicial Circuit has been increasing with a great many out of state offenders traveling to South Florida to obtain prescription drugs.

Without a Prescription Drug Monitoring Program there is no database for which a dispensing doctor or pharmacist can look to determine if a patient is doctor shopping. Many doctors, in good faith, prescribe medications to patients who are lying to them. It is naïve to think that a trafficker, dealer or user of prescription drugs is going to truthfully reveal to a doctor that he has just purchased 240 Oxycodone pills earlier that day from another doctor or clinic. As the statute is written we allow doctors to rely upon the word of an addict to truthfully reveal to a doctor that he has already obtained the maximum supply of pills he can obtain by statute for the month.

Good intentioned doctors who are interested in the care of the patient often see through the lies and refuse to prescribe prescription drugs to those who do not need them. The above statutes do not make these doctors' conduct criminal. Even if the doctor suspected that the patient was lying to him and still prescribed drugs to him, the doctor would not be criminally liable unless the sole purpose in writing the prescription was to obtain a monetary benefit for the doctor or the medication prescribed was in excess of what was medically necessary to treat the patient.

The "dance" is created when a patient goes to a clinic seeking drugs. He takes an MRI, (fake, forged, showing injury or showing no injury – it does not matter), tells the doctor he has pain and describes some non-existent symptoms. An unscrupulous doctor, unaware or even aware that the patient has already obtained prescription drugs from several other clinics, may prescribe a cocktail of drugs to the patient and dispense them on site for cash. The doctor can plausibly deny that he knew that the patient was doctor shopping. There is no database to check. You can never prove that the doctor's sole purpose in prescribing the drugs was to make money, or that the prescription was not medically necessary. And, the doctor can claim that the patient produced an MRI and described pain and injuries. Unless law enforcement officers follow the patient from clinic to clinic, or stumble upon a patient with multiple prescription bottles on him, there is no available method to prove that he has been doctor shopping and violating the statute.

Addicts presented testimony to your Grand Jury as to how they easily obtained prescription drugs from some pain clinics after their family physicians refused to provide drugs to them. They explained how they brought MRI's to pain clinics and lied about

their pain. The MRI's did not show injuries that coincided with the pain they described to the doctors. The patients spent a few minutes with the doctors and the doctors then gave the patients a prescription for a cocktail of drugs. The patients paid \$150-\$250 cash for the visit and anywhere from \$200 to \$800 for the drugs on site.

E. The Oxycodone Pipeline to and from Kentucky

Your Grand Jury heard testimony regarding a prescription drug trafficking pipeline that exists between Kentucky and Florida. Since Kentucky is bordered by seven states, it is extremely difficult to enforce the drug laws in Kentucky. In the 1990's prescription medication abuse exploded in Kentucky. Oxycontin was being used, sold and diverted everywhere. Doctor shopping was rampant. Oxycodone became known in Kentucky as hillbilly heroin.

In response to this dilemma, Kentucky, in 1999, enacted the KASPER system, the Kentucky All Scheduled Prescription Electronic Reporting system, a Prescription Drug Monitoring Program. It took a couple of years to implement the system and then it took a couple of more years of working to perfect the system so that it became effective. Initially, many doctors did not access the system. There was also a one month delay from when law enforcement requested information from the system to the time they obtained the information they requested. Today, the KASPER system has a one hour real time delay in receiving the information from the time it is imputed into the database. The KASPER system is one of the strictest Prescription Drug Monitoring Programs in the country and has effectively cut off all doctor shopping in Kentucky and become a model for many other states' programs.

In August 2005 the Federal Government passed the National All Scheduled Prescription Electronic Reporting Act (NASPER). The NASPER Act allowed and encouraged states to develop and set up prescription drug monitoring programs. It also provided extra funding for states that develop prescription drug monitoring programs that link up or network with other states. It was based on KASPER but was not funded by the Federal Government until recently.

As a result of the KASPER system eliminating doctor shopping in Kentucky, Florida, and specifically Broward County, has become a destination for traffickers from Kentucky. They travel to Florida and illegally purchase drugs here and then transport them to Kentucky to sell there. Drug Traffickers from Kentucky sponsor carloads of patients to travel to the pain clinics in Broward County. For example, a sponsor who funds a carload of patients fronts the money for 5 to travel to Broward County. A manager holds the money for the 5 patients. The manager takes the 5 to a clinic, giving the patients the money prior to them entering the clinic. Each patient pays \$150 to \$250 cash for the doctor's visit. Each patient then receives a cocktail. As previously mentioned, the typical cocktail consists of Roxicodone, Percocet, Xanax and Soma. Roxicodone is Oxycodone in 30 milligram tablets with a street value of \$1 per milligram per pill. Soma has a street value of \$2 to \$3 per pill. And, Xanax has a street value of \$2 to \$4 per pill. The manager takes the 5 to multiple clinics, then returns to Kentucky and sells the drugs for thousands of dollars.

F. Florida Trafficking Penalties for Oxycodone

In the State of Florida pursuant to Florida State Statute 893.135(1)(c)1.a., if you knowingly sell, purchase, manufacture, deliver or bring into Florida, or you knowingly are in actual or constructive possession of 4 to 14 grams of Oxycodone, you are facing up to 30 years in Florida State Prison with a 3 year minimum mandatory prison sentence, and a \$50,000.00 mandatory fine.

In the State of Florida pursuant to Florida State Statute 893.135(1)(c)1.b., if you knowingly sell, purchase, manufacture, deliver or bring into Florida, or you knowingly are in actual or constructive possession of 14 to 28 grams of Oxycodone, you are facing up to 30 years in Florida State Prison with a 15 year minimum mandatory prison sentence, and a \$100,000.00 mandatory fine.

And, in the State of Florida pursuant to Florida State Statute 893.135(1)(c)1.c., if you knowingly sell, purchase, manufacture, deliver or bring into Florida, or you knowingly are in actual or constructive possession of 28 grams or more, up to 30 kilograms of Oxycodone, you are facing up to 30 years in Florida State Prison with a 25 year minimum mandatory prison sentence, and a \$500,000.00 fine.

It takes approximately 33 pills of 30 milligram Oxycodone to make a gram. So, it would take approximately 132 Oxycodone pills to reach the 3 year minimum mandatory prison level, 462 Oxycodone pills to reach the 15 year minimum mandatory prison level and approximately 924 Oxycodone pills to reach the 25 year minimum mandatory prison level.

G. Enforcing the Laws

Testimony was received how clinic parking lots are seen with cars bearing Kentucky plates, the occupants waiting for the clinics to open. As one witness testified before your Grand Jury, “If you’ve ever been to a pain clinic in Broward County recently, people who are waiting to get in the doors to see the doctors are wrapped around the buildings.” Armed guards hired by the clinics patrol the lots while video cameras scan the lots. Without a Prescription Drug Monitoring Program law enforcement cannot successfully enforce the existing laws. By the time law enforcement initiates and completes a successful investigation leading to the arrest of a doctor, user or dealer, several new clinics have opened. Doctor shopping is prevalent as there is no monitoring program. One law enforcement official testified to your Grand Jury, “We’ve made some incredible progress in the particular places that we’re investigating, although I think we could spend the next 20 years investigating different clinics and different providers of the medication and there’d be ten more pop up if you take one out. The only way that there’s going to be a change in the problem is the legislative change with the prescription drug monitoring system.”

Your Grand Jury heard testimony from several law enforcement sources regarding pending criminal investigations involving persons and organizations trafficking in prescription drugs. Additionally, your Grand Jury heard testimony regarding successful prosecutions of doctors and individuals who traffick in prescription drugs. Finally, your Grand Jury heard testimony regarding the law’s potential harsh treatment of abusers who are caught with trafficking amounts of Oxycodone. No indictments are being issued by your Grand Jury as the focus of our inquiry has been upon the proliferation of the pain

clinics, and their substantial dangers to our communities. We do note that it was recently reported that over 300 individuals had been arrested in Kentucky for dealing in prescription drugs from South Florida.

H. Local Communities' Solutions

A couple of cities in Broward County have attempted to restrict the growing number of pain clinics in their cities by enacting ordinances to prohibit the location of pain management clinics that dispense narcotic drugs on site. On July 28, 2009, the City of Dania Beach, Florida enacted Ordinance No. 2009-009 that changed the city's zoning code regarding medical offices that offer on site dispensing of narcotic drugs. Under the ordinance future clinics are not allowed to open in areas marked for redevelopment and they will not be allowed to dispense medications on site. It also defined a Pain management clinic as a "type of medical office providing a variety of personal services by an on-site physician who is currently licensed by either the Florida Board of Medicine or Board of Osteopathic Medicine and his or her staff, which, individually or collectively, are intended to reduce or manage pain."

On April 23, 2009, the City of Coconut Creek, Florida passed Ordinance No. 2009-005 that established a moratorium on the submission, processing, or issuance of Business Tax Receipts for a period of one hundred fifty (150) days to provide the City staff with the necessary time to research the issues surrounding the dispensing of prescription drugs at various business locations within the City. After establishing a moratorium, the City of Coconut Creek, Florida passed Ordinance No. 2009-014 on September 10, 2009. The ordinance aimed to provide adequate protection to the community and establish the

legitimacy of Pain Clinic Facilities. It requires officials to scrutinize Special Land Use Applications pain clinics submit to the city, particularly those clinics that only accept cash and not medical insurance. It also regulates owners, employees and operators of pain clinics.¹⁶

¹⁶ Coconut Creek Ordinance No. 2009-014, Section 3 amended Article III Zoning Regulations, Division 8 Master Business List, Section 13-621 Master Business List, Pain Clinics (8)a.-j. to read as follows:

(8) To provide adequate protection to the community and establish the legitimacy of the facility, the Special Land Use Application Submission for Pain Clinics, must, in addition to the criteria set forth in Section 13-35, address the following:

a. No business approved as a special land use under this section shall limit the form of payment for services or prescriptions to cash only.

b. In the event the business applying for approval under this section does not accept insurance reimbursement, it must state the reason for such policy in its application and the failure of any business to accept insurance, Medicare or Medicaid reimbursements shall be considered by the Planning and Zoning Board in making its decision as to the appropriateness of granting a special land use permit.

c. The application for special land use shall disclose in detail the owners and operators of the facility, and shall be required to update the owner/operator information annually at the time of application for business tax receipts for the business, or at any time that there is a change of owner/operator.

d. No business operating under a special land use permit under this section shall be owned, either in whole, or in part, or have any contractual relationship, whether through employment or by independent contract, with a physician who, within the five year period prior to the date of application for a special land use or at any time after application for a special land use under this section, has been denied the privilege of prescribing, dispensing, administering, supplying or selling any controlled substance or who has, within the five year period prior to the date of application for a special land use under this section or at any time after application for a special land use under this section, had any state Medical Board action taken against his or her medical license as a result of dependency on drugs or alcohol.

e. The business shall be operated by a medical director who is a Florida licensed physician.

f. The business shall not be owned in whole or in part by any person who has been convicted of or who has pled guilty or nolo contendere to any felony in this State or in any other state within the five year period prior to the date of application for a special land use. However, in no event shall the business be owned in whole or in part by any person who has been convicted of or who has pled guilty or nolo contendere at any time to an offense constituting a felony in this State or in any other state involving the prescribing, dispensing, supplying or selling of any controlled substance.

g. The application for special land use shall include an affidavit by the medical director attesting to the fact that no employees of the facility have been convicted of a drug-related felony within the five year period to the date of application and that the business shall not employ any such convicted felons thereafter.

h. Any business approved as a special land use under this section shall maintain the appropriate diagnostic equipment to diagnose and treat patients complaining of chronic pain.

The efforts the cities of Dania Beach and Coconut Creek have taken to regulate pain clinics in their cities are commendable. Their actions will certainly benefit their cities; however, their city ordinances only address the issue in their cities. If Dania Beach makes it difficult to open new clinics in Dania Beach, the clinics will open just north of Dania Beach in Fort Lauderdale or south of Dania Beach in Hollywood. If Coconut Creek requires pain clinics to accept insurance in order to operate in Coconut Creek, then the new clinics will open in the city of Margate next door to the city of Coconut Creek. The ordinances also do not affect the already established clinics that are grandfathered in. Those clinics will continue to operate as they have before. While the cities' efforts are admirable, a more universal approach is needed that globally addresses the dilemma in Florida.

i. Any business seeking approval as a special land use under this section shall be required to file with its application a natural disaster management plan.

j. Any business seeking approval as a special land use under this section shall be required to file with its application a floor plan showing the location and adequate security for protection of any controlled substance to be dispensed in the course of the business.

VII. PRESCRIPTION DRUG MONITORING PROGRAM

A. Creates an Electronic Database

While your Grand Jury was in session, the Florida Legislature passed legislation enacting a Prescription Drug Monitoring Program. On June 18, 2009, the Governor signed Senate Bill 440 and Senate Bill 462 into law, effective July 1, 2009. Section 1, Chapter 2009-197 created Florida Statute 893.0551. Section 1, Chapter 2009-198, Laws of Florida created Florida Statute 893.055. Section 2, Chapter 2009-198, Laws of Florida created the Program Implementation and Oversight Task Force within the Executive Office of the Governor. Section 3, Chapter 2009-198, Laws of Florida added subsections (4), (5), and (6) to section 458.309, Florida Statutes, giving the Florida Board of Medicine rulemaking authority over pain clinics. Section 4, Chapter 2009-198, Laws of Florida added subsections (3), (4), and (5) to section 459.005, Florida Statutes, giving the Florida Board of Osteopathic Medicine rulemaking authority over pain clinics.

Under Florida Statute 893.055, the Florida Department of Health is responsible for designing and establishing a comprehensive electronic database system that has controlled substance prescriptions provided to it, by December 1, 2010. The law requires the Department of Health, in consultation with the Office of Drug Control, to adopt rules “concerning the reporting, accessing the database, evaluation, management, development, implementation, operation, security, and storage of information within the system.” The new law requires the pharmacy dispensing the controlled substance and each prescriber who directly dispenses a controlled substance to submit to the electronic system specific detailed information for inclusion in the database.

B. Authorizes Boards to Develop Rules

The law requires the Department of Health to 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.

Florida Statutes 458.309 and 459.005 now require pain clinics to register with the Department of Health and subjects the clinics to annual inspections. Florida Statute 458.309 allows the Board of Medicine to adopt rules setting forth standards of practice for physicians practicing in pain clinics and prescribing or dispensing controlled substance medications through pain clinics. The statute also allows the Board of Medicine to adopt rules relating to Facility operations, Physical operations, Infection control requirements, Health and safety requirements, Quality assurance requirements, Patient records, Training requirements for all facility health care practitioners who are not regulated by another board, Inspections and Data collection and reporting requirements. Florida Statute 459.005 allows the Board of Osteopathic Medicine to adopt rules setting forth standards of practice for physicians practicing in pain clinics and prescribing or dispensing controlled substance medications and similarly allows the Board of Osteopathic Medicine to adopt the same rules the Board of Medicine can adopt.

C. Fifteen (15) Day Reporting Requirement

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 15 days after the date the controlled substance is dispensed unless an extension is approved by the department for cause as determined by rule. 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.

D. Access to the Database

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. Law Enforcement does not have direct access to information in the prescription drug monitoring program database. Law Enforcement may request information from the program manager during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances. Prior to the information being released to Law Enforcement the program manager must verify that the request from Law Enforcement is authentic and authorized by the requesting entity.

E. Funding

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 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. Subsection (11) provides that 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.

F. Oversight Task Force

Section 2, Chapter 2009-198, Laws of Florida created the Program Implementation and Oversight Task Force within the Executive Office of the Governor. The purpose of the task force is to monitor the implementation and safeguarding of the electronic system established for the prescription drug monitoring program under section 893.055, Florida Statutes, and to ensure privacy, protection of individual medication history, and the electronic system's appropriate use by physicians, dispensers, pharmacies, law enforcement agencies, and those authorized to request information from

the electronic system. The Office of Drug Control must submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1 of each year which contains a summary of the work of the task force during that year and the recommendations developed in accordance with the task force's purpose. The task force must provide a final report on July 1, 2012, to the Governor, the President of the Senate, and the Speaker of the House of Representatives. That task force will then expire unless the Legislature reenacts this section.

VIII. RECOMMENDATIONS

A. Prescription Drug Monitoring Program

When your Grand Jury was empanelled there was no Prescription Drug Monitoring Program enacted in the State of Florida. For various reasons, for several years, the legislation had always failed to pass. It was obvious to your Grand Jury, from listening to the testimony presented, a Prescription Drug Monitoring Program was and is desperately needed in the State of Florida.¹⁷ The arguments against a Prescription Drug Monitoring Program simply are not valid when compared to the necessity for one.¹⁸

Halfway through your Grand Jury's term, a Prescription Drug Monitoring Program was enacted in Florida. Your Grand Jury applauds the Legislature for finally passing this important legislation and encourages the Legislature, the Department of Health and the Office of Drug Control to diligently and swiftly implement the system. Many witnesses who testified before your Grand Jury expressed concern that the system would not be adequately funded. As the legislation is currently written, the system is to be funded through federal grants or private funding. Although your Grand Jury has confidence that the direct support organization, which will be established by the Office of Drug Control, will assiduously endeavor to locate funding for the system, your Grand Jury considers funding the system to be of the utmost importance.

¹⁷ Even opponents of the legislation that was passed are concerned about the proliferation of pill mills and their effects upon the community. "We are struggling with this. And obviously there's a problem when a bunch of people that live in the mountains of Kentucky are driving to Fort Lauderdale to get prescriptions. Obviously there's something wrong here and it's got to be stopped. I think we all get that. The question is, do we take a bazooka and shoot a fly?"

¹⁸ The opposition to the legislation was summed up as follows: "It is not our job to use government to protect the addicts from themselves. You know, when you hear that whole thing about activist judges and the role of government in people's lives, this is what we're talking about. Should we give up all of our privacy rights to protect an addict from themselves? I'm not giving up my rights. Because somebody out there has got a drug problem and because I want to protect him, therefore, I'm giving up my rights? I don't think that's right. I don't think that's fair."

(1) Your Grand Jury recommends that the Prescription Drug Monitoring Program be swiftly implemented and adequately funded, by any means necessary; and, if the direct support organization cannot obtain the necessary federal grants or private funding to implement and run the system that the Legislature authorize the expenditure of state government money to fund the program..

Your Grand Jury heard testimony regarding other states' Prescription Drug Monitoring Programs' successes and failures. The Prescription Drug Monitoring Program enacted by the Florida Legislature allows the person who dispensed the controlled substance no more than 15 days after dispensing the controlled substance to report the data to the department through the system. Other states' experiences tell us that a 15 day period to report the information to the database is not going to be effective in stopping doctor shopping. Drug traffickers, dealers and users travel to numerous pain clinics in a single day. Sponsors from Kentucky can bring 5 people to Florida to purchase drugs, go to 5 different clinics, 5 days in a row and then bring 5 different individuals the next trip. Your Grand Jury was informed that Kentucky offered assistance to Florida with implementing our system; assistance that would allow the time period to be similar to Kentucky's. Your Grand Jury recognizes that it was important to get the Legislation enacting the Prescription Drug Monitoring Program passed and that concessions had to be made to accomplish this; however, since the system will not be operating for another year, the technology is certainly available and the political will attainable to reduce the time to report the data to the system.

(2) Your Grand Jury recommends that the Legislature change the statute's reporting requirement time from 15 days to a time that makes the program effective in eliminating doctor shopping.

There is no requirement in the statute that dispensing doctors access the database to see if a patient has purchased drugs within the past 30 days. The law allows physicians to voluntarily access the database. While a doctor who has an established long term relationship with a patient may not need to access the database, as he is familiar with the patient, doctors at pain clinics who first meet a patient for a few moments and prescribe opioids to that patient, and every other patient, need to access the database. If they do not access the database, they will turn a blind eye to doctor shopping and continue to dispense opioids to traffickers, dealers and users who are doctor shopping.

(3) Your Grand Jury recommends that the Florida Legislature, the Florida Board of Medicine and/or the Florida Board of Osteopathic Medicine require all doctors who work at pain clinics to access and view patients' databases prior to prescribing and dispensing medication to patients.

The Professional Staff of the Health and Human Services Appropriations Committee noted in their analysis of the Florida Senate Bill that ultimately became Florida Statute 893.055, the goals of other states' "Prescription Drug Monitoring Programs are dependent on the mission of the state agency that operates the program or uses the data. Each state that has implemented a Prescription Drug Monitoring Program has its own set of goals for its program." One of the concerns opponents to the legislation

had to the Prescription Drug Monitoring Program was that Law Enforcement would have access to the database without probable cause and that this could violate a person's right to privacy.¹⁹ Law Enforcement does not have direct access to the information in the database. Law Enforcement may request information from the program manager during active investigations regarding potential criminal activity, fraud or theft regarding prescribed controlled substances. The Legislature recognized people's privacy concerns when it enacted the Prescription Drug Monitoring Program. Florida Statute 893.0551(5) makes it a third degree felony for any person who willfully and knowingly divulges information contained in the Prescription Drug Monitoring Program database in a manner that violates the statute. Additionally, the Program Implementation and Oversight Task Force is "to monitor the implementation and safeguarding of the electronic system established for the prescription drug monitoring program under section 893.055, Florida Statutes, and to ensure privacy, protection of individual medication history, and the electronic system's appropriate use by physicians, dispensers, pharmacies, law enforcement agencies, and those authorized to request information from the electronic system." It is interesting to note that pharmacy records are now readily available to law enforcement.

¹⁹ One respected legal scholar, an opponent of the legislation, testified "I can not be clear enough on this. This is the most dangerous legislation of the last 50 years. There is no legal standard that the police are held to." He cautioned, "If you just turn this over to law enforcement, I tell you, mark my words, five years from now the nightmare stories will be all over. And they won't be you reading about them in the papers. It will be your friends; it will be your children; it will be your spouses." He further predicted, "I assure you, this law will not withstand a constitutional attack in court. It just won't. You can't have law enforcement have access to your prescription history. It's blatantly illegal and irresponsible." A legislator who pushed for the enactment of the legislation testified that the constitutionality of the legislation was never an issue.

B. Pain Clinics acting as Pharmacies

In less than 2 years the number of pain clinics in South Florida went from 4 to 176, unleashing 9 million dose units of Oxycodone in our community every 6 months. In February and March of 2009 there was even a shortage of Oxycodone in South Florida because the demand was so high. Supporters of pain clinics argue that pain clinics provide a necessary medical service to our community and that reforms must not inhibit their doctors who are treating patients with legitimate ailments. Opponents counter that pain clinics are unregulated facilities supplying prescription drugs to traffickers, dealers and users and are practicing profit making medicine rather than treating patients' ailments.

Pain Clinics advertise the availability of prescription drugs and dispense prescription drugs to patients. It does not make any sense that a pain clinic that advertises and dispenses prescription drugs would be subjected to lesser standards of practice than a pharmacy. The new legislation now requires pain clinics to register with the Department of Health and subjects them to regulations by the Board of Medicine and Board of Osteopathic Medicine. However, until the Prescription Drug Monitoring Program is implemented,

(4) Your Grand Jury recommends that prescription drugs be prohibited from being dispensed at pain clinics, unless there is no pharmacy within 10 miles of the pain clinic.

(5) In the alternative to recommendation (4) Your Grand Jury recommends that a pain clinic be allowed to dispense only a 3 day supply of prescription drugs to patients instead of a 30 day supply.

(6) Your Grand Jury recommends that pain clinics be prohibited from advertising that they sell prescription drugs.

Most Pain Clinics deal exclusively in cash. A few are now advertising that they accept credit cards. None accept medical insurance. Cash only clinics have the ability to avoid scrutiny by not engaging in business with insurance companies and they have the ability to hide proceeds more effectively. If pain clinics accepted medical insurance then the Department of Health could further regulate them, and ensure that they are not contributing to doctor shopping.

(7) Your Grand Jury recommends that pain clinics be required to accept major medical insurance.

C. The Regulation of Pain Clinics

Prior to the enactment of this legislation the Florida Board of Medicine and the Florida Board of Osteopathic Medicine did not have the authority to regulate the pain clinics. They could regulate the doctors who worked at the pain clinics; however, a member of the Florida Board of Medicine testified that the Board could not initiate a complaint against a doctor without a specific complainant filing a complaint against a doctor. With the enacted legislation the Boards of Medicine will have the authority to adopt rules regulating the doctors and pain clinics. A panel of physicians, recently appointed to listen to suggestions and discuss potential regulations and solutions, is currently conducting public hearings regarding rules for pain clinics. Whether the Boards of Medicine will have the fortitude to regulate and discipline its members in this very

lucrative field is another question. If the Board of Medicine and the Board of Osteopathic Medicine do not exercise their authority to aggressively regulate the doctors and pain clinics then the Prescription Drug Monitoring Program alone will lack the teeth to make an impact against doctor shopping. While your Grand Jury recognizes that the Board of Medicine and the Board of Osteopathic Medicine will earnestly address regulations impacting pain clinics and rules governing physicians who work at pain clinics, your Grand Jury implores the Legislature, the Board of Medicine and the Board of Osteopathic Medicine to consider the following:

(8) Your Grand Jury recommends that the Legislature consider whether it is appropriate for nonphysicians to own pain clinics and whether owners of pain clinics should be physicians.

(9) Your Grand Jury recommends that a Medical Director for a pain clinic be Board Certified in pain medicine.

(10) Your Grand Jury recommends that only doctors Board Certified in Pain Medicine be allowed to dispense drugs from a pain clinic.

(11) Your Grand Jury recommends that the Board of Medicine and the Board of Osteopathic Medicine establish minimum qualifications and training for physicians working at pain clinics.

(12) Your Grand Jury recommends that background checks be undertaken of all owners, doctors and employees at pain clinics.

(13) Your Grand Jury recommends that pain clinics not be owned in whole or part by a person who has been convicted of or who has pled guilty or nolo contendere to an offense that constitutes a felony.

(14) Your Grand Jury recommends that pain clinics not be owned, either in whole or in part, by or have any contractual relationship, whether through employment or by independent contract, with a physician who during the course of his practice has been denied the privilege of prescribing, dispensing, administering, supplying, or selling any controlled substance and who has, during the course of his practice, had board action taken against his medical license as a result of dependency on drugs or alcohol.

(15) Your Grand Jury recommends that pain clinics not be owned in whole or in part by a person who has been convicted of or who has pled guilty or nolo contendere to an offense that constitutes a misdemeanor, the facts of which relate to the distribution or illegal prescription of any narcotic.

D. The Treatment of Patients

Throughout your Grand Jury's term, pain medicine specialists questioned how a physician at a pain clinic could medically treat so many patients and provide the appropriate follow up care to the patients. The answer they all opined was that the physicians at the pain clinics could not ethically treat that many patients at a time.

(16) Your Grand Jury recommends that the Board of Medicine and Board of Osteopathic Medicine establish standards of care for doctors employed at pain clinics that limit the number of active patients a doctor can medically treat to 100 to ensure that all patients are receiving the proper care and follow up care at the facility for their ailments.

(17) Your Grand Jury recommends that pain clinics be allowed to treat only a certain small percentage of patients residing from out of state.

IX. CONCLUSION

In the past 2 years the number of pain clinics in South Florida mushroomed from 4 to 176, dumping 9 million dose units of Oxycodone in our community every 6 months. Although the pain clinics originated in Broward County, they have spread north quickly throughout the rest of Florida, particularly in the major metropolitan areas.

With the enactment of the Prescription Drug Monitoring Program and the legislation that provides the medical licensing boards with authority to regulate the pain clinics, there is hope that the legislation will effectively eliminate doctor shopping once the Prescription Drug Monitoring Program is implemented and the medical licensing boards set rules and standards of practice for the pain clinics and the doctors who work at the clinics.

While obviously not all pain clinics are Pill Mills, Pill Mills are a true danger whose harms will be affecting our communities long into the future in ways unbeknownst to us. With the implementation of the Prescription Drug Monitoring Program, our community should see the eradication of Pill Mills and the further emergence of pain medicine that truly addresses patients' ailments.

Finally,

(18) Your Grand Jury recommends that a future Broward County Grand Jury be empanelled prior to the March 2012 Spring Term and prior to the Program Implementation and Oversight Task Force's presentation of its final report in July 2012, to review the status of Pill Mills in South Florida, the status and effectiveness of

the Prescription Drug Monitoring Program and the rules and regulations the Florida Board of Medicine and the Florida Board of Osteopathic Medicine enact to regulate the pain clinics.

DATED this 19th day of November, A.D., 2009

Lancea V. LeBlanc, Foreperson
Broward County Grand Jury
Spring Term, 2009

APPENDIX A

Chapter 893

DRUG ABUSE PREVENTION AND CONTROL

893.0551 Public records exemption for the prescription drug monitoring program.--

(1) For purposes of this section, the term:

(a) "Active investigation" has the same meaning as provided in s. 893.055.

(b) "Dispenser" has the same meaning as provided in s. 893.055.

(c) "Health care practitioner" or "practitioner" has the same meaning as provided in s. 893.055.

(d) "Health care regulatory board" has the same meaning as provided in s. 893.055.

(e) "Law enforcement agency" has the same meaning as provided in s. 893.055.

(f) "Pharmacist" means any person licensed under chapter 465 to practice the profession of pharmacy.

(g) "Pharmacy" has the same meaning as provided in s. 893.055.

a

(h) "Prescriber" has the same meaning as provided in s. 893.055.

(2) The following information of a patient or patient's agent, a health care practitioner, a dispenser, an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy that is contained in records held by the department under s. 893.055 is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution:

(a) Name.

(b) Address.

(c) Telephone number.

(d) Insurance plan number.

(e) Government-issued identification number.

(f) Provider number.

(g) Drug Enforcement Administration number.

(h) Any other unique identifying information or number.

(3) The department shall disclose such confidential and exempt information to the following entities after using a verification process to ensure the legitimacy of that person's or entity's request for the information:

(a) The Attorney General and his or her designee when working on Medicaid fraud cases involving prescription drugs or when the Attorney General has initiated a review of specific identifiers of Medicaid fraud regarding prescription drugs. The Attorney General or his or her designee may disclose the confidential and exempt information received from the department to a criminal justice agency as defined in s. 119.011 as part of an active investigation that is specific to a violation of prescription drug abuse or prescription drug diversion law as it relates to controlled substances. The Attorney General's Medicaid fraud investigators may not have direct access to the department's database.

(b) The department's relevant health care regulatory boards responsible for the licensure, regulation, or discipline of a practitioner, pharmacist, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a specific controlled substances investigation for prescription drugs involving a designated person. The health care regulatory boards may request information from the department but may not have direct access to its database. The health care regulatory boards may provide such information to a law enforcement agency pursuant to ss. 456.066 and 456.073.

(c) A law enforcement agency that has initiated an active investigation involving a specific violation of law regarding prescription drug abuse or diversion of prescribed controlled substances. The law enforcement agency may disclose the confidential and exempt information received from the department to a criminal justice agency as defined in s. 119.011 as part of an active investigation that is specific to a violation of prescription drug abuse or prescription drug diversion law as it relates to controlled substances. A law enforcement agency may request information from the department but may not have direct access to its database.

(d) A health care practitioner who certifies that the information is necessary to provide medical treatment to a current patient in accordance with ss. 893.05 and 893.055.

(e) A pharmacist who certifies that the requested information will be used to dispense controlled substances to a current patient in accordance with ss. 893.04 and 893.055.

(f) A patient or the legal guardian or designated health care surrogate for an incapacitated patient, if applicable, making a request as provided in s. 893.055(7)(c)4.

(g) The patient's pharmacy, prescriber, or dispenser who certifies that the information is necessary to provide medical treatment to his or her current patient in accordance with s. 893.055.

(4) Any agency or person who obtains such confidential and exempt information pursuant to this section must maintain the confidential and exempt status of that information.

(5) Any person who willfully and knowingly violates this section commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(6) This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2014, unless reviewed and saved from repeal through reenactment by the Legislature.

History.--s. 1, ch. 2009-197.

APPENDIX B

Chapter 893 DRUG ABUSE PREVENTION AND CONTROL

¹893.055 Prescription drug monitoring program.--

(1) As used in this section, the term:

(a) "Patient advisory report" or "advisory report" means information provided by the department in writing, or as determined by the department, to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances. All advisory reports are for informational purposes only and impose no obligations of any nature or any legal duty on a prescriber, dispenser, pharmacy, or patient. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The advisory reports issued by the department are not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of the report; and a person who participates in preparing, reviewing, issuing, or any other activity related to an advisory report may not be permitted or required to testify in any such civil action as to any findings, recommendations, evaluations, opinions, or other actions taken in connection with preparing, reviewing, or issuing such a report.

(b) "Controlled substance" means a controlled substance listed in Schedule II, Schedule III, or Schedule IV in s. 893.03.

(c) "Dispenser" means a pharmacy, dispensing pharmacist, or dispensing health care practitioner.

(d) "Health care practitioner" or "practitioner" means any practitioner who is subject to licensure or regulation by the department under chapter 458, chapter 459, chapter 461, chapter 462, chapter 464, chapter 465, or chapter 466.

(e) "Health care regulatory board" means any board for a practitioner or health care practitioner who is licensed or regulated by the department.

(f) "Pharmacy" means any pharmacy that is subject to licensure or regulation by the department under chapter 465 and that dispenses or delivers a controlled substance to an individual or address in this state.

(g) "Prescriber" means a prescribing physician, prescribing practitioner, or other prescribing health care practitioner.

(h) "Active investigation" means an investigation that is being conducted with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings, or that is ongoing and continuing and for which there is a reasonable, good faith

anticipation of securing an arrest or prosecution in the foreseeable future.

(i) "Law enforcement agency" means the Department of Law Enforcement, a Florida sheriff's department, a Florida police department, or a law enforcement agency of the Federal Government which enforces the laws of this state or the United States relating to controlled substances, and which its agents and officers are empowered by law to conduct criminal investigations and make arrests.

(2)(a) By December 1, 2010, the 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 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.

(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 15 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) 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.

(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 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(5)(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.

(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 department in the furtherance of the prescription drug monitoring program.

(b) The direct-support organization is not considered a lobbying firm within the meaning of s. 11.045.

(c) The director of the Office of Drug Control shall appoint a board of directors for the direct-support 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 Office of Drug Control. The director shall provide guidance 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.

(d) The direct-support organization shall operate under written contract with the Office of Drug Control. The contract must, at a minimum, provide for:

1. Approval of the articles of incorporation and bylaws of the direct-support organization by the Office of Drug Control.
2. Submission of an annual budget for the approval of the Office of Drug Control.
3. Certification by the Office of Drug Control 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 Office of Drug Control 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 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 Office of Drug Control, as determined by the office in consultation with the department, and in the best interests of the state. The direct-support organization must obtain a written approval from the director of the Office of Drug Control 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 Office 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 Office of Drug Control if the direct-support organization is no longer approved by the Office 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 Office of Drug Control 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 Office 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.

(13) 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.

History.--s. 1, ch. 2009-198.

¹**Note.**--Section 2, ch. 2009-198, provides that:

"(1) The Program Implementation and Oversight Task Force is created within the Executive Office of the Governor. The director of the Office of Drug Control shall be a nonvoting, ex officio member of the task force and shall act as chair. The Office of Drug Control and the Department of Health shall provide staff support for the task force.

"(a) The following state officials shall serve on the task force:

- "1. The Attorney General or his or her designee.
- "2. The Secretary of Children and Family Services or his or her designee.
- "3. The Secretary of Health Care Administration or his or her designee.
- "4. The State Surgeon General or his or her designee.

"(b) In addition, the Governor shall appoint 12 members of the public to serve on the task force. Of these 12 appointed members, one member must have professional or occupational expertise in computer security; one member must be a Florida-licensed, board-certified oncologist; two members must be Florida-licensed, fellowship-trained, pain-medicine physicians; one member must be a Florida-licensed primary care physician who has experience in prescribing scheduled prescription drugs; one member must have professional or occupational expertise in e-Prescribing or prescription drug monitoring programs; two members must be . . . Florida-licensed pharmacists; one member must have professional or occupational expertise in the area of law enforcement and have experience in prescription drug investigations; one member must have professional or occupational expertise as an epidemiologist and have a background in tracking and analyzing drug trends; and two members must have professional or occupational expertise as providers of substance abuse treatment, with priority given to a member who is a former substance abuser.

"(c) Members appointed by the Governor shall be appointed to a term of 3 years each. Any vacancy on the task force shall be filled in the same manner as the original appointment, and any member appointed to fill a vacancy shall serve only for the unexpired term of the member's predecessor.

"(d) Members of the task force and members of subcommittees appointed under subsection (4) shall serve without compensation, but are entitled to reimbursement for per diem and travel expenses as provided in s. 112.061, Florida Statutes.

"(e) The task force shall meet at least quarterly or upon the call of the chair.

"(2) The purpose of the task force is to monitor the implementation and safeguarding of the electronic system established for the prescription drug monitoring program under s. 893.055, Florida Statutes, and to ensure privacy, protection of individual medication history, and the electronic system's appropriate use by physicians, dispensers, pharmacies, law enforcement agencies, and those authorized to request information from the electronic system.

"(3) The Office of Drug Control shall submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1 of each year which contains a summary of the work of the task force during that year and the recommendations developed in accordance with the task force's purpose as provided in subsection (2). Interim

reports may be submitted at the discretion of the chair.

"(4) The chair of the task force may appoint subcommittees that include members of state agencies that are not represented on the task force for the purpose of soliciting input and recommendations from those state agencies as needed by the task force to accomplish its purpose as provided in subsection (2). In addition, the chair may appoint subcommittees as necessary from among the members of the task force in order to efficiently address specific issues. If a state agency is to be represented on any subcommittee, the representative shall be the head of the agency or his or her designee. The chair may designate lead and contributing agencies within a subcommittee.

"(5) The direct-support organization created in s. 893.055, Florida Statutes, may collect, expend, and provide funds and other assistance to the department for the development, implementation, and operation of the task force.

"(6) The task force shall provide a final report in accordance with the task force's purpose as provided in subsection (2) on July 1, 2012, to the Governor, the President of the Senate, and the Speaker of the House of Representatives. Such report shall be prepared using only data that does not identify a patient, a prescriber, or a dispenser. The task force shall expire and this section is repealed on that date unless reenacted by the Legislature."

APPENDIX C

Chapter 458 Medical Practice

458.309 Rulemaking authority.--

(1) The board has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it.

(2)(a) Any rules which the board adopts relating to the classroom phase of medical education shall not apply to any person who is enrolled in the classroom phase of medical education or has graduated prior to or at the time the rule becomes effective, so long as such person does not interrupt his or her medical education.

(b)1. Any rules which the board adopts relating to the clinical clerkship phase of medical education shall not apply to any person who is enrolled in the clinical clerkship phase of medical education prior to or at the time the rule becomes effective, so long as such person does not interrupt his or her medical education.

2. Rules adopted by the Florida Board of Medical Examiners prior to October 1, 1986, and relating to clinical clerkships for graduates of foreign medical schools do not apply to any such graduate who:

a. Had completed a clinical clerkship prior to the effective date of the rule; or

b. Had begun a clinical clerkship but had not completed the clinical clerkship prior to the effective date of the rule, so long as the clinical clerkship took no longer than 3 years to complete.

(c) Any rules which the board adopts relating to residency shall not apply to any person who has begun his or her residency prior to or at the time the rule becomes effective, so long as such person does not interrupt the residency.

(3) All physicians who perform level 2 procedures lasting more than 5 minutes and all level 3 surgical procedures in an office setting must register the office with the department unless that office is licensed as a facility pursuant to chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the Board of Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed.

(4) 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 a physician who is primarily engaged in the treatment of pain by prescribing or

dispensing controlled substance medications, must register with the department by January 4, 2010, unless that clinic is licensed as a facility pursuant to chapter 395. A physician may not practice medicine in a pain-management clinic that is required to but has not registered with the department. Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic. If the clinic is licensed as a health care clinic under chapter 400, the medical director is responsible for registering the facility with the department. If the clinic is not registered pursuant to chapter 395 or chapter 400, the clinic shall, upon registration with the department, designate a physician who is responsible for complying with all requirements related to registration of the clinic. The designated physician shall be licensed under this chapter or chapter 459 and shall practice at the office location for which the physician has assumed responsibility. The department shall inspect the clinic annually to ensure that it complies with rules of the Board of Medicine adopted pursuant to this subsection and subsection (5) unless the office is accredited by a nationally recognized accrediting agency approved by the Board of Medicine. The actual costs for registration and inspection or accreditation shall be paid by the physician seeking to register the clinic.

(5) 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, the following subjects:

- (a) Facility operations;
- (b) Physical operations;
- (c) Infection control requirements;
- (d) Health and safety requirements;
- (e) Quality assurance requirements;
- (f) Patient records;
- (g) Training requirements for all facility health care practitioners who are not regulated by another board;
- (h) Inspections; and
- (i) 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) A privately owned clinic, facility, or office that advertises in any medium for any type of pain-management services or employs one or more physicians who are primarily engaged in the treatment of pain by prescribing or dispensing controlled substances is exempt from the registration provisions in subsection (4) if the majority of the physicians who provide services in the clinic, facility, or office primarily provide surgical services.

History.--ss. 1, 8, ch. 79-302; ss. 2, 3, ch. 81-318; ss. 5, 22, 25, 26, ch. 86-245; s. 4, ch. 91-429; s. 200, ch. 97-103; s. 120, ch. 98-200; s. 92, ch. 99-397; s. 3, ch. 2009-198.

APPENDIX D

Chapter 459

OSTEOPATHIC MEDICINE

459.005 Rulemaking authority.--

(1) The board has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it.

(2) All physicians who perform level 2 procedures lasting more than 5 minutes and all level 3 surgical procedures in an office setting must register the office with the department unless that office is licensed as a facility pursuant to chapter 395. The department shall inspect the physician's office annually unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the Board of Osteopathic Medicine. The actual costs for registration and inspection or accreditation shall be paid by the person seeking to register and operate the office setting in which office surgery is performed.

(3) 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 a physician who is licensed under this chapter and who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, must register with the department by January 4, 2010, unless that clinic is licensed as a facility under chapter 395. A physician may not practice osteopathic medicine in a pain-management clinic that is required to but has not registered with the department. Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic. If the clinic is licensed as a health care clinic under chapter 400, the medical director is responsible for registering the facility with the department. If the clinic is not registered under chapter 395 or chapter 400, the clinic shall, upon registration with the department, designate a physician who is responsible for complying with all requirements related to registration of the clinic. The designated physician shall be licensed under chapter 458 or this chapter and shall practice at the office location for which the physician has assumed responsibility. The department shall inspect the clinic annually to ensure that it complies with rules of the Board of Osteopathic Medicine adopted pursuant to this subsection and subsection (4) unless the office is accredited by a nationally recognized accrediting agency approved by the Board of Osteopathic Medicine. The actual costs for registration and inspection or accreditation shall be paid by the physician seeking to register the clinic.

(4) The Board of Osteopathic Medicine shall adopt rules setting forth standards of practice for physicians who practice 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, the following subjects:

- (a) Facility operations;
- (b) Physical operations;

- (c) Infection control requirements;
- (d) Health and safety requirements;
- (e) Quality assurance requirements;
- (f) Patient records;
- (g) Training requirements for all facility health care practitioners who are not regulated by another board;
- (h) Inspections; and
- (i) 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.

(5) A privately owned clinic, facility, or office that advertises in any medium for any type of pain-management services or employs one or more physicians who are primarily engaged in the treatment of pain by prescribing or dispensing controlled substances is exempt from the registration provisions in subsection (3) if the majority of the physicians who provide services in the clinic, facility, or office primarily provide surgical services.

History.--ss. 1, 6, ch. 79-230; ss. 2, 3, ch. 81-318; ss. 27, 29, ch. 86-290; s. 4, ch. 91-429; s. 121, ch. 98-200; s. 101, ch. 99-397; s. 4, ch. 2009-198.