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EXECUTIVE SUMMARY

In Florida, an average of seven people die every day because of lethal overdoses from the illegal, non-medical misuse of one or more prescription drugs. In 2009, Orange County had approximately 100 deaths involving the misuse of prescription drugs claiming the youngest victim at age 15 and in 2010, the number rose to 146 prescription drug-related deaths. The number of prescription drug-related deaths statewide has increased by 8.9% from 2009-2010.

The proliferation of pain management clinics and access to home medicine cabinets has increased availability and diversion of dangerous narcotics in our community. A Broward County Grand Jury Interim Report on “The Proliferation of Pain Management Clinics in South Florida,” released November 2009, indicated that 49 of the top 50 oxycodone dispensing practitioners were in nine counties in Florida and dispensed 9.2 million oxycodone units during the fourth quarter of 2008 and the first quarter of 2009. Orange County was one of the top nine counties with 133,800 units dispensed during this sixth month period. Local law enforcement have been addressing this problem for several years, in fact, the Metropolitan Bureau of Investigation (MBI) reported that the number of controlled prescription-drug investigations in Orlando increased from 10% of all drug-related investigations in 2009 to 70% in 2011. In 2010, one pain management clinic in Orlando prescribed more oxycodone in the fourth quarter than was prescribed by all doctors in the entire State of California during the same time frame.

We have seen these numbers climb across the State and in 2010, the U.S. Drug Enforcement Administration (DEA) records show that Florida led the nation in prescription drug misuse. DEA records indicate that Florida practitioners purchased 41.2 million oxycodone pills during the first six months of 2010, compared to a total of 4.8 million purchased by practitioners in the other 49 states. When you combine pharmacists, dispensing physicians and other sources, we sold more than 620 million oxycodone pills in 2010, more than any other state. In 2011, the number of doses of the narcotic painkillers sold by Florida pharmacies and other sources fell by 20% to 497 million. In addition, due to the passage of Florida’s comprehensive prescription drug legislation, during the 2010 and 2011 legislative sessions, we have seen the number of oxycodone units purchased by practitioners drop to less than 1 million in the first five months of 2011.

In December 2010, Orange County Board of County Commissioners passed the “Chad Phillips Act” an ordinance relating to pain management clinics. This ordinance placed a moratorium on new pain management clinics and established hours of operation for existing pain management clinics, prohibited cash-only as the only method of transaction and required county staff to
report to the Board on its findings and recommendations on issues relating to pain management clinics. When Orange County passed its moratorium and ordinance in 2010, several cities and neighboring counties followed suit. These include the Cities of Orlando, Winter Park, Maitland, Winter Garden, and Ocoee as well as Seminole and Osceola County. A report from the Attorney General’s Office in July 2011, indicated that over 30 cities and counties have enacted moratoriums on new pain management clinics and regulations for existing clinics as they further examine this serious public health issue.

On June 3, 2011, Mayor Jacobs announced the formation of a Prescription Drug Task Force (Task Force) to address the escalating problem of prescription drug abuse in our community. The Task Force was charged to examine the extent of the prescription drug problem, conduct a review of state legislation and local ordinances and determine the need for substantive regulations for pain management clinics through a collaborative, multijurisdictional effort. The 18-member Task Force chaired by Former Orange County Mayor Richard Crotty, brought together law enforcement, healthcare, pharmacies, education, prevention and public policy professionals to address this growing problem. The Task Force is responsible for providing viable solutions that will reduce the misuse and non-medical use of prescription drugs and diversion in our county.

During the County’s moratorium period, the Task Force met for four months and conducted an intense review of state law and local ordinances, enforcement actions and best practices. The Task Force held three meetings and created two subcommittees, the Enforcement and Healthcare & Pharmacy Subcommittees, which held seven meetings; five of those meetings were held jointly to address the problem comprehensively. The joint subcommittees included participation from Task Force members as well as pain management physicians and attorneys, medical associations, independent pharmacists, prevention and treatment agencies, law enforcement, and county staff.

The proposed Task Force recommendations addressing this serious public health issue in our community include:

1) Expand the Pain Management Clinic (PMC) definition by including “Dangerous Drugs”, designed to be a very narrow subset of prescription drugs that have proved to be most dangerous to the community. Limit the exceptions included in state legislation.

2) Registration and Operational Guidelines for PMC’s include:
   a. Registration of PMC
   b. Display of Licenses
   c. Prohibiting on-site sale and dispensing of controlled substances at PMC’s
   d. Prohibiting alcoholic beverages on premises
e. Requiring adequate inside waiting area
f. Establishing operating hours Monday-Friday 7am-7pm
g. Requiring PMC’s submit monthly business records to the County
h. Maintaining personnel records on all employees and volunteers
i. Zoning and Locational restrictions (Industrial Zone I-4)
j. Separation distances for PMC and pharmacy
k. Requiring adequate parking
l. Defining landlord responsibility

3) Regulations for pharmacies include:
   a. Identification requirement
   b. Verification of prescription
   c. Requirement to maintain records
   d. Pharmacy compensation restrictions
   e. Separation distances

4) Requirements for physicians to check Prescription Drug Monitoring Program before prescribing “dangerous drugs.”

5) Requirements for pharmacists to check Prescription Drug Monitoring Program before dispensing “dangerous drugs.”

6) Providing for criminal penalties

7) Increasing healthcare provider education on the misuse and abuse of prescription drugs

8) Increasing prescription drug education and awareness in the Drug Retail Industry and among Independent Pharmacists & Drug Free Workplaces, Parents and Other Sectors

9) Increasing training for law enforcement, crisis intervention team, prevention and treatment

10) Information sharing of prescription drug abuse and misuse data

11) Developing an evidence-based prescription drug public awareness campaign

12) Promoting and advertising Prescription Take Back Days in the community

13) Beta test the Clinical Decision Support System (CDSS) tool for management of opioid therapy
In November 2010, the Board of County Commissioners passed the “Chad Phillips Act” which placed a moratorium on new pain management clinics and an ordinance on existing pain management clinics regulating the hours of operation from 7am – 9pm and prohibiting cash-only transactions as the only form of payment. The moratorium was set to expire on December 14, 2011.

After the passage of the County pain management clinic moratorium ordinance, the Law Enforcement Pain Management Clinic workgroup (Enforcement Workgroup) was formed and began meeting in March of 2011. The Enforcement Workgroup included federal, state and local law enforcement, U.S., state and county attorney’s office representatives, County zoning, code enforcement and planning personnel and staff from other cities and counties in the area. The purpose of the Enforcement Workgroup was to review various county and city ordinances relating to permitting, land use and zoning regulations as well as to research options for additional local regulations such as requiring clinics to use tamper-proof prescription pads (or pad storage policies), immediately reporting controlled substances prescribed and/or dispensed, and engaging in additional daily reporting relating to staff and activity in the clinic as it relates to controlled substances. The Enforcement Workgroup closely monitored legislative activity, specifically, the comprehensive prescription drug legislation that took effect on July 1, 2011.

In April 2011, Mayor Jacobs’ formed the Prescription Drug Abuse Healthcare and Pharmacy Workgroup (Healthcare & Pharmacy Workgroup) to bring healthcare, pharmacy, law enforcement, prevention and treatment professionals together to develop strategies on information sharing, training and education. With access to patients, physicians and other medical providers, hospitals and pharmacies play a vital role to addressing this public health problem. In May, 2011, the Healthcare & Pharmacy Workgroup members signed a resolution to advocate for the Prescription Drug Monitoring Program and the resolution was forwarded to the Orange County Legislative Delegation in the 2011 session.

On June 3, 2011, Mayor Jacobs’ announced the formation of a comprehensive Prescription Drug Task Force (Task Force) to address the escalating problem of prescription drug abuse and misuse in Orange County.

**Task Force Purpose:** Our state has become a focal point for a national epidemic of prescription drug abuse, especially addictive pain medications such as oxycodone. The U.S. Drug Enforcement Administration
records show that Florida leads the nation in prescription drug misuse. DEA records indicate that Florida practitioners purchased 41.2 million oxycodone pills during the first six months of 2010, compared to a total of 4.8 million purchased by practitioners in the other 49 states.

The proliferation of pain management clinics and access to home medicine cabinets has increased availability and diversion of dangerous narcotics in our community. In Florida, an average of seven people die every day because of lethal overdoses from the illegal, non-medical misuse of one or more prescription drugs. In 2009, Orange County had approximately 100 deaths involving the misuse of prescription drugs with the youngest at age 15.

The Task Force was a collaborative, multijurisdictional effort to address the non-medical misuse of prescription drugs and the proliferation of pain management clinics through use of enforcement, healthcare, pharmacies, education, prevention and public policy objectives.

**Meeting:**

The Task Force will met three times to produce a report on the extent of the prescription drug problem, and to provide recommendations on regulation of pain management clinics and an action plan for community awareness and prevention strategies to Orange County Mayor Teresa Jacobs and the Board of County Commissioners.

**Subcommittee(s):**

Two subcommittees were created. The function of each subcommittee was to address the deliverables set by the Task Force by gathering and analyzing information through local, state and national resources in their respective subject matter areas (Healthcare & Pharmacy and Enforcement). The information gathered by the subcommittees was used to produce the work product of the Task Force. Each subcommittee was staffed with Orange County personnel as well as subject matter experts. The subcommittees met on a frequent and regular basis and presented their respective reports to the full Task Force at its final meeting on October 31, 2011.
**Law Enforcement Subcommittee:**
- Honorable Jerry L. Demings, Orange County Sheriff
- Joe Cocchiarella, State Attorney’s Office, Ninth Judicial Circuit & MBI Prosecutor

**Healthcare & Pharmacy Subcommittee:**
- Marlin Hutchens, Vice President, Walgreens
- Charles Chase, D.O., Winnie Palmer Hospital and Anesthesiologists of Greater Orlando

**Task Force Coordinators:**
- Carol Burkett, Director, Orange County Drug Free Office
- Dana Crosby-Collier, Assistant County Attorney, County Attorney’s Office
PRESCRIPTION DRUG TASK FORCE MEMBERS

Richard T. Crotty, Former Orange County Mayor, Chair

George Ralls, M.D., Orange County Medical Director/Health Services Dir., Vice Chair

Detective Barb Bergin, CrimeLine

Charles Chase, D.O., Winnie Palmer Hospital and Anesthesiologists of Greater Orlando

Joe Cocchiarella, State Attorney’s Office, Ninth Judicial Circuit & MBI General Counsel

Joyce Dawley, Director, Florida Department of Law Enforcement

Honorable Jerry L. Demings, Orange County Sheriff

Carolann Duncan, Regional Director, Florida Department of Children and Families

Dr. Jan Garavaglia, Orange County Medical Examiner

Marlin Hutchens, Vice President Walgreens

Meena Morgan, Pharm.D., Pharmacy Manager, Orlando Regional Medical Center

Rich Morrison, Senior Vice President, Florida Hospital

Michael Rathel, Rathel Law Group

Chief Paul Rooney, City of Orlando Police Department

Kevin Sherin, M.D. Orange County Health Department Director

Alan Villaverde, President, Peabody Hotels

Phil Williams, Director, Metropolitan Bureau of Investigation
The National Office of Drug Control issued a report in 2011 titled “Epidemic: Responding to America’s Prescription Drug Abuse Crisis.” The report indicated that prescription drug abuse is the nation’s fastest-growing drug problem. Second to marijuana, abuse of prescription painkillers is the nation’s most prevalent illegal drug problem. The National Survey on Drug Use and Health indicates nearly one-third of all persons ages 12 and over who used drugs for the first time in 2009 began by using a prescription drug non-medically. The report also indicates that prescription drugs are the second most-abused category of drugs after marijuana among young people. Prescription drug abuse in Florida has also caught nationwide attention over the last several years by having 98 of the top 100 prescribing oxycodone physicians, practitioners purchasing 41.2 million oxycodone pills during the first six months of 2010, a proliferation of pain management clinics resulting in an increase in non-medical use, diversion and an influx of people from other states. Lastly, state reports indicate an average of seven people die every day because of lethal overdoses from the illegal, non-medical misuse of one or more prescription drugs in Florida.

Listed below are national, state and local prescription drug-related statistics that Task Force and subcommittee members reviewed during their discussions.

National Prescription Drug-Related Data:
Commonly Abused Medications (National Institute of Drug Abuse):
• Opioids – usually prescribed to treat pain (Oxycontin and Vicodin)
• Depressants – used to treat anxiety and sleep disorders (Xanax and Valium)
• Stimulants – prescribed to treat ADHD (Adderall and Ritalin)

The National Survey on Drug Use and Health in 2009 and 2010 revealed that:
• 7 million people reported taking prescription drugs non-medically in the past month (Aged 12 or Older)
• Abuse of prescription pain-killers now ranks second—only behind marijuana - as the nation's most prevalent illegal drug problem.
• Approximately two million older adults used prescriptions drugs non-medically.

Source: SAMHSA, 2009 & 2010 National Survey on Drug Use and Health (September 2011)

Emergency Department Visits statistics are as follows:
• Emergency department visits for non-medical use of pain relievers rose 144,000 to 305,000 from 2004-2008; this is an increase of 98%.
• Emergency department visits related to prescription drug misuse of abuse increased from 627,000 visits in 2004 to 1.2 million in 2009.
• Emergency department visits increased among patients younger than 21 for oxycodone and hydrocodone and visits also increased among patients 21 or older for oxycodone, hydrocodone, fentanyl and morphine.

Source: Drug Abuse Warning Network

Youth Related Data on the Non-Medical Use of Prescription Drugs is as follows:
• Every day 2,500 kids aged 12 to 17 abuse pain relievers for the first time.
• 1 in 5 high school students indicated taking prescription drugs without a doctor’s prescription.
• In 2008, 2.1 million teens aged 12 to 17 reported abusing prescription drugs.
• Prescription drugs are the number one choice for 12 and 13 year olds.

Why Teens/Young Adults Use Prescription Drugs Non-Medically:
• Teens have a false sense of security about safety of abusing prescription medications.
• Over half of teens agree prescription drugs are easier to obtain than illegal drugs.
  o Primary Sources: Home Medicine Cabinet or Friend’s House
• 1 in 3 teens report a close friend who abuses pain relievers to get high.
• 1 in 3 teens surveyed report there is - “nothing wrong” with abusing prescription drugs “every once in a while.”
• Young adults misuse prescriptions to get high, stay awake to study and control weight.

Source: Centers for Disease Control and Prevention: 2009 National Youth Risk Behavior Survey & Office of Drug Control Teens and Prescription Drugs
Methods of Diversion:

- Friends and Family – 70% of those 12 and older obtain pain relievers for free, bought them or took them from a friend or relative

Other Methods of Diversion:

- Doctor Shopping – visit several doctors to obtain multiple prescriptions.
- Fraudulent Scripts & Theft – prescribing pads stolen from medical offices.
- Pill Mills – “pseudo pain clinics” large volume of patients, few questions asked and large quantities of controlled substances dispensed.
- Street Dealers – obtaining prescription drugs through “pill mills” to sell on the street.

Oxycodone Purchases by State Medical Practitioners – First six months of 2010

In 2011, the U.S. Drug Enforcement Administration (DEA) records show that Florida leads the nation in prescription drug misuse. DEA records indicate that Florida practitioners purchased
41.2 million oxycodone pills during the first six months of 2010, compared to a total of 4.8 million purchased by practitioners in the other 49 states. The first five months of 2011 reported Florida medical practitioners purchased approximately 925,000 oxycodone units, a dramatic decrease for the first five months in 2011. DEA also reported Florida medical practitioners and pharmacists dispensed approximately 610 million oxycodone units for 2010.

State and Local Data:
Florida Medical Examiner’s Report (2009 and 2010):

- 5,275 individuals died in Florida during 2009 and another 5,647 (7.1% more than 2009) individuals died in 2010 with one or more prescription drugs in their system.
- Oxycodone occurrences increased by 22.4% in 2010 and deaths caused by Oxycodone increased by 27.9% when compared with 2009 (1,948 in 2009 compared to 2,384 in 2010 – Oxycodone occurrences; 1,183 in 2009 compared to 1,516 in 2010 for deaths caused by Oxycodone).
- The Orange County Medical Examiner’s Office reported approximately 100 deaths involving the misuse of prescription drugs, including one claiming the youngest victim at age 15, in 2009 and 146 prescription drug-related deaths in 2010.

Source: Florida Department of Law Enforcement (FDLE) Medical Examiners, Drugs Identified in Deceased Person by Florida Medical Examiners in 2009 and 2010.

Treatment Admissions:

- Treatment admissions for prescription and opioid addiction increased 5 ½ times in Florida over the past decade. The number of prescription opioid treatment clients age 12 to 30 rose from 488 in 1999 to 7,649 in 2009, a 1,467% increase.
- The Center for Drug Free Living Addictions Receiving Facility reported in 2008-2009 clients presenting for opiate dependence was 50% pharmaceuticals and 47% Heroin. In 2009-2010, clients presenting for opiate dependency included 65% for pharmaceuticals and 32% for Heroin.
- Addictions Receiving Facility October 2010 – 83% of clients presenting for opiate dependence was pain pills and most notably, 50% of those are also dependent on Xanax and other Benzodiazepines

Source: Treatment Episode Data Sets (TEDS) submitted by the FL Department of Children and Families reported to the US Department of Health & Human Services: SAMHSA (September 2010); The Center for Drug Free Living, Addictions and Receiving Facility

Youth Substance Abuse Survey:

- Among Florida 12th graders in 2010, 11% reported having misused a prescription pain reliever non-medically in their life, 3.4% have done so in the past month.
Among Orange County high school students in 2010, 10.7% reported having misused a prescription pain reliever non-medically in their life, 3.4% have done so in the past 30 days.

Source: Florida Youth Substance Abuse Survey 2010; Orange County Youth Substance Abuse Survey 2010

Infant Withdrawal Syndrome

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- The number of infants treated for withdrawal symptoms in Florida Hospitals increased by 173% between 2006 and 2009. In 2010, 1,374 infants were born addicted to drugs which indicated a 42% increase from last year.
- In 2010, Orange County had 104 infants treated for drug withdrawal syndrome – third most in the state.
- In 2008, Department of Children and Families reopened the Dependent Newborn Unit due to the increase in cases.

Source: Florida Agency for Healthcare Administration, Florida Department of Children and Families and Orlando Sentinel

DEA Prescription Drug Take Back Day:

- Nationally, DEA, state, local and tribal law enforcement and community partners have hosted three Prescription Take Back Days at approximately 5,327 collections sites. The Take Back sites removed 995,185 pounds (498.5 tons) of unwanted and expired medications for safe and proper disposal.
- Orange County has participated in three DEA Prescription Drug Take Back Days in 2010 and 2011 with local and state law enforcement, hospitals and community agencies. A total of 17 take back sites collected more than 2,000 pounds of unwanted and expired prescription medications. DEA’s Central Florida region collected approximately 3,200 pounds of unwanted and expired prescription drugs in 2010 which was the same as was
collected in the State of Ohio. In 2011, Central Florida law enforcement collected over 2,500 pounds of unwanted and expired prescription medications.

*Source: US Drug Enforcement Administration, National Take Back Day Initiative & Central Florida Drug Enforcement Administration*
Effective December 15, 2010, Orange County Board of County Commissioners passed an ordinance known as the "Chad Phillips Act" which placed a moratorium on the issuance of Business Tax Receipts for new pain management clinics. The ordinance also regulates existing pain management clinics by established hours of operations (7am – 9pm), and established that no pain management clinic may limit its business to cash-only. The ordinance also required staff to study, analyze and report to the Board its findings and recommendations by July 12, 2011. The initial moratorium was for a period of one year expiration date December 14, 2011. On December 6, 2011, the Board of County Commissioners adopted an ordinance extending the period of the initial moratorium for 180 days (until June 12, 2012).

On July 11, 2011, staff provided the Board of County Commissioners with an update on the Orange County Pain Management Clinic moratorium and ordinance, status on the Law Enforcement Workgroup, highlights on HB 7095 (2011 Session), the Comprehensive Prescription Drug Legislation passed on July 1, 2011, and Mayor Jacobs’ Prescription Drug Task Force.

Listed below is snapshot of city and county ordinances and moratoriums regulating pain management clinics (PMC).

**Substantive Regulation on Pain Management Clinics:**

- Sarasota – Comprehensive pain management clinic ordinance
- Miami-Dade – Registration for pain clinics and PMC’s (developed pain clinic registration program - SPEED)
- Pinellas County – Registration for PMC’s and operational standards
- Manatee County – Registration of PMC’s and requirements for Prescription Drug Monitoring Program
- Hillsborough County – Registration of PMC’s, licensure, and operational standards
- Polk County – Registration of PMC’s and permitting requirements
- Flagler Beach – Regulation of PMC’s, certificate of use, operational standards
- Broward County – Zoning regulations and certificate of use
- Charlotte County – PMC regulations, zoning, and operational standards
- Martin County – Zoning regulations
- Satellite Beach – LDR amendments regulating PMC’s and daily reporting
- Ft. Lauderdale – Zoning regulations and pharmacy definitions
• Palm Beach – Zoning regulations and pharmacy and dispensing requirements
• Maitland – Registration of PMC’s and regulation of pharmacies
• West Palm Beach – Zoning and permitting for new use of pharmacy
• Sanford – Zoning regulations
• Parkland – Zoning regulations and operational requirements
• Port Canaveral – Zoning regulations and operational standards
• Miramar – Zoning regulations
• Palm Coast – PMC definitions, certificate of use, and other regulations
• Daytona Beach Shores – Zoning requirements- certificate of use, and operational standards
• Port Orange – PMC definition, zoning requirements, land use, and operational standards
• Coral Springs – New PMC conditional use, and zoning regulations
• Village of North Palm Beach – Zoning regulations, pharmacy regulations
• Tampa - Registration, permit or licensure of PMCs
• Winter Haven - Registration, permit or licensure of PMCs
• St. Cloud – Licensure for PMC’s and pharmacies

Local Moratoriums/Extension of Moratoriums on New Pain Management Clinics:
• Seminole County
• Osceola County
• Flagler County
• Lake County
• Collier County
• Pinellas County
• Kissimmee
• Winter Park
• Ocoee
• Winter Garden
• North Lauderdale
• Bradenton
• Mt. Dora
• Bonita Springs
FLORIDA COMPREHENSIVE PRESCRIPTION DRUG LEGISLATION


FS section 458.3265, re: Pain-management clinics.—
(1) REGISTRATION.—
(a)1. As used in this section, the term:
   a. “Chronic nonmalignant pain” means pain unrelated to cancer or rheumatoid arthritis which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.
   b. “Pain-management clinic” or “clinic” means any publicly or privately owned facility:
      (I) That advertises in any medium for any type of pain-management services; or
      (II) Where in any month a majority of patients are prescribed opioids, benzodiazepines, barbiturates, or carisoprodol for the treatment of chronic nonmalignant pain.

2. Each pain-management clinic must register with the department unless:
   a. That clinic is licensed as a facility pursuant to chapter 395;
   b. The majority of the physicians who provide services in the clinic primarily provide surgical services;
   c. The clinic is owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation’s most recent fiscal quarter exceeded $50 million;
   d. The clinic is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
   e. The clinic does not prescribe controlled substances for the treatment of pain;
   f. The clinic is owned by a corporate entity exempt from federal taxation under 26 U.S.C. s. 501(c)(3);
   g. The clinic is wholly owned and operated by one or more board-certified anesthesiologists, physiatrists, or neurologists; or
   h. The clinic is wholly owned and operated by one or more board-certified medical specialists who have also completed fellowships in pain medicine approved by the Accreditation Council for Graduate Medical Education, or who are also board-certified in pain medicine by a board approved by the American Board of Medical Specialties and perform interventional pain procedures of the type routinely billed using surgical codes.

(b) Each clinic location shall be registered separately regardless of whether the clinic is operated under the same business name or management as another clinic.
(c) As a part of registration, a clinic must designate a physician who is responsible for complying with all requirements related to registration and operation of the clinic in compliance with this
section. Within 10 days after termination of a designated physician, the clinic must notify the department of the identity of another designated physician for that clinic. The designated physician shall have a full, active, and unencumbered license under this chapter or chapter 459 and shall practice at the clinic location for which the physician has assumed responsibility. Failing to have a licensed designated physician practicing at the location of the registered clinic may be the basis for a summary suspension of the clinic registration certificate as described in s. 456.073(8) for a license or s. 120.60(6).

(d) The department shall deny registration to any clinic that is not fully owned by a physician licensed under this chapter or chapter 459 or a group of physicians, each of whom is licensed under this chapter or chapter 459; or that is not a health care clinic licensed under part X of chapter 400.

(e) The department shall deny registration to any pain-management clinic owned by or with any contractual or employment relationship with a physician:
1. Whose Drug Enforcement Administration number has ever been revoked.
2. Whose application for a license to prescribe, dispense, or administer a controlled substance has been denied by any jurisdiction.
3. Who has been convicted of or pleaded guilty or nolo contendere to, regardless of adjudication, an offense that constitutes a felony for receipt of illicit and diverted drugs, including a controlled substance listed in Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03, in this state, any other state, or the United States.

(f) If the department finds that a pain-management clinic does not meet the requirement of paragraph (d) or is owned, directly or indirectly, by a person meeting any criteria listed in paragraph (e), the department shall revoke the certificate of registration previously issued by the department. As determined by rule, the department may grant an exemption to denying a registration or revoking a previously issued registration if more than 10 years have elapsed since adjudication. As used in this subsection, the term “convicted” includes an adjudication of guilt following a plea of guilty or nolo contendere or the forfeiture of a bond when charged with a crime.

(g) The department may revoke the clinic’s certificate of registration and prohibit all physicians associated with that pain-management clinic from practicing at that clinic location based upon an annual inspection and evaluation of the factors described in subsection (3).

(h) If the registration of a pain-management clinic is revoked or suspended, the designated physician of the pain-management clinic, the owner or lessor of the pain-management clinic property, the manager, and the proprietor shall cease to operate the facility as a pain-management clinic as of the effective date of the suspension or revocation.

(i) If a pain-management clinic registration is revoked or suspended, the designated physician of the pain-management clinic, the owner or lessor of the clinic property, the manager, or the
proprietor is responsible for removing all signs and symbols identifying the premises as a pain-
management clinic.

(i) Upon the effective date of the suspension or revocation, the designated physician of the
pain-management clinic shall advise the department of the disposition of the medicinal drugs
located on the premises. The disposition is subject to the supervision and approval of the
department. Medicinal drugs that are purchased or held by a pain-management clinic that is
not registered may be deemed adulterated pursuant to s. 499.006.

(k) If the clinic’s registration is revoked, any person named in the registration documents of the
pain-management clinic, including persons owning or operating the pain-management clinic,
may not, as an individual or as a part of a group, apply to operate a pain-management clinic for
5 years after the date the registration is revoked.

(l) The period of suspension for the registration of a pain-management clinic shall be prescribed
by the department, but may not exceed 1 year.

(m) A change of ownership of a registered pain-management clinic requires submission of a new
registration application.

(2) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any physician who provides
professional services in a pain-management clinic that is required to be registered in subsection
(1).

(a) A physician may not practice medicine in a pain-management clinic, as described in
subsection (4), if the pain-management clinic is not registered with the department as required
by this section. Any physician who qualifies to practice medicine in a pain-management clinic
pursuant to rules adopted by the Board of Medicine as of July 1, 2012, may continue to practice
medicine in a pain-management clinic as long as the physician continues to meet the
qualifications set forth in the board rules. A physician who violates this paragraph is subject to
disciplinary action by his or her appropriate medical regulatory board.

(b) A person may not dispense any medication on the premises of a registered pain-
management clinic unless he or she is a physician licensed under this chapter or chapter 459.

(c) A physician, a physician assistant, or an advanced registered nurse practitioner must perform
a physical examination of a patient on the same day that the physician prescribes a controlled
substance to a patient at a pain-management clinic. If the physician prescribes more than a 72-
hour dose of controlled substances for the treatment of chronic nonmalignant pain, the
physician must document in the patient’s record the reason for prescribing that quantity.

(d) A physician authorized to prescribe controlled substances who practices at a pain-
management clinic is responsible for maintaining the control and security of his or her
prescription blanks and any other method used for prescribing controlled substance pain
medication. The physician shall comply with the requirements for counterfeit-resistant
prescription blanks in s. 893.065 and the rules adopted pursuant to that section. The physician
shall notify, in writing, the department within 24 hours following any theft or loss of a prescription blank or breach of any other method for prescribing pain medication.

(e) The designated physician of a pain-management clinic shall notify the applicable board in writing of the date of termination of employment within 10 days after terminating his or her employment with a pain-management clinic that is required to be registered under subsection (1). Each physician practicing in a pain-management clinic shall advise the Board of Medicine, in writing, within 10 calendar days after beginning or ending his or her practice at a pain-management clinic.

(f) Each physician practicing in a pain-management clinic is responsible for ensuring compliance with the following facility and physical operations requirements:

1. A pain-management clinic shall be located and operated at a publicly accessible fixed location and must:
   a. Display a sign that can be viewed by the public that contains the clinic name, hours of operations, and a street address.
   b. Have a publicly listed telephone number and a dedicated phone number to send and receive faxes with a fax machine that shall be operational 24 hours per day.
   c. Have emergency lighting and communications.
   d. Have a reception and waiting area.
   e. Provide a restroom.
   f. Have an administrative area, including room for storage of medical records, supplies, and equipment.
   g. Have private patient examination rooms.
   h. Have treatment rooms, if treatment is being provided to the patients.
   i. Display a printed sign located in a conspicuous place in the waiting room viewable by the public with the name and contact information of the clinic’s designated physician and the names of all physicians practicing in the clinic.
   j. If the clinic stores and dispenses prescription drugs, comply with ss. 499.0121 and 893.07.

2. This section does not excuse a physician from providing any treatment or performing any medical duty without the proper equipment and materials as required by the standard of care. This section does not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(g) Each physician practicing in a pain-management clinic is responsible for ensuring compliance with the following infection control requirements.

1. The clinic shall maintain equipment and supplies to support infection prevention and control activities.
2. The clinic shall identify infection risks based on the following:
   a. Geographic location, community, and population served.
b. The care, treatment, and services it provides.
c. An analysis of its infection surveillance and control data.
3. The clinic shall maintain written infection prevention policies and procedures that address the following:
   a. Prioritized risks.
   b. Limiting unprotected exposure to pathogens.
   c. Limiting the transmission of infections associated with procedures performed in the clinic.
   d. Limiting the transmission of infections associated with the clinic’s use of medical equipment, devices, and supplies.

(h) Each physician practicing in a pain-management clinic is responsible for ensuring compliance with the following health and safety requirements:
1. The clinic, including its grounds, buildings, furniture, appliances, and equipment shall be structurally sound, in good repair, clean, and free from health and safety hazards.
2. The clinic shall have evacuation procedures in the event of an emergency, which shall include provisions for the evacuation of disabled patients and employees.
3. The clinic shall have a written facility-specific disaster plan setting forth actions that will be taken in the event of clinic closure due to unforeseen disasters and shall include provisions for the protection of medical records and any controlled substances.
4. Each clinic shall have at least one employee on the premises during patient care hours who is certified in Basic Life Support and is trained in reacting to accidents and medical emergencies until emergency medical personnel arrive.

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

1. The designated physician for each pain-management clinic shall report all adverse incidents to the department as set forth in s. 458.351.

2. The designated physician shall also report to the Board of Medicine, in writing, on a quarterly basis the following data:
   a. The number of new and repeat patients seen and treated at the clinic who are prescribed controlled substance medications for the treatment of chronic, nonmalignant pain.
   b. The number of patients discharged due to drug abuse.
   c. The number of patients discharged due to drug diversion.
   d. The number of patients treated at the pain clinic whose domicile is located somewhere other than in this state. A patient’s domicile is the patient’s fixed or permanent home to which he or she intends to return even though he or she may temporarily reside elsewhere.

(3) INSPECTION.—

(a) The department shall inspect the pain-management clinic annually, including a review of the patient records, to ensure that it complies with this section and the rules of the Board of Medicine adopted pursuant to subsection (4) unless the clinic is accredited by a nationally recognized accrediting agency approved by the Board of Medicine.

(b) During an onsite inspection, the department shall make a reasonable attempt to discuss each violation with the owner or designated physician of the pain-management clinic before issuing a formal written notification.

(c) Any action taken to correct a violation shall be documented in writing by the owner or designated physician of the pain-management clinic and verified by follow-up visits by departmental personnel.

(4) RULEMAKING.—

(a) The department shall adopt rules necessary to administer the registration and inspection of pain-management clinics which establish the specific requirements, procedures, forms, and fees.

(b) The Board of Medicine shall adopt rules setting forth training requirements for all facility health care practitioners who are not regulated by another board.

(5) PENALTIES; ENFORCEMENT.—

(a) The department may impose an administrative fine on the clinic of up to $5,000 per violation for violating the requirements of this section; chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act; chapter 893, the Florida
Comprehensive Drug Abuse Prevention and Control Act; or the rules of the department. In determining whether a penalty is to be imposed, and in fixing the amount of the fine, the department shall consider the following factors:

1. The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the pain-management clinic’s actions or the actions of the physician, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated.

2. What actions, if any, the owner or designated physician took to correct the violations.

3. Whether there were any previous violations at the pain-management clinic.

4. The financial benefits that the pain-management clinic derived from committing or continuing to commit the violation.

(b) Each day a violation continues after the date fixed for termination of the violation as ordered by the department constitutes an additional, separate, and distinct violation.

(c) The department may impose a fine and, in the case of an owner-operated pain-management clinic, revoke or deny a pain-management clinic’s registration, if the clinic’s designated physician knowingly and intentionally misrepresents actions taken to correct a violation.

(d) An owner or designated physician of a pain-management clinic who concurrently operates an unregistered pain-management clinic is subject to an administrative fine of $5,000 per day.

(e) If the owner of a pain-management clinic that requires registration fails to apply to register the clinic upon a change of ownership and operates the clinic under the new ownership, the owner is subject to a fine of $5,000.

(6) EXPIRATION.—This section expires January 1, 2016.

State Surgeon General Declares Public Health Emergency

- On July 1, 2011, Dr. Frank Framer issued a statewide public health emergency declaration in response to the ongoing prescription drug abuse problem and diversion in Florida. The declaration requires dispensing practitioners who are no longer authorized to dispense controlled substance listed in Schedule II and III to dispose of inventory and fully cooperate with the Department of Health, FDLE and local law enforcement.

- Within two days after July 1st, Department of Health will identify dispensing practitioners who purchased more than an average of 2,000 unit doses of controlled substances listed in Schedule II or III per month in the previous six months and who pose the greatest threat to public health.

- Disposal of inventory - return drugs to wholesale distributor or turn the inventory over to law enforcement.
ENFORCEMENT SUBCOMMITTEE RECOMMENDATIONS

Purpose Statement: Mayor Jacobs’ Prescription Drug Task Force will define the extent of the prescription drug abuse problem in the community, review zoning and substantive regulations, educate and engage community stakeholders and provide viable solutions that will reduce the misuse and non-medical use of prescription drugs and diversion in our county.

Co-Chairs:
Honorable Jerry L. Demings, Orange County Sheriff
Joe Cocchiarella, State Attorney’s Office, Ninth Judicial Circuit & MBI General Counsel

Task Force Members:
- Captain Mark Pilkington, Orange County Sheriff’s Office on behalf of Sheriff Demings
- Director Phil Williams, MBI
- Dr. Kevin Sherin, Orange County Health Department Director
- Alan Villaverde, Peabody Hotels
- George Ralls, M.D., Director of Health Services
- Meena Morgan, Pharm.D., Orlando Regional Healthcare
- Carolann Duncan, Department of Children and Families
- Danny Banks, ASIC Florida Department of Law Enforcement (FDLE) on behalf of Director Dawley
- Deputy Chief Robinson, Orlando Police Department on behalf of Chief Rooney

Members:
- Chief Brett Railey, Winter Park PD
- Tom Foy, Special Agent Supervisor, FDLE & MBI
- Lt. Ted Silberstein, Ocoee PD
- Det. Lloyd Randolph, Orlando PD
- Lt. Bruce McMullen, Orange County Sheriff’s Office
- Steve Collins, Central Florida HIDTA
- Captain Art King, Winter Park PD
- Linda Rhinesmith, City of Orlando
- Shelly Simon, DOH Investigator
- Roxanne McCarthy, DOH, Medical Malpractice Investigator
- Jennifer Lalani, Pharmacy Supervisor, CVS
- Michael Judd, Market Health Wal-Mart
- Alan Brown, Community Advocate
Members’ Continued:

- Fred Brown, Community Advocate
- Jeffrey Zipper, M.D., National Pain Institute
- Stacy Seikel, M.D. P.A., Medical Director, CFDFL
- Jennifer Lieberman, National Pain Institute
- Dan Frohwein, M.D., Orlando Orthopedic Center
- Lois Adams, Freedom Pharmacy
- Angie King, Tax Collector’s Office
- Emily Kilianek, National Pain Inst.
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- Bill Brooks, M.D., Advantagecare
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- Jeff Scott, Florida Medical Association
- James Shea, M.D., Physical Medicine Pain Center
- Zelda Hanna, Spine & Scoliosis Center
- Mark Flynn, CVS
- Matt Imfeld, M.D., Florida Society of Phys. Med Rehab
- Catherine Jackson, RN, Endo Pharmaceuticals
- Marion Steble, Colonial Medical Practice
- Robert Gutman, Colonial Medical Practice

County Staff:

- Dana Crosby-Collier, Orange County Attorney’s Office
- Carol Burkett, Orange County Drug Free Office
- Chris Schmidt, Orange County Planning
- Kurt Fasnacht, Orange County Code Enforcement
- Rocco Relvini, Orange County Zoning

Objectives:

- Review state legislation and existing local ordinances relating to permitting, land use, zoning, and substantive regulations.

Subcommittee Action: Reviewed state laws and local ordinances including House Bill 7095 (2011 session), which is reprinted in full in the pages above, and, in summary created a Prescription Drug Monitoring Program (PDMP), – E-FORCSE, and implemented a 7-day time frame for dispensing data for Schedule II-IV controlled substances to be entered into the PDMP,
required PMC’s to register, imposed standards of care, prohibited physician dispensing in pain management clinics (PMC’s) and requiring a community pharmacy be permitted in order to dispense Schedule II and III controlled substances (effective July 2012). The bill also requires additional reports to the Department of Health (DOH) on distribution of controlled substances, requires DOH conduct annual Level 2 screening on pharmacy owners/controlling interest, and imposes stronger administrative and criminal penalties for physicians that overprescribe (please see Florida’s Prescription Drug Law tab contained within the text of this report, for additional information).

Local Ordinances Reviewed:
- Sarasota (operational regulations, zoning, PMC’s must check PDMP, redefined PMC definition)
- Broward County (Grand Jury Report – Zoning regulations and certificate of use)
- Palm Beach (zoning, regulations on pharmacies and dispensing)
- Miami-Dade (registration for PMCs)
- Pinellas (registration and operational regulations)
- Manatee County (registration of PMCs, and check PDMP)
- Hillsborough, Manatee, Pinellas & Polk counties; (Registration, permit or licensure of PMCs)
- Tampa and Winter Haven (Registration, permit or licensure of PMCs)
- Satellite Beach (LDR amendments for PMCs and daily reporting)
- Maitland (Regulates pharmacies)

- Collect information on prescription drug-related arrests in the community and work jointly with the Healthcare and Pharmacy committee on strategies.

Subcommittee Action: Reviewed prescription drug-related crimes focusing on FDLE arrests, MBI Investigations and other local law enforcement agencies as well as Medical Examiner prescription drug-related deaths.

- Further training of law enforcement agencies on prescription drug investigations and prosecution.

Subcommittee Action: Supported Central Florida HIDTA training for law enforcement (May 25, 2011). The next training is scheduled for May 2012 and will focus on case studies and best practices, effective undercover techniques and prosecution of prescription drug cases. The training will also offer a prevention/treatment track as well as a joint plenary. We will partner with local, state and federal law enforcement agencies as well as the Central Florida Drug Enforcement Strike Force in preparation for the training.
Proposed Recommendations:

Definitions

- Acute Pain – means the normal, predicted, physiological response to an adverse chemical, thermal, or mechanical stimulus and is associated with surgery, trauma or illness.
- Chronic Pain – Chronic Pain means pain, which includes one or more of the following characteristics: (a) the pain persists beyond the usual course of a disease that is the cause of the pain; (b) the pain persists beyond the expected time for healing from an injury or trauma that is the cause of the pain; or (c) the pain is associated with a long-term incurable or intractable medical illness or disease and is not amenable to routine pain control methods.
- Controlled substance means any substance named or described in Schedules I-V of s. 893.03, Florida Statutes.
- Dangerous Drugs means a controlled substance, specifically an opiate analgesic, listed in Schedule II and Schedule III, in section 893.03, Florida Statutes.
- Health Care Physician or Physician means any practitioner who is subject to licensure or regulation by the Florida Department of Health under Chapters 458 (physician) or 459 (osteopathic physician), Florida Statutes.
- Pain means an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage. Categories of pain include Acute Pain or Chronic Pain.
- Pain Management means the use of pharmacological and non-pharmacological interventions to control a patient’s identified pain. Pain Management often extends beyond pain relief, encompassing the patient’s quality of life, ability to work productively, to enjoy recreation, and to function normally in family and society.
- Pain Management Clinic means any privately-owned clinic, facility or office, whatever its title, including but not limited to a “wellness center,” “urgent care facility,” or “detox center,” which has at least one of the following characteristics:
  - Where a physician practices who issues prescriptions for a Dangerous Drug to more than twenty (20) patients in a single day;
  - It holds itself out through a sign or advertising in any medium as being in business to prescribe or dispense pain medication whether for Acute Pain or Chronic Pain;
  - It holds itself out through a sign or advertising in any medium as being in business to provide services for the treatment or management of pain and where the services are also accompanied with the prescription or dispensing of a Dangerous Drug for the treatment of pain, whether Acute Pain or Chronic Pain.
It meets the definition of Pain Management Clinic in section 458.3265, Florida Statutes, as may be amended from time to time, or is registered as a Pain Management Clinic with the State.

Exceptions. There is an affirmative defense that a business is not a Pain Management Clinic if it has at least one of the following characteristics:

- Licensed as a hospital or other licensed facility pursuant to Chapter 395, Florida Statutes, as may be amended;
- The majority of the physicians who provide services in the clinic primarily provide surgical services;
- Affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
- Does not prescribe or dispense controlled substance for the treatment of pain; or
- Operated for the sole purpose of serving a governmental entity.

Pharmacist means any person licensed pursuant to chapter 465, Florida Statutes, to practice the profession of pharmacy.

Pharmacy means the same as that term is defined in section 465.003, Florida Statutes, as may be amended from time to time, and includes community pharmacy, internet pharmacy, and special pharmacy, but does not include institutional pharmacy or nuclear pharmacy, as each of those terms are used in that section.

Physician Primarily Engaged in the Treatment of Pain means a physician who prescribes or dispenses Dangerous Drugs when a substantial portion of the patients seen are prescribed or dispensed Dangerous Drugs for the treatment of chronic pain. For purposes of this definition, the term "substantial portion" means more than an insignificant or incidental portion. The term "substantial portion" does not necessarily mean a majority or predominant amount.

Registration and Operational Regulations

- Registration - required for PMCs in Orange County.
- Persons Responsible - Physician shall be designated as responsible for complying with all requirements relating to registration and operation of PMC.
- Display of Licenses – valid PMC registration with the state and county shall display in a public area copies of all licenses.
- Controlled Substances – Prohibits on-site sale and dispensing of controlled substances at PMC.
- Alcoholic Beverages – Prohibits alcoholic beverages from being consumed or served on the premises (includes parking, sidewalks or right-of-way).
• Adequate Inside Waiting Area Required – PMC shall not provide or allow waiting area outside; all business conducted inside the building with adequate indoor waiting areas.
• Operating Hours – PMC may operate only Monday-Friday, during the hours 7am – 7pm.
• Monthly Business Records – each month a PMC would provide to the County Administrator (CA) or designee monthly sworn summary of certain limited information from the prior business day.
  o Total number of prescriptions written for Dangerous Drugs
  o Total number of persons seen by PMC
  o State of residence for each person prescribed or dispensed Dangerous Drugs
  o Log of all attempts to access and review the Prescription Drug Monitoring Program
• Personnel Records; Monthly Report – PMC would maintain personnel records for all owners, operators, employees and volunteers onsite and make records available during inspection; forward a sworn statement to CA or designee on monthly basis.
  o Name and title
  o Current home address, phone number and date of birth
  o State or federal issued driver’s license
  o Copy of current driver’s license or government issued photo identification
  o List of all criminal convictions for all persons hired
  o Send monthly list of #1, #2, and #3

Requirements for New Pain Management Clinics:
• Zoning and Locations – any new PMC shall only be allowed in the I-4 Industrial Zone and shall be prohibited as a home occupation.
  o Building and use permits required.
• Separation Distances – a new PMC shall not co-locate on the same property as a pre-existing pharmacy.
  o New PMC shall not operate within 1,000 feet of any pre-existing pharmacy, school, daycare center or day care home.
  o Applicant may request a variance from the requirements.
• Parking - any parking demand created by PMC shall not exceed the parking spaces allocated on site as per county parking regulations.
  o Traffic impact analysis must be approved by the County staff.
  o PMC shall ensure that vehicles do not cue in a public right-of-way.
Other Requirements:

- Landlord Responsibility – landlord, leasing agent or owner of property where PMC operates should exercise reasonable care to ensure that the PMC or Pharmacy is not operating in violation of Orange County Code, or other Florida laws.
- Certification Affidavit by Applicants for Related Uses Any application for Business Tax Receipt in identified categories (such as a doctor’s office) shall have an executed affidavit certifying registration as a PMC, or that the new use will not be a PMC.
  - County Zoning Division will review the proposed use.

Regulation of Pharmacies:

- Identification Requirement – prior to filing or dispensing a script for a dangerous drug, the pharmacist or pharmacist’s agent would require at least one form of identification of the patient for whom the medication is prescribed.
- Verification of Prescription – If Pharmacist doubts the validity of a prescription, the pharmacist or agent shall personally contact the prescribing physician or their agent in order to verify the script.
- Records – pharmacy will keep record of all prescriptions filled for no less than two (2) years and records of dangerous drugs will be provided to law enforcement or code enforcement within seventy-two (72) hours of the request.
- Pharmacist Compensation – unlawful to pay any pharmacist a bonus, incentive compensation or reward solely for filling a prescription for specific dangerous drug.
- Separation Distances – new pharmacy shall not co-locate on the same property as a preexisting PMC.
  - Applicant for a new pharmacy may request a variance from the requirements.

Prescription Drug Monitoring Program (PDMP):

- Requirement of prescribing physician or physician’s agent to check the prescription drug monitoring database within 24 hours prior to prescribing any dangerous drug; the prescribing physician or physicians agent shall access the PMDP to review the patient’s controlled drug prescription history (not required under state law).
- Requirement of pharmacists or pharmacist’s agent to check PDMP prior to dispensing any dangerous drug; the pharmacist or agent shall access the PDMP to review the patient’s controlled drug prescription history and report the dangerous drug dispensed (not required under current state law; pharmacists who dispense controlled substances Schedule II-IV are required to enter the information in the state’s PDMP E-FORCSE within 7 days).
- PDMP is Not Available
Compliance is not required if PDMP is not available and three good-faith but unsuccessful attempts have been made.

A log of dates and times of attempts to access the state maintained PDMP must be kept for 24 months.

**Enforcement Actions:**

- **Criminal:** Violations can be punished pursuant to Section 1-9 of the Orange County Code. In addition, the County may bring any other action available at law or equity to penalize or enjoin violations of this article.
HEALTHCARE & PHARMACY SUBCOMMITTEE RECOMMENDATIONS

**Purpose Statement:** Mayor Jacobs’ Prescription Drug Task Force will define the extent of the prescription drug abuse problem in the community, review zoning and substantive regulations, educate and engage community stakeholders and provide viable solutions that will reduce the misuse and non-medical use of prescription drugs and diversion in our county.

**Co-Chairs:**
- Charles Chase, D.O., Winnie Palmer Hospital and Anesthesiologists of Greater Orlando
- Marlin Hutchens, Vice President, Walgreens

**Task Force Members:**
- George Ralls, M.D., Director of Health Services
- Director Phil Williams, MBI
- Kevin Sherin, M.D., Director, Orange County Health Department
- Meena Morgan, Pharm.D., Orlando Regional Healthcare
- Carolann Duncan, Department of Children and Families
- Barb Bergin, Director, CrimeLine
- Alan Villaverde, President, Peabody Hotels
- Deputy Chief Charles Robinson, Orlando Police Dept. on behalf of Chief Rooney
- Tom Foy, Florida Department of Law Enforcement (FDLE) on behalf of Director Dawley
- Captain Mark Pilkington, Orange County Sheriff’s Office on behalf of Sheriff Demings

**Members:**
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- James Shea, MD, Physical Medicine Pain Center
- Zelda Hanna, Spine & Scoliosis Center
- Mark Flynn, CVS
- Matt Imfeld, M.D., Florida Society of Phys. Med Rehab
- Catherine Jackson, RN, Endo Pharmaceuticals

County Staff:
- Dana Crosby-Collier, Orange County Attorney’s Office
- Carol Burkett, Orange County Drug Free Office

Objectives:
- Examine current training for prescribing opiate-based narcotics for physicians and dentists as well as training on the identification of prescription drug misuse, abuse and diversion for pharmacists.

Subcommittee Action: Reviewed current training outlined in SB 2272 (2010 session). The training requirements for physicians practicing in pain management clinics (PMC’s) are as follows:
  - Board certification by a specialty board recognized by American Board of Medical Specialties and holds a specialty in pain medicine.
  - Board certification in pain medicine by ABPM.
  - Successful completion of pain medicine fellowship accredited by the Accreditation Council for Graduate Medical Education.
  - Successful completion of residency program in physical medicine, rehab, anesthesiology, neurology, family practice, internal, orthopedics or psychiatry approved by the Accreditation Council for Graduate Medical Education.
  - Current staff privileges at a Florida-licensed hospital to practice pain medicine or perform pain medicine procedures.
  - Three years of documented full-time practice (average of 20 hours a week per year in pain management).
Proposed Recommendations:

- Increase healthcare provider education (Misuse and Abuse of Prescription Drugs – In-Person Training, Webinars & Forums) for the following groups:
  - Florida Academy of Family Physicians
  - Florida Medical Association
  - General Practitioner Society
  - Emergency Physicians
  - Florida Board of Pharmacy
  - Florida Retail Federation
  - Florida Pharmacy Association
  - UCF College of Medicine
  - Dentists
  - Podiatry
  - Orthopedic
  - Florida Society of Addiction Medicine
  - Florida Osteopathic Medicine
  - Florida Independent Pharmacy Network
  - Community Health Centers
  - Florida Society of Interventional Pain Medicine
  - Veterans Administration
  - OBGYN/Pediatrics
  - Higher Education Institutions
  - Florida Realtors
  - Florida State University
  - University of Florida
  - Veterans Administration

- Review best practices and current training curriculum

- Explore training opportunities with UCF College of Medicine and Florida Hospital and Orlando Health Residency Programs.

- Work with the Pharmacy Education Association on training.

- On-line training for physicians with Florida Medical Association and hospitals to support training; one time completion and two years to complete.

Drug Retail Industry & Independent/Community Pharmacies:

- Increase Prescription Drug Education & Awareness for Drug Retail Industry and Independent/Community Pharmacies.
  - Review best practices and current training curriculum
  - Develop Prescription Drug Pharmacy Toolkit
Drug Free Workplace:

- Increase Prescription Drug Education through Drug Free Workplace.
  - Educate workforce on dangers of prescription drug misuse and non-medical use.
  - Work with local legislators on policy – drug screening to include opioids.

- Increase training for law enforcement, crisis intervention team (CIT), prevention and treatment professionals on trends, non-medical use and misuse of prescription drugs.

- **Information sharing of prescription drug abuse related data - area hospitals, poison control, treatment providers, and the medical examiner’s office - to determine trends and patterns.**

**Subcommittee Action:** The subcommittee discussed the importance of sharing prescription drug-related information across agencies and jurisdictions to track trends and patterns of abuse and misuse as it relates to emergencies room visits, arrests, use and abuse, drug related deaths.

**Proposed Recommendation:**

- Establish means of sharing information on Prescription Drug Abuse and Misuse data (analysis and quarterly summary reports). Data sources to include:
  - Emergency Room Visits/Admissions
  - Medical Examiner’s (semi-annual report)
  - Urgent Care Centers
  - Treatment Centers
  - Infant Withdrawal Syndrome (DCF)
  - Law Enforcement
  - Poison Control Center
  - Florida Youth Substance Abuse Survey (bi-annual report)
  - CORE Survey (annual report)

- *Increase awareness on dangers of prescription drug misuse and non-medical use - public health campaigns engaging parents, seniors, hospitals, physicians, pharmacies and schools.*

**Subcommittee Action:** Subcommittee members discussed strategies to increase prescription drug education and awareness on the misuse of prescription drugs and legal consequences utilizing media campaigns, webinars, and classroom instruction. A copy of the Informed Families/National Family Partnership “Lock Your Meds” campaign materials was provided to the committee for review and consideration. The committee also discussed increasing awareness
Mayor Jacobs’ Prescription Drug Task Force

of DEA’s Prescription Take Back Day with local law enforcement and community partners and increasing promotion of proper disposal guidelines.

Proposed Recommendations:

• Develop strategic plan to increase Prescription Drug Education & Awareness on non-medical use and misuse of prescription drugs. Develop materials, webinars and trainings targeted to specific sectors to include but not limited to:
  o Parents
  o Seniors (Seniors First)
  o Schools (Secondary/Higher Educ.)
  o Youth/Young Adults
  o Community-Based Agencies
  o Providers
  o Campus Health Professionals
  o Community

• Work with community partners and Orange TV on advertisement of availability of prescription drug education webinars and materials for specific audiences.

• Provide educational/campaign materials and programs that encourage parents and seniors to keep track of the prescription medications in their medicine cabinets (Lock Your Meds Campaign).

• Work with area pharmacists to speak in classrooms in secondary and higher education on prescription drug abuse and misuse.

• Provide information on the serious legal consequences of holding/possession of controlled substances that are not prescribed to you.

• Develop an evidence-based Prescription Drug Public Awareness Campaign (billboard, radio, theatre, Orange TV, schools, library, parks, etc.).
  o National Family Partnership – Lock Your Meds
  o Multi-media campaign designed to reduce prescription drug abuse
  o Advertisements
  o Posters
  o Educational Materials
  o Home Medicine Inventory Card

• Promote and advertise Prescription Take Back Days in the community to increase proper disposal of unused and unwanted prescription medications.
• Work with DEA, state and local law enforcement, hospitals, pharmacies, schools, government, community-based agencies and print and electronic media to increase awareness and participation during prescription take back days.
  o Increase community education, awareness and promotion of guidelines for proper disposal of unused and unwanted medications.
  o Schedule prescription take back days on a regular basis with law enforcement and community partners.

Proposed Recommendation:
• Beta test the Clinical Decision Support System (CDSS) tool for the management of opioid therapy on patients with chronic non-cancer pain in Orange County.
  o Background: A proposed clinical decision support system (CDSS) that assists primary care physicians with management of opioid therapy for patients with chronic non-cancer pain. The CDSS will provide a backbone of required processes to support effective opioid therapy while providing enough management tools to safeguard against abuse or diversion.

Other Recommendations:
• Extend moratorium for additional 180 days to allow the Board of County Commissioners time to thoroughly review the Task Force’s proposed recommendations.
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<td>Memo to Orange County Board of County Commissioners - Update on Pain Management Clinic Moratorium and Ordinance</td>
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<tr>
<td>July 19, 2011</td>
<td>Extent of the Prescription Drug Problem presented to Mayor Jacobs’ Prescription Drug Task Force</td>
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<td>Presentations by:</td>
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<td>Orange County Mayor Teresa Jacobs, <em>Opening Remarks on Prescription Drug Problem</em></td>
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<td>Carol Burkett, Orange County Drug Free Office, <em>Overview of the Prescription Drug Problem</em></td>
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<td>Dr. Jan Garavaglia, Orange County Medical Examiner, <em>Prescription Drug Related Deaths</em></td>
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<td>Marlin Hutchens, Vice President, Walgreens, <em>Increase in Opiate Prescriptions</em></td>
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<td>Andy Benard, Florida Office of the Attorney General, <em>Prescription Drug Abuse: Florida’s Healthcare Crisis</em></td>
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<td>August 8, 2011</td>
<td>Update on Enforcement and Healthcare &amp; Pharmacy Recommendations presented to Mayor Jacobs’ Prescription Drug Task Force</td>
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<td>September 21, 2011</td>
<td>Update on Mayor Jacobs’ Prescription Drug Task Force presented to Sheriff Demings Crime Summit</td>
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<td>September 23, 2011</td>
<td>Update on Mayor Jacobs’ Prescription Drug Task Force presented to the Council of Mayor’s Meeting</td>
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<td>October 31, 2011</td>
<td>Final Recommendations of the Enforcement and Healthcare &amp; Pharmacy Subcommittees presented to the full Mayor Jacobs’ Prescription Drug Task Force</td>
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<td>Presented by:</td>
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<td>Charles Chase, D.O., Winnie Palmer Hospital and Anesthesiologists of Greater Orlando, Co-Chair, Healthcare &amp; Pharmacy Subcommittee</td>
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<td>Marlin Hutchens, Vice President of Walgreens, Co-Chair, Healthcare &amp; Pharmacy Subcommittee</td>
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<td>Joe Cocchiarella, State Attorney’s Office, Ninth Judicial Circuit &amp; MBI General Counsel, Co-Chair, Enforcement Subcommittee</td>
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APPENDIX A

Orange County Pain Management Clinic Moratorium and Ordinance, “Chad Phillips Act.”

ORDINANCE NO. 2011-19

AN ORDINANCE OF ORANGE COUNTY, FLORIDA RELATING TO PAIN MANAGEMENT CLINICS; AMENDING ARTICLE XIV, CHAPTER 2, ORANGE COUNTY CODE, RELATING TO PAIN MANAGEMENT CLINICS; ADOPTING FINDINGS; UPDATING DEFINITIONS; EXTENDING A MORATORIUM ON THE ISSUANCE OF BUSINESS TAX RECEIPTS FOR NEW PAIN MANAGEMENT CLINICS FOR 180 DAYS; PROVIDING THAT NO PAIN MANAGEMENT CLINIC MAY LIMIT ITS BUSINESS TO CASH ONLY; PROVIDING HOURS OF OPERATION FOR PAIN MANAGEMENT CLINICS; DIRECTING STAFF TO STUDY, ANALYZE AND REPORT TO THE BOARD ON ISSUES RELATING TO PAIN MANAGEMENT CLINICS; PROVIDING FOR PENALTIES; PROVIDING AN EFFECTIVE DATE.

WHEREAS, the Orange County Sheriff’s Office and the Metropolitan Bureau of Investigation for the Ninth Judicial Circuit have advised the Orange County Board of County Commissioners (“Board”) that a pattern of illegal drug use and distribution has been linked in large part to certain pain management clinics operating in and around Orange County; and

WHEREAS, the illegal distribution of prescription drugs, increased crime associated with such activity, and the high number of deaths in Orange County relating to prescription drug abuse has created an urgent situation requiring immediate action to reduce the threat to the health, safety and welfare of county citizens; and

WHEREAS, the Florida Legislature has identified concerns regarding the increased use and abuse of substances controlled by federal and/or state law and the frequency of injury and death occurring as a result of the increased availability of controlled substances via medical practitioners operating in pain management clinics or facilities; and

WHEREAS, Florida Statutes require physicians and other persons dispensing prescription drugs through pain management clinics, facilities or offices, to register with the State Department of Health in order to conduct such business; and

WHEREAS, several counties and municipalities in Florida have established moratoria on certain new pain management clinics to curb the immediate negative impacts created by these clinics,
such as illegal prescription drug trafficking and sales of illegal drugs around the clinics, and loitering in areas surrounding the clinics; and

WHEREAS, the negative impacts associated with certain pain management clinics creates an urgent situation necessitating immediate investigation into and potential regulation of such clinics in Orange County; and

WHEREAS, it is not the intent of this Ordinance to interfere with the legal prescription, dispensation, or use of controlled substances; and

WHEREAS, under its home rule authority Orange County can pass additional legislation to further regulate pain management clinics as long as these additional regulations are not preempted in the law and are not inconsistent with the statutory provisions; and

WHEREAS, on December 7, 2010 the Board adopted a moratorium on the issuance of any new Business Tax Receipts for pain management clinics and to direct County staff to analyze the effects of pain management clinics on our community and to prepare recommendations to better promote, protect and improve the health, safety and welfare of the citizens of the county by local regulation of pain management clinics and to restrict cash only operations and hours of operation of existing clinics through the period of the moratorium; and

WHEREAS, during the period of the moratorium, Mayor Teresa Jacobs appointed a Task Force to provide recommendations to the Board on reducing the illegal distribution of prescription drugs and reducing prescription drug abuse in our community;

WHEREAS, the Task Force has recommended and the Board finds that the moratorium shall be extended an additional 180 days or until such time as the Task Force recommendations can be adequately vetted by the Board, whichever is earlier.

THEREFORE, BE IT ORDAINED BY THE BOARD OF COUNTY COMMISSIONERS OF ORANGE COUNTY, FLORIDA:
Section 1. Recitals. The foregoing "WHEREAS" clauses are hereby ratified and confirmed as being true and correct and are hereby made a specific part of this Ordinance upon adoption hereof.
Section 2. Article XIV, Chapter 2, Orange County Code of Ordinances, consisting of sections 2-461 through 2-467, is hereby amended as follows with underlines showing new text and strikethroughs showing deletions.
Sec. 2-461. Title. This Ordinance shall be known as the “Chad Phillips Act.”

Sec. 2-462. Definitions.
For the purposes of this Ordinance, the following terms, whether appearing in the singular or plural form, shall have the following meanings. Where reference is made to Florida Statutes, the definition is that found in Florida Statutes, as the definition may be amended from time to time:

Chronic nonmalignant pain means pain unrelated to cancer or rheumatoid arthritis, which persists beyond the usual course of the disease or injury that is the cause of the pain, for or more than ninety (90) days after surgery.

Controlled substance is defined as in section 893.02, Florida Statutes, and means a controlled substance listed in Schedules I to V in section 893.03, Florida Statutes.

Pain management clinic means any privately owned pain management clinic, facility or office which advertises in any medium for any type of pain management services, or employs a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medication has the meaning ascribed in sections 458.3265 or 459.0137, Florida Statutes, as applicable, and is a clinic that is required to register with the Florida Department of Health pursuant to sections 458.3265 or 459.0137, Florida Statutes, as may be amended from time to time. Pain management clinic does not include a clinic:

1. Licensed as a facility pursuant to Chapter 395, Florida Statutes, as may be amended;

2. Where the majority of the physicians who provide services in the clinic primarily provide surgical services;

3. Owned by a publicly held corporation whose shares are traded on a national exchange or on the over-the-counter market and whose total assets at the end of the corporation’s most recent fiscal quarter exceeded $50 million dollars;

4. Affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;

5. That does not prescribe or dispense controlled substances for the treatment of pain; or
6. Owned by a corporate entity exempt from federal taxation under 26 U.S.C. 501(c) (3) or (4) as may be amended.

7. Physician primarily engaged in the treatment of pain means a physician who prescribes or dispenses controlled substance medications when the majority of the patients seen are prescribed or dispensed controlled substance medications for the treatment of chronic nonmalignant pain.

Sec. 2-463. Moratorium.
A. Beginning on December 15, 2011, a moratorium shall exist for one hundred eighty (180) days and expire on June 12, 2012, or sooner as provided herein, during which time the Tax Collector shall not issue any new Local Business Tax Receipt to any person for the purpose of engaging in, operating, or managing a pain management clinic. The Tax Collector is authorized to renew or transfer any Local Business Tax Receipt or Occupational License to any person for the purpose of engaging in or managing a pain management clinic existing on the effective date of this ordinance. However, if a pain management clinic is not registered with the Florida Department of Health, as required by sections 458.3265 or 459.0137, Florida Statutes, on December 15, 2010 through June 12, 2012, or until such time as this moratorium is lifted, whichever is earlier, the Local Business Tax Receipt or Occupational License is not eligible for renewal or transfer. Provided, however, that any pain management clinic in unincorporated Orange County which holds a valid Local Business Tax Receipt or Occupational License on the effective date of this ordinance that seeks to relocate its existing clinic to a different address within unincorporated Orange County shall be authorized to transfer its Local Business Tax Receipt or Occupational License for this limited purpose.

B. The moratorium shall expire upon the earlier of the following:
1. On June 12, 2012;
2. The effective date of an ordinance, adopted by the Board of County Commissioners, to address drug use and distribution associated with pain management clinics which dispense narcotic drugs on site in Orange County; or
3. At such time as the Board of County Commissioners receives a report from County staff on issues relating to pain management clinics and votes by majority vote to repeal this moratorium.

C. If, during the period of this moratorium, an application is made for issuance of a Local Business Tax Receipt for the operation of any of the following categories, which the applicant represents at the time of application, is not being operated and will not be operated during the period of term covered by the Local Business Tax Receipt as a pain management clinic, the
applicant, as a condition of issuance of the Local Business Tax Receipt, shall execute and deliver to the Tax Collector an affidavit confirming such representation. If, during the time covered by the Local Business Tax Receipt, the clinic, facility or office is found to be, in fact, operating as a pain management clinic, the Local Business Tax Receipt shall be subject to immediate suspension or revocation in proceedings before the Code Enforcement Special Magistrate, in addition to any other civil or criminal remedies or penalties available under local, county, state, and federal laws. Failure or refusal of applicant to execute and deliver the above-described affidavit shall result in a denial of the issuance of the Local Business Tax Receipt. An executed affidavit shall accompany an application for a Local Business Tax Receipt in all of the following categories:

Local Business Tax Receipt
Category Number Description
2711 Amusement Center
3001 Physician
3005 Dentist
3011 Massage Therapist (state certified)
3012 Chiropractor
3014 Ophthalmologist
3016 Psychologist
3020 Miscellaneous professional
3100 Miscellaneous
3110 Consulting
3200 Retail store
3502 Wholesale
5000 Business

Sec. 2-464. No Cash Only.
During the moratorium established herein, no pain management clinic in operation as of December 15, 2010 through June 12, 2012, or until such time as this moratorium is lifted, whichever is earlier, shall limit patient payment options to cash only.

Sec. 2-465. Hours of Operation.
During the moratorium established herein, the hours of operation of a pain management clinic in operation as of December 15, 2010 through June 12, 2012, or until such time as this moratorium is lifted, whichever is earlier, shall be limited to 7 a.m. to 9 p.m. of the same day.
Sec. 2-466. Staff Report.
A. This moratorium has been established and is extended for the minimum time period necessary for County staff to analyze the effects and impacts of pain management clinics in Orange County; analyze the criteria for additional standards needed, if any, under zoning, land use, land development, and general police power regulations in connection with the issuance of any development permits, business licenses, business tax receipts, or approvals for pain management clinics within the County; analyze any new laws regarding pain management clinics enacted by the Florida Legislature; complete an analysis of illegal drug use, distribution patterns, and other public health, safety and welfare issues that are associated with some pain management clinics that dispense narcotics on site; and, to make recommendations to the Board of County Commissioners regarding whether there is a need to enact an ordinance regulating pain management clinics so as to better promote the health, safety and general welfare of the citizens of the County.
B. County staff is directed to provide a report to the BCC of its findings and recommendations by not later than July 12, 2011.

Sec. 2-467. Penalties.
Unless as otherwise provided herein, violations of this Ordinance shall be punishable in accordance with Section 1-9 of the Orange County Code of Ordinances. In addition, the County may bring any other action available at law or equity to penalize or enjoin violations of this Ordinance.

Section 3. Effective Date. This Ordinance shall become effective on December 15, 2011.
ADOPTED THIS 6th DAY OF DECEMBER, 2011.
ORANGE COUNTY, FLORIDA
By: Board of County Commissioners

By:______________________________
Teresa Jacobs
County Mayor

ATTEST: Martha O. Haynie, County Comptroller
As Clerk of the Board of County Commissioners

By:______________________________________
Deputy Clerk
APPENDIX B

Publications and Articles:

- Orange County Resolution Advocating Support for the Prescription Drug Monitoring Program (May 2011)
- Pain Management Moratoriums and Restrictions, Central Florida Region, FDLE (2010)
- Prescription Drug Abuse – An Epidemic in Florida, Fact Sheet (2011)
- Florida’s Prescription Drug Monitoring Program, E-FORCSE: Fact Sheet for Healthcare Practitioners (July 2011)
- Florida Senate, Committee on Health Regulation, CS/CS/HB7095 3rd Engrossed – Prescription Drugs Summary (2011)
- National Family Partnership Parents Guide to Prescription Drug Abuse (Brochure)
- National Family Partnership – Lock Your Meds Prevention Awareness Campaign
- Prescription Drug Abuse “What’s In The Medicine Cabinet?” (Brochure)

• CDSS for the Management of Opioid Therapy on Patients with Chronic Non-Cancer Pain (August 11, 2011)

• National Office of Drug Control, Parents The Anti-Drug Prescription Drug Campaign

• Prescription Drug Article – “Rx for Danger: Number of Florida Babies Born Addicted to Drugs Skyrockets” Orlando Sentinel (July 2011)

• Prescription Drug Article - “Nearly 100 Arrested, 350 Guns, 12K Oxycodone Pills Seized in Palm Beach County Crackdown” Palm Beach Post (July 28, 2011)

• Prescription Drug Article – “Under Fire, Pain Clinics try to Open Their Own Drugstores, DEA Deals with a Wave of Suspicious Pharmacies in Florida, “ Sun Sentinel (September 2011)

• Prescription Drug Article – “Loophole for Pain Clinics? New Pharmacy Applications Surge”, Orlando Sentinel (September 2011)

• Prescription Drug Article – “Florida's Prescription-Drug Database Launches” Orlando Sentinel (September 2011)

• Prescription Drug Article – “Feds launch Orlando Prescription-Drug Squad” Orlando Sentinel (October 2011)