

Manatee County Permanent Prescription Drug Ordinance: a community health and safety initiative

Sharon Kramer, M.Ed., CPP
Rita Chamberlain, MBA





- ▶ Established in 2001
- ▶ Funding
 - Drug Free Communities – Office of National Drug Control Policy (ONDCP)/Substance Abuse and Mental Health Services Administration [SAMHSA]
 - FL Division of Children and Families (DCF)
 - Governor's Office of Drug Control*
 - OJJDP/EUDL (Enforcing Underage Drinking Laws)*

*Prior years

Community Snapshot

- ▶ **Manatee County** admissions to Manatee Glens for treatment for prescription drug addiction rose from 238 (2010) to 284 in the just the first 8 months of 2011, a 19% increase. Most admissions were for patients age 35 and younger *(Manatee Glens)*
- ▶ Since 2008, while the number of DCF Child Abuse Hotline calls/verified abuse reports from **Manatee County** decreased 15% and 7% respectively, the number of children removed from their homes due to parental substance misuse/neglect rose from 33% to 40% of all cases, or almost 270 children annually. *(Manatee County Children's Services 2010 Annual Report, MCSO Child Protective Investigations data)*
- ▶ Prescription drug abuse is the primary reason for the need to shelter children in **Manatee County** (over 50% of removals) *(DCF, 2010)*. This costs the child welfare system @ \$10,000/child/year or a total of almost \$2.7million annually *(Florida Alcohol and Drug Abuse Association, 2011)*
- ▶ The highest rate (36%) of **Manatee County** admissions of pregnant women for treatment is for opiate or other synthetics abuse *(DHHS, SAMHSA Treatment Episode Data - TEDS/A, 2010)*
- ▶ The number of substance exposed newborns (SEN)/newborns experiencing withdrawal in **Manatee County** rose from two (2) in 2007 to 27 in 2010, a 1,250% increase *(DCF, 2010)*



Dependent on Prescription Drugs, Even Before Birth

By ABBY GOODNOUGH and KATIE ZEZIMA New York Times Published: April 9, 2011

Partnerships

Manatee County Sheriff's Office

Manatee County Health Department

Manatee County School District

Pittsburgh Pirates

Manatee Glens & Hanley Center – Service Providers

City Police Departments (Palmetto, Holmes Beach, Bradenton)

FL Division of Business and Professional Regulation (DBPR/ABT)

FL Division of Children and Families

Chamber of Commerce

Florida Coalition Alliance

IMG Academies

Manatee Youth Commission

Healthy Teens Coalition of Manatee

Community Health Improvement Partnership (CHIP) Health Provocateurs

Central Florida Behavioral Health Network

Florida Alcohol Drug Addictions Association (FADDA)

Families Against Addictive Drug Abuse

Making a Difference

Prescription Take Back Program – permanent prescription drug drop off sites (MCSO, BPD, Holmes Beach PD) with additional take back days.

The graphic features a teal background with a large, stylized 'SAFE RX' logo at the top left. Below it, a circular inset contains the text 'Are you dumping medicines down the drain?' in orange, with a subtext explaining that disposing of medications in the sink or toilet leads to water contamination. To the right of this inset is an image of an orange pill bottle. At the bottom, there are four columns of text listing drop-off locations in Sarasota, Manatee, Charlotte, and DeSoto counties, along with a footer with the slogan 'Drive up. Drop off. Drive out. No questions asked.' and the website 'www.SafeRxFlorida.org'.

SAFE RX

Now is the time to safely get rid of unwanted and expired medications for humans and pets. Dispose of your unwanted and expired medications properly at prescription drug drop boxes, which can be found at one of the following locations.

Are you dumping medicines down the drain?

Disposing of medications in the sink or toilet leads to water contamination.

MISUSE OF PRESCRIPTION MEDICATION IS A GROWING PROBLEM

HELP PROTECT OUR COMMUNITY & OUR ENVIRONMENT

SARASOTA COUNTY Sarasota County Sheriff's Office 2071 Ringling Blvd., Sarasota 4531 State Road 776, Venice North Port Police Department 4980 City Hall Blvd, North Port <i>Additional drop box expected at the Venice Police Dept in summer 2011</i>	MANATEE COUNTY Manatee County Sheriff's Operation Center 600 US Hwy 301 Bradenton	CHARLOTTE COUNTY Charlotte County Sheriff's Office <i>These boxes operational May 2011</i> 6868 San Case Dr., Englewood 3280 Tamiami Trail, Port Charlotte Punta Gorda Fire Department 1410 Tamiami Trail, Punta Gorda	DeSOTO COUNTY <i>A prescription drug drop box is expected in Arcadia by fall of 2011</i>
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Drive up. Drop off. Drive out. No questions asked.

Watch out for future pharmaceutical drop-off days. For more information, visit www.SafeRxFlorida.org

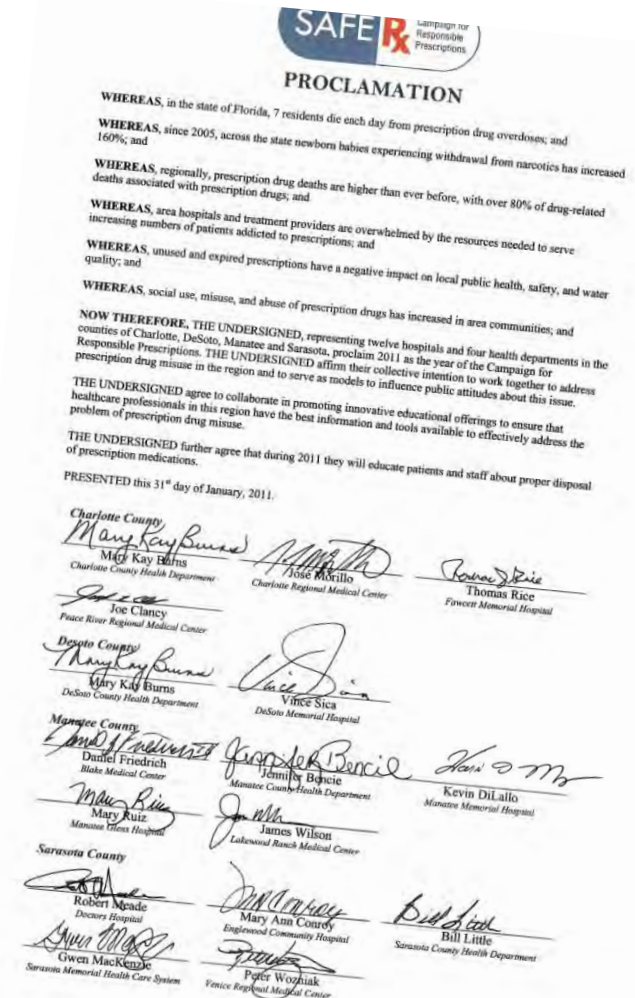
Making a Difference

Doctor Education Program

- Launched January 31, 2011 with Safe Rx proclamation.
- Educated 350 medical professionals on prescription drug misuse and encouraged doctors to sign up for prescription drug monitoring database and share safe disposal information with patients.



CHIP
Community Health
Improvement Partnership



Making a Difference

Drug Free Workplace

- Encouraged community businesses to participate in program to educate work force on dangers of prescription drug misuse.

Pain Clinic Ordinance

- Advocated for and supported the 1 year Moratorium to stop pain clinic proliferation.
- Some clinics closed as a result.
- One of the first communities in the Suncoast region to enact a moratorium.
- Partnered with neighboring counties and municipalities in establishing local regulations.

Making a Difference

MCSAC launched a media awareness campaign to “**MONITOR, SECURE, DISPOSE**” of Prescription Drugs that included:

- PSA by Sheriff Brad Steube produced by METV
- Poster design and distribution in partnership with law enforcement



Prescription Drug Abuse
KILLS At Least 7
Floridians EVERY DAY!

Most teens who abuse prescriptions get them from family and friends.

Act now to protect them:

MONITOR: Count pills, keep track of refills and control access.

SECURE: Remove meds from medicine cabinet and nightstand and secure well, preferably in a locked cabinet.

DISPOSE of unused or expired meds at the permanent drug drop, Manatee County Sheriff, 800 US Hwy 301 West, Bradenton.

Ask grandparents & parents of your teens' friends to do the same.

Manatee County
MCSAC
Substance Abuse Coalition

www.drugfreemanatee.org

EACH DAY 2500 TEENS ABUSE PRESCRIPTION DRUGS FOR THE FIRST TIME!



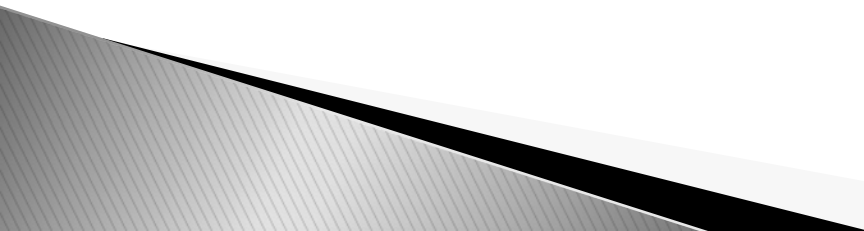
State & Federal Guidance

- ▶ Florida Office of the Attorney General Local Ordinance Best Practice Recommendations:
 - Zoning restrictions
 - Prohibit cash only clinics
 - Prohibit Pharmacy co-location
 - Limit hours of operation
- ▶ United States Center for Disease Control and Prevention
 - Improve legislation, local regulation, and enforcement
 - Improve use of Prescription Drug Monitoring Programs

State Regulations

- ▶ HB 7095 (Governor Scott signed on June 3)
 - Imposes new criminal and administrative penalties for overprescribing
 - Bans doctors from dispensing controlled substances (II and III)
 - Minimum floor space requirement
 - Quarterly reporting requirements
 - Tightens PDMP timeline to 7 days
- ▶ PDMP
 - Requires dispensing practitioners and pharmacies to enter prescription controlled substances data within 7 days of dispensing
 - Voluntary for practitioners and pharmacists to use prior to dispensing
 - Law enforcement does not have direct access, but may obtain during investigation
 - Misdemeanor for failure to report

Ordinance Highlights

- ▶ Applicability
 - ▶ Exemptions specific to patient needs rather than physician license
 - ▶ Ownership restrictions
 - ▶ Records management (Personnel and Operational)
 - ▶ Patient Education – Monitor, Secure, Dispose
 - ▶ Pregnancy determination before prescribing
 - ▶ PDMP use
 - ▶ Civil and Criminal penalties
 - ▶ Provision for fees
- 

Manatee cannot be the weak link on the Suncoast...



...and leave the door open for pill mills to relocate from Pinellas or Sarasota to “**friendlier**” environs.

MCSAC supports the passage of Ordinance No. 12-14

- ▶ Attorney Minix listened to all stakeholders' concerns through a series of face-to-face meetings, incorporated their suggestions, then crafted a strong, effective, enforceable ordinance
- ▶ Two remaining areas of concern:
 - ▶ Operational Records
 - ▶ Probation, Revocation, Suspension, Denial of Permit

Partners in support of Ordinance No. 12-14

- Manatee County Sheriff's Office
- Manatee County Health Department
- Manatee Glens
- Central Florida Behavioral Health Network
- Manatee County Youth Commission
- FAADA (Families Against Addictive Drug Abuse)
- FADDA (Florida Alcohol Drug Addictions Association)
- Florida Coalition Alliance (34 prevention coalitions across the state, representing 34 of 67 FL counties)
- Circuit 12 (DCF) Regional Planning Council
(healthcare providers, hospitals & governmental agencies from Manatee, DeSoto & Sarasota counties)



www.drugfreemanatee.org.

Sharon Kramer: skramer@drugfreemanatee.org

Rita Chamberlain: rchamberlain@drugfreemanatee.org

Manatee County Gov. Admin. Center

1112 Manatee Ave. West

Bradenton, FL 34205

941-749-3030, ext. 3491

Briefing:

Florida Prescription Drug Monitoring Program Implementation

Rebecca Poston, Director of the Florida Prescription Drug Monitoring Program, and her staff have provided information on the first months of the FL PDMP's implementation.

The volume of reports issued in just the first two and a half months is, in my experience, unprecedented. The extent of pharmacists' involvement appears very encouraging and unusually high, particularly during early implementation stages; i.e. half or more of reports are being issued to pharmacists.

The FL PDMP contracted with Heath Information Design (HID) on May 26, 2011,

Data Collection:

- On September 1, 2011 the Florida PDMP initiated collection of data on all Schedule II through IV prescriptions dispensed on and after December 1, 2010.
- 25.9 million prescriptions were collected by December 31, 2011.
- These prescriptions were issued by 57,409 in-state and 118,406 out of state prescribers.

Enrollment of Prescribers and Dispensers:

- Enrollment of prescribers and pharmacies began on October 1, 2011.
- 4,257 prescribers and 3,843 pharmacists were enrolled by December 31, 2011
- This means that 7.4% of all in-state prescribers have enrolled in the PMP within the first 3 months (i.e. in-state prescribers who issued one or more controlled substance prescriptions as reported to the PDMP for the thirteen months, December 1, 2010 to December 31, 2011).

Reports Generated:

Prescribers and Pharmacists

- Prescribers and pharmacists were permitted to request patient advisory reports as of October 17, 2011.
- 337,635 patient specific controlled substance dispensing queries had been performed by prescribers and pharmacies as of December 31, 2011.

Law Enforcement

- Law Enforcement officers were permitted to request investigative reports pursuant to an active investigation as of November 14, 2011.
- 1,186 reports had been approved and released to them by December 31, 2011.

Briefing prepared by John L. Eadie,
Director, PMP Center of Excellence at Brandeis University
January 20, 2012



Brandeis University

The Prescription Monitoring Program Center of Excellence is a joint project of the Institute of Behavioral Health at Brandeis University and the Bureau of Justice Assistance.

BCC-WS SK
Pain Management
Ord
Packet 2/14/12

Sarasota County Pain Management Clinic Operational Records Report.

September 1, 2011-December 31, 2011

	September	October	November	December
TOTAL PATIENTS	3806	4350	5295	5058
TOTAL PRESCRIPTIONS ISSUED	6314	6845	8550	8181
PATIENT ADVISORY REPORTS	33	1640	4899	5033
% MALE PATIENTS	46.7%	45.6%	47.4%	46.9%
% FEMALE PATIENTS	53.3%	54.4%	52.6%	53.1%
% FEMALES OF CHILDBEARING-AGE	64.6%	58.5%	64.8%	61.2%
% CAUCASIAN PATIENTS	93.3%	92.3%	93.1%	92.6%
% AFRICAN-AMERICAN PATIENTS	3.4%	3.6%	4.5%	4.5%
% OTHER/UNSPECIFIED PATIENTS	3.3%	4.0%	2.4%	2.8%
% PATIENTS UNDER AGE 50	42.0%	40.2%	41.7%	41.7%
% PATIENTS OVER AGE 50	58.0%	59.8%	58.3%	58.3%

**Data collected from Sarasota County pain management clinics in accordance with Florida Municode Chapter 62, Article XI.*

Monthly Update
January, 2012

Sarasota County Health & Human Services Behavioral Health Strategic Planning Workgroup



To learn more about Sarasota County behavioral health prevention efforts visit
www.scgov.net/drugfreesarasota

Or contact

Behavioral Health Planning Coordinators:

Brooke Baker
Brooke_Baker@doh.state.fl.us
(941) 861-2704

or

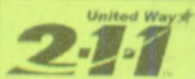
Andria Wendell
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(941) 861-2575

Behavioral Health Policy Coordinator

Pam Meunier
Pam_Meunier@doh.state.fl.us
(941) 861-2578

Criminal Justice Policy Coordinator

Wayne Applebee
wapplebee@scgov.net
(941) 861-2577



211 is an important resource for anyone with questions regarding access to the Health and Human Services system.



Drug Free Sarasota

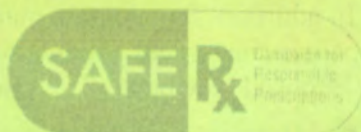
Priority 1: Prescription Drug Misuse

Safe Rx

- We are continuing our work with the Sarasota County Sheriff's Office to expand *Safe Rx* campaign initiatives.
- Staff is working to develop a brief *Safe Rx* training module for all medical practitioners on the Florida Prescription Drug Monitoring Program (E-FORCSE). This system is currently not required for all medical practitioners to use and yet is a very beneficial tool for practice management and patient safety. As of January 1, 2012, medical practitioners in Sarasota County were registering for E-FORCSE at the **highest rate** in the state of Florida.
- Staff is working to develop *Safe Rx: Part II* training specifically targeting Pediatricians and Obstetricians to educate on the increased incidence of Substance Exposed Newborns in local communities. Treatment best practices, parenting strategies, drug testing options, and other strategies will be recommended for practitioners.

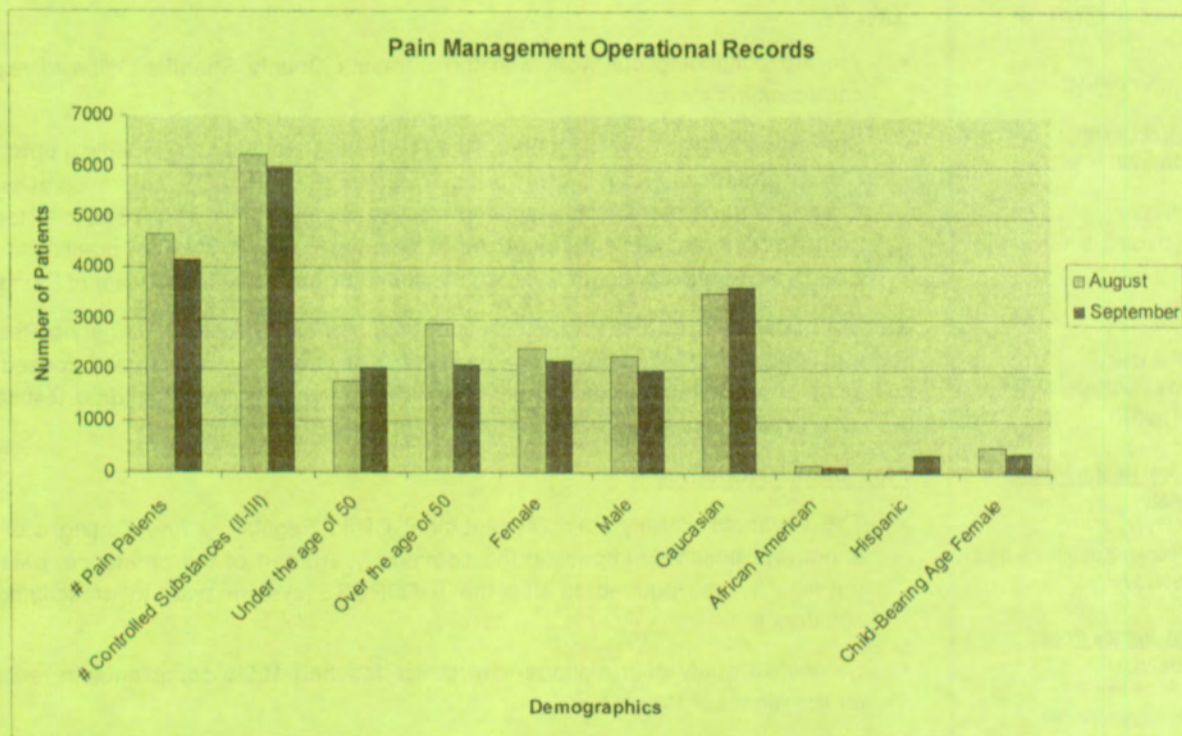
Pain Clinic Ordinance

- The Sarasota County Pain Management Clinic Regulatory and Zoning ordinances are in effect and positively impacting the community. As part of the ordinance, pain management physicians are required to use the E-FORCSE system prior to prescribing a controlled substance.
- Sarasota County pain management clinics reached 100% compliance in record submission for the month of November.
- Since August, a total of **29,293** prescriptions for a controlled substance were written.
- Since the E-FORCSE system became operational in October, over **6,500** Patient Advisory Reports have been requested for patients.
- Data analysis of pain management clinic patient records indicated that 52% of patients were female, 80% were Caucasian, and 40% of the patients were under the age of 50; however, the same age group represents only 25% of Sarasota's total population. Analysis also found that the odds of a woman of child-bearing age being prescribed a controlled substance were over **3 times** that of women who were not of child-bearing age.



Pain Management Clinic Operational Records Summary

	<u>August</u>	<u>September</u>
# Pain Patients	4655	4168
# Controlled Substances (II-III)	6227	5965
Under the age of 50	1768	2018
Over the age of 50	2887	2075
Female	2390	2158
Male	2265	1974
Caucasian	3510	3626
African American	158	125
Hispanic	58	362
Child-Bearing Age Female	492	389



There are on average 4500 patients per month being treated in pain management clinics in Sarasota County. These patients are prescribed approximately 6000 controlled substance prescriptions per month, which represents 1.3 prescriptions per person, with a range of 0-4 prescriptions per patient. Of the pain management patients in Sarasota County, they are predominately Caucasian and evenly split by gender. One interesting emerging trend to note is that patients under the age of 50 represent 40% of pain management patients in Sarasota County. However, this same age group only makes up 25% of the total county population. In addition, female pain management patients of child-bearing age represent 10% of pain management patients, which is important given the recent increase in the Substance Exposed Newborn (SEN) population across the state and most notably in Sarasota County.

Date: _____

Phone: _____

City/St/ZIP: _____

Submitted by _____

[illegible]

Dr. Id: 4001
Clinic Id: 8001

Doctor: #N/A
Clinic: _____
Address: _____
City/St/ZIP: _____

Date: _____
Phone: _____

"Under penalty of perjury, I swear that the submitted records contain true and complete information."

Submitted by: _____

Clinic ID	Dr. ID	Month	Year	Total # of Scheduled II Prescriptions	Total # of Scheduled III Prescriptions	Total # of Prescriptions for Drugs Containing Alprazolam
8001	4001	January	2012			

SAFE RX

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Are you dumping medicines down the drain?

Disposing of medications in the sink or toilet leads to water contamination.

MISUSE OF PRESCRIPTION MEDICATION IS A GROWING PROBLEM

SARASOTA COUNTY

Sarasota County Sheriff's Office
2071 Ringling Blvd., Sarasota
4531 State Road 776, Venice

North Port Police Department
4980 City Hall Blvd, North Port

Additional drop box expected at the Venice Police Dept in summer 2011

MANATEE COUNTY

Manatee County Sheriff's Operation Center
600 US Hwy 301 West, Bradenton

HELP PROTECT OUR COMMUNITY & OUR ENVIRONMENT

CHARLOTTE COUNTY

Charlotte County Sheriff's Office
These boxes operational May 2011
6868 San Casa Dr., Englewood
3280 Tamiami Trail, Port Charlotte

Punta Gorda Fire Department
1410 Tamiami Trail, Punta Gorda

DESOTO COUNTY

No prescription drug drop boxes are currently operational in DeSoto County. Check website for future pharmaceutical drop-off days.

Drive up. Drop off. Drive out. No questions asked.

April 2011

Watch out for future pharmaceutical drop-off days. For more information, visit www.SafeRxFlorida.org

HOME MEDICATION INVENTORY CARD

Use the following chart to help keep track of the medications in your medicine cabinet.

List the name and strength of the prescription and nonprescription medications. Include the date filled, the expiration date, and the original quantity. Regularly count the pills remaining and mark the date.

Medication Name & Quantity	Date Filled	Expiration Date	Original Quantity	Quantity Remaining			
				Date	Date	Date	Date



Hospitals, health departments and substance abuse prevention coalitions in Charlotte, DeSoto, Manatee and Sarasota Counties are working together to combat prescription drug abuse and misuse.

www.SafeRxFlorida.org

Proposed Ordinance No. 12-14 “The Manatee County Pain Management Clinics Registration Ordinance”

Presented by:
Jim Minix, Esquire
Chief Deputy County Attorney
Manatee County Attorney's Office



ORDINANCE 12-14

AN ORDINANCE OF THE BOARD OF COUNTY COMMISSIONERS OF MANATEE COUNTY, FLORIDA, FOR THE **LICENSING AND REGULATION OF PAIN MANAGEMENT CLINICS** AS DEFINED HEREIN; PROVIDING FOR **AUTHORITY**; PROVIDING FOR LEGISLATIVE FINDINGS OF FACT; PROVIDING FOR THE **INTENT AND PURPOSE**; PROVIDING FOR A **DEFINITION OF TERMS**; PROVIDING FOR **EXEMPTIONS**; PROVIDING FOR **INSPECTIONS**; PROVIDING FOR **REGULATION OF PAIN MANAGEMENT CLINICS**; PROVIDING FOR **REGISTRATION FOR A PAIN MANAGEMENT CLINIC PERMIT**; PROVIDING FOR AN **APPLICATION PROCESS**; PROVIDING FOR **PROBATION AND REVOCATION OF PERMIT**; PROVIDING FOR **VIOLATIONS**; PROVIDING FOR SERVICE OF NOTICE AND PUBLIC RECORDS; PROVIDING FOR **BOUNDARIES**; PROVIDING FOR REPEAL OF CONFLICTING LAWS; PROVIDING FOR **ENFORCEMENT AND PUNISHMENT FOR VIOLATIONS**; PROVIDING FOR SEVERABILITY; PROVIDING FOR AN EFFECTIVE DATE; AND PROVIDING FOR CODIFICATION.

Intent & Purpose

What will the ordinance achieve?

Assurance of health, safety and general welfare of Manatee County's citizens, businesses and residents.

Regulation of Pain Management Clinics.

How will it be achieved?

Through analysis and effectiveness of regulatory efforts, and by implementing location & establishment criteria.

*Ord. No. 12-14 is NOT intended to affect land-use
or any activities protected under the First
Amendment.*

Enforcement

Who is authorized to enforce Ordinance 12-14?

*Any official Manatee County Code Enforcement Officer.

Definition: Any designated employee or agent of Manatee County... or designated employee or agent of the municipalities or other law enforcement officers (including MSO) whose duty is to enforce codes and ordinances enacted.

**Manatee County Code Enforcement Officers are immune from civil or criminal prosecution for trespass while officially discharging his/her duties.*

Pain Management Clinic and/or Pain Clinic Defined

A privately owned pain management clinic, facility, or office, including but not limited to, a “wellness center,” “urgent care facility”, or “detox center,” which engages in pain management and holds itself out as providing, or advertising as providing, any type of pain management services and that its primary purpose is to prescribe/dispense pain medication for payment by cash, check or charge.

What entities are included in this the definition?

Any that employ a physician engaged in the treatment of pain by prescribing/dispensing controlled substance medications, and who is required to register with the Florida Department of Health pursuant to §§458.309(4) or 459.005(3), Fla. Stat. (2009), or any successor state law.

Pain Management Clinic and/or Pain Clinic (cont.)

What are things to consider in determining whether a clinic, medical facility, practitioner's office, or pharmacy is operating as a Pain Management Clinic?

- Whether it employs one or more licensed physicians who, in a single day, issues 25 or more prescriptions for controlled substances for the treatment of pain.
- whether major medical insurance is accepted;
- whether the owner/operator is a physician;
- whether the medical director is Board Certified in pain medicine;
- whether the owner/operator has been convicted of or has pled guilty or nolo contendere to, any offense that constitutes a felony or a misdemeanor related to, or included the distribution or illegal sale or prescription of a narcotic; and
- the percentage of patients of the pain management clinic residing out of state.

Permit

A certificate issued by Manatee County acknowledging the submission and accurate completion of the pain management clinic registration forms required in order to conduct business in Manatee County as a pain management clinic.

“Pill Mill”

An entity employing a doctor, a doctor, a clinic, or pharmacy that is prescribing or dispensing controlled substances inappropriately, unlawfully, or for non medical reasons and whose operations and practices do not comply with the requirements of federal law, Florida Statutes and regulations, or this Article.

Exemptions

What constitutes an exemption to Ord. No. 12-14?

- Any clinic, facility or office licensed by the Florida Dept. of Health as a facility Ch. 395, Fla. Stat.
- A clinic, facility, or office where the majority of patients primarily receive surgical services;
- A clinic, facility, or office that is owned by a publically 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;

Exemptions (cont.)

- A clinic, facility, or office that is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;
- A clinic, facility, or office that does not prescribe or dispense controlled substances for the treatment of pain;
- A clinic, facility, or office that is owned by a corporate entity exempt from federal taxation under 26 U.S.C.S. 501(c)(3).

Exemptions (cont.)

- Any clinic, facility, or office in which the majority of patients receive treatment for terminal illness.
- Any clinic, facility, or office in which the majority of patients receive cancer treatment.
- Any clinic, facility, or office in which the majority of patients receive hospice treatment.

Inspections

Who is responsible for performing Inspections?

An inspection shall be performed by any law enforcement officer, code enforcement officer, or employee of the department who has been designated by the County Administrator and who is authorized by the head of that department to access and inspect any facility registered under this ordinance for proof of registration, at any reasonable hour, without notice.

Operational Records

For the purpose of studying the patterns of health and illness and prescriptions issued within Manatee County, and to verify that a pain management clinic is operating in compliance with the requirements of Federal law, Florida Statutes and Rules, and this Article, pain management clinics shall make and maintain *quarterly* operational records for a period of one year. Operational records shall consist of a quarterly register of the following information for each patient: gender, race, age (by age group), and zip code of patient's address.

Operational Records (cont.)

In addition, the records shall include a list of the total number of prescriptions for Schedule II drugs, Schedule III drugs, and drugs containing Alprazolam, prescribed per physician licensed under Chapter 458 and 459, Florida Statutes, per month. The quarterly period of collection for the operational records described in this paragraph shall begin on the first day of the calendar month. All signature blocks for these quarterly registers shall include the printed full name of the signing party, the printed title of the signing party, the printed name of

Operational Records (Cont.)

the pain management clinic, the printed mailing address of the pain management clinic, and a signature of the signing party presented in a legible manner.

Personnel Records

- *Personnel records shall apply to owners, operators, employees, and volunteers and, at a minimum, contain:
 - Person's full name and title;
 - current home address, telephone number, and date of birth;
 - List of all criminal convictions (misdemeanor or felony);
 - Copy of a current driver's license or a government issued photo identification; and
 - Fingerprints.

**Pain management clinics shall maintain personnel records on site and make those records available during any inspection.*

Personnel Records (cont)

Time frames associated with personnel records.

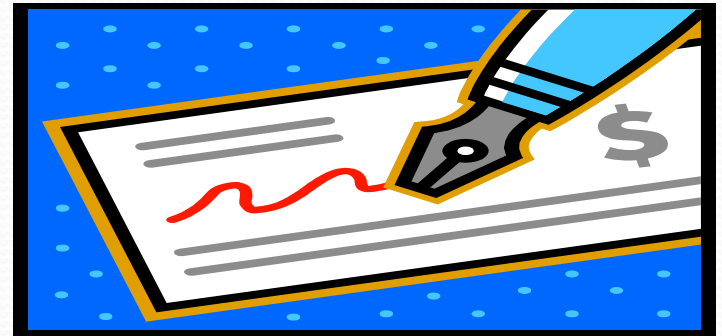
- Records shall be submitted to the department or designee by existing pain management clinics no later than thirty (30) days after the passage of this ordinance;
- New clinics shall submit their personnel records within fifteen (15) days of beginning operation;
- Any change in personnel (new employee), or upon arrest, adjudication or conviction in any criminal matter of any employee, shall warrant an update to personnel records that shall be submitted to the department or designee within fifteen (15) days.

Acceptable Payment

How shall operating clinics handle payment for prescriptions and services provided?

- No pain management clinic or pharmacy shall limit the form of payment for goods or services to “cash only.”
“Cash only” shall mean paper currency or coins.

“Pill Mills” are typically a *cash only* business.



Registration & Permit

Granting a Permit.

What are requirements for permit approval?

- If there is no basis for denial of a pain management clinic permit pursuant to the criteria set forth herein, the department shall grant the permit, notify the applicant, and issue the permit to the applicant. Each permit shall be valid for a period of two (2) years and may be renewed within thirty (30) days of the expiration date.

Registration & Permit (cont.)

Denial of Permit

Under what circumstances will permits be denied?

The director shall deny a pain management clinic permit on the basis of any one of the following grounds:

- Failure to allow entry to a clinic for inspection of the premises and applicable records.
- The department has other credible evidence that the applicant is in fact operating a “pill mill.”
- There are 14 total grounds for a denial.

Registration & Permit (cont.)

Expiration

What are the time frames involved with permitting?

- Each permit shall remain valid for a period of two (2) calendar years from the date of issuance unless otherwise suspended or revoked. Permits may be renewed **within** thirty (30) days of expiration.



Probation, Suspension or Revocation

What would cause a permit to be revoked, suspended or put into probationary status?

A permit for a pain management clinic may be subject to probation or revocation by order of the Board of County Commissioners in the event that any of the following occur:

- Failure to make or maintain adequate personnel records;
- Failure to make or maintain adequate operational records
- There are a total of 14 reasons that could revoke or suspend a permit, or place a clinic on probation.

Geographical Boundaries

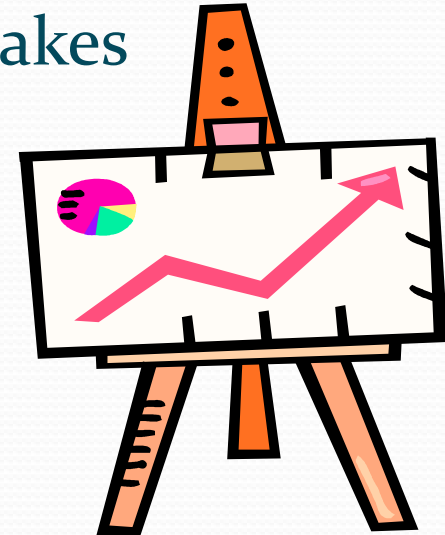
To what areas of Manatee County will the Ordinance apply and be enforceable?

- The provisions of this ordinance shall apply to all territory within the legal boundaries of Manatee County, which includes all incorporated and unincorporated areas.
- Cities are included but can “opt out” by enacting their own Ordinance.



Benefits

- Reduced deaths from prescription drug overdose.
- Reduced crimes to pay for drugs.
- Reduced Interstate & Intrastate trafficking to obtain prescription drugs.
- Increased community health.
- Pain Management Ordinance 12-14 makes Manatee County consistent with neighboring counties' ordinances.



Conclusion

Question/Answer



Thank you.

ORDINANCE NO. 12-14

AN ORDINANCE OF THE BOARD OF COUNTY COMMISSIONERS OF MANATEE COUNTY, FLORIDA, FOR THE LICENSING AND REGULATION OF PAIN MANAGEMENT CLINICS AS DEFINED HEREIN; PROVIDING FOR AUTHORITY; PROVIDING FOR LEGISLATIVE FINDINGS OF FACT; PROVIDING FOR THE INTENT AND PURPOSE; PROVIDING FOR A DEFINITION OF TERMS; PROVIDING FOR EXEMPTIONS; PROVIDING FOR INSPECTIONS; PROVIDING FOR REGULATION OF PAIN MANAGEMENT CLINICS; PROVIDING FOR REGISTRATION FOR A PAIN MANAGEMENT CLINIC PERMIT; PROVIDING FOR AN APPLICATION PROCESS; PROVIDING FOR PROBATION AND REVOCATION OF PERMIT; PROVIDING FOR VIOLATIONS; PROVIDING FOR SERVICE OF NOTICE AND PUBLIC RECORDS; PROVIDING FOR BOUNDARIES; PROVIDING FOR REPEAL OF CONFLICTING LAWS; PROVIDING FOR ENFORCEMENT AND PUNISHMENT FOR VIOLATIONS; PROVIDING FOR SEVERABILITY; PROVIDING FOR AN EFFECTIVE DATE; AND PROVIDING FOR CODIFICATION.

WHEREAS, Manatee County has broad Home Rule powers granted by the Florida Constitution and Chapter 125, Fla. Stat. to protect the public health, safety, and welfare of the citizens, residents, and businesses of Manatee County; and

WHEREAS, the Broward County Florida Grand Jury issued an interim report entitled “The Proliferation of Pain Clinics in South Florida” which established the following facts: (i) dealers and users have shifted their efforts from acquiring illegal drugs to the diversion of legal prescription drugs to illegal uses; (ii) it was recently reported that over 300 individuals had been arrested in Kentucky for dealing in prescription drugs obtained from South Florida; (iii) under Florida law, if the pain clinic is not physician-owned, then it is unregulated by any state agency; (iv) there is no requirement that owners and employees of pain management clinics undergo a criminal background check; (v) nearly all “pill mills” operate on a cash basis; and (vi) in 2008, an average of 13.5 deaths per day in Florida were attributed to prescription drug abuse; and

WHEREAS, the Manatee County Board of County Commissioners (the “Board”) has been made aware of the problem as a result of past and recent newspaper articles published describing the proliferation of pain management clinics in South Florida, and the “pipeline” trafficking of drugs from some South Florida pain clinics to users from other states such as Georgia, North Carolina, Tennessee, Kentucky, and Ohio; and

WHEREAS, the threat of illegal narcotic activity and increased crime associated with pain management clinics is significant and could undermine the economic health of Manatee

County's development and redevelopment efforts as well as the safety and well-being of its citizens, residents, and businesses; and

WHEREAS, officials with the Sheriffs' Offices in both Sarasota and Manatee Counties have also met with Drug Enforcement Agency (DEA) officials for training the local law enforcement agencies on tactics to investigate pain clinics and prescription drug abuse; and

WHEREAS, in Chapter 2009-198, Laws of Florida, the legislature recognized that pharmaceutical drug diversion hurts the State of Florida significantly in terms of lost lives, increased crime, and human misery from addiction, ballooning health care costs, and Medicare fraud; and

WHEREAS, the United States Department of Health and Human Services has released data showing prescription drug deaths are now the fourth leading cause of death in the United States; and

WHEREAS, the Florida Legislature has enacted Chapter 2010-211, Laws of Florida, that establishes a more comprehensive regulatory scheme for such pain management clinics; and

WHEREAS, it is necessary to establish a process for the registration, application, and permitting of certain pain management clinics; and

WHEREAS, the Board of County Commissioners intends to enact a permanent ordinance regulating pain management clinics; and

WHEREAS, Ch. 2011-141, Laws of Florida, was recently enacted by the State to provide a comprehensive regulatory scheme for the distribution of prescription drugs and regulating pain management clinics; and

WHEREAS, the reputation of pain management clinics suffer from the proliferation of "pill mills"; and

WHEREAS, legally prescribing controlled substances by pain management clinics is necessary for public health; and

WHEREAS, the Board believes that additional local enforcement authority is needed to supplement Chapters 2010-211 and 2011-141, Laws of Florida, in the regulation of illegitimate pain management clinics in order to protect the citizens of Manatee County; and

WHEREAS, valid patients and legitimate doctors are also victims of the current proliferation of illegal pill mill activity; and

WHEREAS, legitimate medical treatment of chronic pain is much needed and is in the best interest of the community to preserve and protect these medical services, especially in our county with an increased number of seniors suffering from this devastating disease.

NOW THEREFORE, BE IT ORDAINED BY THE BOARD OF COUNTY COMMISSIONERS OF MANATEE COUNTY, FLORIDA, AS FOLLOWS:

SECTION 1: A new Article I, Chapter 2-18, of the Manatee County Code of Ordinances is hereby created and known as: the “**Manatee County Pain Management Clinic Registration Ordinance**” and state as follows:

Sec. 2-18-1: Authority.

This ordinance is enacted pursuant to Section 125.66(3), Fla. Stat. (2009) and under the Home Rule powers as outlined in Chapter 125, Fla. Stat. providing for the public interest of the health, peace, safety, and general welfare of the citizens, residents, and businesses of Manatee County. This ordinance shall be known as the “Manatee County Pain Management Clinic Registration Ordinance.” This ordinance is the successor ordinance to Ordinance 10-73, which is now repealed.

Sec. 2-18-2: Legislative Findings of Fact.

(a) The *Whereas* clauses are incorporated herein and represent legislative findings of the Board. The Board further finds and declares that it is in the best interests of the citizens, residents, and businesses of Manatee County to enact a permanent ordinance requiring a permitting and regulatory process for pain management clinics operating, or desiring to operate, in Manatee County.

(b) In 2009, through the enactment of Section 893.055, Fla. Stat. the Legislature directed the Department of Health to establish a Prescription Drug Monitoring Program (PDMP) to track prescriptions for controlled substances dispensed by various health practitioners. The purpose of the PDMP is to prevent the practice of “doctor shopping” wherein a person illegally obtains multiple prescriptions of a controlled substance from different doctors for the purpose of illegally reselling the controlled substance.

(c) Thirty-four (34) states have a PDMP. Florida is the largest state which did not have an operational drug monitoring program to help prevent the illegal distribution of controlled substances.

(d) During the 2009 Legislative Session, in Chapter 2009-198, Laws of Florida, the Florida Legislature recognized that pain management clinics should be registered with the Florida Department of Health, and that new regulations governing same should be promulgated by the Board of Medicine and Board of Osteopathic Medicine.

(e) Through Sections 458.309(4) or 459.005(3), Fla. Stat. (2009), the Florida Legislature authorized the Board of Medicine and Board of Osteopathic Medicine to adopt new rules setting forth standards of practice for health care practitioners who practice in privately-owned pain management clinics.

(f) During the 2011 Legislative Session, a new law enacted as Chapter 2011-141 incorporated many of the draft pain management clinic rules proposed by the State Board of Medicine.

(g) Pill Mills generate a high volume of clients and traffic and, therefore, require more stringent regulation of location and use than other medical facilities. Legitimate medical pain practices should not have any different regulation regarding location than any other medical specialty.

(h) Some pharmacies have been operating in conjunction with “pill mills”; including those that operate on a “cash only” basis and have sales of controlled substances that exceed the industry norm.

(i) “Pill mills” that illegally prescribe and dispense controlled substances for the treatment of pain, whether acute pain or chronic pain, are associated with a wide variety of adverse secondary effects including, but not limited to, personal and property crimes, public safety risks, illicit drug use and drug trafficking, undesirable and criminal behavior associated with alcohol consumption, and negative impacts on surrounding properties.

(j) According to statistics from the Centers for Disease Control and Prevention, the death rate for prescription drugs increased 84.2%, from 7.3 to 13.4 per 100,000 population from 2003 to 2009. The greatest increase in death rate was observed for the prescription drug Oxycodone (264.6%), followed by Alprazolam (233.8%), Methadone (79.2%), Hydrocodone (34.9%), and Morphine (26.2%).

(k) Manatee County Sheriff officials say crimes related to prescription pills have reached epidemic proportions, including an increase in burglaries involving medicine cabinets. There is also an increase in jail population because of more drug arrests.

Sec. 2-18-3: Intent and Purpose.

It is further the intent and purpose of this ordinance to promote the health and general welfare of the citizens, residents, and businesses of Manatee County through the analysis of impacts from pain management clinics, the effectiveness of existing and emerging regulatory efforts, and a thorough consideration of the criteria for the establishment and location of pain management clinics within Manatee County. It is the intent of this ordinance to regulate conduct and not to affect land use or activities protected by the First Amendment.

It is also the intent of this ordinance to protect the access of legitimate medical care to citizens suffering from chronic pain. The ordinance should include the steps necessary to identify and protect legitimate pain practices and physicians from the current stigma of control substance prescription. The ordinance should not increase the burden to legitimate practices with requirements without a clear and measurable predetermined objective. Legitimate pain practices are in a unique position to assist society in the fight against Pill Mills and should cooperate in order to collect the data that precisely will differentiate and identify them as legitimate medical practices.

Sec. 2-18-4: Definitions.

(a) *Acute Pain* is the normal, predicted physiological response to an adverse chemical, thermal or mechanical stimulus and is associated with surgery, trauma, or illness. It is generally short-lived. Acute pain responses may vary between patients and between pain episodes within an individual patient. Acute pain episodes may be present in patients with chronic pain.

(b) *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 long-term incurable or intractable medical illness or disease. It is not amenable to routine pain control methods. Patients with chronic pain may have either continuous or intermittent pain, including episodes of acute pain related to disease progression or reoccurrence.

(c) *Code Enforcement Officer* means any designated employee or agent of Manatee County whose duty it is to enforce codes and ordinances enacted by Manatee County, or designated employee or agent of the municipalities whose duty is to enforce codes and ordinances enacted by Manatee County. Employees or agents who may be Code Enforcement Officers for purposes of this Article may include, but are not limited to, code inspectors, nuisance abatement coordinators, law enforcement officers, animal control officers, building inspectors, or fire safety inspectors. Code Enforcement Officers shall be immune from prosecution, civil or criminal, for trespass upon real property while in the discharge of said duties.

(d) *Controlled Substance* means a controlled substance listed in Schedule II, Schedule III, or Schedule IV in Section 893.03, Fla. Stat. recognized as effective for pain relief such as, but not limited to, Buprenorphine, Butorphenol, Codeine, Hydrocodone, Hydromorphone, Levorphanol, Methadone, Morphine, Oxycodone, Propoxyphene, and Fentanyl.

(e) *Department* shall mean the department designated by the County Administrator to administer the temporary mandate of this ordinance, or whatever regulatory scheme is subsequently enacted by a future ordinance.

(f) *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) of the Florida Statutes.

(g) *Licensed Medical Professional* means an individual who has successfully completed a prescribed program of study in a variety of health fields and who has obtained a license or certificate indicating his or her competence to practice in that field.

(i) *Operator* means any person on the premises of a pain management clinic who puts or keeps the business in operation or who is authorized to manage the business or exercise overall operational control of the business premises. A person may be found to be an operator of a pain management clinic regardless of whether that person is an owner, part owner, or licensee of the business.

(j) *Opioids* are any morphine-like synthetic narcotic that produces the same effects as drugs derived from the opium poppy (opiates), such as pain relief, sedation, constipation and respiratory depression.

(k) *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.

(l) *Pain Management* means the use of pharmacological and non-pharmacological interventions to control the 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.

(m) *"Pain Management Clinic" and/or "Pain Clinic"* means a privately owned pain management clinic, facility, or office, whatever its title, including but not limited to, a "wellness center," "urgent care facility", or "detox center," which engages in pain management and holds itself out as providing, or advertises in any medium as providing, any type of pain management services and that the primary business purpose of such clinic, medical office, or practitioner's office is to prescribe or dispense pain medication including, but not limited to, opioids, including Fentanyl, Hydrocodone, Morphine, and Oxycodone, to individuals for payment by cash, check or charge; and includes an entity that employs a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications, and is required to register with the Florida Department of Health pursuant to Sections 458.309(4) or 459.005(3), Fla. Stat. (2009), or any successor state law.

In determining whether a clinic, medical facility, practitioner's office, or pharmacy is a pain clinic or pain management clinic, the County Administrator, or his or her designee, may also consider the following: whether it employs one or more physicians licensed under Chapter 458 or 459, Florida Statutes, who, in a single day, issues in excess of twenty-five (25) prescriptions for controlled substances for the treatment of pain; whether major medical insurance is accepted; whether the owner/operator is a physician; whether the medical director is Board Certified in pain medicine and; whether the owner/operator has been convicted of or has pled guilty or nolo contendere to, an offense that constitutes a felony or a misdemeanor which was related to, or included the distribution or illegal sale or prescription of a narcotic; and the percentage of patients of the pain management clinic residing out of state.

(n) *Permit* shall mean a certificate issued by Manatee County acknowledging the submission and accurate completion of the pain management clinic registration forms required in order to conduct business in Manatee County as a pain management clinic.

(o) *Person* means any individual, firm, partnership, joint venture, syndicate, or other group or combination acting as a unit, association, corporation, estate, trust, business trust, trustee, executor, administrator, receiver, or other fiduciary, and includes the plural as well as the singular.

(p) *Pharmacy* shall mean the same as that term is defined in Section 465.003, Fla. Stat., 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.

(q) *Pill Mill* is an entity employing a doctor, a doctor, a clinic, or pharmacy that is prescribing or dispensing controlled substances inappropriately, unlawfully, or for non-medical reasons and whose operations and practices do not comply with the requirements of federal law, Florida Statutes and regulations, or this Article.

(r) *Probation* means that the permittee may receive additional supervision by the Board of County Commissioners for a specific period of time as determined by the Board but not exceeding the two (2) year term of the permit. Such supervision may include:

- (i) shortening the reporting period of the permittee;
- (ii) increasing the information to be provided in each quarterly report;
- (iii) restricting the days and hours of operation;
- (iv) making additional unannounced inspections of the premises;

(s) *Revocation* means that the permit is terminated for the remainder of its term and the applicant may reapply at the conclusion of the revocation period.

(t) *Surgical Services* shall mean the practice that deals with the diagnosis and treatment of oral health, injury, deformity, and disease by in which part of the body is entered by puncture or incision and treatment takes place through manual and instrumental means.

(u) *Suspension* means that the permit may be suspended by the Board of County Commissioners for a period not to exceed three (3) months. After the suspension concludes, the permit is automatically reinstated for the remainder of its term.

Sec. 2-18-5: Exemptions.

The following are exempted from this Article:

- Any clinic, facility, or office licensed by the Florida Department of Health as a facility pursuant to Chapter 395, Fla. Stat.;
- A clinic, facility, or office where the majority of patients primarily receive surgical services;
- A clinic, facility, or office that is owned by a publically 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;
- A clinic, facility, or office that is affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;

- A clinic, facility, or office that does not prescribe or dispense controlled substances for the treatment of pain;
- A clinic, facility, or office that is owned by a corporate entity exempt from federal taxation under 26 U.S.C.S. 501(c)(3).
- Any clinic, facility, or office in which the majority of patients receive treatment for terminal illness.
- Any clinic, facility, or office in which the majority of patients receive cancer treatment.
- Any clinic, facility, or office in which the majority of patients receive hospice treatment.

Sec. 2-18-6: Inspection.

(a) An inspection shall be performed by any law enforcement officer, code enforcement officer, or employee of the department who has been designated by the County Administrator and who is authorized by the head of that department to access and inspect any facility registered under this ordinance for proof of registration, at any reasonable hour, without notice.

(b) In the event that a suspected “pill mill” or pain management clinic refuses a lawful inspection, then a law enforcement officer, code enforcement officer or employee of the department designated by the County Administrator who is authorized by the head of that department may seek all remedies available, in law or equity, including but not limited to, a criminal warrant, inspection warrant pursuant to Sections 933.20-933.30, Fla. Stat., subpoena after any required notice, or other court order from a court of competent jurisdiction.

(c) Nothing in this ordinance shall be read to limit the authority of law enforcement in any matter as relates to their authority to conduct criminal investigations.

(d) In the event that an inspection is conducted at a practice that is not suspected to be a Pill Mill and that does not refuse a lawful inspection, and, in order to protect good practices, personnel and legitimate patients from the current stigma, the designated inspector(s) should present as inspectors and if needed, only with concealed weapons without giving the appearance that a "raid" is being conducted or that the medical practice is being subject of a "criminal investigation."

Sec. 2-18-7: Regulation of Pain Management Clinics

(a) *Hours of operation:* The hours of operation for any pain management clinic shall be limited from 7:00 a.m. to 9:00 p.m., Monday through Saturday unless surgical procedures are being performed. It is the responsibility of the designated medical director, on-site physicians and/or the clinic owner to adhere to all requirements contained within this Article and the following applicable operational standards:

1. Maintain the routine diagnostic equipment necessary to diagnose and treat patients complaining of chronic pain.
2. Secure prescription pads so that only authorized persons may access them.

3. Provide for patient education on how to “monitor, secure, or dispose” of prescribed pain medications, as well as educational materials for distribution.

4. Unless a patient refuses or it is deemed unnecessary by the physician, provide for medical determination of pregnancy status of female patients prior to prescribing prescription pain medications as well as educational materials specific to taking these medications during pregnancy.

5. For the purpose of studying the patterns of health and illness and prescriptions issued within Manatee County, and to verify that a pain management clinic is operating in compliance with the requirements of Federal law, Florida Statutes and rules, and this Article, pain management clinics shall make and maintain quarterly operational records for a period of one (1) year. Operational records shall consist of a quarterly register of the following information for each patient: gender, race, age group (under 20, 20-29, 30-39, 40-49, 50-59, 60-69, 70-79, and 80 and above), and the zip code of the patient’s address. In addition, the records shall include a list of the total number of prescriptions for Schedule II drugs, Schedule III drugs, and drugs containing Alprazolam, prescribed per physician licensed under Chapter 458 and 459, Florida Statutes, prescriptions given with refills, or prescriptions given in advance up to the next three (3) months, will be counted as one prescription. The quarterly period of collection for the operational records described in this paragraph shall begin on the first day of the calendar month. All signature blocks for these quarterly registers shall include the printed full name of the signing party, the printed title of the signing party, the printed name of the pain management clinic, the printed mailing address of the pain management clinic, and a signature of the signing party presented in a legible manner. Operational records, as described in this paragraph, shall be submitted on a quarterly basis by the fifth (5th) day of every fourth (4th) month or upon completion to the department or designee whichever shall first occur. Copies of this monthly register shall be made available to any code enforcement officer upon demand.

(b) *Management:* A pain management clinic shall be managed by a designated physician who is recognized as meeting the training requirements for physicians practicing in pain management clinics established by rules promulgated by the Board of Medicine and Board of Osteopathic Medicine. The designated physician shall be responsible for ensuring compliance with all federal, state and local regulations of this Article.

(c) *Ownership, Business Relationship and Employment Restrictions:* No pain management clinic shall be wholly or partially owned by, have any contractual relationship with (whether as a principal, partner, officer, member, managing member, employee, or independent contractor), or employ any person who has been convicted of a crime, has adjudication withheld for a crime, or had final administrative action taken:

(i) Involving:

(1) Any felony or misdemeanor involving the possession, sale, delivery, fraudulent obtainment, distribution, or manufacture of any controlled substance, narcotic, or prescription drug; or any misdemeanor involving a crime of dishonesty or false statement;

(2) Any violation of pain management clinic regulations of any county, city, state or government;

(3) Any administrative or other similar action in which the applicant has been denied the privilege of prescribing, dispensing, administering, supplying or selling any other state; or

(4) Any administrative or other similar action in which the state or any other state's medical action taken against the applicant's medical license as a result of dependency on drugs or alcohol.

(ii) For which:

(1) Less than two (2) years have elapsed since the date of conviction or the date of release from confinement for the conviction, whichever is later, if the conviction is a misdemeanor offense;

(2) Less than five (5) years have elapsed since the date of conviction or the date of release from confinement for the conviction, whichever is later, if the conviction is of a felony offense;

(3) Less than five (5) years have elapsed since the date of the last conviction or the date of release from confinement for the last conviction, whichever is later, if the convictions are of two (2) or more misdemeanor offenses or combination of misdemeanor offenses occurring within any twenty-four (24) month period;

(4) Less than five (5) years have elapsed for any final administrative or other action.

(iii) The fact that a conviction is being appealed has no effect on the disqualifications of the applicant under subsection (a) above.

(d) *Payment for Prescriptions and Services:* No pain management clinic or pharmacy shall limit the form of payment for goods or services to "cash only." "Cash only" shall mean paper currency or coins.

(e) *Personnel Records:* Pain management clinics shall maintain personnel records for all owners, operators, employees, and volunteers on site for each pain management clinic, and make them available during any inspection. Personnel records shall, at a minimum, contain the following information: (a) the person's full name and title; (b) current home address, telephone number, and date of birth; (c) a list of all criminal convictions whether misdemeanor or felony; (d) a copy of a current driver's license or a government issued photo identification; and (e) a set of fingerprints. In addition, personnel records shall be submitted by existing pain management clinics to the department or designee no later than thirty (30) days after the passage of this ordinance. New clinics shall submit their personnel records within fifteen (15) days of beginning operation. Any change in personnel (new employee), or upon arrest, adjudication or conviction

in any criminal matter of any employee, an update to personnel records shall be submitted to the department or designee within fifteen (15) days.

(f) *Prescription Drug Monitoring Program (PDMP)*: All physicians licensed under Chapters 458 and 459, Fla. Stat., shall, unless the website is down or inaccessible and at least once every three months prior to the prescribing of a controlled substance, request a "Patient Advisory Report" from the PDMP, review its contents, and shall document same by placing a printout of the report in each patient's file. A copy of that printout shall be made available for inspection by law enforcement officers, code enforcement officers, or any employee of the department designated by the County Administrator who is authorized by the head of that department to inspect any facility registered under this ordinance.

Sec. 2-18-8: Registration and Permit.

(a) Beginning thirty (30) days after the effective date of this ordinance, no pain management clinic, unless otherwise exempted, shall operate in Manatee County by any means without having been issued a pain management clinic permit by the department. Upon issuance of such permit to a pain management clinic, it will be considered a Registered Pain Management Clinic.

(b) The department shall maintain a database of registered pain management clinics operating in Manatee County.

(c) Proof of registration shall be prominently displayed in the common public area of the pain management clinic.

(d) Any person with multiple physical pain management clinic locations shall secure a separate permit and registration for each business location.

(e) Time period for granting or denying:

1. The department shall grant a new or a renewal pain management clinic permit within thirty (30) days from the date of proper filing of an application provided the applicant is registered with the Florida Department of Health pursuant to Sections 458.309 or 459.005, Fla. Stat. (2009), or any successor state law, as of the effective date of this ordinance.
2. The director of the department, or his or her designee, shall mail a Notice of Intent to deny a pain management clinic permit within thirty (30) days from the date of its filing. The applicant may respond, in writing, to the Notice of Intent within ten (10) days of its receipt.
3. The director, or his or her designee, shall send a Notice of Denial based on any of the grounds set forth herein in subparagraph (g).
4. The Notice of Denial shall be sent within twenty (20) days of mailing of the Notice of Intent to Deny if no written response to the notice is received within the ten (10) day time period. If a written response is received, the director or his designee shall have an additional ten (10) days to consider the applicant's written response before a Notice of Denial is sent.

5. Any applicant who receives a Notice of Denial of a pain management clinic permit may request a hearing before the director of the department within fifteen (15) days of the date of mailing of the Notice of Denial. The director shall set a date for the requested hearing within thirty (30) days of receipt of the request for hearing and decide whether to uphold the denial or to grant the permit.
6. The denial of a permit after a hearing under this section shall be the final order of the County.

(f) *Granting of permit.* If there is no basis for denial of a pain management clinic permit pursuant to the criteria set forth herein, the department shall grant the permit, notify the applicant, and issue the permit to the applicant. Each permit shall be valid for a period of two (2) years and may be renewed within thirty (30) days of the expiration date.

(g) *Denial of the permit.* The director shall deny a pain management clinic permit on the basis of any one of the following grounds:

1. An applicant has submitted an application which contains material false information.
2. An applicant has had a registration issued under either Section 458.309 or 459.005, Fla. Stat. (2009), or any successor state law, suspended or revoked or the controlled substance registration issued by the United States Department of Justice, Drug Enforcement Administration to any person prescribing, administering, or dispensing controlled substances at the pain management clinic has been suspended, revoked, or denied renewal.
3. An applicant is not registered pursuant to Sections 458.309 or 459.005, Fla. Stat. (2009) or any successor state law.
4. Failure to allow entry to a clinic for inspection of the premises and applicable records.
5. Failure to prominently display in a public area near the front entrance copies of all state and county licenses bearing the name of the clinic owner, operator, and designated physician responsible for compliance with state and county laws.
6. The designated physician, clinic owner, or any person with authority to issue prescriptions under Florida Statutes has been convicted of a crime or had final administrative action taken against him or her.
7. If a clinic is not owned and/or operated by a physician who holds an active Florida Board of Medicine or Florida Board of Osteopathic Medicine license and who is board certified by either an American Board of Medical Specialties recognized board, the American Osteopathic Association, or the American Board of Pain Medicine, and the primary business purpose of such clinic, medical office, or practitioner is to provide a comprehensive pain medicine service.
8. The department has other credible evidence that the applicant is in fact operating a "pill mill."
9. Allowing any person to work or volunteer at the clinic, whether paid or unpaid, who has been convicted of or plead guilty or nolo contendere to, (even if sealed or expunged) an

offense that constitutes a felony for receipt, possession, delivery, distribution, selling, manufacturing or purchase of illicit drugs, including any controlled substance listed in Schedule I, Schedule II, Schedule III, Schedule IV or Schedule V of Section 893.03 Fla. Stat. or any other state, or the United States.

10. The facility is owned or operated by any person or has any contractual or employment relationship with a physician or other licensed health care practitioner as defined by Section 456.001(4), Fla. Stat.:
 - a) whose Drug Enforcement Administration number has ever been revoked;
 - b) whose application for a license to prescribe, dispense, supply, sell, give, compound or administer a controlled substance has been denied or revoked by any jurisdiction;
 - c) who has been convicted of or plead guilty or nolo contendere to (even if sealed or expunged) an offense that constitutes a felony for receipt, possession, delivery, distribution, selling, manufacturing or purchase of illicit drugs, including any controlled substance listed in Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V of Section 893.03, Fla. Stat., or any other state, or the United States; or
 - d) whose permit has been suspended or revoked or has had other disciplinary action taken as a result of physician or other licensed health care provider's abuse of drugs or alcohol, or from the improper prescribing, dispensing, administering, supplying, selling, giving, mixing or otherwise preparing any controlled substance listed in Schedule I, Schedule II, Schedule III, Schedule IV, or Schedule V of Section 893.03, Fla. Stat. or any other state, or the United States.
11. The department may grant an exception to sub-sections 9 and 10 above if more than five (5) years have elapsed since the adjudication date.
12. The fact that an appeal is pending for any items listed in sub-sections 9 and 10 above has no effect on the department's determination to grant or deny a permit.
13. The owner or operator of a clinic whose license or permit related to the ownership or management of a medical clinic that provided pain management services for chronic pain in another jurisdiction has been denied or revoked.
14. Failure to abide by any other provision of this Article may be considered on the department's decision to grant or deny a permit.

(h) *Expiration of Permit.* Each permit shall remain valid for a period of two (2) calendar years from the date of issuance unless otherwise suspended or revoked. Permits may be renewed within thirty (30) days of expiration.

Sec. 2-18-9: Application.

(a) *Application required.* Any pain management clinic operating in Manatee County and not exempt from this ordinance shall file a sworn application created by the department, which shall contain the following information:

1. Proof that the applicant has registered with the State Department of Health as of the effective date of this ordinance as required by Sections 458.309 or 459.005, Fla. Stat. (2009), or any successor State law; and
2. A copy of the applicant's State application form, including all additional information required for the Florida Department of Health registration as referenced above; and
3. A sworn statement attesting to the veracity and accuracy of the information provided in the application.

(b) *Application.* Application shall be made within thirty (30) days of the effective date of this Article, or within thirty (30) days of receipt of Notice by the department whichever comes later.

(c) *Incomplete application.* If the application for a pain management clinic permit is not properly completed, the department shall notify, in writing, the person designated for service. If the application is not amended or supplemented within fifteen (15) days of mailing of the notice, it shall be automatically denied.

(d) *Application for renewal.* Application for renewal of permit can be made ninety (90) days prior to the expiration date, but no later than thirty (30) days from the expiration date.

(e) *Temporary Permit.* Permits issued under Ordinances 10-52 or 10-73 shall be effective for one (1) year from the date of issuance. Under no circumstances shall a Temporary Permit continue for longer than one (1) year. Application pursuant to this Article shall be made at least thirty (30) days prior to expiration of the Temporary Permit.

Sec. 2-18-10: Fees

The Board of County Commissioners is authorized to establish fees and charges associated with the permitting of a pain management clinic in Manatee County by separate resolution and adopted at any regular meeting of the Board.

Sec. 2-18-11: Probation, Suspension or Revocation.

(a) A permit for a pain management clinic may be subject to probation or revocation by order of the Board of County Commissioners in the event that any of the following occur:

1. The clinic is no longer registered with the Florida Department of Health, pursuant to Sections 458.3265 or 459.0137, Fla. Stat., or the controlled substance registration issued by the United States Department of Justice, Drug Enforcement Administration to any person prescribing, administering, or dispensing controlled substances at the pain management clinic has been suspended, revoked, or denied renewal;

2. The designated physician, clinic owner, or any person with authority to issue prescriptions under Florida Statutes has been convicted of a crime or had final administrative action taken against him or her;

3. Failure of the clinic to notify the proper authorities of all suspected cases of criminal activity on the premises;

4. Failure to allow any law enforcement officer, code enforcement officer or employee of the department who has been designated by the County Administrator and is authorized by the head of that department to enter a clinic for inspection;

5. Failure to make or maintain adequate personnel records;

6. Failure to make or maintain adequate operational records;

7. Failure to display prominently in a common public area near their front entrance, copies of all state and county licenses, and the name of the clinic owner, operator, and designated physician responsible for compliance with state and county law;

8. A false statement of material fact is knowingly made by the clinic owner, medical director, physician, or other clinic employee or is made by same when such person has reason to know of its falsity, in any of the following areas:

- a. Personnel records;
- b. Operational records;
- c. Information submitted for reimbursement from any payment source; or
- d. Advertisement.

9. Failure to confirm the identity of each patient seen and treated for pain;

10. Failure to comply with any other provisions of this Article or any other provision of this Chapter;

11. Failure to prohibit the consumption of alcohol on the premises of a pain management clinic or outside a pain management clinic where the clinic operates, including in any parking areas, sidewalks, rights-of-ways, or neighboring properties;

12. Operation of a pain management clinic for the purpose of seeing patients or writing prescriptions during prohibited days or hours;

13. Failure to protect patient privacy rights under state or federal law.

14. An order of probation, suspension or revocation is the final order of the County and is subject to judicial review under any available procedure in any court of competent jurisdiction.

Sec. 2-18-12 Violation.

It shall be unlawful for any person to violate any provision of this Article or to operate a pain management clinic or a “pill mill” without a permit.

Sec. 2-18-13: Service of Notice and Public Records.

Any notice required under this ordinance shall be in writing and sent by certified mail or hand delivered to the mailing address set forth on the application for the business registration. This mailing address shall be considered the correct mailing address unless the department has been otherwise notified in writing.

Any information contained in an application under this ordinance is subject to the Public Records Law, Chapter 119, Fla. Stat.

Sec. 2-18-14: Boundaries.

The provisions of this ordinance shall apply to all territory within the legal boundaries of Manatee County, which includes all incorporated and unincorporated areas.

Sec. 2-18-15: Repeal of Conflicting Laws.

All existing ordinances or parts of ordinances in conflict herewith are hereby repealed to the extent they conflict with this ordinance.

Sec. 2-18-16: Enforcement and Penalties.

(1) The owner or operator of a pain management clinic operating in Manatee County after the effective date of this ordinance and without a pain management clinic permit or an exemption therefrom, is in violation of this ordinance and shall be prosecuted in the same manner as misdemeanors are prosecuted. Upon conviction, he or she shall be punished by a fine not to exceed Five Hundred (\$500) Dollars, or by imprisonment in the county jail not to exceed sixty (60) days, or by both fine and imprisonment. Each day that the pain clinic operates in violation of this ordinance shall be considered a separate incident for purposes of prescribing penalties.

(2) In addition to the criminal penalties provided in this section, citations may also be issued to enforce any violations of this ordinance per provisions of Part II of Chapter 162, Fla. Stat., as may be applicable. A code enforcement officer is specifically authorized to issue a citation for each violation. Each day of any violation shall constitute a separate and distinct offense.

(3) The Board of County Commissioners may also enforce this ordinance by action in equity, including injunctive or declaratory relief, in the appropriate court of competent jurisdiction, in order to prevent or abate violations of this Article. In the event that the County prevails in any such action, the County shall be entitled to an award of its costs and reasonable attorneys' fees.

SECTION 2: Severability. If any section, subsection, sentence, clause, phrase or portion of this ordinance is for any reason held or declared to be unconstitutional, inoperative or void, or otherwise unenforceable, such holding shall not affect the remaining portions of this ordinance,

which shall remain in full force and effect. If this ordinance or any provision thereof shall be inapplicable to any person, property or circumstances, such holding shall not affect its applicability to any other person, property or circumstances.

SECTION 3: Effective Date. This ordinance shall become effective immediately upon filing in the office of the Department of State in Tallahassee, Florida.

SECTION 4: Codification. This permanent ordinance shall be codified into the Manatee County Code of Ordinances by the Municipal Code Corporation as Chapter 2-18, Article I.

PASSED AND DULY ADOPTED in open session, with a quorum present and voting this ____ day _____, 2012.

BOARD OF COUNTY COMMISSIONERS
MANATEE COUNTY, FLORIDA

By: _____
John R. Chappie, Chairman

Attest:

R.B. SHORE
CLERK OF THE CIRCUIT COURT

By: _____
Deputy Clerk