

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.

ESTABLISHED FOR STATE
TALLAHASSEE, FLORIDA

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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 painful diseases.

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.
- (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.

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 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 Department for a specific period of time as determined by the Department 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 monthly 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 in which part of the body is entered by puncture or incision and treatment takes place through manual and instrumental means. This includes interventional pain management procedures such as spinal injections, spinal cord stimulators, intrathecal pumps, and similar medical procedures.
- (u) *Suspension* means that the permit may be suspended by the Department for a period not to exceed three (3) months. After the suspension concludes, the permit is automatically reinstated for the remainder of its term but the permitted organization is still subject to any and all enforcement remedies e.g. Probation, Suspension, Revocation on the occasion of any subsequent violation(s) of the terms of this Article.

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.

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. 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 monthly operational records for a period of two (2) years. Operational records shall consist of a monthly 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 monthly 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 monthly 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 monthly basis by the fifth (5th) day of every month or upon completion to the department 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 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 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 within fifteen (15) days.

(f) *Prescription Drug Monitoring Program (PDMP):* All physicians licensed under Chapters 458 and 459, Fla. Stat., shall, 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.

(g) *Recording:* All recordings under this section may be submitted to the Department electronically by facsimile transmittal, by email transmission, or by direct submittal to a website set up by the Department for that purpose. All facsimile transmittals shall be accompanied by a cover sheet containing the sender's name, firm, address, telephone number, facsimile number, and number of pages being transmitted. The recording occurs when transmission is complete.

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 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 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 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 sixty (60) 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 sixty (60) 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, suspension or revocation by order of the Department 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 Article 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 Article is subject to the Public Records Law, Chapter 119, Fla. Stat.

Sec. 2-18-14: Boundaries.

The provisions of this Article shall apply to all territory within the legal boundaries of Manatee County, which includes all incorporated and unincorporated areas. Any municipality may opt

out of this Article by enacting a resolution to do so and submitting a conformed copy to the Department.

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 Article and without a pain management clinic permit or an exemption therefrom, is in violation of this Article 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 Article 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 Article 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 Article by an 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 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 27 day March, 2012.

BOARD OF COUNTY COMMISSIONERS
MANATEE COUNTY, FLORIDA

By: [Signature]
John R. Chappie, Chairman

Attest:

R.B. SHORE
CLERK OF THE CIRCUIT COURT

By: [Signature]
Deputy Clerk



STATE OF FLORIDA, COUNTY OF MANATEE
This is to certify that the foregoing is a true and correct copy of the documents on file in my office.

Witness my hand and official seal this 28th day of MARCH, 2012

R.B. SHORE
Clerk of Circuit Court

By: [Signature] D.C.



FLORIDA DEPARTMENT *of* STATE

RICK SCOTT
Governor

KEN DETZNER
Secretary of State

April 3, 2012

Honorable R. B. "Chips" Shore
Clerk of the Circuit Court
Manatee County
Post Office Box 25400
Bradenton, Florida 34206

RECEIVED

APR - 9 2012

BOARD RECORDS

Attention: Ms. Nancy Harris, Deputy Clerk

Dear Mr. Shore:

Pursuant to the provisions of Section 125.66, Florida Statutes, this will acknowledge receipt of your letter dated March 28, 2012 and certified copy of Manatee County Ordinance No. 12-14, which was filed in this office on April 2, 2012.

As requested, one date stamped copy of is being return for your records.

Sincerely,

A handwritten signature in cursive script that reads "Liz Cloud".

Liz Cloud
Program Administrator

LC/srd

Enclosure