

CITIZENS' COMMENTS

Do your comments refer to an item on today's agenda? NO YES

Item #: _____

CONSENT: NO YES

The Board of County Commissioners welcomes your comments. Your presentation will be limited to two (2) minutes. If appropriate, the matter(s) you present will be placed on a future commission agenda.

It is requested that you complete this form and return it to the receptionist prior to the beginning of the Citizens' Comments portion of the agenda.

Name: _____

Ruth Leyerly

Address: _____

201 23rd St. W.

Phone: (Home) _____

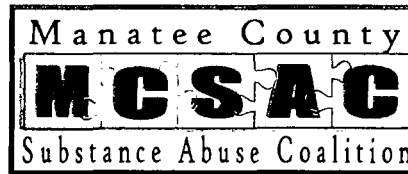
747-9638

(Work) _____

465-0030

Brief description of problem or concern: _____

*permanent pass management
Ordinance # 11-047*



Manatee County Substance Abuse Coalition: White Paper
...areas of concern...areas requiring greater clarity

Options for Consideration for Ordinance No. 11-047, Licensing and Regulation of Pain Management Clinics

Sec. 2-18-5 Exemptions

A. MCSAC believes it would be valuable to establish an exemption based on a maximum threshold of physician-issued prescriptions of a controlled substance in a single day for the treatment of pain. This would, depending on the level identified and based on our research, provide exemptions for many prescribing physicians in Manatee County and relieve them of any substantive burden under this ordinance, which is a valid consideration. Pending feedback from the healthcare community, MCSAC recommends a threshold of 25 prescriptions of a controlled substance for the treatment of pain in a single day.

a. Further, both Sarasota ("*one or more physicians licensed under chapters 458 or 459, Florida Statutes, who in a single day issue more than twenty [20] prescriptions of a controlled substance for the treatment of pain*") and Pinellas ("*a physician...who issues more than thirty-four [34] prescriptions of CII or CIII controlled substances for treatment of pain in a single day*") have this language in their ordinances. In addition Pinellas references those writing more than 34 CII or CIII scripts/day as "high prescribing", language which we endorse.

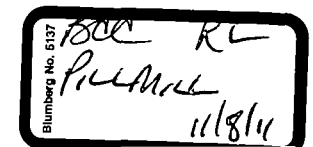
B. In that same vein, and to clearly address concerns regarding possible barriers to legitimate access to pain management for suffering patients, MCSAC believes it would be valuable to establish additional exemptions based on type of services provided in addition to descriptors of ownership/affiliation/licensure. This would include in addition to previously indicated exemptions:

- a. Any clinic, facility or office in which the majority of the patients receive treatment for terminal illness;
- b. Any clinic, facility or office in which the majority of the patients receive cancer treatment; and
- c. Any clinic, facility or office in which the majority of the patients receive Hospice treatment

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

A. MCSAC has identified a gap in this section, specifically the omission of a description or criteria for Operational Standards, Records and Reporting, despite the fact that a "failure to make or maintain adequate operational records" is noted as a reason for Probation or Revocation (Sec 2-18-10). **Establishing Operational Standards, Records and Reporting is a crucial element for consistent regulation and enforcement of Pain Management Clinics.** Law enforcement representatives' response to an inquiry by MCSAC

1 Nov 8, 2011



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clearly indicates the need for a clear statement of Operational Standards, Records and Reporting in order to facilitate enforcement efforts: *Maintaining these records is very important when it comes to compliance with the provisions of the ordinance. We have a cliché that we like to use here- it's not what you expect, it's what you inspect. Having the records maintained will allow for proper inspections to be performed and appropriate action to be followed up. The definition of Operational Records is very important for both enforcement and for the physician. For physicians, it spells out the requirement of record keeping in conjunction with the PDMP. For law enforcement, it clarifies the responsibilities of physicians which will assist in inspections of these locations.*

All of the current Operational Standards (a – h) in Sec 2-18-7 are critical to this process. The inclusion of two specific items e.g. identifying Landlord Responsibility (b, pg 7) and requiring that licensed physicians request and review a “patient advisory report” from the PDMP prior to prescribing controlled substances, with a printout of the report for the patient’s file (h, pg 9) are exemplary best practices for which we thank the drafters of this ordinance and the Commissioners. MCSAC respectfully requests consideration of the following additions in this section:

Options for Consideration: Operational Standards	Reference/Context
Provision for securing prescription pads so that only authorized persons may access them	Due diligence for most physician offices; included in Pinellas Ordinance Sec. 86-139 (c 6)
Provision for patient education on how to “monitor, secure, dispose” of prescribed pain medications; provision of educational materials for distribution	included in Pinellas Ordinance Sec. 86-139 (c 13) MCSAC has secured funding to print and distribute educational materials from the American Medical Association for patient education on prescription drugs
Provision for the medical determination of pregnancy status of female patients prior to prescribing prescription pain medications; provision of educational materials specific to taking these medications during pregnancy	included in Pinellas Ordinance Sec. 86-139 (c 14) MCSAC has secured funding to print and distribute educational materials from the American Medical Association for patient education on prescription drug use during pregnancy
Options for Consideration: Operational Records	Reference/Context
Provision in Sec 2-18-7 Regulation of Pain Management Clinics a titled section: <i>Operational Records</i> between (c) <i>Management</i> and (d) <i>Ownership, Business Relationship and Employment Restrictions</i>	Both Sarasota and Pinellas Ordinances offer specific reference to maintaining Operational Records, though the criteria differ. MCSAC believes this section is critical to buy-in and understanding by all stakeholders

<p>Adopt language for “Operational Records” from Sarasota Ordinance #2011-016, (Sec 5), Sec 62-331, from beginning through “...and a signature of the signing party presented in a legible manner.”</p>	<p>Section attached as separate document for easier reading. This section’s action will generate a single Excel Document, essentially a log (template/format based on Sarasota’s; to be provided to appropriate clinics in e-format for download and printing) that provides a timely snapshot of clinic activity for monitoring efforts without violating any HIPAA statutes</p>
<p>Options for Consideration: Monthly Reporting</p>	<p>Reference/Context</p>
<p>Provision in Sec 2-18-7 Regulation of Pain Management Clinics/Operational Records for a sub-section requiring monthly submission of the Operational Log by the fifth of the following month (Nov 5 for the month of October) to a designee. It should be specified that forms may be faxed, mailed or hand delivered.</p>	<p>MCSAC is prepared to take on the responsibility of collecting, monitoring and securing this data and reporting on it as required or requested so that no burden accrues to any County agency or department.</p>
<ul style="list-style-type: none"> • Reporting: monthly vs annual. Monthly reporting generates more reliable data. It also allows for a timely response; annual reporting misses the opportunity to act on the data. <ul style="list-style-type: none"> a. In Sarasota, monthly data revealed several clinics that predominantly prescribe to women of childbearing age. This allowed them to focus efforts to prevent substance-exposed newborns on these clinics. b. It also provides valuable data for law enforcement. Monthly data indicated that most clinics saw 100-200 patients/month. However a few saw 2,000-3,000 patients/month, so law enforcement immediately knew where to focus surveillance and undercover efforts. c. Data submitted annually is likely to be less reliable. It took Sarasota 3 months to get complete data from most clinics. So the first few months were spent correcting mistakes. If they only submit annually, there is no opportunity for correction, so you may get a whole year of “bad” data (rather than just 1-3 months worth). d. Annual reporting only decreases the frequency of <i>submitting</i> paperwork. Clinics would still have to <i>collect</i> it throughout the year. Annual reporting would likely result in lax collection efforts. 	

From Sarasota County Ordinance #2011-016 re: Pain Management Clinics

Section 62-331 (amended) Regulation of Pain Management Clinics

“(6) Operational Records. For the purpose of study[ing] the patterns of health and illness and prescriptions issued within Sarasota County, and to verify that a pain management clinic is operating within 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 one year. The 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); the initial two digits of zip code of the patient’s address; and a statement acknowledging use of the Department of Health’s Prescription Drug Monitoring Program. In addition, the records shall include a list of the total number of prescriptions for schedule II drugs, schedule III drugs, or drugs containing Alprazolam, prescribed per physician licensed under chapters 458 and 459, Florida Statutes, per month. Each physician who prescribes schedule II drugs, schedule III drugs, or drugs containing Alprazolam shall swear to the veracity of the information contained in this list. The one month period for the purpose of collection of the operational records described in this paragraph shall begin on the first day of the calendar month. Each physician in his or her own submission shall swear that, “Under penalty of perjury, I swear that the submitted records contain true and complete information.” 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.”

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Name: _____

Rita Chamberlain

Address: _____

4504 Mount Vernon Drive, Bradenton 34210

Phone: (Home) _____

941-761-0580

(Work) _____

Brief description of problem or concern:

Ordinance # 11-047 Pain Mgmt Clinic Ordinance

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Name: _____

Address: _____

Phone: (Home) _____

(Work) _____

Brief description of problem or concern:

Ordinance 11/047
prescribing opiates to pregnant women.

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Name:

~~Kim Holt~~

Address:

~~3611 118 St. W Bradenton~~

Phone: (Home)

~~713-3012~~

(Work)

~~778-4849~~

Brief description of problem or concern:

~~Pill kills - Drug abuse~~

~~My son's death - overdose~~

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Name: LUIZ CORCUERA, HEALTHY START
Address: 2424 Manatee Ave West Suite 210 Bradenton FL 34205
Phone: (Home) 941 776 7472 (Work) 714-7541 X 302

Brief description of problem or concern: Prescription
Ordinance 11 / 047 Substance abuse exposure
(Newborns / Pregnant Women)