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A Statement of Estimated Regulatory Cost (SERC) of Proposed Rules in Regulation of Pain Management Clinics in Florida

Florida Department of Health

January 18, 2011

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Project Timeline

12/15/2010 to 1/18/2011

Institutional Capacity

The Center for Economic Forecasting and Analysis (CEFA) is part of the Florida State University Institute of Science and Public Affairs (ISPA), which is a multi-disciplinary research institute. CEFA specializes in applying advanced, computer-based economic models and techniques to examine and help resolve pressing public policy issues across a spectrum of research areas. CEFA provides advanced research and training to students in the areas of health care, education, high technology, energy, and environmental economics, economic impact analysis, among others.

Scope and Deliverable

CEFA has estimated the costs for both the agencies and the Pain Management Clinics (PMC) that are required to comply with the following proposed Board of Medicine (BOM), Board of Osteopathic Medicine (BOOM) and Department of Health (DOH) rules:

- BOM Rule: 64B8-9.0131 Standards of Practice for Physicians Practicing in PMC
- BOM Rule: 64B8-9.0132 Requirement for PMC Registration; Inspection or Accreditation
- BOM: 64B8-9.0131(Subparagraph (2)(n): Training Requirements
- BOM/BOOM: 64B8-9.0134/64B15-14.0054 Maximum Number of Prescriptions in Registered PMC.
- BOM/BOOM: 64B8-9.0133/64B15-14.0053 Approval of Nationally Recognized Pain Management Accrediting Organizations
- DOH: 64B-7.001: Pain Management Clinic Registration Requirements
- DOH: 64B-7.003: Counterfeit-Resistant Prescription Blanks

CEFA has estimated for each of the rules:

1. The number of individuals that are likely to be required to comply with the rule and a general description of the types of individuals likely to be affected by the rule.
2. The cost to state and local government entities of implementing and enforcing the proposed rules and their anticipated effect on state and local revenues.
3. The transaction costs likely to be incurred by individuals and government agencies, required to comply with the rules

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The Florida Pain Management Clinic Industry Overview

Sections 458.3265, and 459.0137, F.S., created the registration and inspection of pain management clinics with the Department of Health and required the Boards of Medicine and Osteopathic Medicine to promulgate rules for the standards of practice of physicians practicing in pain management clinics and rules to implement certain other pain management clinic provisions. The Allopathic Medical Practice Act, Chapter 458, F.S. (MD) and the Osteopathic Medical Practice Act, Chapter 459, F.S. (DO) are similar and the proposed pain management clinic rules of both of these physician boards are also similar. Pain management clinics may have MD or DO licensed Florida physicians or a combination of both practicing at the clinic at any one time. The Board of Osteopathic Medicine has in effect a standards of practice rule, a training rule and a registration/inspection or accreditation rule which are similar to the proposed Board of Medicine rules being addressed in this SERC.

Below is an overview of the Pain Management Clinics in Florida. The data is from a December 9, 2010 download of the "Application Status" file from the Florida Department of Health. No changes since 12/09/2010 have been considered – therefore if an additional clinic was approved, or a clinic lost its "clear" status after December 9, 2010, they have not been accounted for in this study.

This data includes records for clinics adding locations, adding new physicians and some are in progress and haven't been approved as of December 9, 2010. Others are listed as withdrawn, "admin. revoked", closed, denied or under emergency suspension. The records that were not listed as "clear" were deleted. Then, all multiples for any clinic were deleted to give the final number of clinics with clear status as 932 on the December 9, 2010 date.

Clinic Locations: this table shows the number of registered Pain Management Clinics, ranked from largest to smallest, by county, for the top 10 counties as of 12/09/2010.

County	Clinics
BROWARD	117
HILLSBOROUGH	113
PALM BEACH	108
MIAMI-DADE	89
DUVAL	51
ORANGE	49
PINELLAS	47
PASCO	31
VOLUSIA	30
LEE	29

Density: To estimate the density of Pain Management Clinics by county, the number of clinics was divided by the population, 18 and over, in the county. This yields the following density figures, from highest to lowest for the top 10 counties.

County	Clinics/100k pop.
HILLSBOROUGH	12.52
PALM BEACH	10.68
FRANKLIN	10.63
BROWARD	8.61
PASCO	8.34
DUVAL	7.88
SARASOTA	7.74
VOLUSIA	7.50
NASSAU	7.31
HERNANDO	7.27
PUTNAM	7.15
MANATEE	7.14

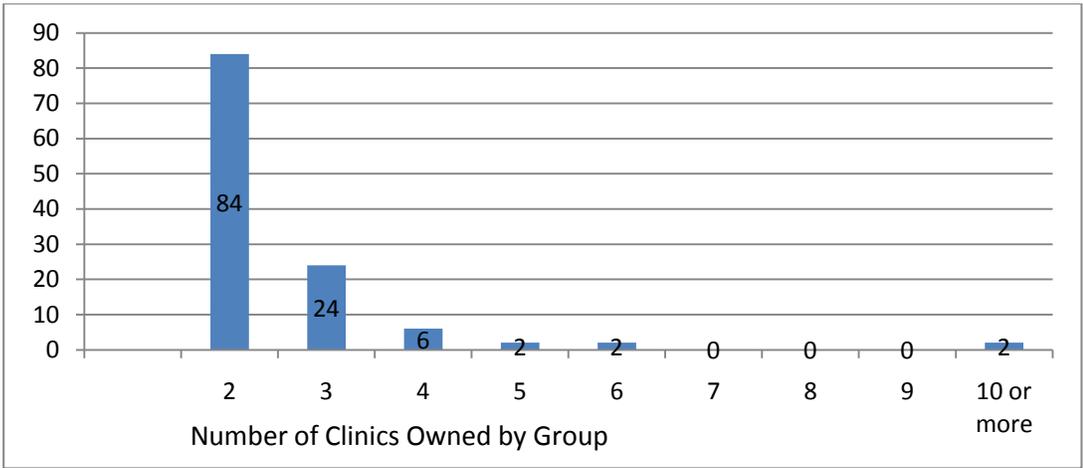
Appendix 1 shows the total for all counties that have at least 1 registered Pain Management Clinic.

Many of the clinics have physicians who are registered to dispense medication on the premises of the clinic. To do this, the physician must register with the Florida Department of Health and pay a \$100 fee. The following table shows the number of clinics whose Designated Physician is registered to dispense medication for the top 10 counties in Florida.

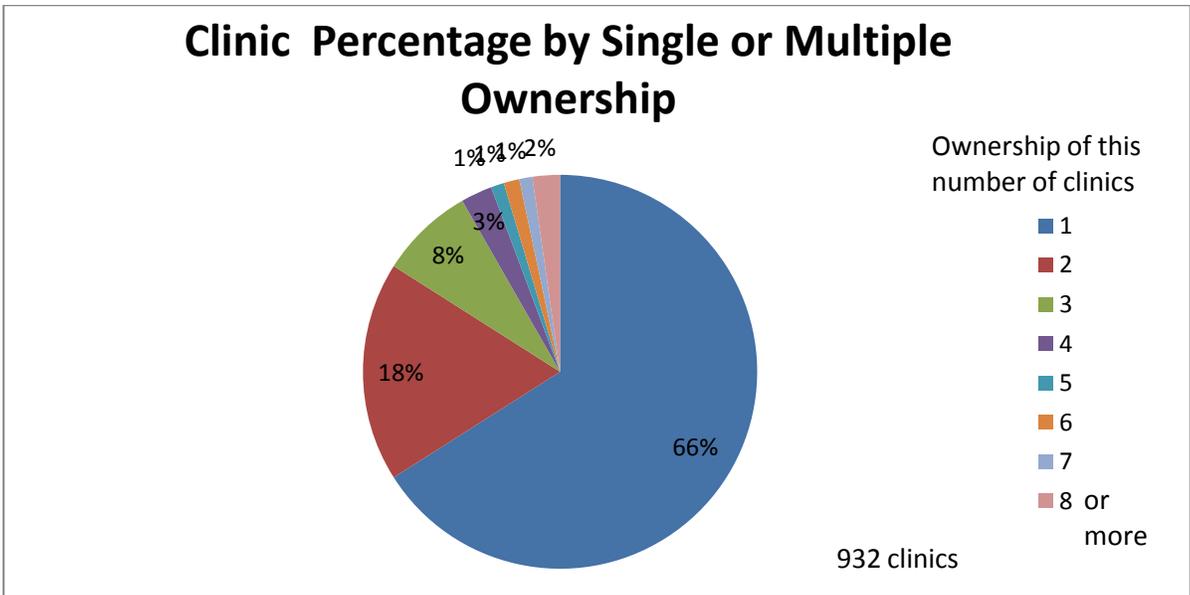
County	Clinics	Dispensing
PALM BEACH	108	77
BROWARD	117	73
MIAMI-DADE	89	50
HILLSBOROUGH	113	45
PINELLAS	47	32
DUVAL	51	31
ORANGE	49	29
PASCO	31	18
SARASOTA	24	18
LEE	29	16

Appendix 1 shows the total for the whole state.

To check for concentration of ownership, the data was analyzed to see how many groups own more than one Pain Management Clinic in Florida. The number of clinics that are owned as an individual clinic is 615 clinics (66%). Of the remaining 317 clinics, the below graph shows that there are 84 groups that own 2 clinics, 24 that own 3 clinics, 6 that own 4 clinics, 2 that own 5 clinics, 2 that own 6 clinics and then one group that owns 10 clinics and one that appears to own 21 clinics. Checking the concentration, the clinics owned by groups that four or less Pain Management Clinics compose 94.31% of the clinics. These were found by analyzing the data for common listed owners and common mailing addresses and are shown in the graph below.

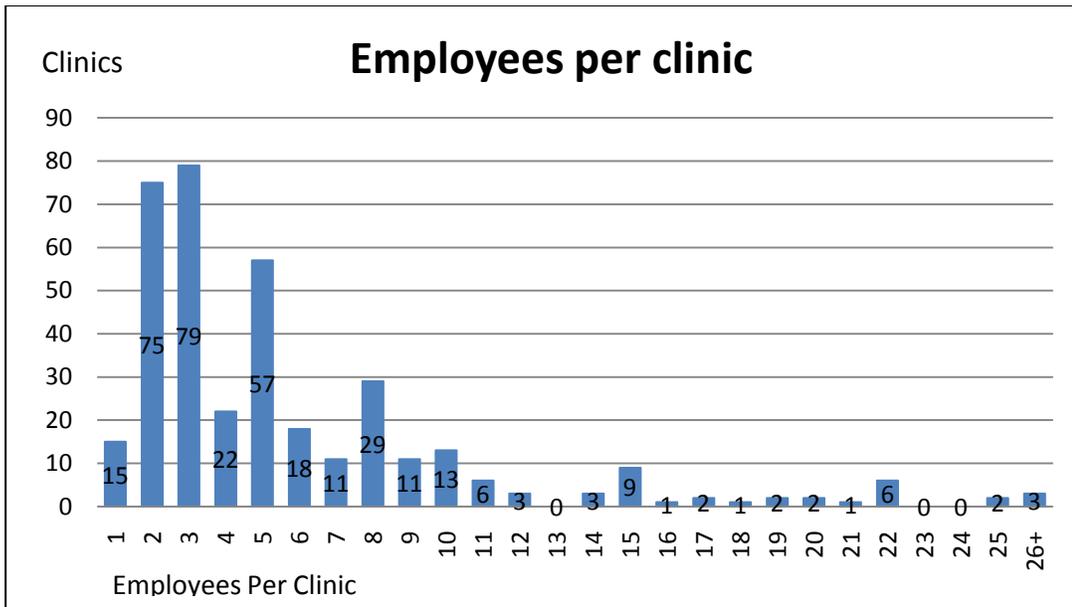


The graph below shows the same information, by percentage of the total clinics.



To check for concentration in any given county or group of counties, the ownership groups were analyzed to see which counties they operated in. Appendix 2 shows the list of those groups owning three or more pain clinics and the counties that they operate in.

Data from the same database as above, as well as additional data from Dun & Bradstreet’s Selectory database was obtained and analyzed. Cross-referencing the DOH data and the current Selectory database, 371 of the 932 clinics were found on the database. Information on the number of employees was recorded and analyzed. The median number of employees was 4 for this sample. The employee number was derived using Selectory data for total sales and sales per employee.



A majority, 248 of the 371 (66.8%) of the clinics found in the Selectory database have 5 employees or less. Those that have 3 or less employees (169 of 371) account for 45.5% of these clinics.

Estimating the Number of Physicians

Establishing an upper and lower bound: Physicians are allowed work at more than one clinic at a time, including working part-time at a Pain Management Clinic and having a separate practice. There is no requirement for all physicians to register with DOH. However, each clinic must register a Designated Physician that is responsible for the clinic.

To establish an upper and lower bound for the “actual number of physicians working” to estimate things like the number of patients seen and the number of prescriptions written, the lower bound will be 932 for physicians, one for each Pain Management Clinic.

Since data is not available, other methods are used to estimate physicians working in Pain Management Clinics. Data was obtained from an advertising website and analyzed. The number of clinics found on one marketing website was 366, showing 574 physicians. That website is Ucomparehealthcare.com.

Their data was analyzed and it showed the doctors per clinic in the below percentages:

Clinics with	Percentage
1 physician	74.90%
2 physicians	13.10%
3 physicians	7.10%
4 physicians	1.40%
5 physicians	1.40%
6 or more	0.02%

Although we cannot identify how similar this sample is to the rest of the population, the analysis of the above data yields 1.57 physicians per clinic. That would lead us to an estimate of 1462 physicians as an upper bound. This data is possibly skewed upward for a couple of reasons. First, it might be more likely that the larger businesses would seek opportunities to advertise. Most importantly, one of the groups in this sample shows 20 physicians working at their clinic. The clinic is, indeed registered as a Pain

Management Clinic in Florida, yet having 20 physicians shown working at one clinic likely skews this sample upward.

Using this sample, there are 566 physicians that are known, although one cannot be sure what percentage of time each physician is working at that clinic. If one uses the minimum (one physician at the clinic) for the unknown clinics in addition to this number, one obtains a lower-bound estimate of 1140.

To estimate the actual number of physicians working at Pain Management Clinics in Florida, a normal distribution was set up, with a 90% confidence interval between the lower and upper bounds. This resulted in a distribution with a mean of 1314 physicians and a standard deviation of 106.4.

The estimate that will be used for the number of physicians working full-time at registered Pain Management Clinics in Florida is a normal probability distribution function with a mean of 1314 and a standard deviation of 106.4. This yields an expectation of a 90% probability of the actual physician number being between 1140 and 1462.

Small business and number of PMCs affected: Most of the 932 registered PMCs in Florida will qualify as a small businesses under Florida 288.703.

Methods Used in this Study

Data was requested, purchased and gathered from various sources and then confirmed with physicians and industry professionals. Data that had a significant amount of uncertainty was estimated at upper and lower bounds, and then by statistical means. This study estimates some items and costs by the Monte Carlo method, where probability distributions are developed to use in the analysis. During each of the iterations of the model, values are drawn from the input probability distribution and used in calculating the range of the outputs.

Full-time is defined as 250 work days per year. When used, calculations use 40 hour work weeks and 50-week years.

Summary of Proposed Rule 64B8-9.0131. *Standards of Practice for Physicians Practicing in Pain Management Clinics.*

This proposed rule is applicable to allopathic physicians practicing in privately owned pain management clinics that are required to be registered pursuant to Section 458.3265, F.S. who primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications. Allopathic (M.D.) and Osteopathic (D.O.) physicians both practice in Pain Management Clinics. The statute provides that both the allopathic board of medicine and the osteopathic board of medicine establish rules for standards of practice at Pain Management Clinics. A rule similar to this one is in effect for osteopathic medical physicians practicing at PMCs.

The requirements are presented in the following categories:

- a. Evaluation of patient and medical diagnosis
- b. Treatment plan
- c. Informed consent and agreement for treatment
- d. Periodic review
- e. Consultation
- f. Patient drug testing
- g. Patient medical records
- h. Denial or termination of controlled substance therapy
- i. Facility and physical operations
- j. Storage and handling of prescription drugs
- k. Health and safety
- l. Quality assurance
- m. Data collection and reporting

A complete copy of the proposed rule is shown in Appendix 3.

Total Estimated Statewide Costs: Given the below assumptions, there is a 90% probability that the statewide cost of this rule is:

1st year: \$56.449 Million to \$72.519 Million, with a mean of \$64.459 Million

Year 2 thru 5: \$52.902 Million to \$68.972 Million, with a mean of \$60.912 Million

On a **per-clinic** basis, at the mean

1st Year: \$69,162

Year 2 thru 5: \$65,356

Per Existing Patient

1st Year: \$43.73

Year 2 thru 5: \$40.91

Per New Patient

1st Year: \$60.83

Model Clinic

This estimate will be for an average existing clinic. Characteristics of the average clinic, for estimation purposes, are that they:

1. Are currently meeting drug storage and drug records requirements under the statute
2. Meet the facility requirements for clinics
3. Have a phone line that is listed, but do not have a 24-hour dedicated fax line
4. Use in-house drug testing, unless required to do otherwise

To meet the other requirements of the proposed rule, this average clinic needs:

1. Indoor Sign
2. Outdoor Sign
3. Dedicated fax line plus installation
4. Basic Life Support Training for one person
5. Infection control program
6. Quality Assurance program established and inspection every three years
7. Emergency lighting and communications
8. Written, facility-specific disaster plan

Estimates were obtained for salaries of office personnel in these type clinics from online salary estimates and from discussions with physicians. For use in this study, although there is a wide range in Florida physician office and outpatient clinic salaries, the office manager is estimated at \$40 per hour and other clinic personnel at \$20 per hour, including benefits.

Evaluation of the Patient: A complete medical history, physical exam, written individualized treatment plan, informed consent and agreement for treatment, written controlled substance agreement, consultation, and possible referral are required for each patient. Any time involved in taking on a new patient, in this example, is assumed to be built in to new patient office visit charges typically used by Pain Management Clinics.

Patient Drug Testing: The drug test cup used for this estimate is a Clinical Laboratory Improvement Amendment (CLIA)-waived 12-panel test that measures ph, specific gravity and temperature and includes a built-in adulterant test. The cost estimate, including freight, is figured at \$10.43. Administrative costs will be calculated at 20 minutes per in-house drug test. In the administrative cost is time for administrative employee to order and receive drug-test cups, deal with patient, collect cup, and view and record results. This administrative time estimate is \$6.66 per in-house drug test. Outside drug tests, where a specimen is collected in the physician's clinic and sent out for either gas or liquid chromatography/mass spectrometry test will be estimated at \$100, including administrative time to receive and record results. Cost estimates for sending a patient to an outside laboratory for their drug test are estimated at \$150 to \$300. This is one of the available options under the proposed rule, but it is not used in the following estimate due to the high cost.

For the following estimate, a minimum cost strategy was used for this example of a one-physician clinic. Drug testing is estimated to be done in the clinic, using CLIA-waived drug test cups. Drug testing will be sent out for gas or liquid chromatography/mass spectrometry, only when it meets the following requirements to do so:

1. The result indicates an adulterant was used
2. The result indicates absence of an expected substance
3. The result indicates the presence of a substance that is not expected
4. Either the patient or the physician dispute the outcome of the in-clinic test

Given that it's extremely difficult to estimate the number of unexpected results, including any false positives and false negatives that might occur; an example of additional costs will be shown separately to indicate the possible additional cost of these occurrences.

Therefore, when interpreting the results for the following drug testing model, one should note that it only includes the costs of drug testing in the clinic where none of the drug tests have results that would require the clinic to send the sample out for gas or liquid chromatography/mass spectrometry. Once again, examples of those additional costs will be separate.

To estimate drug testing costs on a state-wide basis requires a significant amount of analysis. The costs are influenced heavily by:

1. The amount of patients a physician sees
2. The number of new patients. They must be drug tested 3 times per year
3. The number of existing patients. They must be drug tested 2 times per year
4. The frequency of the patient visiting the physician. An existing patient taking up a "patient slot" versus a new patient in that slot influences the cost

Estimating the lower and upper bounds:

The lower bound example uses a clinic that sees 20 patients per day, with none being new patients. If these patients all come in 12 times per year, each would expect to be drug tested once every 6 visits – the required 2 tests per year. Therefore the expected daily number of drug tests would be 3.33. Expected daily cost of this example would be \$57.00, given that each drug test cup costs \$10.43 and the labor cost to administer the test and record the results is \$6.67. Assuming the full-time example of 250 working days per year, this comes out to \$14,250 on a yearly basis for this physician.

The upper bound example of drug testing assumes 50 patients per physician per day, and of those, 5 are new patients. Note that this example is on a per-physician basis, where the lower-bound uses the minimum number of physicians (1 physician per clinic) to keep the 932 clinics open. Existing patients come in four times per year in this upper-bound example; therefore they are expected to be drug-tested on half of their visits. This physician would expect to average 27.5 drug tests per day. To be clear, the 45 existing patients would have a 50% probability of being drug tested, and the 5 new patients would have 100% probability of being tested. Expected drug-test cost would be \$470.25 per day for this physician. This upper-bound estimate yields \$117,562.50 per physician, more than 8 times the amount for the lower bound.

The Model for estimating Drug-Testing Costs:

First, a table was developed to show the range of expected daily drug tests for a clinic seeing from 20 to 50 patients per day. This table assumes existing patients have 6 visits per year – a balance between those that come in monthly versus those that come in the minimum of four times per year to the clinic. Note that new patients are subtracted from total patients when calculating the probability of being drug-tested and obtaining the estimated number of drug tests.

Table 1: Expected Number of In-clinic Drug Tests Per Day:

		Total Patients per Day						
New Patients		20	25	30	35	40	45	50
0		6.7	8.3	10.0	11.7	13.3	15.0	16.7
1		7.3	9.0	10.7	12.3	14.0	15.7	17.3
2		8.0	9.7	11.3	13.0	14.7	16.3	18.0
3		8.7	10.3	12.0	13.7	15.3	17.0	18.7
4		9.3	11.0	12.7	14.3	16.0	17.7	19.3
5		10.0	11.7	13.3	15.0	16.7	18.3	20.0

To show the static results on a per-physician basis, as would the typical economic impact study, those costs would be estimated at the mean and multiplied together. For this static example, the following table shows the expected drug costs per day.

Table 2: Expected Drug Testing Costs Per Day.

		Total Patients Per Day						
New Patients		20	25	30	35	40	45	50
0		\$114.00	\$142.50	\$171.00	\$199.50	\$228.00	\$256.50	\$285.00
1		\$125.40	\$153.90	\$182.40	\$210.90	\$239.40	\$267.90	\$296.40
2		\$136.80	\$165.30	\$193.80	\$222.30	\$250.80	\$279.30	\$307.80
3		\$148.20	\$176.70	\$205.20	\$233.70	\$262.20	\$290.70	\$319.20
4		\$159.60	\$188.10	\$216.60	\$245.10	\$273.60	\$302.10	\$330.60
5		\$171.00	\$199.50	\$228.00	\$256.50	\$285.00	\$313.50	\$342.00

This is the dollar figure matching the earlier table of Expected number of Drug tests. Each drug test in this example costs \$10.43 for the cup and \$6.67 in administrative time – yielding a cost for each in-clinic drug test of \$17.10.

On a yearly basis, the figures are multiplied by 250 – the number of working days used in this paper. Note that the reason these estimates are different from the ones used in the upper and lower bound examples is that this table assumes the patients visit the clinic 6 times per year, whereas the upper bound uses four times per year, the lower bound uses 12 times per year.

Table 3: Estimated yearly cost of drug testing per clinic:

		Total Patients Per Day					
New Patients	20	25	30	35	40	45	50
0	\$28,500	\$35,625	\$42,750	\$49,875	\$56,999	\$64,124	\$71,249
1	\$31,350	\$38,475	\$45,600	\$52,725	\$59,849	\$66,974	\$74,099
2	\$34,200	\$41,325	\$48,450	\$55,575	\$62,699	\$69,824	\$76,949
3	\$37,050	\$44,175	\$51,300	\$58,425	\$65,549	\$72,674	\$79,799
4	\$39,900	\$47,025	\$54,150	\$61,275	\$68,399	\$75,524	\$82,649
5	\$42,750	\$49,875	\$57,000	\$64,125	\$71,250	\$78,374	\$85,499

To estimate the statewide cost of the drug tests in the proposed rule on a per-physician basis, a model clinic to show one day’s patient load was set up. Assumptions in this model are:

Total Number of Patients: (equals existing patients plus new patients) from 20 to 30 per day

Number of New Patients: 0 to 3 per day

Cost of Drug Test Cup: \$8.43

Administrative time: 20 minutes per drug test

Administrative cost: \$20 per hour, including benefits

Patients visit clinic: 6 times per year. Patients must come in a minimum of 4 times per year under the proposed rule to continue to receive treatment. Some patients come in every month. Invasive procedure physicians must do follow-ups more regularly than those that don’t do invasive procedures. Under the proposed rule each existing patient must be randomly drug-tested twice per year and every new patient must be tested on the first visit and then two times per year. To be clear, on the day shown in the model, every existing patient has an expected probability of one-third (6 visits per year, two mandatory drug tests) and each new patient has a 100% probability of being tested. As an example, a clinic with 25 patients on any day where one patient is new would be expected to give 9 drug tests – one to the new patient and one to 8 of the 24 existing patients.

A Monte Carlo simulation model was run on @RISK 5.7 Professional software to estimate the likely statewide drug test costs. The variables used are:

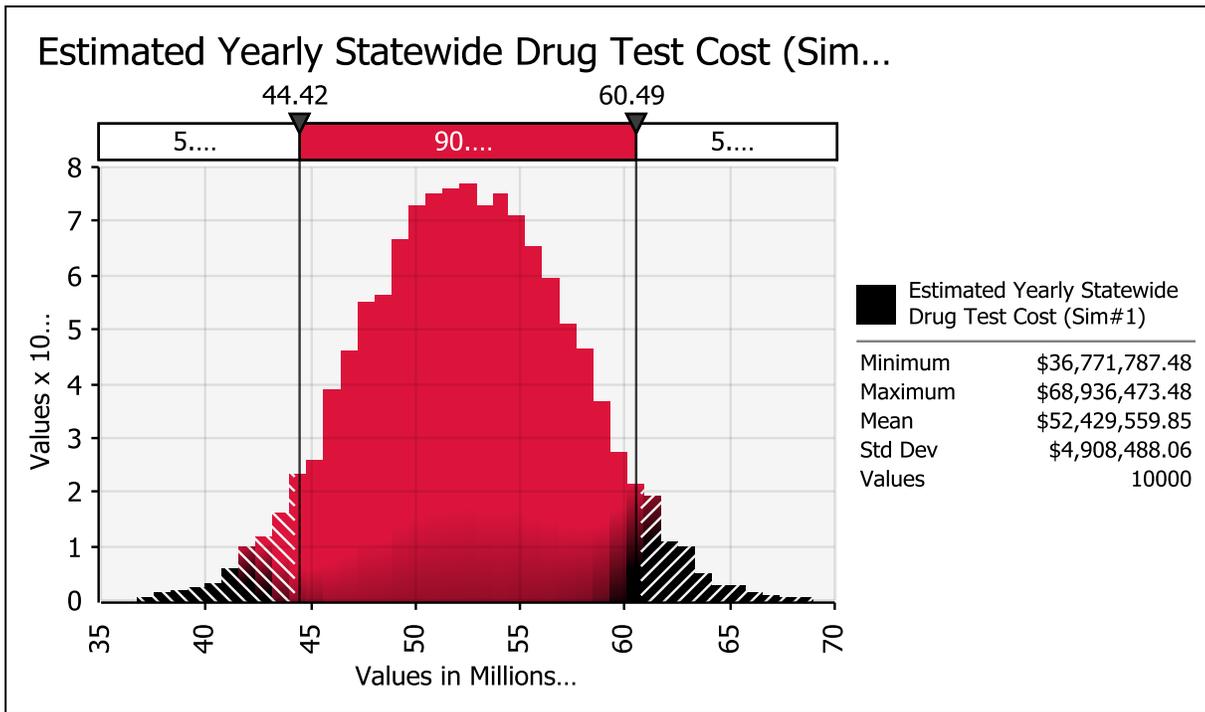
Number of Patients per day: Mean of 25, standard deviation of 1.94, normally distributed

New Patients per day: Uniform distribution with a minimum at zero, maximum at 3

Drug Test Costs: \$17.10. This is the \$10.43 landed cost of the test, plus \$6.67 administrative time.

Full-time Physicians: 1314, estimated earlier.

Below are the results of the stochastic model. The simulation was run 10 times with 10,000 iterations each. You can see that there is a 90% probability that, given the assumptions of the model, the statewide yearly cost of drug testing is between \$44.42 million and \$ 60.49 million – with a mean of \$52.43 million.



One should note that these figures do not include an estimate of the drug tests that are required to be sent to an outside lab in cases of:

1. The result indicates an adulterant was used
2. The result indicates the absence of an expected substance
3. The result indicates the presence of a substance that is not expected
4. Either the patient or the physician dispute the outcome of the in-clinic test

Given that it is unknown how many instances one or more of these events will happen, a table is set up to give an example of the expected yearly cost if 5% of the in-clinic drug tests are sent out for gas or liquid chromatography/mass spectrometry. Note that 5% is not an estimate; it is just used as an example and is not included in the estimated costs of this proposed rule. The table below shows this example, in millions of dollars per year.

Table 4: Example Statewide Additional Drug Testing Cost if 5% are sent to outside lab, in \$Million.

New Patients	Patients Per Day						
	20	25	30	35	40	45	50
0	\$10.950	\$13.687	\$16.425	\$19.162	\$21.900	\$24.637	\$27.375
1	\$12.045	\$14.782	\$17.520	\$20.257	\$22.995	\$25.732	\$28.470
2	\$13.140	\$15.877	\$18.615	\$21.352	\$24.090	\$26.827	\$29.565
3	\$14.235	\$16.972	\$19.710	\$22.447	\$25.185	\$27.922	\$30.660
4	\$15.330	\$18.067	\$20.805	\$23.542	\$26.280	\$29.017	\$31.755
5	\$16.425	\$19.162	\$21.900	\$24.637	\$27.375	\$30.112	\$32.850

Facility and physical operations:

Outdoor Signage: contains the clinic name, hours of operations and street address. Estimate is \$300, including installation. Although there are many types of outdoor signs, a sign to meet the minimum standard was used.

Fax Line: Installation and monthly charges for a dedicated 24-hour fax line: Estimate \$45.95 per month as a statewide average. Installation, paid the first year, was estimated at \$81.00 per line.

Emergency Lighting: Estimated at two simple commercial emergency lights with batteries, plus installation. The estimate used is \$500 per clinic.

Emergency communications: Estimated one pre-paid cell phone for emergencies, plus the cost of printing postcards for patients with emergency number on it. The estimate used is \$500, one-time.

Indoor signage: must list the name and contact information of the clinic Designated Physician, and the names of all physicians practicing in the clinic. Estimate is \$125, no installation charge.

Infection control: Equipment, supplies, analysis of data, written prevention policies and procedures, etc... Estimated at 5 hours of Office Manager time - \$200 in labor for written policy manual. Equipment and supplies costs vary widely for those clinics doing non-invasive procedures versus clinics doing invasive procedures. The estimate for an average clinics' yearly cost of supplies is \$500.

Emergency evacuation procedures, including provisions for the evacuation of disabled patients and employees: Estimated 8 hours of Office Manager's time to put together a basic evacuation plan for clinic, totaling \$320. Evacuation signage for each room used by the public estimated at \$500 as a one-time cost. Total estimate is \$820, one-time.

Written, facility-specific disaster plan: Estimated 32 hours of the Office Manager's time to research and write this facility-specific plan. Estimate is \$1280, one-time. Estimate for training personnel assumed to be normal part of salaries.

Employee trained in Basic Life Support: Estimated to include the cost of a Basic Life Support class for one employee per clinic. Class estimated at \$65 for a health-provider CPR class and \$35 for mileage and/or other incidentals on an every-other-year basis. Alternatively, a Red Cross Basic Life support could be taken every year. This estimate will be \$50 per year. No change in salary is estimated.

Quality Assurance Program, Data Collection and Reporting: Estimated using an outside consultant for set-up, quarterly reporting and handling the inspection every three years. This estimate includes the data collection and reporting required. Likely options at the clinic level are:

1. Hiring a consultant Risk Manager to set up the program, do the quarterly reporting and the 3-year report. Typically the clinic sends weekly data and any incident reports to the consultant.
2. Doing the quarterly reporting by clinic personnel and hiring a Florida-licensed Risk Manager to set up the program and do the report once every three years.

The outside consultant is estimated at a range of \$6,000 to \$10,000 per year. The labor estimate for clinic personnel to gather the information and report weekly to the consultant is at 5% FTE (full-time equivalent) at the office administrative level, approximately \$2,000 per year.

If a Risk Manager sets up the Quality Assurance program for the clinic, the estimate is \$2,500. If the Office Manager does the quarterly reporting at the clinic level, it is estimated that will use 2.5% of the Office Manager's time (\$2000/year) and 5% for administrative personnel time (\$2,000/year). In this case, a Florida-licensed Risk Manager is hired once every three years to do the inspection and the report, at a cost of \$2,500 to \$5,000 plus travel expenses, depending upon the clinic's volume of patients. This estimate ranges from just \$5,666 to \$6,500 on a yearly basis.

The estimate of \$8,000 per clinic will be used for all 932 clinics.

Table 5 shows these costs:

Item Estimated	One-time	Yearly
Indoor Sign	\$ 125	
Outdoor Sign	\$ 300	
Fax line	\$ 81	\$ 551
Life Support Training		\$ 50
Infection Control	\$ 200	\$ 500
Quality Assurance Program		\$ 8,000
Emergency Lighting	\$ 500	
Emergency Evacuation Procedures	\$ 820	
Written, facility-specific disaster plan	\$ 1,280	
Emergency communication	\$ 500	
Per-Clinic Totals	\$ 3,806	\$ 9,101

In the estimated costs, the one-time items will show up only in the first year, the yearly items will be included in both the first year and the subsequent years. Therefore the estimate of these costs is, on a per-clinic basis, \$12,907 for the first year, and \$9,101 for years 2 through 5.

Statement of Estimated Regulatory Costs:

a) The above economic analysis shows that the proposed rule, directly or indirectly:

1. Is not likely to have an adverse impact on economic growth, private-sector job creation or employment, or private-sector investment in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.
2. Is not likely to have an adverse impact on business competitiveness, including the ability of persons doing business in the state to compete with persons doing business in other states or domestic markets, productivity, or innovation in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.
3. Is likely to increase regulatory costs, including any transactional costs, in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.

- b) A good faith estimate of the number of individuals and entities likely to be required to comply with the rule, together with a general description of the types of individuals likely to be affected by the rule.**

The entities affected are the estimated 1314 physicians that are employed by, and the owners of approximately 932 registered Pain Management Clinics in Florida.

- c) A good faith estimate of the cost to the agency, and to any other state and local government entities, of implementing and enforcing the proposed rule, and any anticipated effect on state or local revenues.**

The Board has advised that the Department of Health, Division of Medical Quality Assurance, prepared a good faith estimate in its original SERC dated March 30, 2010 as follows:

A good faith estimate of the cost to the Board of Medicine will be covered by the Department charges of \$150 for registration of the clinic and \$1,500 for the annual inspection, if the clinic is not certified by a board approved health care accrediting organization. Upon approval and implementation of this rule, the inspection program will commence and the results of the inspections will provide data that will provide actual costs incurred and the current fees can be adjusted accordingly if necessary. Costs incurred based on a licensee's failure to comply with the rule resulting in disciplinary action on a licensee are required by law to be recovered in the final order imposing discipline on the licensee.

There are no anticipated costs to any other state or local government agencies in the implementation and enforcing of the proposed rule.

It is unknown how the rule imposing practice standards will impact state or local revenues. If the rule results in higher costs for the care provided, state and local revenues may increase; and if the rule results in fewer clinics providing services the state and local revenues may decrease. Additionally; the rule may well reduce the costs involved in providing law enforcement and other services related to the abuse of prescription drug medication.

- d) A good faith estimate of the transactional costs likely to be incurred by individuals and entities, including government entities, required to comply with this rule.**

Expected statewide transactional costs are \$64.459 Million in the first year, with \$60.912 Million expected in the following years. On a per-clinic basis, this represents an estimated \$69,162 in the first year, with an expected \$65,356 in the following years. On a per-patient basis for an existing patient, 1st Year costs average \$43.73 and Year 2 through 5 costs average \$40.91 per year. For a new patient, 1st year costs average \$60.83 per year.

- e) An analysis of the impact on small businesses as defined by s. 288.703, and an analysis of the impact on small counties and small cities as defined in by s. 120.52. The impact analysis for small businesses must include the basis for the agency's decision not to implement alternatives that would reduce adverse impacts on small businesses.**

Most of the entities registered as Pain Management clinics are small businesses.

There are no expected costs to small counties or small cities.

In response to this inquiry, the Board has advised that during the course of all of its rule meetings and rule hearings it considered alternatives and suggested rule language by interested persons in arriving at the proposed rule language.

Proposed Rule 64B8-9.0132. Requirement for PMC Registration; Inspection or Accreditation

This rule outlines the process for Pain Management Clinics to be inspected annually, unless the Pain Management Clinic is currently accredited by a nationally recognized accrediting agency approved by the Board.

A copy of the complete proposed rule is shown in Appendix 4.

Total Estimated Statewide Costs: None. Inspections and their associated fees are already a statutory requirement.

The statute requires that each Pain Management Clinic have an inspection once per year. The proposed rule outlines the process and indicates that the inspection is unannounced. Although there is likely to be some unknown amount of disruption of the physician's ability to see patients during the once-yearly unannounced inspection, there are no additional regulatory or economic costs imposed.

Statement of Estimated Regulatory Costs:

a) The above economic analysis shows that the proposed rule, directly or indirectly:

1. Is not likely to have an adverse impact on economic growth, private-sector job creation or employment, or private-sector investment in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.
2. Is not likely to have an adverse impact on business competitiveness, including the ability of persons doing business in the state to compete with persons doing business in other states or domestic markets, productivity, or innovation in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.
3. Is not likely to increase regulatory costs, including any transactional costs, in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.

b) A good faith estimate of the number of individuals and entities likely to be required to comply with the rule, together with a general description of the types of individuals likely to be affected by the rule.

The entities required to comply with this rule are the approximately 932 Pain Management Clinics.

c) A good faith estimate of the cost to the agency, and to any other state and local government entities, of implementing and enforcing the proposed rule, and any anticipated effect on state or local revenues.

The Board has advised that the Department of Health, Division of Medical Quality Assurance, prepared a good faith estimate in its original SERC dated March 30, 2010 included the following:

A good faith estimate of the cost to the Board of Medicine will be covered by the Department charges of \$150 for registration of the clinic and \$1,500 for the annual inspection, if the clinic is not certified by a board approved health care accrediting organization. Upon approval and implementation of this rule, the inspection program will

commence and the results of the inspections will provide data that will provide actual costs incurred and the current fees can be adjusted accordingly if necessary. Costs incurred based on a licensee's failure to comply with the rule resulting in disciplinary action on a licensee are required by law to be recovered in the final order imposing discipline on the licensee.

There are no anticipated costs to any other state or local government agencies in the implementation and enforcing of the proposed rule.

d) A good faith estimate of the transactional costs likely to be incurred by individuals and entities, including government entities, required to comply with this rule.

There are no transactional costs expected with this proposed rule. A statement from the Board indicates that the fees charged to the clinics will cover the costs of the inspections.

e) An analysis of the impact on small businesses as defined by s. 288.703, and an analysis of the impact on small counties and small cities as defined in by s. 120.52. The impact analysis for small businesses must include the basis for the agency's decision not to implement alternatives that would reduce adverse impacts on small businesses.

Most of the estimated 932 Pain Management clinics are small businesses.

There are no expected costs to small counties or small cities.

In response to this inquiry, the Board has advised that during the course of all of its rule meetings and rule hearings it considered alternatives and suggested rule language by interested persons in arriving at the proposed rule language.

Summary of Proposed Rule: *BOM: 64B8-9.0131(Subparagraph (2)(n): Training Requirements*

This rule outlines the training requirements for allopathic physicians practicing in Pain Management Clinics (PMC) that primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications, beginning on July 1, 2012.

A copy of the statute and the complete proposed rule is shown in Appendix 5.

Total Estimated Statewide Costs: No negative economic impact. There is expected to be a positive, but unknown economic impact associated with this proposed rule. This is because the statute severely limits the number of physicians that would be qualified to work at PMC, and the rule expands the potential number significantly.

The proposed rule expands the potential number of physicians because the proposed rule allows some existing physicians to be able to continue to practice with certain conditions and allows others who begin practice after July 1, 2012 to qualify. Given that we don't know which physicians are practicing at PMC since they are not currently required to register, one cannot be sure of what their current qualifications are and we cannot reasonably estimate the number of current physicians that would meet either the standard in the statute, or the standard in the proposed rule.

However, it is clear that under the statutory limit of requiring a physician practicing at a PMC to have successfully completed a pain-medicine fellowship accredited or pain medicine residency that is accredited by the ACGME, there would not be enough qualified physicians in Florida to fill the current PMC physician slots. The shortage of physicians would be expected to raise the salaries of those qualified, likely by significant amounts. In an unknown number of cases, PMC would shut down due to the unavailability of qualified physicians.

A study done in 2009 by the Florida Medical Association's Health Policy Center and the Center for Economic Forecasting & Analysis at Florida State University, *The Economic Impact of Florida's Private Practice Physicians in Florida*, indicates that each individual private-practice physician in Florida supports, on average, 19 additional jobs and \$2.3 million in Total Economic Activity. Therefore, restricting the available pool of physicians to significantly less than the number of PMCs in Florida would have a significant negative impact on the clinics, the owners and the employees of those clinics.

For those physicians who would not qualify under numbers 1 through 4 of the proposed rule, there would be costs for complying for those physicians that cannot document hospital privileges or practice under a qualified physician. Those physicians will be required to have their practice reviewed by a Florida-licensed Risk Manager. Those costs are not included in this study, because the significantly more positive benefit to them under the proposed rule should overwhelm the cost.

Also, since physicians must take Continuing Education courses for their license renewal, there would not be any significant additional cost for Continuing Education under the proposed rule.

Statement of Estimated Regulatory Costs:

a) The above economic analysis shows that the proposed rule, directly or indirectly:

1. Is not likely to have an adverse impact on economic growth, private-sector job creation or employment, or private-sector investment in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.
2. Is not likely to have an adverse impact on business competitiveness, including the ability of persons doing business in the state to compete with persons doing business in other states or domestic markets, productivity, or innovation in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.
3. Is not likely to increase regulatory costs, including any transactional costs, in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.

b) A good faith estimate of the number of individuals and entities likely to be required to comply with the rule, together with a general description of the types of individuals likely to be affected by the rule.

This rule would affect the estimated 1314 physicians and any owners of the estimated 932 Pain Management Clinics.

c) A good faith estimate of the cost to the agency, and to any other state and local government entities, of implementing and enforcing the proposed rule, and any anticipated effect on state or local revenues.

The Board has advised that the Department of Health, Division of Medical Quality Assurance, prepared a good faith estimate in its original SERC dated March 30, 2010 included the following:

A good faith estimate of the cost to the Board of Medicine will be covered by the Department charges of \$150 for registration of the clinic and \$1,500 for the annual inspection, if the clinic is not certified by a board approved health care accrediting organization. Upon approval and implementation of this rule, the inspection program will commence and the results of the inspections will provide data that will provide actual costs incurred and the current fees can be adjusted accordingly if necessary. Costs incurred based on a licensee's failure to comply with the rule resulting in disciplinary action on a licensee are required by law to be recovered in the final order imposing discipline on the licensee.

There are no anticipated costs to any other state or local government agencies in the implementation and enforcing of the proposed rule.

d) A good faith estimate of the transactional costs likely to be incurred by individuals and entities, including government entities, required to comply with this rule.

There is no expected adverse impact to individuals, entities including government entities, required to comply with this rule.

- e) **An analysis of the impact on small businesses as defined by s. 288.703, and an analysis of the impact on small counties and small cities as defined in by s. 120.52. The impact analysis for small businesses must include the basis for the agency's decision not to implement alternatives that would reduce adverse impacts on small businesses.**

Most of the estimated 932 Pain Management Clinics are small businesses.

There are no expected costs to small counties or small cities.

In response to this inquiry, the Board has advised that during the course of all of its rule meetings and rule hearings it considered alternatives and suggested rule language by interested persons in arriving at the proposed rule language.

Summary of Proposed Rule 64B8-9.0134/64B15-14.0054. *Maximum Number of Prescriptions in Registered PMC.*

This rule outlines the maximum number of prescriptions per physician at a Pain Management Clinic for Schedule II and Schedule III controlled substances and Alprazolam which may be written during a 24-hour period.

A copy of the complete proposed rule is shown below.

Total Estimated Statewide Cost: Estimated Statewide cost of \$932,000 per year. On a per clinic basis, estimated \$1,000 per clinic per year.

The proposed Rule 64B8-9.0134 is:

The maximum number of prescriptions for Schedule II or Schedule III controlled substances or the controlled substance Alprazolam, which may be written at any one registered pain management clinic during any 24-hour period shall be no more than an average of three prescriptions per patient per physician working at the pain management clinic up to a maximum of 150 prescriptions per physician. In the event that the physician is working less than 8 hours per day in the pain management clinic, the maximum number of prescriptions per physician shall be based upon the following formula: the number of hours worked divided by 8, then multiplied by 150 [(# of hours/8) X 150 = maximum # of prescriptions]. A “do not fill before dated” prescription will not be counted toward the daily limit until the first date the prescription is eligible to be filled.

To analyze the economic impact of this rule, one would need the actual number of prescriptions written by each physician working in a Pain Management Clinic (PMC) and the number of hours they worked. Neither piece of actual data is available.

To derive whether limiting a physician to prescribing 150 prescriptions per day is likely to be a limiting factor, and what the expected costs would be, one can start with an assumed number of patients per day. The average number of patients per week for all Florida physicians is 74¹. One should note that number includes those physicians working less than fulltime. That number includes physicians that see from 0-25 patients per week up through those that see more than 200 per week.

Given that any physician practicing in a PMC, under statute, is required to do the physical examination of the patient on the same day he or she dispenses or prescribes a controlled substance, it is unlikely that physicians in Pain Management Clinics can comfortably see more than 30-35 patients per day. Given the maximum “no more than an average of three prescriptions per patient”, it is unlikely that most physicians will be affected by the 150 daily maximum.

Looking at “no more than an average of three prescriptions per patient” perhaps yields a different result. Physicians and clinic owners indicate that in some cases, a patient is prescribed a short-acting pain killer, a long-acting pain killer and a muscle relaxer.

¹ http://www.doh.state.fl.us/Workforce/Physicians_Workforce_Annual_Rpt_2009.pdf

Physicians are also allowed to write “do not fill before dated” prescriptions and the rule indicates that those prescriptions will count on the first day the prescriptions are eligible to be filled. Therefore, a physician who writes “do not fill before dated” prescriptions will have to be noted and accounted for on the date they are available to be filled.

It would appear that a PMC physician who is near the limits of an average of 3 controlled substance prescriptions per patient will have to track his or her numbers more closely than physicians at an average PMC. It would be the physicians with high patient count, the ones who use mostly pills and not interventional therapies, and ones that often write “do not fill before” prescriptions that would be in this category.

One possible result of this rule is that physicians will reduce the number of “do not fill before dated” prescriptions. This may occur because the physician or the clinic would not want to undertake tracking the hours each physician worked in the clinic, the number of patients seen, the number of prescriptions and the number of “do not fill before dated” prescriptions. This could also have the effect of requiring patients to visit the clinics more often and pay more in physician visit fees. This possible cost is not included in the study because the numbers vary widely depending on the type of practice, and are likely to affect only a small and unknown number of clinics.

To estimate the costs to an average clinic for this rule, the assumption will be that all clinics spend one additional hour of administrative time per week tracking the number of controlled substance prescriptions, including accounting for any “do not fill before” prescriptions. There are, no doubt, some clinics that will spend less time or more time than that. Some clinics will be nowhere near the limit and will spend little time tracking this and others will be near the limit and be required to spend more time. The following estimate uses one hour per week in additional time for the average clinic, at the previously noted \$20 per hour, including benefits.

The calculation of \$20 per clinic per week (for a 50-week year), for the 932 Pain Management Clinics in Florida equals \$932,000 per year. On a per-clinic basis, this is \$1,000 per clinic per year.

Statement of Estimated Regulatory Costs:

a) The above economic analysis shows that the proposed rule, directly or indirectly:

1. Is not likely to have an adverse impact on economic growth, private-sector job creation or employment, or private-sector investment in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.
2. Is not likely to have an adverse impact on business competitiveness, including the ability of persons doing business in the state to compete with persons doing business in other states or domestic markets, productivity, or innovation in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.
3. Is likely to increase regulatory costs, including any transactional costs, in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.

- b) A good faith estimate of the number of individuals and entities likely to be required to comply with the rule, together with a general description of the types of individuals likely to be affected by the rule.**

This proposed rule would affect the estimated 1314 physicians and clinic owners of the estimated 932 Pain Management Clinics.

- c) A good faith estimate of the cost to the agency, and to any other state and local government entities, of implementing and enforcing the proposed rule, and any anticipated effect on state or local revenues.**

The Board has advised that the Department of Health, Division of Medical Quality Assurance, prepared a good faith estimate in its original SERC dated October 27, 2010 as follows:

There will be no fiscal impact on this agency or other governmental entities. Enforcement costs are reimbursed by the Respondent when disciplined.

- d) A good faith estimate of the transactional costs likely to be incurred by individuals and entities, including government entities, required to comply with this rule.**

An estimated \$1,000 per Pain Management Clinic per year, for a statewide total of \$932,000 per year.

- e) An analysis of the impact on small businesses as defined by s. 288.703, and an analysis of the impact on small counties and small cities as defined in by s. 120.52. The impact analysis for small businesses must include the basis for the agency's decision not to implement alternatives that would reduce adverse impacts on small businesses.**

Most of the estimated 932 Pain Management Clinics are small businesses.

There are no expected costs to small counties or small cities.

In response to this inquiry, the Board has advised that during the course of all of its rule meetings and rule hearings it considered alternatives and suggested rule language by interested persons in arriving at the proposed rule language.

Summary of Proposed Rule 64B8-9.0133/64B15-14.0053. Approval of Nationally Recognized Physician Pain Management Accrediting Organizations.

This rule outlines the application and approval process for which outside accrediting organizations can become approved by the Board, the “Board” being defined as the Florida Board of Medicine/Osteopathic Medicine.

A copy of the complete proposed rule is shown in Appendix 6.

Total Estimated Statewide Costs: None. A statement from the Florida DOH indicates that they will use their current staff and they do not anticipate additional staffing or travel costs, as the approval process will be part of regularly scheduled board meetings.

There is no requirement for Pain Management Clinics in Florida to become accredited. The benefits of accreditation include receiving “best-practice” information from the accrediting agency. Another benefit is that if the clinic becomes accredited, it is not subject to an unannounced annual inspection by the Department, and is not required to pay the \$1500 yearly inspection fee.

Statement of Estimated Regulatory Costs:

a) The above economic analysis shows that the proposed rule, directly or indirectly:

1. Is not likely to have an adverse impact on economic growth, private-sector job creation or employment, or private-sector investment in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.
2. Is not likely to have an adverse impact on business competitiveness, including the ability of persons doing business in the state to compete with persons doing business in other states or domestic markets, productivity, or innovation in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.
3. Is not likely to increase regulatory costs, including any transactional costs, in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.

b) A good faith estimate of the number of individuals and entities likely to be required to comply with the rule, together with a general description of the types of individuals likely to be affected by the rule.

No individuals or entities are likely to be required to comply with the rule. There is no requirement for any Pain Management Clinic to become accredited.

c) A good faith estimate of the cost to the agency, and to any other state and local government entities, of implementing and enforcing the proposed rule, and any anticipated effect on state or local revenues.

The Department has advised that it will not incur a cost related to this other than the process of the Board reviewing applications during routine scheduled board public meetings. Meeting and travel costs are already incurred for 4 meetings a year and a small incremental cost would be added to those costs for meetings in which an accreditation application is considered.

There are no anticipated costs to any other state or local government agencies in the implementation and enforcing of the proposed rule.

d) A good faith estimate of the transactional costs likely to be incurred by individuals and entities, including government entities, required to comply with this rule.

Transactional costs likely to be incurred by individuals and entities, including government entities are expected to be zero.

e) An analysis of the impact on small businesses as defined by s. 288.703, and an analysis of the impact on small counties and small cities as defined in by s. 120.52. The impact analysis for small businesses must include the basis for the agency's decision not to implement alternatives that would reduce adverse impacts on small businesses.

Most of the estimated 932 Pain Management Clinics are small businesses.

There are no expected costs to small counties or small cities.

In response to this inquiry, the Department has advised that during the course of all of the Board rule meetings and rule hearings it considered alternatives and suggested rule language by interested persons in arriving at the proposed rule language.

Summary of Proposed Rule 64B-7.001: Pain Management Clinic Registration Requirements

This rule outlines the requirements of who must register as a Pain Management Clinic and requirements for the Designated Physician.

A copy of the complete proposed rule is shown in Appendix 7.

Total Estimated Statewide Costs: None. The cost of registration has been established by a rule currently in effect that is not part of this SERC. Sections 458.3265, and 459.0137, F.S., provide for a one-time registration fee for each pain management clinic location and provide that a change of ownership requires a new application.

Any new Pain Management Clinic must register and maintain a valid registration with the department. This includes indentifying the Designated Physician and notifying the Department upon the departure of the Designated Physician and notifying the Department in cases of change of ownership of the clinic.

Effective October 1, 2010, sections 458.3265, and 459.0137, F.S., limited pain management clinic designated physicians to physicians with a full, active, and unencumbered license. The proposed rule provides specific examples of what this limitation includes.

Sections 458.3265, and 459.0137, F.S provide that the designated physician must practice at the clinic and that the Department shall define the term "practice at the clinic." The proposed rule defines that term by creating the number of clinics one designated physician may be responsible for based upon the number of physicians practicing at the clinic and the amount of controlled substances being prescribed at the clinic. The maximum allowable number of clinics with the same designated physician ranges from 3 "medium size" clinics to 1 "large size" and 1 "medium size" clinic.

As of December 9, 2010, 86% of the Designated Physicians were registered with 3 clinics or less. Only 25 physicians were registered as Designated Physicians at more than 6 clinics. This is less than 2% of the estimated physicians working in Pain Management clinics. Therefore, although there are possible costs to a small number of clinics, there should not be a significant economic impact on a statewide basis.

The Department has advised that during the six month period of July 1, 2010-December 31, 2010, there were 150 pain management clinic applications approved. This included initial applications, change of location, and effective October 1, 2010, change of ownership. The Department further noted that for the month of December 2010, there were a total of 60 applications approved which included 45 new initial applications and the remainder consisting of change of location and change of ownership.

Since pain management clinic registration began in late December 2009, the Department noted that the number of registered pain management clinics has fluctuated between 1,060 and the December 9, 2010 level of 932.

Statement of Estimated Regulatory Costs:

a) The above economic analysis shows that the proposed rule, directly or indirectly:

1. Is not likely to have an adverse impact on economic growth, private-sector job creation or employment, or private-sector investment in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.
2. Is not likely to have an adverse impact on business competitiveness, including the ability of persons doing business in the state to compete with persons doing business in other states or domestic markets, productivity, or innovation in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.
3. Is not likely to increase regulatory costs, including any transactional costs, in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.

b) A good faith estimate of the number of individuals and entities likely to be required to comply with the rule, together with a general description of the types of individuals likely to be affected by the rule.

Any new Pain Management Clinic will be required to have a Designated Physician that meets the requirements and is subject to the limitations on the number of clinics that he or she is responsible for.

c) A good faith estimate of the cost to the agency, and to any other state and local government entities, of implementing and enforcing the proposed rule, and any anticipated effect on state or local revenues.

The Board has advised that the Department of Health, Division of Medical Quality Assurance, prepared a good faith estimate in its original SERC dated September 1, 2010 as follows:

The proposed rule will not affect the costs of registration for the agency. It is anticipated that the department will continue to work with local law enforcement where there are criminal violations with regard to controlled substances. There is no anticipated effect on state or local revenues.

d) A good faith estimate of the transactional costs likely to be incurred by individuals and entities, including government entities, required to comply with this rule.

There are no additional transactional costs expected above the \$150 per clinic fee for new clinics.

e) An analysis of the impact on small businesses as defined by s. 288.703, and an analysis of the impact on small counties and small cities as defined in by s. 120.52. The impact analysis for small businesses must include the basis for the agency's decision not to implement alternatives that would reduce adverse impacts on small businesses.

Most of the estimated 932 Pain Management Clinics are small businesses.

There are no expected costs to small counties or small cities.

In response to this inquiry, the Department advised that during the course of all of its rule meetings and rule hearings it considered alternatives and suggested rule language by interested persons in arriving at the proposed rule language.

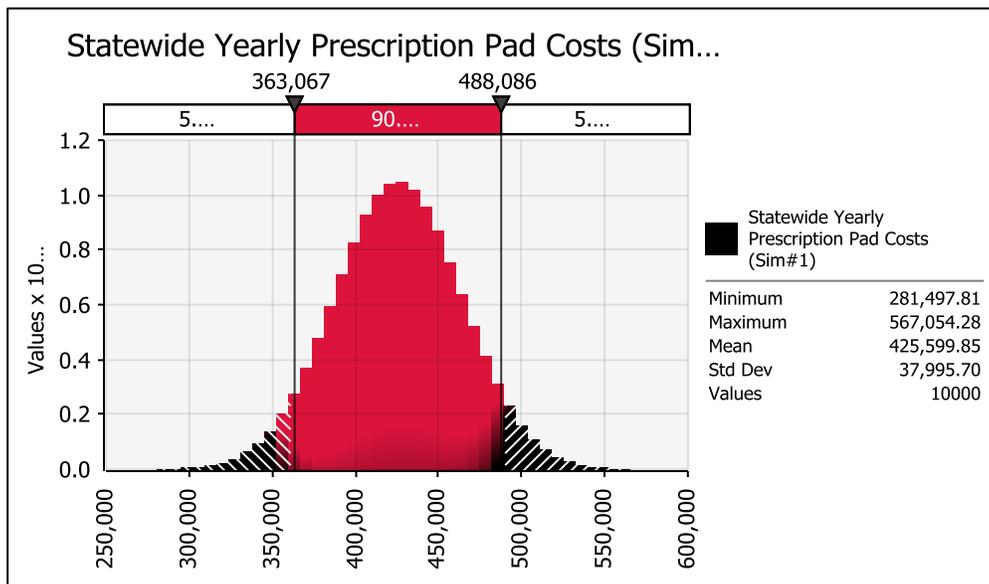
Summary of Proposed Rule 64B-7.003 – Counterfeit-Resistant Prescription Blanks.

When writing a prescription for a controlled substance at a Pain Management Clinic, the prescription pad must have the following security features:

- blue or green background, and be resistant to reproduction
- must be printed on watermarked paper
- must resist erasures and alterations
- the word “void” or “illegal” must appear on any reproduction
- must be pre-printed with name of prescribing physician and clinic address
- a space for the physician’s Drug Enforcement Administration registration number for controlled substances.

A copy of the proposed rule is shown in Appendix 8.

Total Estimated Statewide Costs: There is a 90% probability, given the below assumptions, that the annual costs of requiring secure prescription pads for Florida’s Pain Management Clinics is between \$363,067 and \$488,086. The mean is \$422,599.85. This yields an estimated cost of \$453.43 per clinic per year. This figure represents 3.8 cents per estimated controlled substance prescription.



Methodology: The simple formula of the additional economic impact of this rule is the additional cost of the secure prescription pads, versus the standard prescription pads multiplied by the number of controlled substance prescriptions written by the physicians in the 932 registered Florida PMCs.

This number of controlled substance prescriptions is not known and must be estimated.

Attempts to obtain information on controlled substances from law enforcement sources were unsuccessful. Data is available for purchase, yet for the purposes of this study it is likely unusable. Typically, that data is

measured at the retail pharmacy level and it will not reflect prescriptions written in Florida and filled out-of-state. It also would pick up prescriptions that were written in another state and filled in Florida. Additionally, based on available data, at least 57% of the PMC in Florida have a registered dispensing physician, further potentially skewing the numbers. Therefore other methods were used to develop the estimate of the number of controlled substance prescriptions written by PMC physicians in Florida.

Prescription Pads

As of June 1, 2010, electronic prescriptions for controlled substances are allowed to be used in Florida. Some Florida physicians are using electronic prescribing for other drugs, but according to Ken Whittemore at Surescripts, electronic prescribing of controlled substances in Florida – as well as the rest of the U.S. – is not currently being used. Nationwide rollout of the functionality is expected to begin in June of 2011. Local laws and regulations will dictate whether or not said rollout can proceed in each individual state. Therefore, for the purposes of this study, electronic prescriptions and their associated costs will not be estimated.

To estimate the difference in cost between the two types of prescription pads, online providers of prescription pads were checked. After checking multiple websites for 1-part prescription pads that meet the above standards, pricing was obtained for quantities of pads that would yield 4,000 prescriptions, and 10,000 prescriptions. The resulting cost estimates per prescription for one-part prescription pads in those quantities are shown in the table below:

1 part	4000	10000
Standard	\$ 67.95	\$ 159.96
Secure	\$ 100.95	\$ 230.00
Difference	\$ 33.00	\$ 70.04
Difference/script	\$ 0.00825	\$ 0.007

This shows that, when the physician is purchasing standard prescription pads, the difference per prescription is less than one cent. The true cost difference is potentially higher, given that physicians indicate that one-part standard pads usually do not have to be purchased because many pharmaceutical manufacturers will supply them free to physicians.

For two-part prescription pads, costs are listed in the following table:

2 part	4000	10000
Standard	\$ 169.00	\$ 338.00
Secure	\$ 320.00	\$ 722.00
Difference	\$ 151.00	\$ 384.00
Difference/script	\$ 0.03775	\$ 0.0384

Under current osteopathic medicine rules and proposed allopathic rules, it is a requirement for clinics to keep a copy of any prescription given in the patient file. The physician could use one-part pads and

photocopy the actual signed prescription and place it in the file, or they could use two-part prescription pads. Given the relative cost of photocopying and the extra time involved in doing that, this estimate will assume that the two-part pads would likely be used by all clinics.

One should not forget that prescriptions can be printed on a laser printer on either standard paper or secure paper. For the purposes of this study, one should note that under the proposed rule it is a requirement that the prescription pads be pre-printed with the physician's name and other information. Therefore, for this study we will assume all the prescription pads are purchased.

Prices were obtained from several sources, and then the median of those prices was used for each category. The clinic could be in a position that although there are lower-priced alternatives, they choose a higher-cost one because of things like: better quality, existing relationship with vendor or the person ordering wasn't able to find the lowest price. Therefore the median price was used rather than the lowest. Mean prices were not used because the distribution of the prices is skewed.

Pricing for the two-part pads is higher. When ordering in quantities of 4,000 prescriptions, the difference in cost for the clinic is 3.775 cents per prescription. When ordering in quantities of 10,000 prescriptions, the difference in cost is 3.84 cents per prescription. One might notice that it is unusual in that in quantities of 10,000 it is slightly higher per prescription than ordering in quantities of 4,000. This could be due to competitiveness issues between firms, and higher demand for the pads in smaller quantities, given the storage and security requirements for secure prescription pads. Given that the costs are so close for these two estimates, this study will use 3.8 cents per prescription for all controlled substance prescriptions, as the additional cost of the rule.

Estimating the Number of Controlled Substance Prescriptions

Data on the number of prescriptions of any type written by any individual physician in Florida is not publicly available. The DEA does track controlled substances on their system, Arcos II. Access to this data is described as "restricted to DEA employees on a 'need to know' basis who have appropriate security clearances."² Therefore, the number of controlled substance prescriptions written by this group of physicians must be estimated. To estimate the number of prescriptions written by the physicians in the 932 registered Pain Management Clinics, several methods of estimation were used. These include estimating an average based on the average physician in Florida and using that as a lower bound. Then, estimating an upper bound and an estimate based on information obtained from personal interviews of Pain Management physicians in Florida. Additionally, estimates will be derived by comparing states with known per-capita controlled substance prescription numbers to Florida, adjusting for the difference in population of the two states.

Effective October 1, 2010, the 72-hour rule is in effect for cash-paying customers. This means that a dispensing physician can only dispense 72 hours of a controlled substance prescription. This does not affect workman's compensation patients. For some patients, the physician could write a 72-hour prescription to be filled at the clinic plus another prescription to be filled at a pharmacy. So, in this case, double the normal amount of prescriptions would be written for a small difference in number of pills, potentially skewing the numbers for required secure prescription pads upward.

² http://www.archives.gov/records-mgmt/rcc/schedules/departments/department-of-justice/rg-0170/n1-170-04-003_sf115.pdf

First, the average number of prescriptions written by Florida physicians was estimated. In a 2008³ report where half the allopathic physicians and all the osteopathic physicians were surveyed, the DOH indicated that of this sample there are 21,610 Florida D.O and M.D. physicians actively practicing medicine. Using those figures to estimate the entire 2008 number of active physicians in Florida yields almost 40,000. The estimated percentage of Florida’s physicians working in registered Pain Management Clinics is approximately 3.3% of the total active physicians.

According to the DEA’s March 2010 Economic Impact Analysis of the Interim Final Electronic Prescription Rule⁴, there were (using SDI/Verispan data) a total of 3.8431 billion prescriptions in the U.S. in 2008. If proportional to the population, Florida’s share of the total would be 230,586,000 prescriptions. Alternatively, AARP estimates⁵ that residents of Florida filled about 12 prescriptions per year, on average. Using a 2008 Florida population estimate of 18.6 million, yields an estimate of around 223 million prescriptions per year in the state of Florida.

The DEA estimated that 11% of all prescriptions were for controlled substances. They also indicated that there were 359 Million original and newly authorized refills for controlled substances in 2008.⁶ They indicate that figure is approximately 75% of the total for controlled substance prescriptions, and then estimate a current number at around 475 million.⁷

An article in the October 3, 2010 St. Petersburg Times entitled “Only Strict Rules Can Ease Pain of Pill Mills” indicates that there were 420 million oxycodone pills dispensed in Florida in 2008.⁸ One Florida physician estimated that to be 2,333,333 one-month prescriptions at the FDA approved dosing for moderate to severe pain. Using the Kentucky percentages⁹ from KASPER, (Kentucky All Schedule Prescription Electronic Reporting) and applying them to Florida, one arrives at the 24.5 million controlled substance prescription estimate shown in the table below.

Estimates	Data Sources for Estimates		
	DEA Paper	AARP	KASPER ¹⁰
Total Prescriptions in Florida - Millions	230.6	223	n/a
Controlled Substance Prescriptions in Florida - Millions	25.36	24.53	24.5

This study will use the estimate of the number of all prescriptions in Florida on an annual basis of 225 million. It will use the estimated number of controlled subscriptions in Florida of 25 million per year. One should note that some of these estimates explicitly assume that Florida is similar to the rest of the U.S. population.

³ http://www.doh.state.fl.us/rw_bulletins/workforcerept08.pdf

⁴ http://www.deadiversion.usdoj.gov/ecomm/e_rx/eia_dea_218.pdf

⁵ http://assets.aarp.org/rgcenter/health/state_hcb_09_fl.pdf

⁶ http://www.deadiversion.usdoj.gov/fed_regs/rules/2008/fr0627.pdf

⁷ http://www.deadiversion.usdoj.gov/ecomm/e_rx/eia_dea_218.pdf p.16

⁸ <http://www.tampabay.com/opinion/columns/only-strict-rules-can-ease-pain-of-pill-mills/1125299>

⁹ Note that KASPER will not show prescriptions filled out-of-state, but will show ones filled by mail. See <https://ekasper.chfs.ky.gov/FAQ/FAQ.htm#q8>

¹⁰ <http://chfs.ky.gov/NR/rdonlyres/532A9AD4-B5BE-4B8E-8DC0-BF512B452550/0/KASPERQuarterlyTrendReportQ42008.pdf>

Establishing the lower and upper bounds:

Assuming that the average Florida PMC physician prescribes controlled substances at the same rate as the average Florida physician prescribes any type drug, the simple estimate for number of prescriptions written by Florida PMC physicians would be around 7.43 million. This will be used as a lower bound, given that it is likely that pain management physicians prescribe more controlled substances than the average physician prescribes any type drug. That represents an average of 22.6 controlled substance prescriptions per estimated Florida PMC physician per day.

When estimating the upper bound of the number of prescriptions, although not realistic, is to divide the total number of controlled substance prescriptions by the estimated number of Florida PMC physicians. That would yield 76.1 controlled prescriptions per day per physician. For the average physician, that's just over 3 prescriptions per patient. One should note that this upper bound assumption indicates that every controlled substance prescription in Florida was written by a PMC clinic physician. Therefore, the actual estimate should lie somewhere between 22.6 per day and 76.1 per day.

Using these ranges and information obtained in physician interviews, the estimate of the number of controlled substance prescriptions written by PMC physicians, per year, in Florida is from 9.55 million to 12.85 million. The probability distribution was set up with these properties: mean of 11.2 million, standard deviation of 1 million, distributed normally. This is the estimator used, running 10 times, for 10,000 iterations, to get the result shown on Page 30.

Statement of Estimated Regulatory Costs:

a) The above economic analysis shows that the proposed rule, directly or indirectly:

1. Is not likely to have an adverse impact on economic growth, private-sector job creation or employment, or private-sector investment in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.
2. Is not likely to have an adverse impact on business competitiveness, including the ability of persons doing business in the state to compete with persons doing business in other states or domestic markets, productivity, or innovation in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.
3. Is likely to increase regulatory costs, including any transactional costs, in excess of \$1 million in the aggregate within 5 years after the implementation of the rule.

b) A good faith estimate of the number of individuals and entities likely to be required to comply with the rule, together with a general description of the types of individuals likely to be affected by the rule.

The individuals affected are the estimated 1314 physicians in Pain Management Clinics who write controlled substance prescriptions.

c) A good faith estimate of the cost to the agency, and to any other state and local government entities, of implementing and enforcing the proposed rule, and any anticipated effect on state or local revenues.

There is no anticipated cost to the agency or other state and local entities in implementing the proposed rule and no anticipated effect on state or local revenues.

d) A good faith estimate of the transactional costs likely to be incurred by individuals and entities, including government entities, required to comply with this rule.

It is estimated that on the average, a Pain Management Clinic will spend \$453.43 per year, or approximately 3.8 cents per controlled substance prescription, yielding a statewide total at the mean, of \$422,599.85 per year.

e) An analysis of the impact on small businesses as defined by s. 288.703, and an analysis of the impact on small counties and small cities as defined in by s. 120.52. The impact analysis for small businesses must include the basis for the agency's decision not to implement alternatives that would reduce adverse impacts on small businesses.

Most of the estimated 932 Pain Management Clinics are small businesses.

There are no expected costs to small counties or small cities.

In response to this inquiry, the Department advised that no alternatives to the impact on small business were submitted on this proposed rule. The Department also advised that the statute currently requires physicians in pain management clinics to comply with the requirements for counterfeit-resistant prescription blanks in s. 893.065 and the rules adopted pursuant to that section. The Department proposed rule is consistent with the current rule on counterfeit-resistant prescription blanks.

References

Economic Impact Analysis of the Interim Final Electronic Prescription Rule. Drug Enforcement Administration, U.S. Department of Justice. March 2010

2009 Florida Physician Workforce Annual Report. November 1, 2009

The Economic Impact of Private Practice Physicians' Offices in Florida. Florida Medical Association and the Center for Economic Forecasting & Analysis at Florida State University. March, 2009

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Appendix 1 – Clinic totals, density and dispensing, by county

County	Total Clinics	Clinics/100k population*	Dispensing**	% Dispensing***
ALACHUA	5	2.51	3	60.0%
BAY	4	3.14	2	50.0%
BREVARD	16	3.73	8	50.0%
BROWARD	117	8.61	73	62.4%
CHARLOTTE	7	5.23	4	57.1%
CITRUS	8	6.80	4	50.0%
CLAY	9	6.56	4	44.4%
COLLIER	15	5.91	9	60.0%
COLUMBIA	3	5.60	3	100.0%
DUVAL	51	7.88	31	60.8%
ESCAMBIA	10	4.22	2	20.0%
FLAGLER	3	4.07	2	66.7%
FRANKLIN	1	10.63	0	0.0%
HERNANDO	10	7.27	4	40.0%
HIGHLANDS	2	2.49	1	50.0%
HILLSBOROUGH	113	12.52	45	39.8%
INDIAN RIVER	5	4.58	3	60.0%
JACKSON	1	2.46	1	100.0%
LAKE	11	4.37	9	81.8%
LEE	29	6.21	16	55.2%
LEON	5	2.34	1	20.0%
LEVY	1	3.26	1	100.0%
MANATEE	18	7.14	12	66.7%
MARION	12	4.57	7	58.3%
MARTIN	6	5.27	5	83.3%
MIAMI-DADE	89	4.62	50	56.2%
MONROE	1	1.62	0	0.0%
NASSAU	4	7.31	3	75.0%
OKALOOSA	4	2.92	2	50.0%
OKEECHOBEE	2	6.64	1	50.0%
ORANGE	49	5.98	29	59.2%
OSCEOLA	13	6.60	5	38.5%
PALM BEACH	108	10.68	77	71.3%
PASCO	31	8.34	18	58.1%
PINELLAS	47	6.33	32	68.1%
POLK	13	2.94	5	38.5%
PUTNAM	4	7.15	2	50.0%
SANTA ROSA	8	6.90	4	50.0%
SARASOTA	24	7.74	18	75.0%
SEMINOLE	17	5.36	10	58.8%
ST. JOHNS	9	6.17	3	33.3%
ST. LUCIE	12	5.82	8	66.7%
SUMTER	3	4.48	2	66.7%
VOLUSIA	30	7.50	11	36.7%
WALTON	1	2.28	1	100.0%
WASHINGTON	1	5.34	0	0.0%

* Population over 18, U.S. Census Bureau estimate for 2008

** Dispensing means registered physician that is qualified to dispense

*** Percentage of clinics that have registered physician who is qualified to dispense

Appendix 2 – Groups owning 3 or more PMC, by common owners, partners,
and/or billing addresses.

Clinic Name	# of Clinics	Counties of Clinics
Total Medical Express	3	Palm Beach
Physicians Group Services	4	Clay, Duval(2), Nassau
Gulf-to-Bay Anesthesiology	5	Pinellas, Hillsborough(4)
Neurological Testing Centers of America	5	Broward(2), Miami-Dade(2)
Frank R. Collier, Jr. M.D., P.A.	3	Duval(2), Clay
Edwin Colon, M.D., P.A.	3	Pasco
Robert B. Dehgan, M.D., P.A.	3	Putnam, St. Johns, Duval
Southeastern Integrated Medical	5	Levy, Marion, Lake, Alachua, Columbia
Various Names (Dubravetz, owner)	4	Orange, Broward(2), St. Lucie
International Rehab/Comprehensive Pain Medicine/ Anesthesiology Assoc.	21	Miami-Dade(4), Broward(8), Palm Beach(3) Leon, Okaloosa, Escambia, Santa Rosa(2), Martin
Lescobar, P.A.	3	Broward(2), Miami-Dade
Physician Providers Group	3	Marion, Lake, Citrus
Premier Pain Care	3	Broward, Miami-Dade(2)
Institute of Pain Management	3	Duval(2), Clay
Spine Diagnostics Interventional Center	3	Collier(2), Hillsborough
Pain Care Management of....(Clearwater, Melbourne, Orlando)	3	Pinellas, Brevard, Orange
CMG, LLC	3	Martin, Palm Beach(2)
Laudan Partners, Inc.	3	Miami-Dade
West Coast Anesthesiology Associates, Inc.	3	Sarasota, Seminole, Lee
Comprehensive Pain Management Partners	6	Pasco(3), Sarasota, Hillsborough, Pinellas
Hess Spinal & Medical Centers	10	Hillsborough(4), Polk, Pinellas(3), Pasco, Manatee
Center for Quality Pain Care	3	Miami-Dade(2), Broward
Glory Medclinic, LLC	4	Pasco(2), Polk, Hillsborough
Yili Zhou, LLC	3	Marion(2), Columbia
A Pain Clinic of....(Boca Raton, Delray Beach, Ft. Lauderdale, WPB)	4	Broward, Palm Beach(3)
D.G. & Leeds/Medical Therapies, LLC	3	Orange(2), Seminole
Vidya P. Kini, M.D., P.L.	3	Lee
Biltmore Group, LLC	6	Orange, Marion(2), Broward, Osceola, Lee
PRC Associates, LLC	4	Volusia(3), Flagler
Joseph E. Monhanna, M.D., P.A.	3	Miami-Dade
Occupational and Rehabilitational Center	3	Duval(2), Clay
Various Names (Juan Carlos Perez-Espinoza, owner)	3	Miami-Dade
Advanced Pain Management Center, Inc.	3	Citrus, Hernando, Hillsborough
Sunshine Spine and Pain, P.A.	4	Duval
James D. Shortt, M.D., P.A.	4	Duval
Jose A. Torres, M.D., P.A.	3	Orange(2), Osceola
West Florida Pain Management, P.A.	3	Pinellas

As of 9 December, 2010

Appendix 3. Standards of Practice in PMC

THE FULL TEXT OF THE PROPOSED RULE IS:

64B8-9.0131 Standards of Practice for Physicians Practicing in Pain Management Clinics. THIS RULE IS APPLICABLE TO PHYSICIANS PRACTICING IN PRIVATELY OWNED PAIN MANAGEMENT CLINICS THAT ARE REQUIRED TO BE REGISTERED PURSUANT TO SECTION 458.3265, F.S., WHO PRIMARILY ENGAGE IN THE TREATMENT OF PAIN BY PRESCRIBING OR DISPENSING CONTROLLED SUBSTANCE MEDICATIONS.

(1) Definitions. The following definitions apply to this rule only.

(a) Controlled Substance. A “controlled substance” is any substance named or described in Schedules I-V of Section 893.03, Florida Statutes.

(b) Adverse Incidents. An “adverse incident” is any incident set forth in Section 458.351(4)(a)-(e), Florida Statutes.

(c) “Board-certified pain management physician” means a physician who possesses Board certification by a specialty board recognized by the American Board of Medical Specialties (ABMS) and holds a sub-specialty certification in pain medicine; or Board certification in pain medicine by the American Board of Pain Medicine (ABPM).

(d) “Addiction medicine specialist” means a board certified psychiatrist with a subspecialty certification in addiction medicine or who is eligible for such subspecialty certification in addiction medicine or an addiction medicine physician certified or eligible for certification by the American Society of Addiction Medicine (ASAM).

(e) “Mental health addiction facility” means a facility licensed pursuant to Chapters 394 or 397, Florida Statutes.

(2) Standards of Practice in Pain Management Clinics.

(a) Evaluation of Patient and Medical Diagnosis. A complete medical history and a physical examination must be conducted prior to commencement of any treatment and documented in the medical record. The exact components of the physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of prior medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance.

(b) Treatment Plan. The written individualized treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

(c) Informed Consent and Agreement for Treatment. The physician shall discuss the risks and benefits of the use of controlled substances including the risks of abuse/addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or with the patient's surrogate or guardian if the patient is incompetent. The physician shall employ the use of a written controlled substance agreement between physician and patient outlining patient responsibilities, including, but not limited to:

1. To assure the medical necessity and safety of any controlled substances that the physician may consider prescribing as part of the patient's treatment plan, drug testing shall be conducted and the results reviewed prior to the initial issuance or dispensing of a controlled substance prescription, and thereafter, on a random basis at least twice a year and when requested by the treating physician;

2. Number and frequency of all prescription refills;

3. Patient compliance and reasons for which drug therapy may be discontinued (e.g., violation of agreement); and

4. Agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating physician unless otherwise authorized by the treating physician and documented in the medical record.

(d) Periodic Review. The patient shall be seen by the physician at regular intervals, not to exceed three months, to assess the efficacy of treatment, assure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects and review the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of three-month intervals.

(e) Consultation. The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those pain patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in

patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation, and requires consultation with or referral to an addictionologist or psychiatrist.

(f) Patient Drug Testing. To assure the medical necessity and safety of any controlled substances that the physician may consider prescribing as part of the patient's treatment plan, patient drug testing shall be performed in accordance with one of the collection methods set forth below and shall be conducted and the results reviewed prior to the initial issuance or dispensing of a controlled substance prescription, and thereafter, on a random basis at least twice a year and when requested by the treating physician. Nothing in this rule shall preclude a pain-management clinic from employing additional measures to assure the integrity of the urine specimens provided by patients.

1. Referral to an outside laboratory. A physician shall send the patient to a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory or a collection site owned or operated by a CLIA-certified laboratory;

2. Specimen collected in the pain-management clinic and sent to an outside laboratory for testing. A physician shall collect in the office the patient specimen to be used for drug testing in a device that measures pH, specific gravity, and temperature and then the specimen shall be sent to a CLIA-certified laboratory. The physician shall follow the collection procedures required by the agreement the pain-management clinic has entered into with the CLIA-certified laboratory it uses.

3. Specimen collected and tested in office. A physician shall collect and test in the office the specimen to be used for drug testing using CLIA-waived point-of-care test or CLIA-approved test that uses a device that measures the pH, specific gravity, and temperature. Results of the drug test shall be read according to the manufacturer's instructions.

(g) Patient Medical Records. The physician is required to keep accurate and complete records to include, but not be limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence;

2. Diagnostic, therapeutic, and laboratory results;

3. Evaluations and consultations;

4. Treatment objectives;

5. Discussion of risks and benefits;

6. Treatments;

7. Medications (including date, type, dosage, and quantity prescribed);

8. Instructions and agreements;

9. Periodic reviews;

10. Drug testing results;

11. A photocopy of the patient's government issued photo identification; and

12. If a written prescription for a controlled substance is given to the patient, a duplicate of said prescription must be maintained in the patient's medical record.

13. Each pain management clinic physician's medical record shall contain the physician's full name presented in a legible manner. In addition, each clinic must maintain a log on the premises which shall contain the full name, presented in a legible manner, along with a corresponding sample signature and initials of every physician, anesthesiologist assistant, and physician assistant working in the clinic.

14. Medical records must remain current, they must be maintained in an accessible manner and readily available for review and must be in full compliance with Rule 64B8-9.003, F.A.C., and Section 458.331(1)(m), F.S..

(h) Denial or Termination of Controlled Substance Therapy.

1. If a patient's initial drug testing reflects the adulteration of the specimen or the presence of illegal or controlled substances (other than medications with approved prescriptions), or when the testing result is questioned by either the patient or the physician, the specimen will be sent to a CLIA-certified laboratory for gas or liquid chromatography/mass spectrometry (GC/MS or LC/MS or LC/MS/MS or GC/MS/MS) confirmation. If the result of the GC/MS or LC/MS or LC/MS/MS or GC/MS/MS testing is positive, the physician shall refer the patient for further consultation with a board-certified pain management physician, an addiction medicine specialist, or to a mental health addiction facility as it pertains to drug abuse or addiction. After consultation is obtained, the physician shall document in the medical record the results of the consultation. The treating physician shall not prescribe or dispense any controlled substances until there is written concurrence of medical necessity of continued controlled substance therapy provided by a board-certified pain management physician, an addiction medicine specialist, or from a mental health addiction facility. If the treating physician is a board-certified pain management physician, or an addiction specialist, the physician does not need to refer the patient for further consultation. If the physician suspects diversion, then the patient shall be discharged and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

2. For patients currently in treatment by the physician or any other physician in the same pain management clinic, patients with signs or symptoms of substance abuse, shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period of time prior to receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled

substances and those steps taken to assure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician will incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record.

3. For patients currently in treatment by the physician or any other physician in the same pain management clinic, evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy and the patient shall be discharged and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

(i) Facility and Physical Operations.

1. A pain management clinic shall be located and operated at a publicly accessible fixed location and shall contain the following:

- a. A sign that can be viewed by the public that contains the clinic name, hours of operations, and a street address;
- b. A publicly listed telephone number and a dedicated phone number to send and receive faxes with a fax machine that shall be operational twenty-four hours per day;
- c. Emergency lighting and communications;
- d. Reception and waiting area;
- e. Restroom;
- f. Administrative area including room for storage of medical records, supplies and equipment;
- g. Private patient examination room(s);
- h. Treatment room(s) if treatment is being provided to the patient;
- i. A printed sign located in a conspicuous place in the waiting room viewable by the public disclosing the name and contact information of the clinic Designated Physician, and the names of all physicians practicing in the clinic;
- j. Storage and handling of prescription drugs. Clinics that store and dispense prescription drug shall comply with Section 499.0121, Florida Statutes, Section 893.07, Florida Statutes, and Rule 64F-12.012, Florida Administrative Code.

2. Nothing in this subsection shall excuse a physician from providing any treatment or performing any medical duty without the proper equipment and materials as required by the standard of care.

(j) Infection Control.

1. The clinic shall maintain equipment and supplies to support infection prevention and control activities.

2. The clinic shall identify infection risks based on the following:

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

(k) Health and Safety.

1. The clinic, including its grounds, buildings, furniture, appliances and equipment shall be structurally sound, in good repair, clean, and free from health and safety hazards.

2. The clinic shall have evacuation procedures in the event of an emergency which shall include provisions for the evacuation of disabled patients and employees.

3. The clinic shall have a written facility-specific disaster plan which sets forth actions that will be taken in the event of clinic closure due to unforeseen disasters which shall include provisions for the protection of medical records and any controlled substances.

4. Each clinic shall have at least one employee on the premises during patient care hours that is certified in Basic Life Support and is trained in reacting to accidents and medical emergencies until emergency medical personnel arrive.

(l) Quality Assurance. Each pain management clinic shall have an ongoing quality assurance program that objectively and systematically monitors and evaluates the quality and appropriateness of patient care, evaluates methods to improve patient care, identifies and corrects deficiencies within the facility, alerts the Designated Physician to identify and resolve recurring problems, and provides for opportunities to improve the facility's performance and to enhance and improve the quality of care provided to the public. The Designated Physician shall establish a quality assurance program that includes the following components:

1. The identification, investigation, and analysis of the frequency and causes of adverse incidents to patients,
2. The identification of trends or patterns of incidents,
3. The development of measures to correct, reduce, minimize, or eliminate the risk of adverse incidents to patients, and
4. The documentation of these functions and periodic review no less than quarterly of such information by the designated physician.

5. The Quality Assurance program must be reviewed once every three (3) years by a Florida-licensed risk manager and documentation of said review must be provided to the Department together with any corrective action plan within 30 days of the review and maintained for inspection purposes.

(m) Data Collection and Reporting.

1. Reporting of adverse incidents. The Designated Physician for each pain-management clinic shall report all adverse incidents to the Department of Health as set forth in Section 458.351, Florida Statutes.

2. The Designated Physician shall also report to the Board of Medicine, in writing, on a quarterly basis the following data:

a. Number of new and repeat patients seen and treated at the clinic who are prescribed or dispensed controlled substance medications for the treatment of chronic, non-malignant pain;

b. The number of patients discharged due to drug abuse;

c. The number of patients discharged due to drug diversion; and

d. The number of patients treated at the pain clinic whose domicile is located somewhere other than in Florida. A patient's domicile is the patient's fixed or permanent home to which he intends to return even though he may temporarily reside elsewhere.

3. All physicians practicing in pain-management clinics shall advise the Board of Medicine in writing, within 10 calendar days of beginning or ending his or her practice at a pain-management clinic.

Appendix 4

64B8-9.0132 Requirement for Pain Management Clinic Registration; Inspection or Accreditation

(1) Registration.

(a) Every designated physician of a pain management clinic, as defined in Section 458.309(4) and (5), Florida Statutes, shall register the clinic with the Department of Health. It is the Designated Physician's responsibility to ensure that the clinic is registered, regardless of whether other physicians are practicing in the same office or whether the office is non-physician owned.

(b) In order to register a pain management clinic, the Designated Physician must comply with Department Rule 64B-4.005 and 64B-4.006, F.A.C., and provide documentation to support compliance with Rule 64B8-9.0131, F.A.C.

(c) The Designated Physician must notify the Board within 10 calendar days, in writing, of any changes to the registration information, including the termination of his or her employment with the pain management clinic.

(d) Documentation of registration shall be posted in a conspicuous place in the waiting room viewable by the public.

(2) Inspection

(a) Unless the Designated Physician has previously provided written notification of current accreditation by a nationally recognized accrediting agency approved by the Board the clinic shall submit to an annual inspection by the Department. All nationally recognized accrediting organizations shall be held to the same Board-determined practice standards for registering Florida pain management clinic sites.

(b) The Department shall conduct unannounced annual inspections of pain clinics pursuant to this rule.

(c) The Designated Physician shall cooperate with the inspector(s), make medical records available to the inspector, and be responsive to all reasonable requests.

(d) The inspector(s) shall determine compliance with the requirements of Rule 64B8-9.0131, F.A.C. This shall include review of a random selection of patient records for patients who are treated for pain, selected by the inspector(s) for each physician practicing in the clinic or who has practiced in the clinic during the past six months.

(e) If the clinic is determined to be in noncompliance, the Designated Physician shall be notified and shall be given a written statement at the time of inspection. Such written notice shall specify the deficiencies. Unless the deficiencies constitute an immediate and imminent danger to the public, the Designated Physician shall be given 30 days from the date of inspection to correct any documented deficiencies and notify the Department of corrective action plan. Upon written notification from the Designated Physician that all deficiencies have been corrected, the Department is authorized to re-inspect for compliance. If the Designated Physician fails to submit a corrective action plan within 30 days of the inspection, the Department is authorized to re-inspect the office to ensure that the deficiencies have been corrected.

(f) The written results of the inspection, deficiency notice and any subsequent documentation shall be forwarded to the Department. This shall include:

1. Whether the deficiencies constituted an immediate and serious danger to the public;
2. Whether the Designated Physician provided the Department with documentation of correction of all deficiencies within 30 days from the date of inspection; and
3. The results of any reinspection.

(g) The Department shall review the results of the inspection(s) and determine whether action against the clinic registration is merited.

(h) Nothing herein shall limit the authority of the Department to investigate a complaint without prior notice.

(i) If the clinic is accredited by a nationally recognized accrediting agency approved by the Board, the Designated Physician shall submit written notification of the current accreditation survey of his or her office(s) in lieu of undergoing an inspection by the Department.

(j) The Designated Physician shall submit, within thirty (30) days of accreditation, a copy of the current accreditation survey of the clinic and shall immediately notify the Board of Medicine of any accreditation changes that occur. For purposes of initial registration, the Designated Physician shall submit a copy of the most recent accreditation survey of the clinic in lieu of undergoing an inspection by the Department.

(k) If a provisional or conditional accreditation is received, the Designated Physician shall notify the Board of Medicine in writing and shall include a plan of correction.

Appendix 5

Under the current Florida Statute 458.3265:

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

(a)(i) A physician may not practice medicine in a pain-management clinic, as described in subsection (4), if:

(1.) The pain-management clinic is not registered with the department as required by this section; or

(2.) Effective July 1, 2012, the physician has not successfully completed a pain-medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education or a pain-medicine residency that is accredited by the Accreditation Council for Graduate Medical Education or, prior to July 1, 2012, does not comply with rules adopted by the board.

The proposed rules for training requirements, if passed, allow physicians with the following levels of training to practice in Pain Management Clinics:

64B8-9.0131 (Subparagraph (2)(n) – Proposed language

(n) Training Requirements. Effective July 1, 2012, physicians who have not met the qualifications set forth in subsections 1. through 6., below, shall have successfully completed a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education (ACGME) or a pain medicine residency that is accredited by ACGME. Prior to July 1, 2012, physicians prescribing or dispensing controlled substance medications in pain-management clinics registered pursuant to Section 458.3265, Florida Statutes, must meet one of the following qualifications:

- 1. Board certification by a specialty board recognized by the American Board of Medical Specialties (ABMS) and holds a sub-specialty certification in pain medicine;*
- 2. Board certification in pain medicine by the American Board of Pain Medicine (ABPM);*
- 3. Successful completion of a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education (ACGME) or a pain medicine residency that is accredited by the ACGME;*
- 4. Successful completion of a residency program in physical medicine and rehabilitation, anesthesiology, neurology, neurosurgery, or psychiatry approved by the ACGME;*
- 5. Current staff privileges at a Florida-licensed hospital to practice pain medicine or perform pain medicine procedures;*
- 6. Three (3) years of documented full-time practice, which is defined as an average of 20 hours per week each year, in pain-management and within six months of the effective date of this rule, attendance and successful completion of 40 hours of in-person, live-participatory AMA Category I CME courses in pain management that address all the following subject areas:*
 - a. The goals of treating both short term and ongoing pain treatment;*
 - b. Controlled substance prescribing rules, including controlled substances agreements;*
 - c. Drug screening or testing, including usefulness and limitations;*
 - d. The use of controlled substances in treating short-term and ongoing pain syndromes, including usefulness and limitations;*
 - e. Evidenced-based non-controlled pharmacological pain treatments;*
 - f. Evidenced-based non-pharmacological pain treatments;*
 - g. A complete pain medicine history and a physical examination;*
 - h. Appropriate progress note keeping;*
 - i. Comorbidities with pain disorders, including psychiatric and addictive disorders;*
 - j. Drug abuse and diversion, and prevention of same;*
 - k. Risk management; and*
 - l. Medical ethics.*

In addition to the CME set forth in paragraph 6. above, physicians must be able to document hospital privileges at a Florida-licensed hospital; practice under the direct supervision of a physician who is qualified in subsection 1. through 4. above; or have the practice reviewed by a Florida-licensed risk manager and document compliance with all recommendations of the risk management review.

7. Upon completion of the 40 hours of CME set forth above, physicians qualifying under 6. above, must also document the completion of 15 hours of live lecture format, Category I CME in pain management for every year the physician is practicing pain management.

Appendix 6.

64B8-9.0133/64B15-14.0053 Approval of Nationally Recognized Physician Pain Management Accrediting Organizations.

(1) Definitions.

(a) "Accredited" means full accreditation granted by a Board of Medicine/Osteopathic Medicine approved accrediting agency or organization. "Accredited" shall also mean provisional accreditation provided that the pain management clinic is in substantial compliance with the accrediting agency or organization's standards; any deficiencies cited by the accrediting agency or organization that do not affect the quality of patient care, and the deficiencies will be corrected within thirty days of the date on which the pain management clinic was granted provisional accreditation.

(b) "Department" means the Department of Health.

(c) The "Board " means the Florida Board of Medicine/Osteopathic Medicine.

(2) Application. An application for approval as an accrediting organization shall be filed with the Board office in a paper or in a portable document format (PDF) at 4052 Bald Cypress Way, Bin #C03, Tallahassee, Florida 32399-3253/4052 Bald Cypress Way, Bin #C06, Tallahassee, Florida 32399-3256, and shall include the following information and documents:

(a) Name and address of applicant;

(b) Date applicant began to operate as an accrediting organization;

(c) Copy of applicant's current pain management clinic accreditation standards;

(d) Description of accreditation process, including composition and qualifications of accreditation surveyors and survey teams; accreditation activities; criteria for determination of compliance; and deficiency follow-up activities. Accreditation survey teams shall meet the following qualifications:

1. The surveyor or at least one member of the survey team shall have at least two (2) years experience performing pain management and must be a physician who meets one of the following requirements:

a. board certification or sub-certification certified in pain management by a specialty board recognized by the American Board of Medical Specialties (ABMS) or holds a sub-specialty certification in pain medicine; board certification in pain medicine by the American Board of Pain Medicine (ABPM); board certification by the American Board of Interventional Pain Physicians (ABIPP); ~~or~~ board certification or sub-certification in pain management by a specialty board recognized by the American Association of Physician Specialists (AAPS); or who holds a Certificate of Added Qualification in Pain Management by the American Osteopathic Association (AOA), and shall have at least two (2) years experience performing pain management; or

b. training requirements set forth in Rule 64B8-9.0131 /64B15-14.0051, F.A.C.

2. In addition to the above-outlined qualification, accreditation surveyors may not have any discipline imposed on his or her license within the preceding seven (7) years, may not be in direct competition with the subject of the review or have any direct or indirect contractual relationship with the inspected facility, its director, any person holding ownership interest in the facility, or any of its physicians.

3. The board certified pain management physician on the survey team must hold a license to practice allopathic or osteopathic medicine issued by any jurisdiction within the United States or its territories.

(e) A list of all pain management clinics located in Florida that are accredited by the applicant, if any. If there are no accredited Florida pain management clinics, but there are accredited pain management clinics outside Florida, a list of the accredited pain management clinics outside of Florida is required.

(3) Standards. The standards adopted by an accrediting organization for pain management clinics shall meet or exceed provisions set forth in Chapter 458.3265, F.S./459.0137, F.S., and rules promulgated thereunder. Standards shall require that all health care practitioners be licensed or certified to the extent required by law.

(4) Requirements. In order to be approved by the Board, an accrediting organization must demonstrate compliance with the following requirements:

(a) Accreditation periods shall not exceed three years.

(b) The accrediting organization shall obtain ~~written~~ authorization from the accredited entity to release accreditation reports and corrective action plans to the Board. The accrediting organization shall provide a copy of any accreditation report and any corrective action plans to the Board office within 30 days of completion of accrediting activities in a portable

document format (PDF).

(c) An accrediting agency or organization shall send to the Board any change in its accreditation standards within 30 calendar days after making the change.

(d) An accrediting agency or organization shall comply with confidentiality requirements regarding protection of patient records.

(5) Accrediting Organizations shall be approved for a period of time not to exceed three (3) years.

(6) If the Board discovers that an approved accrediting agency has violated or failed to comply with any provision of this rule, the Board shall issue an order to show cause outlining the alleged violation and requiring a representative from the accrediting agency to appear before the Board at its next regularly scheduled meeting to address the Board's concerns. After such an appearance, if the Board determines that a violation occurred, the accrediting agency's status as a **pain management clinic** ~~an office surgery accrediting agency~~ shall be revoked. Failure to appear before the Board upon receipt of an order to show cause shall not preclude the Board from taking action against an accrediting agency.

(7) Renewal of Approval of Accrediting Organizations. Every accrediting organization approved by the Board pursuant to this rule is required to submit to the Board a new complete written application at least four months prior to the end of its term of approval. Upon review of the submission by the Board, written notice shall be provided to the accrediting organization indicating the Board's acceptance of the certification and the next date by which a renewal submission must be filed or of the Board's decision that any identified changes are not acceptable and on that basis denial of renewal of approval as an accrediting organization.

(8) Upon denial of its application, the accrediting organization must wait a minimum of six (6) months prior to reapplying.

(9) Any person interested in obtaining a complete list of approved accrediting organizations may contact the Board of Medicine/Osteopathic Medicine or Department of Health.

64B-7.001 Pain Management Clinic Registration Requirements.

(1) Every ~~practice location or~~ clinic location that is advertising pain-management services or employing a physician who is primarily treating pain by ~~administering, prescribing or dispensing controlled substance medications, unless exempt under Sections 458.3265(1) or 459.0137(1), F.S., must register and maintain a valid registration with the Department. Every registered ~~practice~~ clinic location upon change of ownership must register and maintain a valid registration with the Department. To be eligible to register with the Department, the clinic must meet the statutory requirements, which include the requirement that the clinic be fully owned by a physician or group of physicians who are currently licensed pursuant to Chapter 458 or 459 or licensed as a health care clinic with the Agency for Health Care Administration pursuant to Part X of Chapter 400, F.S. With regard to the surgical services exemption, interventional pain procedures of the type routinely billed using surgical codes are included in the term surgical services.~~

(2) The clinic's designated physician must have a full, active, and unencumbered license, which includes:

(a) Having a clear, active license as a medical doctor or osteopathic physician under Chapter 458 or 459, F.S., that permits the physician to perform all duties authorized by holding a license without restriction.

(b) Having a license that is not designated as limited, restricted, retired, temporary, or training, ~~or that includes other limitations.~~

(c) Having a license with no restrictions on practice and no current disciplinary or other unsatisfied obligations imposed by the Board of Medicine, Board of Osteopathic Medicine, or the Department that limits or restricts the practice of medicine or osteopathic medicine, which includes suspension, probation, or any other restrictions on practice.

(3) Having considered the needs of small and rural clinic locations, the designated physician "shall practice at the clinic location," which means retaining documentation of being physically present and practicing medicine or osteopathic medicine at that location for no less than at least 33% of the hours per week that the clinic is open for business. For clinic locations with 3 or more physicians administering, prescribing, or dispensing controlled substance medications, including the designated physician, or for those clinic locations administering, prescribing or dispensing more than half the maximum number of controlled substance prescriptions that the boards by rule allow a clinic to issue over a 24-hour period, the designated physician must be present at least 67% of the hours per week that the clinic is open for business. When the designated physician is unable to practice at the clinic location as required by this subsection, ~~be present to meet these requirements,~~ any administering, prescribing or dispensing of controlled substance medications at the clinic must cease unless and until the name of another designated physician who meets the statutory requirements is received by the Department by mail, facsimile, or electronic mail, ~~approved by the board~~ which may include the date of return of the former designated physician intending to resume the position if he or she is qualified to serve in that capacity and the absence from the clinic location is temporary.

(4) To register with the Department, the designated physician must submit Application for Pain Management Clinic Registration, Form #DH-MQA 1219, 10/10, incorporated herein by reference. This form can be obtained from the Department of Health, Division of Medical Quality Assurance, at: 4052 Bald Cypress Way, Bin C-01, Tallahassee, FL 32399 or on the Board of Medicine or Board of Osteopathic Medicine website, which can be accessed at: www.flhealthsource.com or at MQA_medicine@doh.state.fl.us. At this mail or electronic address, the clinic ~~owner~~ is responsible to provide notice to the Department of the departure of the designated physician and, within 10 days after termination, the identity of another designated physician for the clinic. At this mail or electronic address, the designated physician at a registered clinic also within 10 days of departure shall notify the board of the date of termination from employment.

Appendix 8

64B-7.003 Counterfeit-Resistant Prescription Blanks.

(1) A physician who prescribes on the premises of a registered pain-management clinic must use a counterfeit-resistant prescription blank when writing a hard copy prescription for a controlled substance listed in Section 893.03, F.S.

(2) The counterfeit-resistant prescription blank must contain the following security features:

(a) The background color must be blue or green and resist reproduction;

(b) The blank must be printed on watermarked paper;

(c) The blank must resist erasures and alterations and;

(d) The word “void” or “illegal” must appear on any photocopy or other reproduction of the blank. This language shall not obstruct or render illegible any portion of the drug name, quantity or directions for use.

(3) The counterfeit-resistant prescription blank must contain the following information:

(a) The preprinted name of the prescribing physician and the address of the clinic;

(b) A space for the prescribing physician’s federal Drug Enforcement Administration registration number for controlled substances.

(4) The counterfeit-resistant prescription blank is not transferable and shall not be used by any person other than the prescribing physician.

(5) Within 24 hours following the theft or loss of a prescription blank or the discovery of a breach with regard to the prescribing of controlled substances, the physician must notify the department in writing at e-mail address MQA_Medicine@doh.state.fl.us or by letter to Department of Health, Pain Clinic Registration Program, 4052 Bald Cypress Way, Bin #C03, Tallahassee, FL 32399-3253.