The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL:	SB 2168
INTRODUCER:	Health Regulation Committee
SUBJECT:	Ratification of Rules
DATE:	April 6, 2011
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HR	**Pre-meeting**
2.				
3.				
4.				
5.				
6.				

I. Summary:

The bill ratifies two rules relating to the maximum number of prescriptions for certain controlled substances that may be written in a registered pain management clinic during any 24-hour period. These two rules were filed for adoption by the Department of Health, Board of Medicine and Board of Osteopathic Medicine.

This bill does not amend, create, or repeal any section of the Florida Statutes.

II. Present Situation:

Current Law

Chapter 2010-279, Laws of Florida (L.O.F.), became effective on November 17, 2010,[1] when the Legislature over-rode the Governor's Veto of CS/CS/HB 1565, which was passed during the 2010 Regular Session. This law requires a proposed administrative rule that has an adverse impact or regulatory costs that exceed certain thresholds to be submitted to the Legislature for ratification before the rule can take effect. The Legislature provided for a statement of estimated regulatory costs (SERC) as the tool to assess a proposed rule's impact.

[1] House Joint Resolution 9-A passed during the 2010A Special Session on November 16, 2010.

An agency proposing a rule is required to prepare a SERC of the proposed rule if the proposed rule:[2]

- Will have an adverse impact on small business; or

- Is likely to directly or indirectly increase regulatory costs in excess of $200,000 in the aggregate in this state within 1 year after the implementation of the rule.

A SERC is required to include:[3]

- An economic analysis showing whether the rule directly or indirectly:
  - Is 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;

  - Is 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; or

  - 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.

If the adverse impact or regulatory costs of the rule exceed any of these criteria, then the rule may not take effect until it is ratified by the Legislature;

- 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;

- 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;

- A good faith estimate of the transactional costs likely to be incurred by individuals and entities, including local government entities, required to comply with the requirements of the rule. "Transactional costs" are direct costs that are readily ascertainable based upon standard business practices, and include filing fees, the cost of obtaining a license, the cost of equipment required to be installed or used or procedures required to be employed in complying with the rule, additional operating costs incurred, the cost of monitoring and reporting, and any other costs necessary to comply with the rule;

- An analysis of the impact on small businesses,[4] and an analysis of the impact on small counties and small cities.[5] The impact analysis for small businesses must include the basis for

[2] *See* s. 120.54(3)(b)1., F.S.
[3] *See* s. 120.541(2), F.S.
[4] "Small business" is defined to mean an independently owned and operated business concern that employs 200 or fewer permanent full-time employees and that, together with its affiliates, has a net worth of not more than $5 million or any firm

the agency's decision not to implement alternatives that would reduce adverse impacts on small businesses;

- Any additional information that the agency determines may be useful; and

- A description of any regulatory alternative submitted by a substantially affected person and a statement adopting the alternative or a statement of the reasons for rejecting the alternative in favor of the proposed rule.

Regulation of Pain Management Clinics

The 2010 Legislature enacted CS/CS/SB 2272 and CS/CS/SB 2722[6] to help address the prescription drug abuse epidemic that is fueled by "pill mills." This law created ss. 458.3265 and 459.0137, F.S., to enhance a registration and inspection program for pain management clinics in which allopathic physicians and osteopathic physicians who primarily engage in the treatment of pain by prescribing or dispensing controlled substance medications may practice. These two sections of law are similar for the respective practice acts.

Among other things, this law requires each board to adopt a rule establishing 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.[7]

The two boards initiated rulemaking by publishing the Notice of Rule Development in the Florida Administrative Weekly on October 29, 2010. After completing the statutory requirements for rulemaking, the rules were filed for adoption with the Department of State on March 25, 2011.

The rules set 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 at 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. If a physician is working less than 8 hours per day in the pain-management clinic, the maximum number that may be written is pro-rated for the number of hours worked. The rule also provides that "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.

based in this state which has a Small Business Administration 8(a) certification. As applicable to sole proprietorships, the $5 million net worth requirement shall include both personal and business investments.

[5] "Small county" and "small city" are defined to mean any county that has an un-incarcerated population of 75,000 or less and any municipality that has an un-incarcerated population of 10,000 or less, respectively, according to the most recent decennial census.

[6] Ch. 2010-211, L.O.F.

[7] *See* s. 458.3265(4)(c), F.S., and s. 459.0137(4)(c), F.S.

SERC for Rule 64B8-9.0131

The Center for Economic Forecasting and Analysis (CEFA), part of the Florida State University Institute of Science and Public Affairs, was engaged to estimate the costs for the Department of Health and the pain-management clinics for proposed rules 64B8-9.0134 and 64B15-14.0054, for the Board of Medicine and the Board of Osteopathic Medicine, respectively. For purposes of determining whether the proposed rule requires Legislative ratification, the SERC indicates the proposed rule "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."[8]

Specifically, the SERCs indicate a total estimated statewide cost of $932,000 per year. This cost is arrived at by estimating $20 per clinic per week (for a 50-week year), for one hour of administrative time per week tracking the number of controlled substance prescriptions, including accounting for any "do not fill before" prescriptions, written by each physician practicing in the pain-management clinic. That equals $1,000 per clinic and when multiplied by the 932 clinics (as of December 9, 2010) totals $932,000 per year.

Controlled Substances

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. This chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances.

- A Schedule I substance has a high potential for abuse and no currently accepted medical use in treatment in the United States and its use under medical supervision does not meet accepted safety standards. Examples: heroin and methaqualone.

- A Schedule II substance has a high potential for abuse, a currently accepted but severely restricted medical use in treatment in the United States, and abuse may lead to severe psychological or physical dependence. Examples: cocaine and morphine.

- A Schedule III substance has a potential for abuse less than the substances contained in Schedules I and II, a currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. Examples: lysergic acid; ketamine; and some anabolic steroids.

- A Schedule IV substance has a low potential for abuse relative to the substances in Schedule III, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule III. Examples: alprazolam; diazepam; and phenobarbital.

[8] *See* The SERC of Proposed Rules in Regulation of Pain Management Clinics in Florida, BOM 64B8-9.0134, Maximum Number of Prescriptions in Registered PMC, January 18, 2011, page 10, paragraph (a)3 and The SERC of Proposed Rules in Regulation of Pain Management Clinics in Florida, BOOM 64B15-14.0054, Maximum Number of Prescriptions in Registered PMC, January 18, 2011, page 10, paragraph (a)3. A copy of each SERC is on file in the Senate Health Regulation Committee.

- A Schedule V substance has a low potential for abuse relative to the substances in Schedule IV, a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical or psychological dependence relative to the substances in Schedule IV. Examples: low dosage levels of codeine; certain stimulants; and certain narcotic compounds.

A prescription for a controlled substance listed in Schedule II may be dispensed only upon a written prescription of a practitioner, except that in an emergency situation, as defined by department rule, it may be dispensed upon oral prescription but is limited to a 72-hour supply. A prescription for a controlled substance listed in Schedule II may not be refilled.[9] A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription issued in this state.[10]

III. Effect of Proposed Changes:

The bill provides for Legislative ratification of the Board of Medicine's Rule 64B8-9.0134, Maximum Number of Prescriptions in Registered Pain Management Clinics and the Board of Osteopathic Medicine's Rule 64B15-14.0054, Maximum Number of Prescriptions in Registered Pain Management Clinics.

The act shall take effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

[9] s. 893.04(1)(f), F.S.
[10] s. 893.04(2)(e), F.S.

B. Private Sector Impact:

The SERC estimates that an average annual cost per clinic to track the number of prescriptions dispensed is $1,000. This takes into account tracking "do not fill before dated" prescriptions which are counted toward the daily limit on the first date the prescription is eligible to be filled.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.