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 1990
INTRODUCER:	Health Regulation Committee
SUBJECT:	Ratification of Rules
DATE:	March 17, 2011 REVISED:

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

I. Summary:

The bill ratifies a rule relating to Standards of Practice for Physicians Practicing in Pain Management Clinics that has been filed for adoption by the Department of Health, Board of 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

[2] *See* s. 120.54(3)(b)1., F.S.
[3] *See* s. 120.241(2), F.S.

basis for 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 create 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 the Board of Medicine and the Board of Osteopathic Medicine to adopt rules setting forth standards of practice for physicians and osteopathic physicians practicing in pain management clinics, as they are defined in law. The rules are required to address, at a minimum, facility operations; physical operations; infection control requirements; health and safety requirements; quality assurance requirements; patient records; training requirements for all facility health care practitioners who are not regulated by another board; inspections; and data collection and reporting requirements.[7]

Both boards proceeded through the rulemaking process, with similar language. The Board of Osteopathic Medicine filed its rule 64B15-14.0051, Standards of Practice for Physicians Practicing in Pain Management Clinics, on October 10, 2010, and the rule became effective on November 11, 2010. The Board of Medicine filed its rule for adoption on November 8, 2010. However, ch. 2010-279, L.O.F., became effective on November 17, 2010, before the Board of Medicine's rule became effective.[8]

The Board of Medicine's rule 64B8-9.0131 that was filed for adoption provides standards of practice in pain management clinics in the following broad categories:

- Evaluation of patient and medical diagnosis;
- Treatment plan;

[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 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 unincarcerated population of 75,000 or less and any municipality that has an unincarcerated population of 10,000 or less, respectively, according to the most recent decennial census.
[6] Ch. 2010-211, L.O.F.
[7] *See* ss. 458.3265(4)(d) and 459.0137(4)(d), F.S.
[8] A proposed rule is adopted on being filed with the Department of State and becomes effective 20 days after being filed, on a later date specified in the notice of proposed rulemaking, or on a date required by statute. *See* s. 120.54(3)(d)6., F.S.

- Informed consent and agreement for treatment;
- Periodic review;
- Consultation;
- Patient drug testing;
- Patient medical records;
- Denial or termination of controlled substance therapy;
- Facility and physical operations;
- Infection control;
- Health and safety;
- Quality assurance; and
- Data collection and reporting.

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 rule 64B8-9.0131, Standards of Practice for Physicians Practicing in Pain Management Clinics, for the Board of Medicine. 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."[9]

Specifically, the SERC indicates the expected statewide transactional costs are $64.459 million in the first year, with $60,912 million in costs expected in the following years. On a per-clinic basis, this represents estimated costs of $69,162 in the first year with an expected $65,356 in costs in the following years. On a per-patient basis for an existing patient, the costs average $43.73 in the first year and $40.91 per year for years 2 through 5. For a new patient, the first year costs average $60.83 per year.[10]

In summary, the bulk of the expected statewide transactional costs is related to the patient drug testing requirement. The proposed rule provides:

> 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[11] 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

[9] *See* The SERC of Proposed Rules in Regulation of Pain Management Clinics in Florida, BOM 64B8-9.0131, Standards of Practice for Physicians Practicing in PMC, January 18, 2011, page 15, paragraph (a)3. A copy of the SERC is on file in the Senate Health Regulation Committee.
[10] *Id*, page 17, paragraph (d).
[11] The collection methods set forth in the proposed rule include referral to an outside laboratory, specimen collection in the pain management clinic and sent to an outside laboratory for testing, and specimen collected and tested in the office.

in this rule shall preclude a pain management clinic from employing additional measures to assure the integrity of the urine specimens provided by patients.[12]

The SERC bases this component of the estimate on several assumptions and statistical modeling methods. To provide a perspective, estimates included 932 pain management clinics and 1,314 full time physicians seeing between 20 – 30 patients per day, for 250 annual work days.

III. Effect of Proposed Changes:

The bill provides for Legislative ratification of the Board of Medicine's Rule 64B8-9.0131, Standards of Practice for Physicians Practicing in Pain Management Clinics.

The act shall take effect upon becoming a law.

Other Potential Implications: The Board of Osteopathic Medicine adopted a similar rule with an effective date of November 8, 2010. Osteopathic physicians or allopathic physicians, or both, may practice in a pain management clinic. The absence of similar practice standards could prove unmanageable from a quality of care perspective, an operational perspective, and an enforcement perspective.

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.

B. Private Sector Impact:

The bill ratifies a rule for which its SERC indicates the expected statewide transactional costs are $64.459 million in the first year, with $60,912 million in costs expected in the

[12] *See* proposed rule 64B8-9.0131(2)(f).

following years. On a per-clinic basis, this represents estimated costs of $69,162 in the first year with an expected $65,356 in costs in the following years. On a per-patient basis for an existing patient, the costs average $43.73 in the first year and $40.91 per year for years 2 through 5. For a new patient, the first year costs average $60.83 per year.

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.