

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 Committee on Health Policy

BILL: SPB 7012

INTRODUCER: Health Policy Committee

SUBJECT: Ratification of Department of Health Rules

DATE: February 22, 2017

REVISED: _____

| ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|------------|----------------|-----------|---------------------------------------|
| 1. Stovall | Stovall | | HP Submitted as Committee Bill |

I. Summary:

SPB 7012 ratifies Rule 64B8-9.009, F.A.C., adopted by the Department of Health (department) and the Board of Medicine (board) for the Standard of Care for Office Surgery. This adopted rule requires two additional drugs be maintained in the office when performing Level I office surgery. Level I office surgery includes minor procedures with minimal sedation or topical or local anesthesia where the chances of complication requiring hospitalization are remote.

The Statement of Estimated Regulatory Costs (SERC) developed by the board determined that the proposed rule will likely increase regulatory costs in excess of \$1 million in the aggregate within 5 years after implementation of the rule. Accordingly, the rule must be ratified by the Legislature before it may go into effect.

This act takes effect upon becoming a law.

II. Present Situation:

Rulemaking Authority and Legislative Ratification

A rule is an agency statement of general applicability that interprets, implements, or prescribes law or policy.¹ Rulemaking authority is delegated by the Legislature to an agency in law, and authorizes an agency to adopt, develop, establish, or otherwise create a rule.² An agency may not engage in rulemaking unless it has a legislative grant of authority to do so.³ The statutory authority for rulemaking must be specific enough to guide an agency's rulemaking and an agency rule must not exceed the bounds of authority granted by the Legislature.⁴

¹ Section 120.52(16), F.S.

² Section 120.52(17), F.S.

³ See ss. 120.52(8) and 120.536(1), F.S.

⁴ See *Sloban v. Florida Board of Pharmacy*, 982 So. 2d 26 (Fla. 1st DCA 2008) and *Southwest Florida Water Management District v. Save the Manatee Club, Inc.*, 773 So. 2d 594 (Fla 1st DCA 2000).

Prior to the adoption, amendment, or repeal of any rule an agency must file a notice of the proposed rule in the Florida Administrative Register (F.A.R.).⁵ The notice of the proposed rule must include:

- An explanation of the purpose and effect;
- The specific legal authority for the rule;
- The full text of the rule;
- A summary of the agency's SERC, if one is prepared; and
- Whether legislative ratification is required.⁶

SERC Requirements

Agencies must prepare a SERC for a rule that has an adverse impact on small businesses or that increases regulatory costs more than \$200,000 in the aggregate within 1 year after implementation of the rule.⁷

A SERC must include estimates of:

- The number of people and entities effected by the proposed rule;
- The cost to the agency and other governmental entities to implement and enforce the proposed rule;
- Transactional costs likely to be incurred by people, entities, and governmental agencies for compliance; and
- An analysis of the proposed rule's impact on small businesses, counties, and cities.⁸

The SERC must also include an economic analysis on the likelihood that the proposed rule will have an adverse impact in excess of \$1 million within the first 5 years of implementation on:

- Economic growth, private-sector job creation or employment, or private-sector investment;
- Business competitiveness,⁹ productivity, or innovation; or
- Regulatory costs, including any transactional costs.^{10,11}

If the economic analysis results in an adverse impact or regulatory costs in excess of \$1 million within 5 years after implementation of the rule, then the rule must be ratified by the Legislature in order to take effect.¹²

⁵ Section 120.54(3)(a)2., F.S.

⁶ Section 120.54(3)(a)1., F.S.

⁷ Sections 120.54(3)(b) and 120.541(1)(b), F.S.

⁸ Section 120.541(2)(b)-(e), F.S. A small city has an unincarcerated population of 10,000 or less. A small county has an unincarcerated population of 75,000 or less. A small business employs less than 200 people, and has a net worth of \$5 million or less. *See ss.* 120.52(18), (19), and 288.703(6), respectively.

⁹ Business competitiveness includes the ability of those doing business in Florida to compete with those doing business in other states or domestic markets.

¹⁰ Transactional costs are direct costs that are readily ascertainable based upon standard business practices. They include filing fees, the cost of obtaining a license, the cost of equipment required to be installed or used, procedures required to be employed to comply with the rule, additional operating costs, the cost of monitoring and reporting, and any other costs necessary to comply with the rules.

¹¹ Section 120.541(2)(a), F.S.

¹² Section 120.541(3), F.S. Legislative ratification is not required for adoption of federal standards, amendments to the Florida Building Code, or amendments to the Florida Fire Prevention Code. *See s.* 120.541(4), F.S.

Level I Office Surgery Rule

The Board of Medicine is created within the department to ensure that every physician practicing in the state meets minimum requirements for safe practice.¹³ The practice of medicine is regulated under ch. 458, F.S., and the board has authority to adopt rules to implement the provisions of that chapter.¹⁴

More specifically, the board may establish by rule standards of practice and standards of care for particular practice settings, including but not limited to:

- Education and training,
- Equipment and supplies,
- Medications including anesthetics,
- Assistance of and delegation to other personnel,
- Transfer agreements,
- Sterilization,
- Records,
- Performance of complex or multiple procedures,
- Informed consent, and
- Policy and procedure manuals.¹⁵

The rule relating to the standard of care for office surgery was initially adopted in February 1994, and has been amended numerous times.¹⁶ Under this rule there are general standards relating to all office surgery¹⁷ as well as specific standards for each of three levels of office surgery.¹⁸ The levels of office surgery are differentiated primarily according to the level of sedation and anesthesia required for the procedure and patient risk.

The general standards require the surgeon to examine the patient prior to the surgery to evaluate the patient for any risks from anesthesia and the surgical procedure to be performed. The surgeon must also maintain records of the surgical procedure, including a written informed consent from the patient if required for the particular procedure. Additional general standards regulate liposuction procedures, limit the duration of certain procedures, set the standards for anesthetic monitoring, require a current policy and procedure manual, and require a risk management

¹³ Sections 458.307(1) and 458.301, F.S.

¹⁴ Section 458.309(1), F.S.

¹⁵ Section 458.331(1)(v), F.S.

¹⁶ See the Florida Administrative Code history note for Rule 64B8-9.009, *available at*: <https://www.flrules.org/gateway/ruleNo.asp?id=64B8-9.009> (last visited Feb. 14, 2017).

¹⁷ Office surgery is defined in the rule as surgery which is performed outside of any facility licensed under ch. 390, F.S., (an abortion clinic) or ch. 395, F.S., (a hospital or ambulatory surgical center). See Rule 64B8-9.009(1)(d), F.A.C.

¹⁸ Level I includes minor procedures with minimal sedation or topical or local anesthesia where the chances of complication requiring hospitalization are remote. Level II involves moderate sedation and analgesia or conscious sedation. The physician, or the facility where the procedure is being performed, must have a transfer agreement with a nearby hospital unless the physician has staff privileges at a nearby hospital to perform the same procedure on an out-patient basis. Level III involves surgery in which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia and requires a more rigorous evaluation of the patient as a suitable candidate for Level III office surgery. The surgeon must have staff privileges at a hospital to perform the same procedure or meet other comparable background, training, and experience criteria in order to perform these procedures in an office setting.

program. All physicians must be qualified by education, training, and experience to perform any procedure in the office surgery setting.¹⁹

Specific standards for the levels of office surgery pertain to sedation and anesthesia; transfer agreements to, or staff privileges at, nearby hospitals; the physician's training; required equipment and supplies, including medications; assistance of other personnel; and emergency policies and procedures.

Level I office surgery includes the following:

- Minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas and repair of lacerations or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient.
- Liposuction involving the removal of less than 4000cc supernatant fat.
- Incision and drainage of superficial abscesses, limited endoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cysto-scopic procedures, and closed reduction of simple fractures or small joint dislocations.
- Anesthesia is limited to minimal sedation. The patient's level of sedation is that of minimal sedation and anxiolysis and the chances of complications requiring hospitalization are remote. Minimal sedation and anxiolysis is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilator and cardiovascular functions are unaffected. Controlled substances²⁰ are limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.²¹
- Chances of complication requiring hospitalization are remote.

Under Level I, the surgeon's continuing medical education must include subjects relating to regional anesthetic drugs and the surgeon must hold current certification in Advanced Cardiac Life Support. At least one assistant must hold current certification in Basic Life Support. The physician's office must have available intravenous access supplies, oxygen, oral airways, and a positive pressure ventilation device. The current rule further requires the following medications in the office: atropine, diphenhydramine, epinephrine, and hydrocortisone.

Amendment to Rule 64B8-9.009, F.A.C.

The board filed an amendment to Rule 648-9.009, F.A.C., for adoption with the Department of State on June 15, 2016. This amendment clarifies language pertaining to Level I office surgery and added two drugs to the list of medications that must be available for Level I office surgery. A physician's office that performs Level I office surgery is required to have Flumazenil if a benzodiazepine is administered and Naloxone if an opiate is administered. Flumazenil is used for

¹⁹ Rule 64B8-9.009(2), F.A.C.

²⁰ Refers to controlled substances as defined in ss. 893.02 and 893.03, F.S.

²¹ This bullet is text from the adopted rule under consideration for ratification. This text is intended to clarify the rule currently in effect.

reversing drowsiness, sedation, and other effects caused by benzodiazepines.²² Naloxone blocks or reverses the effects of opioid²³ medication, including extreme drowsiness, slowed breathing, or loss of consciousness. These newly listed medications may be administered, if needed, to reverse the effects of other medications administered for the surgical procedure.

The department prepared a SERC in accordance with state rulemaking requirements.²⁴ The estimated cost to each physician's office performing Level I office surgeries is \$29.98 for the required quantity of Flumazenil and \$55.96 for the required quantity of Naloxone for a total of \$85.96.²⁵ According to the board, the actual number of physician offices is unknown but the board assumes that approximately 20,468 physicians' offices in private practice would perform a minor procedure defined in the rule as Level I office surgery. The aggregate regulatory costs for initial compliance with the proposed rule is \$1,759,429.²⁶ As a result, the proposed rule amendment requires ratification by the Legislature prior to taking effect.

III. Effect of Proposed Changes:

The proposed bill ratifies Rule 64B8-9.09, F.A.C., Standard of Care for Office Surgery solely to meet the condition for effectiveness of the rule imposed by s. 120.541(3), F.S.

The proposed bill also:

- Directs that the act shall not be codified in the F.S.;
- Requires that after the act becomes law, its enactment and effective date shall be noted in the Florida Administrative Code, the F.A.R., or both, as appropriate;
- Provides that the act does not alter rulemaking authority or constitute a legislative preemption of, or exception to, any other provision of law regarding adoption or enforcement of the rule and is intended to preserve the status of the rule; and
- Does not cure any rulemaking defect or preempt any challenge based on a lack of authority or a violation of requirements governing adoption of the rule.

The act is effective upon becoming a law. At that time, the rule becomes effective.²⁷

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

²² Benzodiazepines include drugs such as Valium, Versed, and Xanax. Among other uses, they may be used before surgery to induce relaxation and amnesia (memory loss). See <https://www.drugs.com/drug-class/benzodiazepines.html> (last visited Feb. 15, 2017).

²³ Opioids reduce the sending of pain messages to the brain and reduce feelings of pain. See <http://www.webmd.com/pain-management/guide/narcotic-pain-medications#1> (last visited Feb. 15, 2017).

²⁴ *Supra* note 7. A copy of the SERC is available in the Senate Health Policy Committee.

²⁵ The SERC states that the shelf life of these drugs is at or exceed 5 years, therefore no replacement costs are included in the fiscal analysis.

²⁶ The SERC indicates that the rule increases regulatory costs by \$1,937,500.88 over the first 5 years of implementation. However, the cost of a medication that is currently required by rule, was inadvertently included in that calculation.

²⁷ Section 120.54(3)(e)6., F.S.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

The proposed bill enables a rule to go into effect that will impose a requirement on physicians who perform Level I office surgery to maintain specified drugs in the office. The estimated cost per physician's office is \$85.96 over a 5-year period.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates an undesignated section of Florida law.

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.