

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 7009      PCB HQS 17-02      Ratification of Rules of the Board of Medicine  
**SPONSOR(S):** Health Quality Subcommittee, Massullo, MD  
**TIED BILLS:**            **IDEN./SIM. BILLS:** SB 7012

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Quality Subcommittee	13 Y, 0 N	Siples	McElroy
1) Health & Human Services Committee	18 Y, 0 N	Siples	Calamas
2) Rules & Policy Committee	13 Y, 0 N	Hamby	Birtman

### SUMMARY ANALYSIS

HB 7009 ratifies an adopted rule amendment to Rule 64B8-9.009, F.A.C., so that the adopted rule amendment may go into effect.

Under ch. 120, F.S., the Administrative Procedures Act, the formal rulemaking process begins by an agency giving notice of the proposed rule. The notice is published by the Department of State in the Florida Administrative Register and must provide certain information, including the text of the proposed rule, a summary of the agency's statement of estimated regulatory costs (SERC), if one is prepared, and how a party may request a public hearing on the proposed rule.

Rule 64B8-9.009, F.A.C., establishes the standard of care for various levels of office surgeries. In 2016, the Board of Medicine adopted an amendment to this rule as it applies to Level I office surgeries. Specifically, the rule amendment requires physician offices in which Level I office surgery procedures are performed to maintain the availability of two drugs, Flumazenil and Naloxone, when performing such procedures.

The SERC developed for the adopted rule amendment to Rule 64B8-9.009, F.A.C., shows that the amendment will create an adverse economic effect of \$1,759,429.28, over the first 5 years the rule is in effect. Section 120.54(3), F.S., requires that any rule having an adverse economic impact exceeding \$1 million over the first 5 years it is in effect must be ratified by the Legislature before it may go in effect.

The bill may have a negative fiscal impact on an individual physician office that performs Level I surgeries of \$85.96. The total number of physician offices that may be impacted is 20,468. The bill has no fiscal impact on state or local governments.

The scope of the bill is limited to this rulemaking procedure and does not adopt the substance of the rule into statute.

The bill is effective upon coming law.

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. EFFECT OF PROPOSED CHANGES:

##### Present Situation

##### Rulemaking Authority and Legislative Ratification

Rulemaking authority is delegated by the Legislature<sup>1</sup> through statute and authorizes an agency to “adopt, develop, establish, or otherwise create”<sup>2</sup> a rule.<sup>3</sup> To adopt a rule an agency must have a general or specific grant of authority from the Legislature to implement a specific law through rulemaking.<sup>4</sup> The grant of rulemaking authority itself need not be detailed.<sup>5</sup> The specific statute being interpreted or implemented through rulemaking must provide specific standards and guidelines to preclude the administrative agency from exercising unbridled discretion in creating policy or applying the law.<sup>6</sup>

The formal rulemaking process begins by an agency giving notice of the proposed rule.<sup>7</sup> The notice is published by the Department of State in the Florida Administrative Register<sup>8</sup> and must provide certain information, including the text of the proposed rule, a summary of the agency’s statement of estimated regulatory costs (SERC), if one is prepared, and how a party may request a public hearing on the proposed rule.

A SERC must be prepared if the proposed rule will have a negative impact on small business or if the proposed rule is likely to directly or indirectly increase the total regulatory costs by more than \$200,000, within one year of the rule’s implementation.<sup>9</sup> The SERC must include an economic analysis projecting a proposed rule’s adverse effect on specified aspects of the state’s economy or increase in regulatory costs.<sup>10</sup> The SERC must analyze a rule’s potential impact over the 5 year period from when the rule goes into effect. The economic analysis should show 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;<sup>11</sup>
- Likely to have an adverse impact on business competitiveness,<sup>12</sup> productivity, or innovation;<sup>13</sup>
- Likely to increase regulatory costs, including any transactional costs.<sup>14</sup>

A rule may be adopted but cannot go into effect if the analysis shows the projected impact of the proposed rule in any one of these areas will exceed \$1 million in the aggregate for the 5 year period.<sup>15</sup>

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<sup>1</sup> *Southwest Florida Water Management District v. Save the Manatee Club, Inc.*, 773 So. 2d 594 (Fla. 1<sup>st</sup> DCA 2000).

<sup>2</sup> Section 120.52(17), F.S.

<sup>3</sup> A rule is an agency statement of general applicability interpreting, implementing, or prescribing law or policy, including the procedure and practice requirements of an agency as well as certain types of forms. See s. 120.52(16), F.S., and *Florida Department of Financial Services v. Capital Collateral Regional Counsel-Middle Region*, 969 So. 2d 527, 530 (Fla. 1<sup>st</sup> DCA 2007).

<sup>4</sup> Section 120.52(8), F.S., and s. 120.536(1), F.S.

<sup>5</sup> *Save the Manatee Club, Inc.*, *supra* note 1 at 599.

<sup>6</sup> *Sloban v. Florida Board of Pharmacy*, 982 So. 2d 26, 29-30 (Fla. 1<sup>st</sup> DCA 2008); *Board of Trustees of the Internal Improvement Trust Fund v. Day Cruise Association, Inc.*, 794 So. 2d 696, 704 (Fla. 1<sup>st</sup> DCA 2001).

<sup>7</sup> Section 120.54(3)(a)1, F.S..

<sup>8</sup> Sections 120.54(3)(a)2., 120.55(1)(b)2, F.S.

<sup>9</sup> Section 120.54(1)(b), F.S.

<sup>10</sup> Section 120.541(2)(a), F.S.

<sup>11</sup> Section 120.541(2)(a)1., F.S.

<sup>12</sup> Including the ability of those doing business in Florida to compete with those doing business in other states or domestic markets.

<sup>13</sup> Section 120.541(2)(a) 2., F.S.

<sup>14</sup> Section 120.541(2)(a) 3., F.S.

<sup>15</sup> Section 120.541(3), F.S.

The law distinguishes between a rule being “adopted” and becoming enforceable or “effective.”<sup>16</sup> A rule must be filed for adoption before it may go into effect<sup>17</sup> and cannot be filed for adoption until completion of the rulemaking process.<sup>18</sup> A rule projected to have a specific economic impact exceeding \$1 million in the aggregate over 5 years<sup>19</sup> must be ratified by the Legislature before it may go into effect.<sup>20</sup>

### Rule 64B8-9.009, F.A.C.

Chapter 458, F.S., provides rulemaking authority for the licensure and regulation of the practice of medicine to the Department of Health (DOH) and the Florida Board of Medicine (Board). The Board has authority to establish, by rule, standards of practice and standards of care for particular settings.<sup>21</sup> Such standards may include education and training, medications including anesthetics, assistance of and delegation to other personnel, sterilization, performance of complex or multiple procedures, records, informed consent, and policy and procedures manuals.<sup>22</sup>

In Rule 64B8-9.009, F.A.C., the Board sets forth the standards of care that must be met for office surgeries. An office surgery is any surgery that is performed outside a facility licensed under ch. 390 or 395, F.S.<sup>23</sup> Prior to performing any surgery, the physician must evaluate the risk of anesthesia and of the surgical procedure to be performed. The physician must maintain a complete record of each surgical procedure, including the anesthesia record, if applicable, and written informed consent.<sup>24</sup>

There are several levels of office surgeries that are governed by the rule, which sets forth the scope of each level of office surgeries, the equipment and medications that must be available, and the training requirements for personnel present during the surgery. Level I involves the most minor of surgeries, which require minimal sedation or local or topical anesthesia, and have a remote chance of complications requiring hospitalization.<sup>25</sup> Level II office surgeries involve moderate sedation and require the physician office to have a transfer agreement with a licensed hospital that is no more than 30 minutes from the office.<sup>26</sup> Level III office surgeries are the most complex and require deep sedation or general anesthesia; the physician performing the surgery must have staff privileges to perform the same procedure in a hospital as that being performed in the office setting.<sup>27</sup>

A Level I office surgery includes the following:

- Minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas, repair of a laceration, or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia;
- Liposuction involving removal of less than 4,000cc supernatant fat;<sup>28</sup>
- 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;
- Procedures that do not require pre-operative medication other than minimal pre-operative tranquilization of the patient; and the anesthesia used is local, topical, or none; or

<sup>16</sup> Section 120.54(3)(e)6. Before a rule becomes enforceable, thus “effective,” the agency first must complete the rulemaking process and file the rule for adoption with the Department of State.

<sup>17</sup> Section 120.54(3)(e)6., F.S.

<sup>18</sup> Section 120.54(3)(e), F.S.

<sup>19</sup> Section 120.541(2)(a), F.S.

<sup>20</sup> Section 120.541(3), F.S.

<sup>21</sup> Section 458.331(v), F.S.

<sup>22</sup> *Id.*

<sup>23</sup> Rule 64B8-9.009(1)(d), F.A.C. Abortion clinics are licensed under ch. 390, F.S., and facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgery centers, mobile surgical facilities, and certain intensive residential treatment programs.

<sup>24</sup> Rule 64B8-9.009(2), F.A.C.

<sup>25</sup> Rule 64B8-9.009(3), F.A.C.

<sup>26</sup> Rule 64B8-9.009(4), F.A.C.

<sup>27</sup> Rule 64B8-9.009(6), F.A.C.

<sup>28</sup> Liposuction may be performed with other separate procedures in a Level II or Level III office setting, but additional restrictions apply.

See Rule 64B8-9.009(2), F.A.C.

- Procedures in which the chances of complication requiring hospitalization are remote.<sup>29</sup>

The Board rule for Level I office surgeries requires the surgeon to have training on regional anesthetic drugs and hold a current certification in advanced cardiac life support. Additionally, there must be an assistant present during the surgery who is certified in basic life support.<sup>30</sup> The rule also requires that the physician's office have available intravenous supplies, oxygen, oral airways, and a positive pressure ventilation device. The office must also have certain quantities of medication including atropine, diphenhydramine, epinephrine, and hydrocortisone.

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

The proposed rule amendment requires physician offices that perform Level I office surgeries to obtain and have available two additional medications. The rule requires Flumazenil, if a benzodiazepine is administered, and Naloxone, if an opiate is administered. Flumazenil is used to reverse the effects of benzodiazepine-induced sedation,<sup>31</sup> and Naloxone is used to reverse the effects of opiate-induced sedation.<sup>32</sup> Both drugs are antagonists that may be used to block or reverse the effects of the sedation drug given during the surgical procedure if there is a case of excessive sedation.

The estimated cost to each physician office performing Level I office surgeries is \$29.98 for the required quantity of Flumazenil and \$55.98 for the required quantity of Naloxone.<sup>33</sup> The board estimates 20,468 physician offices may be affected by the rule change. This creates an adverse economic impact of \$1,759,429.28 over the first 5 years the bill is in effect.<sup>34</sup>

#### **Effect of Proposed Change**

The bill ratifies Rule 64B8-9.009, FA.C., solely to meet the condition for effectiveness imposed by s. 120.541(3), F.S., and expressly limits ratification to the effectiveness of the rule. The bill directs that the act shall not be codified in the Florida Statutes, but only noted in the historical comments to the rule by the Department of State.

The bill is effective upon becoming law.

#### **B. SECTION DIRECTORY:**

**Section 1:** Ratifies Rule 64B8-9.009, F.A.C.,

**Section 2:** Provides that the act goes into effect upon becoming law.

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<sup>29</sup> Rule 64B8-9.009(3), F.A.C.

<sup>30</sup> *Id.* The rule specifically exempts physician performing certain 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 procedures from meeting this requirement.

<sup>31</sup> Scott R Votey et al., *Flumazenil: A New Benzodiazepine Antagonist*, 20 *Annals of Emergency Medicine* 181-188 (1991), available at [http://www.annemergmed.com/article/S0196-0644\(05\)81219-3/pdf](http://www.annemergmed.com/article/S0196-0644(05)81219-3/pdf) (last visited February 12, 2017). Benzodiazepine may include such drugs as Xanax<sup>®</sup>, Ativan<sup>®</sup>, or Valium<sup>®</sup>.

<sup>32</sup> U.S. National Library of Medicine, Medline Plus, "Naloxone Injection," (last rev. February 15, 2016), available at <https://medlineplus.gov/druginfo/meds/a612022.html> (last visited February 12, 2017).

<sup>33</sup> Board of Medicine, "Statement of Estimated Regulatory Costs for Proposed Amendments to Rule 64B8-9.009, F.A.C.," on file with the Health Quality Subcommittee.

<sup>34</sup> *Id.* These medications have a shelf-life that equals or exceeds 5 years.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill is not anticipated to have an adverse impact on the cost to DOH in implementing or enforcing the proposed rule.<sup>35</sup>

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The individual cost for each physician office performing Level I office surgeries, as defined by the rule, will increase by \$85.96. DOH estimates that there are approximately 20,468 physician offices that would be impacted by the rule.

### D. FISCAL COMMENTS:

None.

## III. COMMENTS

### A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

### B. RULE-MAKING AUTHORITY:

The bill meets the final statutory requirement for the board to exercise its rulemaking authority concerning the standards of care for office surgery. No additional rulemaking authority is required.

### C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

## IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

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<sup>35</sup> *Supra* note 33.