

**HOUSE OF REPRESENTATIVES  
FINAL BILL ANALYSIS**

<b>BILL #:</b>	HB 7073	<b>FINAL HOUSE FLOOR ACTION:</b>		
<b>SUBJECT/SHORT TITLE</b>	Ratification of Rules of the Department of Elder Affairs	119	Y's 0	N's
<b>SPONSOR(S):</b>	Children, Families & Seniors Subcommittee; Grant, M.	<b>GOVERNOR'S ACTION:</b>		Approved
<b>COMPANION BILLS:</b>	CS/SB 7020			

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**SUMMARY ANALYSIS**

HB 7073 passed the House on April 20, 2017. The bill was amended in the Senate on May 3, 2017, and returned to the House on May 5, 2017. The House concurred in the Senate amendment and passed the bill as amended on May 5, 2017.

Section 120.541, F.S., requires state agencies to prepare a statement of estimated regulatory costs (SERC), for new rules under certain circumstances. Section 120.54, F.S., requires legislative ratification of a rule with an adverse economic impact exceeding \$1 million over the first five years before it may go into effect.

Chapter 2016-40, Laws of Florida expanded oversight of professional guardians, including monitoring and discipline. To implement this new law, the Department of Elder Affairs (DOEA) adopted Rule 58M-2.009, F.A.C., establishing standards of practice for professional guardians. The DOEA SERC for the rule estimated costs exceeding the statutory threshold. This cost will be borne by wards to pay for the additional work guardians must do to meet requirements regarding fee approval and recordkeeping. The bill ratifies Rule 58M-2.009, F.A.C., so that it may go into effect.

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 to require 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 for the rule amendment estimated costs exceeding this threshold. This cost will be borne by the individual physician offices that performs Level I surgeries. The bill ratifies Rule 64B8-9.009, F.A.C., so that it may go into effect.

The scope of the bill is limited to fulfilling this rulemaking requirement, and the bill does not adopt the substance of the rules into statute.

The bill has no fiscal impact on state or local governments.

The bill was approved by the Governor on June 23, 2017, ch. 2017-165, L.O.F., and became effective on that date.

# I. SUBSTANTIVE INFORMATION

## A. EFFECT OF CHANGES:

### Background

#### Rulemaking Authority and Legislative Ratification

A rule is an agency statement of general applicability that interprets, implements, or prescribes law or policy.<sup>1</sup> Rulemaking authority is delegated by the Legislature<sup>2</sup> through statute and authorizes an agency to “adopt, develop, establish, or otherwise create”<sup>3</sup> a rule.<sup>4</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>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> 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 statement of estimated regulatory costs, if one is prepared;
- Whether legislative ratification is required; and
- How a party may request a public hearing on the proposed rule.<sup>9</sup>

#### *Statement of Estimated Regulatory Costs (SERC)*

Agencies must prepare a SERC 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>10</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, including estimates of:

- The number of people and entities affected by the proposed rule;
- The cost to the 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<sup>11</sup> businesses, counties, and cities.<sup>12</sup>

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<sup>1</sup> S. 120.52(16), F.S.

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

<sup>3</sup> S. 120.52(17), F.S.

<sup>4</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. 1st DCA 2007).

<sup>5</sup> S.120.52(8), F.S., and s. 120.536(1), F.S.

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

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

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

<sup>9</sup> S. 120.54(3)(a)1., F.S.

<sup>10</sup> S. 120.54(1)(b), F.S.

<sup>11</sup> S. 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 fewer than 200 people and has a net worth of \$5 million or less. See ss. 120.52(18), (19), and 288.703(6), F.S., respectively.

The SERC must analyze a rule's potential impact over the five 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;
- Likely to have an adverse impact on business competitiveness,<sup>13</sup> productivity, or innovation; and
- Likely to increase regulatory costs, including any transactional costs.<sup>14</sup>

The law distinguishes between a rule being “adopted” and becoming enforceable or “effective.”<sup>15</sup> A rule must be filed for adoption before it may go into effect and cannot be filed for adoption until completion of the rulemaking process.<sup>16</sup> A rule may be adopted but cannot go into effect until ratified by the Legislature 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 five-year period.<sup>17</sup>

### Regulation of Guardians

When an individual is unable to make legal decisions regarding his or her person or property, such as due to nonage, a developmental disability, mental illness, or dementia, the court may appoint a guardian to act on his or her behalf regarding his or her person or property or both.<sup>18</sup> Guardians are subject to the requirements of ch. 744, F.S. There are three main types of guardians: family or friends of the ward, professional guardians, and public guardians. The two types of guardians overseen by the Department of Elder Affairs (DOEA) are public and professional guardians. A professional guardian is a guardian who has at any time rendered services to three or more wards as their guardian; however, a person serving as a guardian for two or more relatives is not considered a professional guardian.<sup>19</sup>

In 2016, the Legislature passed and the Governor signed CS/SB 232<sup>20</sup> following reports of abuse and inappropriate behavior by professional guardians.<sup>21</sup> The new law directed that the Statewide Public Guardianship Office be renamed the Office of Public and Professional Guardians (OPPG) and expanded the OPPG's oversight of professional guardians, including monitoring and discipline. The law also directed DOEA to adopt rules relating to OPPG to establish standard of practice for public and

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<sup>12</sup> S. 120.541(2)(a), F.S.

<sup>13</sup> Including the ability of those doing business in Florida to compete with those doing business in other states or domestic markets.

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

<sup>15</sup> S. 120.54(3)(e)6., F.S. 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>16</sup> S. 120.54(3)(e), F.S.

<sup>17</sup> S. 120.541(3), F.S.

<sup>18</sup> S. 744.012(9), F.S.

<sup>19</sup> S. 744.012, F.S.

<sup>20</sup> Ch. 16-40, Laws of Fla., substantially revised ch. 744, F.S.

<sup>21</sup> See, e.g., Florida Supreme Court Commission on Fairness, Committee on Guardianship Monitoring, 2003, *available at* <http://flcourts.org/core/fileparse.php/260/urlt/guardianshipmonitoring.pdf> (last visited May 8, 2017) (reviewed how effectively guardians were fulfilling their duties and obligations. The committee received input from citizens that there was abuse, neglect, and misuse of wards' funds. As a result, the committee stated that, though the majority of guardians are law-abiding and are diligently fulfilling their complex responsibilities, a small percentage are not properly handling guardianship matters, and as a result, monitoring is necessary.); Department of Elder Affairs, Guardianship Task Force – 2004 Final Report, *available at* <http://elderaffairs.state.fl.us/doea/pubguard/GTF2004FinalReport.pdf> (last visited May 8, 2017) (advocated for additional oversight of professional guardians); Michael E. Miller, *Florida's Guardians Often Exploit the Vulnerable Residents They're Supposed to Protect*, MIAMI NEWTIMES, May 8, 2014, *available at* <http://www.miaminewtimes.com/2014-05-08/news/florida-guardian-elderly-fraud/full/> (last visited May 8, 2017) (provided anecdotal evidence of fraud within the guardianship system, noting that the appointed court monitor for Broward County has uncovered hundreds of thousands of dollars that guardians have misappropriated from their wards, and, over the course of two years, Palm Beach County's guardianship fraud hotline has investigated over 100 cases; and Barbara Peters Smith, *the Kindness of Strangers – Inside Elder Guardianship in Florida*, SARASOTA HERALD-TRIBUNE, December 6, 2014, *available at* <http://guardianship.heraldtribune.com/default.aspx> (last visited May 8, 2017) (three-part series published in December 2014 detailed abuses occurring in guardianships based on an evaluation of guardianship court case files and interviews with wards, family and friends caught in the system against their will.).

professional guardians, receive and investigate complaints, establish procedures for disciplinary oversight, conduct hearings, take administrative action pursuant to ch. 120, F.S., and specify penalties for violations.

On October 18, 2016, DOEA published proposed rules including:<sup>22</sup>

- Rule 58M-2.001, F.A.C., Professional Guardian Registration;
- Rule 58M-2.009, F.A.C., Standards of Practice; and
- Rule 58M-2.011, F.A.C., Disciplinary Action and Guidelines.<sup>23</sup>

The rules were filed for adoption with the Secretary of State on February 9, 2017. Rules 58M-2.001 and 2.011, F.A.C., went into effect on March 1, 2017. However, due to the level of its projected impact, rule 58M-2.009, F.A.C., must be ratified by the Legislature before it may take effect.

*Rule 58M-2.009, F.A.C.*

The standards of practice contained in rule 58M-2.009, F.A.C., address a variety of topics, including requirements pertaining to:

- The professional guardians' relationship with the courts, their wards, friends and family members of their wards, and other service providers;
- Decision making;
- Confidentiality;
- Record keeping;
- The professional guardians' duties and obligations to their wards; and
- The responsibilities of the professional guardian of the property.

DOEA determined that the main economic impact of rule 58M-2.009, F.A.C., was due to requirements that professional guardians receive court approval of their guardianship fees and through increased record keeping requirements that require the professional guardian to:

- Maintain written documentation of all reports from a ward's family, friends, and medical service providers or other professionals relevant to a decision made on behalf of a ward (informed consent); and
- Develop a written plan setting forth short-term and long-term objectives for meeting the goals, needs, and preferences of the ward, and maintain the plan in a separate file for each ward, along with other specified documentation.<sup>24</sup>

To determine the economic impact of rule 58M-2.009, F.A.C., DOEA contacted all 506 registered professional guardians and requested their response to a survey to determine the economic impact of the proposed rule. The response rate was 21% (106 professional guardians).

*Rule 58M-2.009, F.A.C – Court Fee Costs*

Rule 58M-2.009(22), F.A.C., requires all fees related to the duties of a professional guardian to be reviewed and approved by the court.

Of the 106 respondents to the survey, 97.1% indicated that receiving court approval of their guardianship fees is currently part of their standard practice and procedures.<sup>25</sup> The 2.9% of

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<sup>22</sup> Notice of Proposed Rule (on file with Health and Human Services Committee staff).

<sup>23</sup> Id.

<sup>24</sup> Department of Elder Affairs, Statement of Estimated Regulatory Costs (on file with Health and Human Services Committee staff).

<sup>25</sup> Id. The high response rate can be explained in part by the statutory interpretation of s. 744.108, F.S., which has led many judicial circuits around the state to decree that the judicial approval of guardianship fees is required by statute.

respondents who stated that they do not seek court approval of their guardianship fees estimated a workload increase of one to two hours per ward annually would be necessary to meet the requirement.<sup>26</sup> Based on DOEA's assumptions,<sup>27</sup> it estimated that the requirement that professional guardians receive court approval of their guardianship fees will increase private sector costs \$15,113 to \$30,225 in the first year of implementation, and \$83,505 to \$167,011 over the first five years of implementation of the proposed rule.<sup>28</sup>

#### *Rule 58M-2.009, F.A.C – Record Keeping Costs*

Rule 58M-2.009(6), F.A.C., requires professional guardians to make decisions on behalf of their wards based on informed consent; to that end, the professional guardian must maintain written documentation of all reports from a ward's family, friends, medical service providers, or other professionals relevant to a decision made on behalf of a ward.<sup>29</sup>

Of the respondents, 78% indicated that this requirement is consistent with their current practices.<sup>30</sup> The 22% of respondents stating they did not maintain this documentation estimated that an increase of between half an hour to eight hours per ward annually would be necessary to meet the requirement. DOEA estimated that the requirements for informed consent would increase private sector costs by \$187,785 to \$381,420 in the first year of implementation, and by \$1,037,631 to \$2,107,588 over the first five years of implementation of the proposed rule.

Rule 58M-2.009(13), F.A.C., requires professional guardians to develop a written plan setting forth short-term and long-term objectives for meeting the goals, needs, and preferences of the ward, and that the plan be maintained in a separate file for each ward, along with other specified documentation.

Of the respondents to the survey, 73% indicated that this requirement is consistent with their current practices.<sup>31</sup> The 27% of respondents stating they did not maintain this documentation estimated that an increase of one to 15 hours per ward annually would be necessary to meet the requirement. DOEA estimated that the initial and ongoing responsibilities imposed on the professional guardians would increase private sector costs by \$274,901 to \$582,673 in the first year of implementation, and by \$1,519,001 to \$3,219,637 over the first five years of implementation of the proposed rule.

However, factors such as the difficulty of estimating the time necessary to comply with new requirements, variation in the annual rate of growth in the number of guardians, and differences in the number of wards served by new versus more experienced guardians could affect the SERC. Using different, more conservative assumptions, an alternate cost analysis resulted in a total cost of implementation of \$1.5 million, which, while substantially less, still exceeds the threshold requiring legislative ratification of the proposed rule.<sup>32</sup>

#### Regulation of Physician Office Surgery

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

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<sup>26</sup> Id.

<sup>27</sup> DOEA estimated the average professional guardian hourly fee to be \$65, the average caseload among professional guardians to be 15.5 wards, and a projected annual increase in registered professional guardians of 5%.

<sup>28</sup> Id.

<sup>29</sup> While the proposed rule would require an expansion of reporting requirements for professional guardians, it is the responsibility of the professional guardian in statute to ensure that the ward is involved to the greatest extent possible with decision-making, including any previously executed advance directives.

<sup>30</sup> *Supra*, note 24.

<sup>31</sup> Id.

<sup>32</sup> These assumptions included: an annual rate of growth in the number of new guardians of 3%; that new guardians would have only 10 wards; that the new guardians would have had a compliance rate similar to existing guardians, and that guardians would need one hour less than the average estimate to comply with fee approval requirements and two hours less to comply with each recordkeeping requirement. (Analysis on file with Health and Human Services Committee staff).

authority to establish, by rule, standards of practice and standards of care for particular settings.<sup>33</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>34</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>35</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>36</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>37</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>38</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>39</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>40</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
- Procedures in which the chances of complication requiring hospitalization are remote.<sup>41</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>42</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.

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<sup>33</sup> S. 458.331(v), F.S.

<sup>34</sup> *Id.*

<sup>35</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>36</sup> Rule 64B8-9.009(2), F.A.C.

<sup>37</sup> Rule 64B8-9.009(3), F.A.C.

<sup>38</sup> Rule 64B8-9.009(4), F.A.C.

<sup>39</sup> Rule 64B8-9.009(6), F.A.C.

<sup>40</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.

<sup>41</sup> Rule 64B8-9.009(3), F.A.C.

<sup>42</sup> *Id.* The rule specifically exempts physicians 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.

On May 6, 2016, the Board published proposed amendment to Rule 64B8-9.009, F.A.C. The rule was filed for adoption with the Secretary of State on June 15, 2016. However, due to the level of its projected impact, the rule amendment must be ratified by the Legislature before it may take effect

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>43</sup> and Naloxone is used to reverse the effects of opiate-induced sedation.<sup>44</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>45</sup> The Board estimates 20,468 physician offices may be affected by the rule change. The individual cost for each physician office performing Level I office surgeries, as defined by the rule, will increase by \$85.96. This creates an adverse economic impact of \$1,759,429.28 over the first 5 years the bill is in effect.<sup>46</sup>

### **Effect of Proposed Changes**

HB 7073 ratifies Rules 58M-2.009, F.A.C., and 64B8-9.009, F.A.C., solely to meet the condition for effectiveness imposed by s. 120.541(3), F.S. The bill expressly limits ratification to the effectiveness of the rules. The bill directs that the act shall not be codified in the Florida Statutes; it will only be noted in the historical comments to the rule by the Department of State.

The bill is effective upon becoming law.

## **II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

### **A. FISCAL IMPACT ON STATE GOVERNMENT:**

1. Revenues:

None.

2. Expenditures:

None.

### **B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

1. Revenues:

None.

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<sup>43</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 May 8, 2017). Benzodiazepine may include such drugs as Xanax®, Ativan®, or Valium®.

<sup>44</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 May 8, 2017).

<sup>45</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>46</sup> *Id.* These medications have a shelf-life that equals or exceeds 5 years.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

See, section I.A., *infra*.

D. FISCAL COMMENTS:

None.