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 Rules

BILL: HB 7145

INTRODUCER: House Rulemaking Oversight and Repeal Subcommittee and Representative Gaetz

SUBJECT: Ratification of Rule of the Department of Health

DATE: April 17, 2014 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Phelps	RC	**Favorable**

I. Summary:

HB 7145 provides legislative ratification of the Department of Health, Rule 64J-2.006 of the Florida Administrative Code, Trauma Registry and Trauma Quality Improvement Program. The rule amendment requires Level I and Level II verified trauma centers to maintain participation in the American College of Surgeons, Trauma Quality Improvement Program (ACS-TQIP). The ACS-TQIP is a national benchmarking tool that provides feedback to participating trauma centers on their relative performance in order to improve the quality of care of trauma patients.

The Department of Health (DOH or department) filed the rule amendment for adoption on July 12, 2013. The Statement of Estimated Regulatory Costs (SERC) for the rule showed an estimated increase in regulatory costs in excess of $1 million in the aggregate for a 5-year period. Accordingly, the rule must be ratified by the Legislature before it may go into effect.

II. Present Situation:

Rulemaking and Legislative Ratification

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.[1] Rulemaking authority is delegated by the Legislature[2] through statute and authorizes an agency to “adopt, develop, establish, or otherwise create”[3] a rule. To adopt a rule an agency must have a general grant of authority to implement a specific law by rulemaking.[4] The specific statute being interpreted or implemented through rulemaking must provide specific

[1] Section 120.52(16); *Florida Department of Financial Services v. Capital Collateral Regional Counsel-Middle Region,* 969 So. 2d 527, 530 (Fla. 1st DCA 2007).

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

[3] Section 120.52(17), F.S.

[4] Section 120.52(8), F.S., and s. 120.536(1), F.S.

standards and guidelines to preclude the administrative agency from exercising unbridled discretion in creating policy or applying the law.[5]

An agency begins the formal rulemaking process by giving notice of rule development and the proposed rule.[6] The notice of the proposed rule is published in the Florida Administrative Register[7] (FAR) which 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, how a party may request a public hearing on the proposed rule, and a proposed effective date.

An agency proposing a rule is required to prepare a SERC of the proposed rule if the proposed rule: 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.[8]

If the SERC is required, it must include an economic analysis projecting the proposed rule's adverse effect over a 5-year period from when the rule goes into effect. The economic analysis must first address the rule's likely adverse impact on economic growth, private-sector job creation or employment, or private-sector investment.[9] Next is the likely adverse impact on business competitiveness,[10] productivity, or innovation.[11] Finally, the analysis must discuss whether the rule is likely to increase regulatory costs, including any transactional costs.[12] 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, the rule cannot go into effect until ratified by the Legislature pursuant to s. 120.541(3), F.S.[13]

Present law distinguishes between a rule being "adopted" and becoming enforceable or "effective."[14] A rule must be filed for adoption before it may go into effect.[15] A rule projected in the SERC to have a specific economic impact exceeding $1 million in the aggregate over 5 years,[16] which requires ratification by the Legislature before going into effect, will typically specify in the FAR that the proposed effective date of the rule is upon legislative ratification.

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[5] *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).
[6] Section 120.54(2)(a) and (3)(a)1, F.S.
[7] Sections 120.54(3)(a)2., 120.55(1)(b)2, F.S. The FAR is maintained by the Department of State and is available online at: https://www.flrules.org/Default.asp, (Last visited April 15, 2014).
[8] *See* ss. 120.54(3)(b)1., and 120.541(1)(b), F.S.
[9] Section 120.541(2)(a)1., F.S.
[10] Including the ability of those doing business in Florida to compete with those doing business in other states or domestic markets.
[11] Section 120.541(2)(a) 2., F.S.
[12] Section 120.541(2)(a) 3., F.S.
[13] Chapter 2010-279, Laws of Florida (L.O.F.), became effective on November 17, 2010, when the Legislature over-rode the Governor's veto of CS/CS/HB 1565, which was passed during the 2010 Regular Session. House Joint Resolution 9-A passed during the 2010A Special Session on November 16, 2010.
[14] 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.
[15] Section 120.54(3)(e)6., F.S.
[16] Section 120.541(2)(a), F.S.

Trauma Centers

The regulation of trauma centers in Florida is established under part II of ch. 395, F.S. Trauma centers treat individuals who have incurred single or multiple injuries because of blunt or penetrating means or burns, and who require immediate medical intervention or treatment. Currently, there are 27 verified and provisional trauma centers in the state, two of which are pediatric-only trauma centers.[17]

Trauma centers in Florida are divided into several categories including Level I, Level II, and Pediatric trauma centers.

- A Level I trauma center is defined as a trauma center that:
  - Has formal research and education programs for the enhancement of trauma care; is verified by the Department of Health (DOH) to be in substantial compliance with Level I trauma center and pediatric trauma center standards; and has been approved by the DOH to operate as a Level I trauma center;
  - Serves as a resource facility to Level II trauma centers, pediatric trauma centers, and general hospitals through shared outreach, education, and quality improvement activities; and
  - Participates in an inclusive system of trauma care, including providing leadership, system evaluation, and quality improvement activities.[18]
- A Level II trauma center is defined as a trauma center that:
  - Is verified by the DOH to be in substantial compliance with Level II trauma center standards and has been approved by the DOH to operate as a Level II trauma center or is designated pursuant to s. 395.4025(14) F.S.;
  - Serves as a resource facility to general hospitals through shared outreach, education, and quality improvement activities; and
  - Participates in an inclusive system of trauma care.[19]
- A Pediatric trauma center is defined as a hospital that is verified by the DOH to be in substantial compliance with pediatric trauma center standards and has been approved by the DOH to operate as a pediatric trauma center.[20,21]

The department is required to adopt, by rule, standards for verification of trauma centers based on national guidelines, including those established by the American College of Surgeons entitled "Hospital and Prehospital Resources for Optimal Care of the Inured Patient" and published appendices thereto.
Trauma centers, whether approved or provisional,[22] must submit trauma registry data required by rule for the department to monitor patient outcomes and ensure compliance with the standards of

[17] *See* http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/%20traumacenterlisting2014.pdf, (last visited April 15, 2014).
[18] Section 395.4001(6), F.S.
[19] Section 395.4001(7), F.S.
[20] Section 395.4001(8), F.S.
[21] For Level I, Level II, and pediatric trauma center standards *see* http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/%20traumacntrstandpamphlet150-9-2009rev1-14-10.pdf (last visited April 15, 2014).
[22] A provisional trauma center has submitted an application found acceptable by the department based on provisional review of critical elements required for a provisional trauma center as set forth in Rule 64J-2.012, F.A.C. and Department of Health Pamphlet 50-9, and may operate as a provisional trauma center pending onsite visits and a determination of compliance with specific standards and quality of care reviews for approval as a designated trauma center. *See* s. 395.4025, F.S.

approval.[23] Additionally, s. 395.4025(9), F.S., authorizes the department to collect trauma care and registry data, as prescribed by rule, from trauma centers.

American College of Surgeons Trauma Quality Improvement Program

The mission of the American College of Surgeons Committee on Trauma is to develop and implement meaningful programs for trauma care in local, regional, national, and international arenas. These programs must include education, professional development, standards of care, and assessment of outcomes.[24] The ACS-TQIP is a national benchmarking tool that provides feedback to participating trauma centers on their relative performance in order to improve the quality of care of trauma patients. It is based on the National Trauma Data Bank and uses the National Trauma Data Standard for uniformity among participating trauma centers. Components of the TQIP include: risk adjusted inter-hospital comparisons; education and training; enhanced data quality; and the sharing of best practices.[25]

Participation in the ACS-TQIP requires application and payment of an annual fee of $9,000. The trauma center must participate in the National Trauma Data Bank, comply with all data submission requirements, and update a HIPAA Business Associate Agreement and Data Use Agreement with the ACS. The trauma medical director must commit to implementation and administration of the program at the hospital, including participation, either personally or through a designee, in conference calls; web conferences; training; and attendance at the annual meeting.

Proposed Rule 64J-2.006, F.A.C.

Proposed Rule 64J-2.006, F.A.C., requires Level I and Level II verified trauma centers to maintain participation in the ACS-TQIP. Participation in this program will enable the trauma centers and the department to collect the National Trauma Data Bank data elements, which will provide the state with the ability to compare the effectiveness of Florida's system and the trauma centers' performance against national data.[26]

The proposed rule was filed with the Department of State and adopted on July 12, 2013. The effective date of the proposed rule is upon legislative ratification. The department submitted a request for legislative ratification of the proposed rule to the President of the Senate and the Speaker of the House of Representatives on February 20, 2014.

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[23] *See* s. 395.404(1)(a), F.S., and Rule 64J-2.011, F.A.C., which requires compliance with submission of registry data in accordance with Rule 64J-2.006, F.A.C.

[24] The American College of Surgeons Trauma Program, homepage, found at: http://www.facs.org/trauma/ (Last visited April 15, 2014).

[25] Additional information on the TQIP may be found at: http://www.facs.org/trauma/ntdb/tqip.html and Getting Started with TQIP found at: http://www.facs.org/trauma/ntdb/tqip-gs.html (last visited April 15, 2014).

[26] Statement of Facts and Circumstances for Rule 64J-2.006, F.A.C., filed with the Department of State on July 12, 2013, a copy of which is available in the Senate Committee on Health Policy.

The SERC prepared for the proposed rule estimates the rule will likely result in an aggregate increase in regulatory costs over 5 years of $1,240,800.[27,28] Because the SERC projects the impact in increased regulatory costs of the proposed rule will exceed $1 million in the aggregate for the 5-year period, the rule cannot go into effect until ratified by the Legislature.[29]

III. Effect of Proposed Changes:

HB 7145 ratifies the DOH Rule 64J-2.006, F.A.C., Trauma Registry and Trauma Quality Improvement Program for the sole purpose of satisfying any condition on effectiveness imposed under s. 120.541(3), F.S. If the bill is enacted into law, the rule will become effective on July 1, 2014.

The bill further clarifies its purpose and effect such that the act:

- Does not alter any rulemaking authority,
- Does not constitute legislative preemption of or exception to any provision of law governing adoption or enforcement of the rule cited,
- Is intended to preserve the status of the cited rule as a rule under ch. 120, F.S., and
- Does not cure any rulemaking defect or preempt any challenge to the rule based on a lack of authority or a violation of the requirements governing the adoption of the rule cited.

The act will not be codified in the Florida Statutes. After the act becomes law, its enactment and effective dates are to be noted in the Florida Administrative Code or the Florida Administrative Register, or both, as appropriate.

The effective date of the act is July 1, 2014.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

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[27] At the time the SERC was prepared, the department stated there were 24 verified trauma centers, the annual fee for participation in the ACS-TQIP was $8,100, and annual aggregated costs for the TQIP national conference was $53,760. Accordingly, the calculation is as follows: ($8,100 annual fee) X (24 verified trauma centers) = $194,400 + ($53,760 conference fee) = $248,160 annual regulatory cost. $248,160 annual regulatory cost X 5 years = $1,240,800.

[28] Department of Health Bureau of Emergency Medical Oversight – Trauma Program Statement of Estimated Regulatory Costs, page 3, on file with the Senate Health Policy Committee.

[29] Section 120.541(3), F.S.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

HB 7145 has no fiscal impact. However, the bill enables a proposed rule to go into effect, which will have a fiscal impact on private hospitals with a verified trauma center. The hospital will incur an annual $9,000 fee to participate in the ACS-TQIP and the cost to attend an annual conference.

C. Government Sector Impact:

The bill has no fiscal impact. However, the bill enables a proposed rule to go into effect, which will have a fiscal impact on government-owned hospitals with a verified trauma center. The hospital will incur an annual $9,000 fee to participate in the ACS-TQIP and the cost to attend an annual conference.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

None.

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.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.