HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	HB 7145	**FINAL HOUSE FLOOR ACTION:**	
SPONSOR(S):	Rulemaking Oversight & Repeal Subcommittee; Gaetz	115 **Y's**	0 **N's**
COMPANION BILLS:	None	**GOVERNOR'S ACTION:**	Pending

SUMMARY ANALYSIS

HB 7145 passed the House on April 11, 2014, and subsequently passed the Senate on April 28, 2014. The bill ratifies Rule 64J-2.006, F.A.C., authorizing the rule to go into effect.

The Department of Health (DOH) amended Rule 64J-2.006, F.A.C., implementing statutory authority to adopt standards for verification of hospitals designated by DOH as trauma centers. 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.

As required by s. 120.541, F.S., DOH prepared a Statement of Estimated Regulatory Costs (SERC). The SERC showed Rule 64J-2.006, F.A.C., would have a specific, adverse economic effect, or would increase regulatory costs, exceeding $1 million over the first 5 years the rule was in effect. Accordingly, under s. 120.541(3), F.S., the rule could not go into effect until ratified by the Legislature. The rule was adopted on July 12, 2013, and initially submitted for ratification on February 20, 2014.

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

Subject to the Governor's veto powers, the bill is effective upon becoming law.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Present Situation

Rulemaking Authority 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. Agencies do not have discretion whether to engage in rulemaking.[4] To adopt a rule an agency must have a general grant of authority to implement a specific law by rulemaking.[5] The grant of rulemaking authority itself need not be detailed.[6] 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.[7]

An agency begins the formal rulemaking process by giving notice of the proposed rule.[8] The notice is published by the Department of State in the Florida Administrative Register[9] 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. 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.[10]

The economic analysis mandated for each SERC must analyze a rule's potential impact over the 5 year period from when the rule goes into effect. First is the rule's likely adverse impact on economic growth, private-sector job creation or employment, or private-sector investment.[11] Next is the likely adverse impact on business competitiveness,[12] productivity, or innovation.[13] Finally, the analysis must discuss whether the rule is likely to increase regulatory costs, including any transactional costs.[14] 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.

Present law distinguishes between a rule being "adopted" and becoming enforceable or "effective."[15] A rule must be filed for adoption before it may go into effect[16] and cannot be filed for adoption until

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[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 120.54(1)(a), F.S.
[5] Section 120.52(8), F.S., and s. 120.536(1), F.S.
[6] *Save the Manatee Club, Inc.,* supra at 599.
[7] *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).
[8] Section 120.54(3)(a)1, F.S..
[9] Sections 120.54(3)(a)2., 120.55(1)(b)2, F.S.
[10] Section 120.541(2)(a), F.S.
[11] Section 120.541(2)(a)1., F.S.
[12] Including the ability of those doing business in Florida to compete with those doing business in other states or domestic markets.
[13] Section 120.541(2)(a) 2., F.S.
[14] Section 120.541(2)(a) 3., F.S.
[15] 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.
[16] Section 120.54(3)(e)6., F.S.

completion of the rulemaking process.[17] A rule projected to have a specific economic impact exceeding $1 million in the aggregate over 5 years[18] must be ratified by the Legislature before going into effect.[19] As a rule submitted under s. 120.541(3), F.S., becomes effective if ratified by the Legislature, a rule must be filed for adoption before being submitted for legislative ratification.

Impact of Rule 64J-2.006, F.A.C.

DOH is required to plan and establish a statewide inclusive trauma system.[20] As part of its responsibilities DOH must establish by rule the procedures for the creation and approval of trauma agencies[21] and the minimum requirements for a trauma agency to conduct annual performance evaluations and submit the results to DOH.[22] Hospitals are selected as trauma centers by DOH.[23]

Only verified or designated hospitals may be identified as trauma centers.[24] DOH is required to adopt standards for trauma center verification based on national guidelines, including standards established by the American College of Surgeons (ACS) in its publication "Hospital and Prehospital Resources for Optimal Care of the Injured Patient"[25] and any appendices.[26] There are currently 24 verified trauma centers in Florida.[27]

Trauma centers must submit trauma registry data required by rule for DOH to monitor patient outcomes and ensure compliance with the standards of approval.[28] DOH by rule also may prescribe the submission of trauma care and registry data to evaluate trauma system effectiveness.[29]

Previously, Rule 64J-2.006, F.A.C., directed the completion and submission of required data through the incorporation by reference of the Florida Trauma Registry Manual (February 2008). The amended rule, for which DOH seeks ratification, additionally requires all Level I and Level II trauma centers in Florida to maintain participation in the ACS Trauma Quality Improvement Program (TQIP). Participation is limited to designated or verified trauma centers. Participants pay an annual fee of $9,000, submit treatment and certain patient data into the National Trauma Data Bank, undergo periodic reviews of

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[17] Section 120.54(3)(e), F.S.
[18] Section 120.541(2)(a), F.S.
[19] Section 120.541(3), F.S.
[20] Section 395.40(3), F.S.
[21] Section 395.401(1)(a), F.S.
[22] Section 395.401(1)(c), F.S.
[23] Section 395.4025(1), F.S.
[24] Section 395.401(1)(k), F.S. DOH may designate as Level II trauma centers hospitals in areas with limited access to trauma center services, provided the designated hospital has a certificate of trauma center verification from the American College of Surgeons. Section 395.4025(14), F.S.
[25] "In June of 1986, the Board of Regents of the American College of Surgeons approved this report and authorized its publication as an official College document. … It is generally recognized that this document is a set of guidelines representing current thinking for optimal care of the injured. Further revisions may be indicated as systems are developed to meet the complex demands of severely injured patients." From "Abstract," *Bulletin of the American College of Surgeons,* 71(10):4-23 (Oct. 1986), available at http://www.ncbi.nlm.nih.gov/pubmed/10278815 (last viewed on March 30, 2014). "*Resources for Optimal Care of the Injured Patient* outlines the resources necessary for optimal care and is used as a guide for the development of trauma centers throughout the United States. It is the document by which trauma centers are reviewed by the ACS-approved site surveyors." ACS, "Consultation Verification Program," at http://www.facs.org/trauma/vcprogram.html (last viewed on March 30, 2014). The ACS program "verifies the presence of the resources listed in *Resources for Optimal Care of the Injured Patient*…" in a particular hospital. ACS, "Verified Trauma Centers," available at http://www.facs.org/trauma/verified.html (last viewed on March 30, 2014).
[26] Section 395.401(2), F.S.
[27] DOH, Bureau of Emergency Medical Oversight – Trauma Program, *"Statement of Estimated Regulatory Costs (SERC),"* page 3 (on file with Health and Human Services Committee staff).
[28] Section 395.404(1)(a), F.S. This trauma registry data is confidential and exempted from s. 119.07(1), F.S., and s. 24(a), Art. I, of the State Constitution. Section 395.404(1)(b), F.S.
[29] Section 395.4025(9), F.S.

their collection and submission processes, agree for certain personnel to participate in monthly conference calls, and commit to attend an annual TQIP national meeting.[30]

DOH prepared a SERC showing the rule increases regulatory costs by $1,240,800 over the first five years of implementation.[31] The SERC was prepared prior to March 18, 2013, using an annual fee amount of $8,100.[32] Applying the annual fee amount of $9,000 currently listed for participation in the ACS/TQIP[33] to the methodology used in the SERC yields a present projected increase of regulatory costs of $1,348,800[34] over the first five years of implementation.

Effect of Proposed Change

The bill ratifies Rule 64J-2.006, F.A.C., allowing the rule to go into effect.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The bill creates no additional source of state revenues.

2. Expenditures:

The bill requires no state expenditures.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

The bill itself has no impact on local government revenues.

2. Expenditures:

The bill does not impose additional expenditures on local governments.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill itself does not directly impact the private sector.

D. FISCAL COMMENTS:
The economic impacts projected in the statement of estimated regulatory costs would result from the annual costs for each verified trauma center in Florida to maintain participation in the ACS/TQIP.

[30] ACS, "Getting Started with TQIP," available at http://www.facs.org/trauma/ntdb/tqip-gs.html (last viewed on March 30, 2014).
[31] {($8,100 annual fee) x (24 verified trauma centers) = $194,400 total annual fees) + ($53,760 total annual cost for all trauma centers to attend annual TQIP national conference) = $248,160 increased annual regulatory costs.} $248,160 total annual costs x 5 years = $1,240,800. DOH, "SERC," supra at 3.
[32] The SERC is not dated but the checklist "Proposed Rule: Is a SERC Required?" is signed by the State Surgeon General/DOH Secretary and dated March 13, 2013. The Notice of Proposed Rule published on March 18, 2013, relied upon the SERC to state ratification likely would be required.
[33] See supra, FN 30.
[34] {($9,000 annual fee) x (24 verified trauma centers) = $216,000 total annual fees} + ($53,760 total annual cost for all trauma centers to attend annual TQIP national conference) = $269,760 increased annual regulatory costs. ($269,760 total annual costs) x (5 years) = $1,348,800.