Health Innovation Subcommittee

Monday, March 27, 2017
12:30 PM – 3:00 PM
Mashburn Hall

Richard Corcoran
Speaker

MaryLynn Magar
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Innovation Subcommittee

Start Date and Time:	Monday, March 27, 2017 12:30 pm
End Date and Time:	Monday, March 27, 2017 03:00 pm
Location:	Mashburn Hall (306 HOB)
Duration:	2.50 hrs

Consideration of the following bill(s):

HB 569 Medical Records by Fitzenhagen
HB 579 Payment of Health Care Claims by Hager
HB 877 Health Insurer Authorization by Harrison
HB 1077 Trauma Services by Trumbull
HB 1191 Medication Synchronization by Cruz

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Friday, March 24, 2017.

By request of the Chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Friday, March 24, 2017.

NOTICE FINALIZED on 03/23/2017 4:06PM by Ellerkamp.Donna

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 569 Medical Records
SPONSOR(S): Fitzenhagen
TIED BILLS: **IDEN./SIM. BILLS:** SB 826

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Siples	Poche
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Under both federal and state law, a health care facility or health care practitioner is authorized to charge a patient for the costs associated with the reproduction of the patient's medical records. Federal law provides that a reasonable, cost-based fee may be charged. Florida law specifies the fee that certain health care facilities may charge. However, it does not specify the fee that health care practitioners may charge but provides that it may be no more than the actual cost of copying, including labor costs. Additionally, the Department of Health (DOH) and regulatory boards are authorized to specify a fee by administrative rule.

HB 569 establishes guidelines for fees a licensed health care facility and a health care practitioner may charge for the reproduction of patient medical records, aligning Florida law with federal law.

The bill repeals the current statutory fee a licensed health care facility may charge for the reproduction of medical records and authorizes a licensed facility to determine the charge for production of such records. However, the charge for production of physical copies or for the digital scanning of such records and reports may not exceed a reasonable fee based on the actual costs of copying, including labor, supplies, and postage.

A licensed health facility may charge a flat fee of no more than $6.50 to provide an electronic copy of patient records and reports that are maintained electronically. The flat fee includes all labor, supplies, and applicable postage. The bill authorizes a health care practitioner to include the cost of labor and postage in its fee for reproducing or for the digital scanning of medical records. The bill also provides a health care practitioner the option of charging a flat fee of no more than $6.50 for providing an electronic copy of patient records and reports that are maintained electronically. The flat fee includes all labor, supplies, and applicable postage.

In addition to current persons having access to medical records, the bill authorizes a licensed facility to release copies of patient records and reports to the patient's attorney. The bill authorizes a health care practitioner to release copies of medical records or reports to a patient's guardian, curator, attorney, or personal representative, or in the absence of such person, to the next of kin of a decedent or the parent of the minor, or to any other person designated in writing by the patient.

The bill repeals the authority of the regulatory boards or the DOH to promulgate rules establishing a fee for the reproduction of medical records or reports.

The bill may have an indeterminate, insignificant fiscal impact on the DOH, and no fiscal impact on local government.

The bill provides that the act shall take effect upon becoming a law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Health Insurance Portability and Accountability Act

The federal Health Insurance Portability and Accountability Act (HIPAA), enacted in 1996, protects personal health information (PHI).[1] In 2000, the U.S. Department of Health and Human Services promulgated privacy rules which established national standards to protect medical records and other PHI.[2] These rules address, among other things, the use and disclosure of an individual's PHI.

Only certain entities are subject to HIPAA's provisions. These "covered entities" include:

- Health plans;
- Health care providers;
- Health care clearinghouses; and
- Business associates of any of the above.[3]

HIPAA requires the disclosure of an individual's PHI to the individual who is the subject of the PHI information or his or her personal representative,[4] upon his or her request.[5] Under HIPAA, if an individual requests a copy of his or her PHI or a summary or explanation of such information, a covered entity may charge a reasonable, cost-based fee, provided the fee includes only the cost of:

- Labor for copying the PHI, whether in paper or electronic form;
- Supplies for creating the paper copy or electronic media if the individual requests that the electronic copy be provided on portable media;
- Postage, when the individual has requested the copy, or summary or explanation, be mailed; and
- Preparing an explanation or summary of the PHI.[6]

The fee may not include costs associated with verification; documentation; searching for and retrieving personal health information; maintaining systems; or recouping capital for data access, storage, or infrastructure or other costs listed above, even if such costs are authorized by state law.[7]

A covered entity may charge individuals a flat fee for all requests for electronic copies of PHI maintained electronically, inclusive of all labor, supplies, and any applicable postage. The flat fee may not exceed $6.50.[8] The flat fee is an option for entities that do not want to go through the process of

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[1] Pub. L. No. 104-191 (1996). Protected health information includes all individually identifiable health information held or transmitted by a covered entity or its business associate.
[2] U.S. Department of Health and Human Services, *Health Information Privacy*, available at https://www.hhs.gov/hipaa/for-professionals/privacy/index.html (last visited March 23, 2017). The rules were modified in 2002.
[3] U.S. Department of Health and Human Services, Office for Civil Rights, *Summary of the HIPAA Privacy Rule*, (last rev. May 2003), available at https://www.hhs.gov/sites/default/files/privacysummary.pdf.
[4] Supra, FN 2. A personal representative is generally a person with authority under state law to make health care decisions on behalf of an individual.
[5] Supra, FN 3. HIPAA limits the access to psychotherapy notes, certain lab results, and information compiled for legal proceedings. A covered entity may also deny access to personal health information in certain situations, such as when a health care practitioner believes access could cause harm to the individual or others.
[6] 45 C.F.R. s. 164.524(c)(4).
[7] U.S. Department of Health and Human Services, *Individuals' Right under HIPAA to Access their Health Information 45CFR§ 164.524*, available at https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/#maximumflatfee (last visited March 23, 2017).
[8] Id.

calculating actual or average allowable costs for requests for electronic copies of PHI maintained electronically.

A covered entity must inform an individual of the approximate fees to be charged, in advance of completing the request.[9] Access to the individual's personal health records must be provided in a form or format requested by the individual if it is readily producible in such form or format, and must generally be provided within 30 days of the request.[10] Under HIPAA, a covered entity must generally obtain an individual's written authorization to disclose PHI; however, there are circumstances in which a covered entity may release records without authorization.[11]

In general, HIPAA privacy rules preempt any state law that is contrary to its provisions.[12] However, if the state law is more stringent, the state law will apply.

Access to Medical Records in Florida

Medical Records Held by Licensed Facilities

Licensed hospitals, ambulatory surgical centers, and mobile surgical centers must timely provide a true and correct copy of a patient's records in its possession upon the request of the patient for such records, in writing, after the patient's discharge.[13] The records may also be released to the patient's guardian, curator, or personal representative, or in the absence of one of those persons, to the next of kin of a decedent or the parent of the minor, or to any other person designated in writing by such patient.

The fee a licensed facility may charge for the reproduction of medical records is determined by statute.[14] For reproduction of paper records, the fee is limited to $1.00 per page, plus sales tax and actual postage. A licensed facility may charge no more than $2.00 for a non-paper record. A fee of up to $1.00 may be charged for each year of records requested. These charges apply to all records furnished directly from the licensed facility or by a copy service on behalf of the facility. If a patient requests medical records so that he or she can continue receiving medical care, a licensed facility may not charge a patient for copying or searching for the records.[15] A licensed facility must also allow a patient to review his or her original records in a manner that will ensure records will not be damaged, destroyed, or altered.

Although patient medical records are confidential, licensed facilities may disclose patient medical records without the patient's consent in certain circumstances, such as pursuant to a subpoena, to facility personnel involved in the care or treatment of the patient, or to certain state agencies required to review patient medical records to fulfill a statutory obligation.[16]

Medical Records Held by Health Care Practitioners

A licensed health care practitioner[17] who provides care or treatment to an individual must provide a copy of the patient medical records it has in its possession to the patient upon the request of the patient

[9] Supra, FN 2.
[10] 45 C.F.R. s. 164.524.
[11] Supra, FN 3. For example, PHI may be released without a patient's authorization for public health activities, law enforcement purposes, or for certain victims of abuse, neglect, or domestic violence.
[12] 45 C.F.R. s. 160.203.
[13] S. 395.3025, F.S. This does not apply to facilities that primarily provide psychiatric care or certain clinical records created at any licensed facility concerning certain mental health or substance abuse services.
[14] S. 395.3025(1), F.S.
[15] Id.
[16] S. 395.3025(4), F.S.
[17] A health care practitioner is any person licensed under ch. 457, F.S., (acupuncture); ch. 458, F.S., (medical practice); ch. 459, F.S., (osteopathic medicine); ch. 460, F.S., (chiropractic medicine); ch. 461, F.S., (podiatric medicine); ch. 462, F.S., (naturopathy); ch. 463, F.S., (optometry); ch. 464, F.S., (nursing); ch. 465, F.S., (pharmacy); ch. 466, F.S., (dentistry, dental hygiene, and dental laboratories); ch. 467, F.S., (midwifery); part I, part II, part III, part V, part X, part XIII, or part XIV of ch. 468, F.S., (speech language pathology and

or his or her legal representative.[18] The patient's medical records must be released without delay for legal review.

Although patient medical records are confidential, a practitioner may disclose patient medical records without the patient's consent in certain circumstances, such as pursuant to a subpoena, to a person who has furnished such care or treatment with the patient's consent, or to a regional poison control center for the purpose of treating and managing a poison episode.[19]

Although Florida law does not specify the fee a health care practitioner may charge for the reproduction of patient medical records, it does provide that a practitioner may charge no more than the actual costs of copying, including reasonable staff time, or the amount specified in administrative rule by the appropriate regulatory board, or the Department of Health (DOH) if there is no board. This applies regardless of whether it is a paper record or the record is made available for digital scanning.[20] The Board of Medicine (Allopathic Board) and the Board of Osteopathic Medicine (Osteopathic Board) have promulgated rules related to the fees its licensees may charge for the duplication of patient medical records.

Florida Board of Osteopathic Medicine Rule

The Osteopathic Board promulgated a rule that limits the fee an osteopathic physician may charge to $1.00 per page for the first 25 pages, and no more than 25 cents for each subsequent page, regardless of the requestor.[21] The rule further requires that a physician must comply with a patient's written request for records within 30 days of such request unless, there are circumstances beyond the physician's control that prevents such compliance. The rule authorizes a physician to charge the actual cost for reproducing certain documents, such as x-rays and other special kinds of records.[22] Actual costs include the materials, supplies, labor, and overhead costs associated with such duplication.

Florida Board of Medicine Rule

The Allopathic Board promulgated a rule that encourages allopathic physicians to provide patients with a copy of their medical records free of charge, especially if the patient is disadvantaged.[23] However, the Allopathic Board recognizes that the cost to reproduce some medical records may be financially burdensome on the physician and therefore, limits the fee that may be charged to a patient or governmental entity for medical records to $1.00 per page for the first 25 pages, and no more than 25 cents for each subsequent page. For all other entities, a physician may charge up to $1.00 per page. The rule authorizes a physician to charge the actual cost for reproducing certain documents, such as x-rays and other special kinds of records.[24] Actual costs include the materials, supplies, labor, and overhead costs associated with such duplication.

In 2012, the Allopathic Board proposed an amendment to its rule to address the costs of reproduction of medical records which were stored in electronic format.[25] The Allopathic Board issued proposed language in May 2013, which would have authorized a fee of $1.00 per page, regardless of format in which the medical records were stored. The Allopathic Board held nine public hearings between June

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audiology, nursing home administration, occupational therapy, respiratory therapy, dietetics and nutrition practice, athletic trainers, or orthotics, prosthetics, and pedorthics); ch. 478, F.S., (electrolysis); ch. 480, F.S., (massage practice); part III or part IV of ch. 483, F.S., (clinical laboratory personnel or medical physicists); ch. 484, F.S., (dispensers of optical devices and hearing aids); ch. 486, F.S., (physical therapy practice); ch. 490, F.S., (psychological services); or ch. 491, F.S., (clinical, counseling, and psychotherapy services).

[18] S. 456.057, F.S. In lieu of copies of certain medical records related to psychiatric or psychological treatment, a practitioner may release a report of examination and treatment.

[19] S. 456.057(7)-(9) F.S.

[20] S. 456.057(17), F.S.

[21] Rule 64B15-15.003, F.A.C.

[22] Id.

[23] Rule 64B8-10.003, F.A.C.

[24] Id.

[25] 38 Fla. Admin. Reg. 61 (October 30, 2012), available at https://www.flrules.org/Gateway/View_notice.asp?id=12212705 (last visited March 25, 2017).

2013 and January 2015, and subsequently published a notice of change to the proposed rule in March 2015.[26] The notice of change indicated that based on a written inquiry by the Joint Administrative Procedures Committee, the Board needed to revise its Statement of Estimated Regulatory Costs to require legislative ratification.[27] The notice of change also indicated that overhead costs were deleted from the definition of actual costs, postage was added to the definition of overhead costs, and a statement was added that accessing medical records through a patient portal does not constitute reproduction of medical records. Four petitions challenging the proposed rule as an invalid exercise of delegated legislative authority were filed with the Division of Administrative Hearings (DOAH) in response.[28]

The petitioners alleged the proposed rule increased the costs of reproducing records, violated HIPAA which limits the charge to the actual cost of producing copies of medical records, violated s. 457.057(17), F.S., which limits the charge to the actual cost of copying records, and creates a distinction based on the medium in which the copies are produced, was arbitrary and capricious, and failed to consider less costly alternatives that substantially accomplish the statutory objectives. A hearing on the merits of the case was held in September 2015.

DOAH upheld the proposed rule, finding that the petitioners failed to present evidence that the proposed rule was an invalid exercise of delegated legislative authority. Specifically, the court held that s. 457.057(17), F.S., allows a practitioner to charge no more than the actual cost of copying records or the amount specified in administrative rule by the appropriate board, or department when there is no board. Therefore, the Board was acting pursuant to its delegated legislative authority. Further, the court held that the evidence presented failed to establish that the Board exceeded its grant of rulemaking authority, that the proposed rule was vague, and that the rule is an invalid exercise of delegated legislative authority or is arbitrary or capricious.[29] The decision was appealed to the First District Court of Appeals.

In August 2016, the Board filed a Motion to Close Case and Relinquish Jurisdiction in the appellate case.[30] According to the motion, the Board determined that the proposed rule should be withdrawn and the existing rule repealed based on guidance issued by the U.S. Department of Health and Human Services that clarified the fees that may be charged for the reproduction of medical records under HIPAA. In September 2016, the court denied the motion with leave to refile. Oral arguments were held on March 21, 2017.

Effect of Proposed Changes

HB 569 repeals the current fee for reproduction of medical records set by statute and authorizes a licensed facility to determine the charge for production of such records in a manner consistent with federal law. However, the charge for production of physical copies or for the digital scanning of such records and reports may not exceed a reasonable fee based on the actual costs of copying, including:

- The labor required for copying such records and reports, whether on paper or in electronic format. Such labor is limited to the labor for creating and delivering the records or reports in the

[26] 41 Fla. Admin Reg. 49 (March 12, 2015), available at https://www.flrules.org/Gateway/View_notice.asp?id=15773963 (last visited March 25, 2017).
[27] Legislative ratification of agency rules is required if the proposed rule will likely have an adverse impact on economic growth, private sector job creation, or private sector investment in excess of $1 million in the aggregate within 5 years of implementation; is likely to have an adverse effect on business competitiveness, productivity, or innovation in excess of $1 million in the aggregate within 5 years of implementation; or is likely to increase regulatory costs, including transactional costs in excess of $1 million in the aggregate within 5 years of implementation.
[28] The cases were filed by Daniel R. Fernandez (DOAH Case No. 15-1774RP), Dax J. Lonetto, Sr., PLLC (DOAH Case No.15-1175RP), Florida Justice Association (DOAH Case No.15-1778RP), and Florida Consumer Action Network, Inc. (DOAH Case No. 15-1794RP). The four cases were consolidated into DOAH Case No. 15-1774-RP. The court granted BACTES Imaging Solutions, Inc., HealthPort Technologies, LLC and the Florida Medical Association permission to intervene in the case.
[29] *Daniel R. Fernandez, et al. v. Department of Health, Board of Medicine*, Case No. 15-774RP (DOAH Dec. 8, 2015).
[30] On file with the Health Innovation Subcommittee.

format requested or agreed upon by the requestor and does not include the cost of reviewing the request or searching for, retrieving, and otherwise preparing the records and reports for copying;
- Supplies used to create a paper copy, or the electronic media necessary to furnish an electronic copy on a portable media device; and
- Postage, if the records are to be mailed at the request of the requestor.

A facility or entity operating on its behalf may charge a flat fee of no more than $6.50 to provide an electronic copy of patient records and reports that are maintained electronically. The flat fee includes all labor, supplies, and applicable postage. The fee may not include:

- Costs associated with the maintenance of systems or data;
- Capital for data storage and maintenance;
- Labor associated with complying with the HIPAA privacy rule and other applicable laws;
- Administrative costs;
- Costs associated with outsourcing responses to individual requests for patient records and reports; and
- Other costs not associated with the provision of patient medical records.

The bill authorizes a health care practitioner, or a business operating on behalf of the health practitioner, to release copies of medical records or reports to the patient that is the subject of such medical records or report. Medical records and reports may also be released to a patient's attorney.

The bill authorizes a health care practitioner to include in its charge for reproducing medical records, the cost of postage. The bill also provides the health care practitioner the option of charging a flat fee of no more than $6.50 for providing an electronic copy of patient records and reports that are maintained electronically. The flat fee includes all labor, supplies, and applicable postage. This aligns state law with federal law.

In addition to current persons having access to medical records, the bill authorizes a licensed facility to release copies of patient records and reports to the attorney of a patient.

The bill repeals the authority of the regulatory boards or the Department of Health to promulgate rules establishing a fee for the reproduction of medical records or reports.

The bill provides that the act shall take effect upon becoming a law.

B. SECTION DIRECTORY:

Section 1: Amends s. 395.3025, F.S., relating to patient and personnel records; copies; examination.
Section 2: Amends s. 456.057, F.S., relating to ownership and control of patient records; report or copies of records to be furnished; disclosure of information.
Section 3: Provides that the act shall take effect upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

To the extent that state entities that provide health care services charge for reproduction of medical records, the entities may receive revenue from providing copies of medical records and reports.

2. Expenditures:

The Department of Health may incur an insignificant negative fiscal impact to repeal the rules related to the fees that may be charge for the reproduction of medical records. To the extent that state entities that provide health care services charge for reproduction of medical records, the entities may lose revenue if the fee charged includes costs that are not allowed under the provisions of the bill.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

If a facility or health care practitioner charges a copying fee that is higher than what is allowable under the bill for the reproduction of patient records, this may have a negative economic impact on that facility or health care practitioner.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill repeals the rulemaking authority of the regulatory boards and the Department of Health to establish fees for the reproduction of medical records, which is no longer necessary as the bill defines, in statute, the fees that may be charged.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to medical records; amending s. 395.3025, F.S.; revising provisions relating to the reproduction of patient reports or records by a hospital, ambulatory surgical center, or mobile surgical facility; providing that the fee for reproduction may not exceed certain specified costs; authorizing licensed facilities to charge a specified flat fee for an electronic copy of patient records; amending s. 456.057, F.S.; revising provisions relating to the reproduction of patient reports or records by a health care practitioner or records owner to include businesses operating on behalf of such practitioner or records owner; providing that the fee for reproduction may not exceed certain specified costs or a specified flat fee; removing rulemaking authority of a board or department to determine the cost of reproduction of patient reports or records; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (1) of section 395.3025, Florida Statutes, is amended to read:

395.3025 Patient and personnel records; copies;

examination.—

(1)(a) Any licensed facility shall, upon written request, and only after discharge of the patient, furnish, in a timely manner, without delays for legal review, to any person admitted therein for care and treatment or treated thereat, or to any such person's guardian, curator, attorney, or personal representative, or in the absence of one of those persons, to the next of kin of a decedent or the parent of a minor, or to anyone designated by such listed persons ~~person~~ in writing, a true and correct copy of all patient records and reports, including X rays, and insurance information concerning such person, which records are in the possession of the licensed facility, provided the person requesting such records agrees to pay a charge, to be determined by the licensed facility. The exclusive charge for furnishing physical copies of patient records and reports or making the records and reports available for digital scanning pursuant to this section may not exceed a reasonable fee based on the actual cost of copying, including the cost of:

1. Labor required for copying the patient records and reports requested by the person, whether on paper or in electronic form. Labor required for copying such records and reports is limited to the labor for creating and delivering the electronic copy or paper copy in the format requested or agreed upon by the requestor and does not include the cost of reviewing

the request and searching for, retrieving, and otherwise preparing the records and reports for copying;

2. Supplies used to create a paper copy or if requested, the electronic media necessary to furnish an electronic copy on a portable media device; and

3. Postage, if the person requests that the records and reports be mailed.

(b) A licensed facility, or a business operating on behalf of such facility, may charge a flat fee of no more than $6.50 for a request for an electronic copy of patient records and reports maintained electronically, inclusive of all labor, supplies, and applicable postage. Such fee may not include costs associated with updates to or maintenance of systems and data, capital for data storage and maintenance, labor associated with ensuring compliance with 45 C.F.R. s. 164.524 and other applicable laws, administrative costs, other costs associated with outsourcing the response to individual requests for patient records and reports, and other costs not included in this subsection ~~may include sales tax and actual postage, and, except for nonpaper records that are subject to a charge not to exceed $2, may not exceed $1 per page. A fee of up to $1 may be charged for each year of records requested~~. These charges shall apply to all records furnished, whether directly from the facility or from a copy service providing these services on behalf of the facility. However, a patient whose records are copied or

searched for the purpose of continuing to receive medical care is not required to pay a charge for copying or for the search. The licensed facility shall further allow any such person to examine the original records in its possession, or microforms or other suitable reproductions of the records, upon such reasonable terms as shall be imposed to assure that the records will not be damaged, destroyed, or altered.

Section 2. Subsection (17) of section 456.057, Florida Statutes, is amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

(17) A health care practitioner or records owner, or a business operating on behalf of such practitioner or owner, that furnishes ~~furnishing~~ copies of reports or records or makes ~~making~~ the reports or records available for digital scanning pursuant to this section to a patient, patient's guardian, curator, attorney, or personal representative, or in the absence of such person, to the next of kin of a decedent or the parent of a minor, or to anyone designated by such listed persons in writing, shall charge no more than the actual cost of copying, including reasonable staff time, and postage for requests for physical copies, or a flat fee of no more than $6.50 for a request for an electronic copy of patient records and reports maintained electronically, inclusive of labor, supplies, and

applicable postage ~~or the amount specified in administrative rule by the appropriate board, or the department when there is no board~~.

Section 3. This act shall take effect upon becoming a law.

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Innovation Subcommittee

Representative Fitzenhagen offered the following:

Amendment

Remove lines 31-103 and insert:

such person's guardian, curator, or personal representative, or in the absence of one of those persons, to the next of kin of a decedent or the parent of a minor, or to anyone designated by such listed persons ~~person~~ in writing, a true and correct copy of all patient records and reports, including X rays, and insurance information concerning such person, which records are in the possession of the licensed facility, provided the person requesting such records agrees to pay a charge, to be determined by the licensed facility. The ~~exclusive~~ charge for furnishing physical copies of patient records and reports or making the

records and reports available for digital scanning pursuant to this section may not exceed a reasonable fee based on the actual cost of copying, including the cost of:

1. Labor required for copying the patient records and reports requested by the person, whether on paper or in electronic form. Labor required for copying such records and reports is limited to the labor for creating and delivering the electronic copy or paper copy in the format requested or agreed upon by the requestor and does not include the cost of reviewing the request and searching for, retrieving, and otherwise preparing the records and reports for copying;

2. Supplies used to create a paper copy or if requested, the electronic media necessary to furnish an electronic copy on portable media;

3. Postage, if the person requests that the records and reports be mailed; and

4. Preparing an explanation or summary of the patient records, if agreed to by the person requesting the records.

(b) In lieu of calculating the labor costs individually for each request, a licensed facility, or a business operating on behalf of such facility, may develop a schedule of costs for labor based on the average labor costs to fulfill standard types of requests, so long as the labor costs included in the schedule are limited pursuant to subparagraph (a)1.

(c) A licensed facility, or a business operating on behalf of such facility, may charge a flat fee of no more than $6.50 in lieu of calculating the actual costs pursuant paragraph (a), for a request for an electronic copy of patient records and reports maintained electronically, inclusive of all labor, supplies, and applicable postage. Such fee may not include costs associated with updates to or maintenance of systems and data, capital for data storage and maintenance, labor associated with ensuring compliance with 45 C.F.R. s. 164.524 and other applicable laws, administrative costs, other costs associated with outsourcing the response to individual requests for patient records and reports, or other costs not included in this subsection ~~may include sales tax and actual postage, and, except for nonpaper records that are subject to a charge not to exceed $2, may not exceed $1 per page. A fee of up to $1 may be charged for each year of records requested~~. These charges shall apply to all records furnished, whether directly from the facility or from a copy service providing these services on behalf of the facility. However, a patient whose records are copied or searched for the purpose of continuing to receive medical care is not required to pay a charge for copying or for the search. The licensed facility shall further allow any such person to examine the original records in its possession, or microforms or other suitable reproductions of the records, upon such reasonable

terms as shall be imposed to assure that the records will not be damaged, destroyed, or altered.

Section 2. Subsection (17) of section 456.057, Florida Statutes, is amended to read:

456.057 Ownership and control of patient records; report or copies of records to be furnished; disclosure of information.—

(17)(a) A health care practitioner or records owner, or a business operating on behalf of such practitioner or owner, that furnishes ~~furnishing~~ copies of reports or records or makes ~~making~~ the reports or records available for digital scanning pursuant to this section to a patient, patient's guardian, curator, or personal representative, or in the absence of such person, to the next of kin of a decedent or the parent of a minor, or to anyone designated by such listed persons in writing, shall charge no more than the actual cost of:

1. Labor required for copying the patient records and reports requested by the person whether on paper or in electronic form. Labor required for copying such records and reports is limited to the labor for creating and delivering the electronic copy or paper copy in the format requested or agreed upon by the requestor and does not include the cost of reviewing the request and searching for, retrieving, and otherwise preparing the records and reports for copying; ~~including reasonable staff time,~~

2. Supplies used to create a paper copy or if requested, the electronic media necessary to furnish an electronic copy on portable media;

3. Postage, if the person requests that the records and reports be mailed; and

4. Preparing an explanation or summary of the patient records, if agreed to in advance by the person requesting the records.

(b) In lieu of calculating the labor costs individually for each request, the health care practitioner or records owner, or business operating on behalf of such practitioner or owner, may develop a schedule of costs for labor based on the average labor costs to fulfill standard types of requests, so long as the labor costs included in the schedule are limited pursuant to subparagraph (a)1.

(c) A health care practitioner or records owner, or business operating on behalf of such practitioner or owner, may charge a flat fee of no more than $6.50, in lieu of calculating the actual costs pursuant to paragraph (a), for a request for an electronic copy of patient records and reports maintained electronically, inclusive of labor, supplies, and applicable postage. Such fee may not include costs associated with updates to or maintenance of systems and data, capital for data storage and maintenance, labor associated with ensuring compliance with 45 C.F.R. s. 164.524 and other applicable laws, administrative

costs, other costs associated with outsourcing the response to individual requests for patient records and reports, or other costs not included in this subsection ~~or the amount specified in administrative rule by the appropriate board, or the department when there is no board~~.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 579 Payment of Health Care Claims
SPONSOR(S): Hager
TIED BILLS: **IDEN./SIM. BILLS:** SB 102

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Tuszynski	Poche
2) Insurance & Banking Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The American Medical Association (AMA) reports that health care providers lose a significant amount of administrative time and revenue due to denied claims. In its most recent National Insurer Report Card, the AMA reported that major insurers deny up to 29 percent of claims. Denials of claims can cost providers thousands of dollars annually.

Claims can be denied both before and after a service or treatment has been provided through a denial of preauthorization requests, denial of claims for payment, or retroactive denial of payment. Claims may be denied for many reasons: incorrect diagnosis code, an incomplete claim submission, a determination that a service is not medically necessary, or insured eligibility issues. For example, an insured may seek a service from a provider prior to that individual's effective date of coverage or after coverage has been terminated.

In the instance of a retroactive denial, the provider may have already verified that the patient was covered, provided services based on that verification, and in some cases already received payment. Retroactive denials can result in the provider or the consumer covering the loss, despite the verified eligibility.

HB 579 amends ss. 627.6131 and 641.3155, F.S., to prohibit a health insurer or health maintenance organization (HMO) from retroactively denying a claim at any time because of insured ineligibility, if the insurer or HMO verified the eligibility of the insured at the time of treatment and provided an authorization number.

The bill has an indeterminate negative fiscal impact on the Statewide Medicaid Managed Care Program, a negative fiscal impact on fully-insured HMO plans in the State Group Insurance Plan, and no apparent fiscal impact on local government.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Denial of Claims

According to the American Medical Association (AMA), health care providers lose a significant amount of administrative time and revenue due to denied claims. In its most recent National Insurer Report Card, the AMA reports that major insurers deny up to 29 percent of claims.[1] A study by the Medical Group Management Association found the cost to rework and resubmit a denied claim is approximately $25.[2]

Potential Financial Impact of Denials on Providers*

Denied claims per physician per month	44
Rework cost per claim	$25
Rework cost per month	$1,100
Annual rework cost	$13,200

*This example assumes 370 visits per month, one claim line per claim, and a denial rate of 12 percent.

Claims can be denied both before and after a service or treatment has been provided through a denial of preauthorization requests, denial of claims for payment, and retroactive denial of payment. Claims may be denied for many reasons: an incorrect diagnosis code, an incomplete claim submission, a determination that a service is not medically necessary, or insured eligibility issues. For example, an insured may seek a service from a provider prior to that individual's effective date of coverage or after coverage has been terminated. Under state and federal laws, denied claims may be appealed.[3]

Insurers and health maintenance organizations (HMOs) may routinely conduct a claims audit to verify the appropriateness and accuracy of the payment of claims. After an audit, if an insurer or HMO determines there is an issue with the claim or eligibility of the insured, it may retroactively deny a claim for a preauthorized service and try to recoup payment from the provider.

In the instance of a retroactive denial, the provider may have already verified that the patient was covered, provided services based on that verification, and in some cases already received payment. Retroactive denials can result in the provider or the consumer covering the loss, despite the verified eligibility.

Exchange Plans and Premium Tax Credits

The federal Patient Protection and Affordable Care Act (PPACA) guarantees access to coverage and mandates certain essential health benefits and other requirements.[4] To address affordability issues, federal premium tax credits and cost-sharing subsidies are available to assist eligible low and

[1] Marting, R. *The Cure for Claims Denials*, American Academy of Family Physicians, Family Practice Management, 2015 Mar-Apr;22(2):7-10, available at: http://www.aafp.org/fpm/2015/0300/p7.pdf (last accessed March 23, 2017).
[2] Id.; Graham T., *You might be losing thousands of dollars per month in 'unclean' claims*. MGMA Connex. 2014;14(2):37-38
[3] S. 627.6141, F.S.
[4] The Patient Protection and Affordable Care Act (Pub. Law No. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. Law No. 111–152), which amended several provisions of the PPACA, was enacted on March 30, 2010.

moderate-income individuals to purchase qualified health plans (QHPs) on a state or federal exchange.[5] In Florida, 1,588,628 individuals enrolled through the federal exchange received a premium tax credit for plan year 2016.[6]

Under PPACA, insurers and HMOs must provide a grace period of at least three consecutive months before cancelling the policy or contract of a federally subsidized enrollee who is delinquent if the enrollee previously paid 1-month's premium.[7] During the first month of the grace period, the insurer must pay all appropriate claims for services provided. For the second and third months, an insurer may review claims and notify providers that may be affected that an enrollee has lapsed in his or her payment of premiums and there is a possibility the insurer may deny the payment of claims incurred during the second and third months.[8] According to a 2014 survey, 48 percent of providers not participating with any PPACA exchange products cited concerns about financial liability during the grace period as a reason for their decision.[9]

Regulation of Insurance in Florida

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, HMOs, and other risk-bearing entities.[10] The Agency for Health Care Administration (AHCA) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from AHCA.[11]

Florida's Prompt Payment Laws

Florida's prompt payment laws govern payment of provider claims submitted to insurers and HMOs, including Medicaid managed care plans, in accordance with ss. 627.6131 and 641.3155, F.S., respectively.[12] These provisions detail the rights and responsibilities of insurers, HMOs, and providers for the payment of claims. An insurer or HMO has 12 months after payment is made to a provider to make a claim for overpayment against the provider, if the provider is licensed under ch. 458, F.S., (physicians), ch. 459, F.S., (osteopaths), ch. 460, F.S., (chiropractors), ch. 461, F.S., (podiatrists), or ch. 466, F.S., (dentists). For all other types of providers, an insurer or HMO has up to 30 months after such payment to make a claim for overpayment.[13] The statutes provide a process and timeline for providers to pay, deny, or contest the claim. The statutes also prohibit an insurer or HMO from retroactively denying a claim because of the ineligibility of an insured or subscriber more than one year after the date the claim is paid.[14]

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[5] In general, individuals and families may be eligible for the premium tax credit if their household income for the year is at least 100 percent but no more than 400 percent of the federal poverty line for their family size. For residents of one of the 48 contiguous states or Washington, D.C., the following illustrates when household income would be at least 100 percent but no more than 400 percent of the federal poverty line in computing your premium tax credit for 2017:
$12,060 (100%) up to $48,240 (400%) for one individual; $16,240 (100%) up to $64,960 (400%) for a family of two; and $24,600 (100%) up to $98,400 (400%) for a family of four. U.S. Department of Health & Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Poverty Guidelines*, available at: https://aspe.hhs.gov/poverty-guidelines (last accessed March 25, 2017).

[6] U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Health Insurance Marketplace Premiums After Shopping, Switching, and Premium Tax Credits, 2015-2016* (Apr. 12, 2016), *available at* https://aspe.hhs.gov/system/files/pdf/198636/MarketplaceRate.pdf (last accessed Mar. 23, 2017).

[7] Example of grace period: Premium is not paid in May. Premium payments are made in June and July, but May remains unpaid, the grace period would end July 31. Coverage would be cancelled retroactively to the last day of May. See https://www.healthcare.gov/apply-and-enroll/health-insurance-grace-period/ (last accessed Mar. 23, 2017); 45 C.F.R. s. 155.430.

[8] 45 C.F.R. s. 156.270

[9] Tracy Gnadinger, Health Policy Brief: The Ninety-Day Grace Period, (Oct. 16, 2014) *available at:* http://healthaffairs.org/blog/2014/10/17/health-policy-brief-the-ninety-day-grace-period/ (last accessed March 23, 2017).

[10] S. 20.121(3), F.S.

[11] S. 641.21(1), F.S.

[12] The prompt pay provisions apply to HMO contracts and major medical policies offered by individual and group insurers licensed under ch. 624, F.S., including preferred provider policies and an exclusive provider organization, and individual and group contracts that only provide direct payments to dentists.

[13] SS. 627.6131 and 641.3155, F.S., provide exceptions to this time limit in cases relating to fraud.

[14] SS. 627.6131(11) and 641.3155(10), F.S

Grace Periods

The federal regulation governing grace periods for federally subsidized policies or contracts does not affect policies or contracts of individuals who are not enrolled in an exchange QHP or who are enrolled in an exchange QHP and do not receive a subsidy. The grace period for these individual policies or contracts is governed by Florida law,[15] which varies by the duration of the premium payment interval. During the grace period, the policy or contract stays in force, and the insurer or HMO must affirm that an individual is insured, even when the premium payment is late and remains unpaid during the grace period. If the insurer or HMO does not receive the full payment of the premium by the end of the grace period, coverage terminates as of the grace period start date and the insurer or HMO may retroactively deny any claims incurred during the grace period.

Florida's Statewide Medicaid Managed Care Program

The Florida Medicaid program is a partnership between the federal and state governments. In Florida, AHCA oversees the Medicaid program, while the Department of Children and Families (DCF) conducts Medicaid eligibility determinations.[16]

The Statewide Medicaid Managed Care (SMMC) program consists of the Managed Medical Assistance (MMA) program and the Long-term Care (LTC) program.[17] AHCA contracts with managed care plans to provide services to eligible recipients. The MMA program covers medical and acute care services for plan enrollees. Most Florida Medicaid recipients who are eligible for the full array of Medicaid benefits are enrolled in an MMA plan. The LTC program covers nursing facility and home and community-based services to eligible adults.

Medicaid managed care plans are responsible for paying claims in accordance with federal and state law and contractual requirements, including s. 641.3155, F.S.,[18] which allows HMOs to deny a claim retroactively because of insured or subscriber ineligibility up to one year after the date of payment of the claim.

The Florida Medicaid Provider General Handbook and Florida Medicaid service-specific coverage policies and handbooks, incorporated by reference in the SMMC contract, require providers to verify each recipient's eligibility each time they provide a service. Although an enrollee may have eligibility on file at the time a service was authorized, the enrollee may have subsequently become ineligible.

Section 409.913(1)(e), F.S., defines "overpayment" to include any amount that is not authorized to be paid by the Medicaid program whether as a result of inaccurate or improper cost reporting, improper claiming, unacceptable practices, fraud, abuse, or mistake. Section 409.907, F.S., prohibits AHCA from demanding repayment from a provider in any instance in which the Medicaid overpayment is attributable to error of DCF in eligibility determination.

Section 1903(d)(2)(C) of the Social Security Act states, "When an overpayment is discovered, which was made by a State to a person or other entity, the State shall have a period of 1 year in which to recover or attempt to recover such overpayment before adjustment is made in the Federal payment to such State on account of such overpayment. Except as otherwise provided in subparagraph (D), the

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[15] SS. 627.608 and 641.31(15), F.S.; The grace period of an individual policy must be a minimum of 7 days for weekly premium; 10 days for a monthly premium; and 31 days for all other periods. The grace period of a HMO contract must be at least 10 days. For group policies, if cancellation is due to nonpayment of premium, the insurer may not retroactively cancel the policy to a date prior to the date that notice of cancellation was provided to the policyholder unless the insurer mails notice of cancellation to the policyholder prior to 45 days after the date the premium was due. Such notice must be mailed to the policyholder's last address as shown by the records of the insurer and may provide for a retroactive date of cancellation no earlier than midnight of the date that the premium was due. Section 627.6645, F.S.; 45 C.F.R. s. 155.735, provisions relating to the termination of Small Business Health Options Program (SHOP) enrollment or coverage obtained through an exchange.

[16] Department of Children and Families, *Medicaid*, available at: http://www.myflfamilies.com/service-programs/access-florida-food-medical-assistance-cash/medicaid (last accessed March 24, 2017).

[17] Part IV of ch. 409, F.S.

[18] S. 409.967(2)(j), F.S.

adjustment in the Federal payment shall be made at the end of the one year period, whether or not recovery was made." This law requires states to return the federal matching portion on overpayments made by the state or the health plan, which could include payments retroactively denied.

Effect of Proposed Language

HB 579 amends ss. 627.6131 and 641.3155, F.S., to prohibit a health insurer or HMO from retroactively denying a claim at any time because of insured ineligibility, if the insurer or HMO verified the insured's eligibility at the time of treatment and provided an authorization number.

The bill provides certainty of payment for insureds and providers who have received authorization numbers from insurers and HMOs. However, the bill prevents insurers and HMOs from pursuing overpayments or payments for non-covered services revealed during a claims audit if the insurer or HMO provided an authorization number. For example, if an insurer authorized treatments X and Y for an eligible insured and the provider provides treatment X, Y, and Z, and treatment Z is not covered by the insurer or HMO, the bill would prevent the insurer from recouping the overpayment for the uncovered service, which may not be discovered until a claims audit is completed.

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 627.6131, F.S., relating to payment of claims.
Section 2: Amends s. 641.3155, F.S., relating to prompt payment of claims.
Section 3: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The inability for SMMC plans to recoup overpayments from providers in cases of retroactive denials, combined with the federal requirement to return the federal matching portion of overpayments, results in an indeterminate negative fiscal impact to the Medicaid program.

   The bill would have a significant negative fiscal impact on the State Group Health Insurance Program's (SGHI) fully insured plans. Initial estimates on impact range from a $0.07 increase per member, per month for the Capital Health Plan (CHP) HMO, to an annual impact of up to $1.4 million for the Florida Health Care Plans (FHCP). SGHI contracts allow for an equitable adjustment to contracts in the middle of a plan-year if a statute or rule creates an impact of $500,000 or more. It does not appear that the bill would have such an impact on CHP or FHCP, but the potential exists for a negative fiscal impact, based on claim history provided by FHCP.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill will reduce unanticipated obligations on patients and loss of revenue on providers by eliminating the ability of a health insurer or HMO to recoup or deny the payment of a claim for a previously authorized treatment. This creates financial liability for a health insurer or HMO that provides authorization for an individual who is later deemed ineligible for coverage by preventing recoupment of overpayment due to retroactive denial.

Federal regulations preempt state and local laws relating to claim payment for federally subsidized products purchased on the exchange. This bill would not apply to such claims.

D. FISCAL COMMENTS:

To ensure that the Medicaid program can continue to seek return of payment from providers and meet the obligation to return federal matching funds, the bill should clarify the program's ability to recoup overpayment.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not Applicable.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not Applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the payment of health care claims; amending s. 627.6131, F.S.; prohibiting a health insurer from retroactively denying a claim under specified circumstances; amending s. 641.3155, F.S.; prohibiting a health maintenance organization from retroactively denying a claim under specified circumstances; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Subsection (11) of section 627.6131, Florida Statutes, is amended to read:

627.6131 Payment of claims.—

(11) A health insurer may not retroactively deny a claim because of insured ineligibility:

(a) At any time, if the health insurer verified the eligibility of an insured at the time of treatment and provided an authorization number.

(b) More than 1 year after the date of payment of the claim.

Section 2. Subsection (10) of section 641.3155, Florida Statutes, is amended to read:

641.3155 Prompt payment of claims.—

(10) A health maintenance organization may not

retroactively deny a claim because of subscriber ineligibility:

(a) At any time, if the health maintenance organization verified the eligibility of an insured at the time of treatment and provided an authorization number.

(b) More than 1 year after the date of payment of the claim.

Section 3. This act shall take effect July 1, 2017.

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION	
ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Innovation Subcommittee

Representative Hager offered the following:

Amendment (with title amendment)

Remove lines 19-29 and insert:

an authorization number. This paragraph applies to policies entered into or renewed on or after January 1, 2018.

(b) More than 1 year after the date of payment of the claim.

Section 2. Subsection (10) of section 641.3155, Florida Statutes, is amended to read:

641.3155 Prompt payment of claims.—

(1) A health maintenance organization may not retroactively deny a claim because of subscriber ineligibility:

(a) At any time, if the health maintenance organization verified the eligibility of a subscriber at the time of treatment and provided an authorization number. This paragraph applies to contracts entered into or renewed on or after January 1, 2018. This paragraph does not apply to Medicaid managed care plans pursuant to part IV of chapter 409.

T I T L E A M E N D M E N T

Remove lines 5-8 and insert:
specified circumstances; applying to policies entered into or renewed on or after January 1, 2018; amending s. 641.3155, F.S.; prohibiting a health maintenance organization from retroactively denying a claim under specified circumstances; applying to contracts entered into or renewed on or after January 1, 2018; exempting Medicaid managed care plans pursuant to part IV of chapter 409, F.S.; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 877 Health Insurer Authorization
SPONSOR(S): Harrison
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Tuszynski	Poche
2) Appropriations Committee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Insurers and health maintenance organizations (HMO) use many cost containment strategies to manage medical and drug spending and utilization. For example, plans may place utilization management requirements on certain procedures and therapies and on the use of certain drugs on their formulary. These requirements can include limiting the quantity of a drug that they will cover over a certain period of time, requiring enrollees to obtain prior authorization from their plan before filling a certain prescription or obtaining a certain treatment (prior authorization), or requiring enrollees to first try a preferred drug to treat a medical condition before obtaining an alternate drug to treat the condition (fail-first or step therapy).

Notification is currently not required if an insurer or HMO modifies any prior authorization guidelines or any timeline for processing prior authorization. Florida does not have any statute or rule regulating the use of fail-first or step therapy.

HB 877 amends s. 627.42392, F.S., to revise criteria for prior authorization forms, requirements for prior authorization information, restrictions on prior authorization procedures, and timeframes for prior authorization request approval or denial.

The bill also creates s. 627.42393, F.S, which requires a health insurer or HMO to publish on its website, and provide in writing, a procedure for an insured and health care provider to request an exception to a fail-first protocol. The bill requires timeframes for the authorization or denial of a fail-first protocol exception request and also details situations in which a fail-first protocol exception request must be granted, including when a preceding prescription drug or medical treatment is:

- Contraindicated or will likely cause an adverse reaction;
- Expected to be ineffective;
- In the same pharmacologic class or same mechanism of action to a drug or treatment previously received by the insured that lacked efficacy or effectiveness; or
- Not in the insured's best interest because use of such a drug is expected to cause a significant barrier to the insured's adherence or compliance with a plan of care, worsen a medical condition that exists simultaneously but independent of the condition under treatment, or decrease the ability to achieve or maintain his or her ability to perform daily activities.

The bill does not have a fiscal impact on state or local government.

The bill has an effective date of July 1, 2017

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Health Insurance

Health insurance is the insurance of human beings against bodily injury or disablement by accident or sickness, including the expenses associated with such injury, disablement, or sickness.[1] Individuals purchase health insurance coverage with the purpose of managing anticipated expenses related to health or protecting themselves from unexpected medical bills or large health care costs. Managed care is the most common delivery system for medical care today by health insurers.[2] Managed care systems combine the delivery and financing of health care services by limiting the choice of doctors and hospitals.[3] In return for this limited choice, however, medical care is less costly due to the managed care network's ability to control health care services. Some common forms of managed care are preferred provider organizations[4] (PPO) and health maintenance organizations[5] (HMO).

Preferred Provider Organization

A PPO is a health plan that contracts with providers, such as hospitals and doctors, for an alternative or reduced rate of payment to create a provider network. PPO plan members generally see specialists without prior referral or authorization from the insurer. Generally, the member is only responsible for the policy co-payment, deductible, or co-insurance amounts if covered services are obtained from network providers. However, if a member chooses to obtain services from an out-of-network provider, those out-of-pocket costs likely will be higher. An insurer that offers a PPO plan must make its current list of preferred providers available to its members.

Health Maintenance Organization

An HMO is an organization that provides a wide range of health care services, including emergency care, inpatient hospital care, physician care, ambulatory diagnostic treatment and preventive health care, pursuant to contractual arrangements with preferred providers in a designated service area. The network is made up of providers who have agreed to supply services to members at pre-negotiated rates. Traditionally, a member must use the HMO's network of health care providers in order for the HMO to pay for covered services. The use of a health care provider outside of the network generally results in the HMO limiting or denying the payment of benefits for such services.[6]

Pharmacy Benefit Managers

Advances in pharmaceuticals have transformed health care over the last several decades. Many health care problems are prevented, cured, or managed effectively using prescription drugs. As a result, national expenditures for prescription drugs have grown from $121 billion in 2000 to $324.5 billion in

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[1] S. 624.603, F.S.
[2] Florida Department of Financial Services, *Health Insurance and Health Maintenance Organizations, A Guide for Consumers,* available at: http://www.myfloridacfo.com/Division/Consumers/understandingCoverage/Guides/documents/HealthGuide.pdf (last visited March 23, 2017).
[3] Id.
[4] S. 627.6471, F.S.
[5] Part I of chapter 641, F.S.
[6] Section 641.31(38), F.S., creates an exception to this general rule. It authorizes an HMO to offer a point-of-service benefit. The benefit, offered pursuant to a rider, enables a subscriber to select, at the time of service and without referral, a nonparticipating provider for a covered service. The HMO may require the subscriber to pay a reasonable co-payment for each visit for services provided by a nonparticipating provider.

2016.[7] Health plan sponsors, which include commercial insurers, private employers, and government plans, such as Medicaid and Medicare, spent $277 billion on prescription drugs in 2015, while consumers paid $45.5 billion out-of-pocket for prescription drugs that year.[8]

Health plan sponsors contract with pharmacy benefit managers (PBMs) to provide specified services, which may include developing and managing pharmacy networks, developing drug formularies, providing mail order and specialty pharmacy services, rebate negotiation, therapeutic substitution, disease management, utilization review, support services for physicians and beneficiaries, and processing claims.[9] Payments for the services are established in contracts between health plan sponsors and PBMs.[10] For example, contracts will specify how much health plan sponsors will pay PBMs for brand name and generic drugs. These prices are typically set as a discount off the average wholesale price[11] for brand-name drugs and maximum allowable cost price for generic drugs, plus a dispensing fee.[12]

Office of Insurance Regulation

The regulatory oversight of insurance companies is generally reserved to the states. In Florida, the Office of Insurance Regulation (OIR), within the Department of Financial Services (DFS), regulates insurers and other risk bearing entities, including licensing, rates, policy forms, market conduct, claims, issuance of certificates of authority, solvency, viatical settlements, premium financing, and administrative supervision, as provided under the Florida Insurance Code (Code).[13]

All persons who transact insurance in the state must comply with the Code.[14] OIR has the power to collect, propose, publish, and disseminate any information relating to the subject matter of the Code,[15] and may investigate any matter relating to insurance.[16]

The Code requires health insurers and HMOs to provide an outline of coverage or other information describing the benefits, coverages, and limitations of a policy or contract. This may include an outline of coverage describing the principal exclusions and limitations of the policy.[17]

Cost Containment in Health Insurance

Insurers use many cost containment strategies to manage medical and drug spending and utilization. For example, plans may place utilization management requirements on certain procedures and therapies and on the use of certain drugs on their formulary. These requirements can include limiting the quantity of drug that they will cover over a certain period of time, requiring enrollees to obtain prior authorization from their plan before filling a prescription (prior authorization), or requiring enrollees to first try a preferred drug to treat a medical condition before obtaining an alternate drug for that condition (fail-first or step therapy).

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[7] Centers for Medicare and Medicaid Services, *National Health Expenditure Data, Historical*, available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (last accessed March 23, 2017).
[8] Id.
[9] Office of Program Policy Analysis & Government Accountability, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (Feb. 2007), available at: http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/0708rpt.pdf (last visited March 23, 2017).
[10] Id.
[11] Average wholesale price is the retail list price (sticker price) or the average price that manufacturers recommend wholesalers sell to physicians, pharmacies and others, such as hospitals.
[12] Supra, FN 9.
[13] S. 20.121(3)(a)1., F.S. The OIR's commissioner is the agency head for purposes of final agency action, and its rulemaking body is the Financial Services Commission, consisting of the Governor and the Cabinet.
[14] S. 624.11, F.S.
[15] S. 624.307(4), F.S.
[16] S. 624.307(3), F.S.
[17] S. 627.642, F.S.

Prior Authorization

Under prior authorization, a health care provider is required to seek approval from an insurer before a patient may receive a specified diagnostic or therapeutic treatment or specified prescription drugs under the plan. For example, most insurers or PBMs will have a preferred drug list (PDL), which is an established list of one or more prescription drugs within a therapeutic class deemed clinically equivalent and cost effective. Prior authorization would limit an insured's ability to obtain another drug within the therapeutic class that is not part of the PDL without the insurer or PBM authorizing that drug.

Section 627.42392, F.S., requires health insurers and HMOs to use an approved form[18] for prior authorization determinations, if they do not provide an electronic prior authorization process. This form can be no longer than 2 pages and at a minimum must include:

- Sufficient patient information to identify the member, date of birth, full name, and Health Plan ID number;
- Provider name, address and phone number;
- The medical procedure, course of treatment, or prescription drug benefit being requested, including the medical reason therefor, and all services tried and failed;
- Any laboratory documentation required; and
- An attestation that all information provided is true and accurate.

Rule 69O-161.010, F.A.C., details the guidelines for a prior authorization form and rule 69O-161.011, F.A.C., incorporates by reference and requires the use of Form OIR-B2-2180[19] by insurers and HMOs, which do not provide an electronic process for prior authorization.

Notification is currently not required if the insurer or HMO modifies prior authorization guidelines. In addition, there is no statutory timeline for processing prior authorizations.

Fail-first Protocols

In some cases, plans require an insured to try one drug first to treat his or her medical condition before they will cover another drug for that condition. For example, if Drug A and Drug B both treat a medical condition, a plan may require doctors to prescribe the most cost effective drug, Drug A, first. If Drug A does not work for a beneficiary, then the plan will cover Drug B. This form of cost containment is commonly called step therapy. Step therapy is also known as fail-first as the insurer restricts coverage of expensive therapies unless patients have already failed treatment with a lower-cost alternative.

Researchers report that there is mixed evidence on the impact of step therapy policies.[20] A review of the literature found that there is little good empirical evidence for or against cost savings and utilization reduction.[21] Some studies suggest that step therapy policies have been effective at reducing drug costs without increasing the use of other medical services,[22] while other studies have found that step therapy can increase total utilization costs over time because of increased inpatient admissions and emergency department visits.[23]

In Florida, there is no law or rule regulating fail-first protocols or step therapy.

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[18] Rule 69O-161.011, F.A.C.
[19] Form OIR-B2-2180, available at: https://www.flrules.org/gateway/readRefFile.asp?refId=7606&filename=Form%20OIR-B2-2180.docx (last accessed March 25, 2017).
[20] Rahul K. Nayak and Steven D. Pearson, *The Ethics Of 'Fail First': Guidelines and Practical Scenarios for Step Therapy Coverage Policies*, Health Affairs 33, No.10 (2014):1779-1785.
[21] Motheral, B.R., *Pharmaceutical Step Therapy Interventions: A Critical Review of the Literature*, Journal of Managed Care Pharmacy 17, no. 2 (2011) 143-55, available at: http://www.jmcp.org/doi/pdf/10.18553/jmcp.2011.17.2.143 (last accessed March 22, 2017).
[22] Supra, FN 20 at pg. 1780.
[23] Id.

Effect of Proposed Language

Prior Authorization

HB 877 amends s. 627.42392, F.S., to revise criteria for prior authorization forms, requirements for prior authorization information, restrictions on prior authorization procedures, and timeframes for prior authorization request approval or denial.

The bill defines an "urgent care situation" as when the standard timeframe to treat an insured's injury or condition would seriously jeopardize the insured's life, health or ability to regain maximum function based on a prudent layperson's judgement or subject the insured to severe pain that cannot be adequately managed, based on the opinion of the treating health care provider. The bill defines "utilization review entity" as a person who reviews and determines whether to authorize or deny a prior authorization request for a health insurer.

The bill adds "utilization review entity" to the list of entities that must use Form OIR-B2-2180 if they do not provide an electronic prior authorization process. The bill requires that the form not require information that is not necessary for the determination of medical necessity of or coverage for a requested medical procedure, treatment, or drug. The type of information that is not necessary for such determination is not identified in the bill.

The bill requires a health insurer, PBM, or utilization review entity to provide detailed descriptions of requirements to obtain prior authorization in easily understandable language and prior authorization forms in writing or electronic format upon request and on a publicly accessible website.

The bill restricts a health insurer, PBM, or utilization review entity from making changes to or implementing any new requirements to for prior authorization. Any changes or restrictions must be available on a publicly accessible website at least 60 days before implementation or provided in writing to policyholders and health care providers affected by the changes. Written notice must be electronic or by another means agreed to by the insured or health care provider, at least 60 days before the changes are implemented. The bill exempts the expansion of health care services from this requirement. Such notice will inform insureds and policyholders about the changes to the prior authorization process in a timely manner.

The bill requires a health insurer, PBM, or utilization review entity to authorize or deny a request and notify the patient and the patient's treating health care provider within 3 business days of receiving a completed prior authorization form for non-urgent care situations or 24 hours for urgent care situations. This provision ensures timely resolution of prior authorization requests with minimal delays in treatment.

These new requirements will add to the administrative burdens of health insurers, PBMs, and utilization review entities. However, the changes add consumer protections for those who must request prior authorization by reducing the amount of information that must be provided to request prior authorization, increasing the amount of plain-language information that must be provided to consumers, restricting the ability to change procedures without public or written notice, and setting timelines for authorization or denial of a prior authorization request.

Fail-First Protocols

HB 877 creates s. 627.42393, F.S, which requires an insurer to publish on its website, and provide in writing, a procedure for an insured and health care provider to request an exception for a fail-first protocol. The bill removes "a managed care plan as defined in s. 409.962(9)" from the definition of "health insurer" in s. 627.42392, F.S., as that cross-reference is obsolete. The bill defines:

- "Fail-first protocol" to mean a written protocol that specifies the order in which certain medical procedures, courses of treatment, or prescription drugs must be used to treat an insured's condition.
- "Health insurer" to mean the same as s. 627.42392, F.S., which means an authorized insurer offering health insurance as defined in s. 624.603 or a health maintenance organization as defined in s. 641.19(12).
- "Preceding prescription drug or medical treatment" to mean a medical procedure, course of treatment, or prescription drug that must be used pursuant to a health insurer's fail-first protocol as a condition of coverage under a health insurance policy or a health maintenance contract to treat an insured's condition.
- "Protocol exception" to mean a determination by a health insurer that a fail-first protocol is not medically appropriate or indicated for treatment of an insured's condition and the health insurer authorizes the use of another medical procedure, course of treatment, or prescription drug prescribed or recommended by the treating health care provider for the insured's condition.

The bill requires an insurer to publish on its website and provide in writing to an insured a procedure for an insured and health care provider to request a protocol exception. This procedure must include:

- A description of the manner in which an insured or health care provider may request a protocol exception;
- The manner and timeframe in which the health insurer is required to authorize or deny a protocol exception request or respond to an appeal to a health insurer's authorization or denial; and
- Conditions in which the protocol exception request must be granted.

The bill requires health insurers to authorize or deny a protocol exception request within 3 business days for non-urgent care situations and 24 hours for urgent care situations. The bill requires an authorization to specify the medical procedure, course of treatment, or prescription drug and for a denial to include a detailed written explanation of the reason for denial including the rationale supporting the denial and the appeal procedure.

The bill requires a health insurer to grant a protocol exception request if a preceding prescription drug or medical treatment is:

- Contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured;
- Expected to be ineffective, based on the medical history of the insured and the clinical evidence of the characteristics of the preceding prescription or medical treatment;
- In the same pharmacologic class or same mechanism of action to a drug or treatment previously received by the insured that lacked efficacy or effectiveness or adversely effected the insured; or
- Not in the insured's best interest because use of such drug is expected to cause a significant barrier to the insured's adherence or compliance with a plan of care, worsen a medical condition that exists simultaneously but independent of the condition under treatment, or decrease the ability to achieve or maintain his or her ability to perform daily activities.

The bill also authorizes an insurer to request a copy of relevant documentation from the insured's medical record in support of a protocol exception request.

These changes will add to the administrative burdens of an insurer, but will add consumer protections similar to the prior authorization changes. These changes increase the amount and accessibility of information available to the insured and his or her health care provider, setting timelines for authorization or denial of a protocol exception request, and detailing conditions in which a protocol exception request must be granted.

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 627.42392, F.S, relating to prior authorization.
Section 2: Creates s. 627.42393, F.S., relating to fail-first protocols.
Section 3: Provides an effective date of July 1, 2017.

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.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The increased notice, information provision requirements, and timeframe requirements will have an indeterminate negative fiscal impact on health insurers, PBMs, and utilization review entities due increased administrative costs and workload.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not Applicable. The bill does not affect local government.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Not Applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to health insurer authorization; amending s. 627.42392, F.S.; revising and providing definitions; revising criteria for prior authorization forms; requiring health insurers and other persons acting on behalf of health insurers to provide the manner, requirements, restrictions, and any changes for insureds and health care providers to request for and obtain prior authorizations; specifying such requirements do not apply to expansion of health care services coverage; providing timeframe to respond to prior authorization requests; creating s. 627.42393, F.S.; providing definitions; requiring health insurers to provide a procedure to obtain protocol exceptions on its website and in writing; providing information that must be included in the procedure; providing a timeframe in which health insurers must make a determination to protocol exception requests; providing notification requirements for such determination; providing circumstances in which health insurers must grant a protocol exception request; authorizing health insurers to request for certain medical records; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 627.42392, Florida Statutes, is amended to read:

627.42392 Prior authorization.—

(1) As used in this section, the term:

(a) "Health insurer" means an authorized insurer offering health insurance as defined in s. 624.603~~, a managed care plan as defined in s. 409.962(9),~~ or a health maintenance organization as defined in s. 641.19(12).

(b) "Urgent care situations" has the same meaning as in s. 627.42393.

(c) "Utilization review entity" means a person who reviews and determines whether to authorize or deny a prior authorization request for a health insurer.

(2) Notwithstanding any other provision of law, effective January 1, 2017, or six (6) months after the effective date of the rule adopting the prior authorization form, whichever is later, a health insurer, ~~or~~ a pharmacy benefits manager on behalf of the health insurer, or a utilization review entity, which does not provide an electronic prior authorization process for use by its contracted providers, shall only use the prior authorization form that has been approved by the Financial Services Commission for granting a prior authorization for a medical procedure, course of treatment, or prescription drug benefit. Such form may not exceed two pages in length, excluding

any instructions or guiding documentation, and must include all clinical documentation necessary for the health insurer to make a decision. At a minimum, the form must include: (1) sufficient patient information to identify the member, date of birth, full name, and Health Plan ID number; (2) provider name, address and phone number; (3) the medical procedure, course of treatment, or prescription drug benefit being requested, including the medical reason therefor, and all services tried and failed; (4) any laboratory documentation required; and (5) an attestation that all information provided is true and accurate. The form, whether in electronic or paper format, may not require information that is not necessary for the determination of medical necessity of, or coverage for, the requested medical procedure, course of treatment, or prescription drug.

(3) The Financial Services Commission in consultation with the Agency for Health Care Administration shall adopt by rule guidelines for all prior authorization forms which ensure the general uniformity of such forms.

(4) Electronic prior authorization approvals do not preclude benefit verification or medical review by the insurer under either the medical or pharmacy benefits.

(5) A health insurer, a pharmacy benefits manager on behalf of the health insurer, or a utilization review entity must provide the following information in writing or in electronic format upon request, and on a publicly accessible

Internet website:

(a) Detailed descriptions of requirements and restrictions to obtain prior authorization for coverage of a medical procedure, course of treatment, or prescription drug in clear, easily understandable language. Clinical criteria must be described in language easily understandable by a health care provider.

(b) Prior authorization forms.

(6) A health insurer, a pharmacy benefits manager on behalf of the health insurer, or a utilization review entity may not implement any new requirements or restrictions or make changes to existing requirements or restrictions to obtain prior authorization unless:

(a) The changes have been available on a publicly accessible Internet website at least 60 days before the implementation of the changes.

(b) Policyholders and health care providers who are affected by the new requirements and restrictions or changes to the requirements and restrictions are provided with a written notice of the changes at least 60 days before the changes are implemented. Such notice may be delivered electronically or by other means as agreed to by the insured or health care provider.

This subsection does not apply to expansion of health care services coverage.

(7) A health insurer, a pharmacy benefits manager on behalf of the health insurer, or a utilization review entity must authorize or deny a prior authorization request and notify the patient and the patient's treating health care provider of the decision within:

(a) Three business days of obtaining a completed prior authorization form for non-urgent care situations.

(b) Twenty-four hours of obtaining a completed prior authorization form for urgent care situations.

Section 2. Section 627.42393, Florida Statutes, is created to read:

627.42393 Fail-first protocols.—

(1) As used in this section, the term:

(a) "Fail-first protocol" means a written protocol that specifies the order in which certain medical procedure, course of treatment, or prescription drug must be used to treat an insured's condition.

(b) "Health insurer" has the same meaning as provided in s. 627.42392.

(c) "Preceding prescription drug or medical treatment" means a medical procedure, course of treatment, or prescription drug that must be used pursuant to a health insurer's fail-first protocol as a condition of coverage under a health insurance policy or a health maintenance contract to treat an insured's condition.

(d) "Protocol exception" means a determination by a health insurer that a fail-first protocol is not medically appropriate or indicated for treatment of an insured's condition and the health insurer authorizes the use of another medical procedure, course of treatment, or prescription drug prescribed or recommended by the treating health care provider for the insured's condition.

(e) "Urgent care situation" means the standard timeframe to treat the insured's injury or condition would:

1. Seriously jeopardize the insured's life, health, or ability to regain maximum function based on a prudent layperson's judgment; or

2. Subject the insured to severe pain that cannot be adequately managed, based on the opinion of the treating health care provider.

(2) A health insurer must publish on its website, and provide to an insured in writing, a procedure for an insured and health care provider to request a protocol exception. The procedure must include:

(a) A description of the manner in which an insured or health care provider may request a protocol exception.

(b) The manner and timeframe in which the health insurer is required to authorize or deny a protocol exception request or respond to an appeal to a health insurer's authorization or denial of a request.

(c) Conditions in which the protocol exception request must be granted.

(3)(a) The health insurer must authorize or deny a protocol exception request or respond to an appeal to a health insurer's authorization or denial of a request within:

1. Three business days of obtaining a completed prior authorization form for non-urgent care situations.

2. Twenty-four hours of obtaining a completed prior authorization form for urgent care situations.

(b) An authorization of the request must specify the approved medical procedure, course of treatment, or prescription drug benefits.

(c) A denial of the request must include a detailed, written explanation of the reason for the denial, the clinical rationale that supports the denial, and the procedure to appeal the health insurer's determination.

(4) A health insurer must grant a protocol exception request if:

(a) A preceding prescription drug or medical treatment is contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured;

(b) A preceding prescription drug is expected to be ineffective, based on the medical history of the insured and the clinical evidence of the characteristics of the preceding prescription drug or medical treatment;

(c) The insured has previously received a preceding prescription drug or medical treatment that is in the same pharmacologic class or has the same mechanism of action, and such drug or treatment lacked efficacy or effectiveness or adversely effected the insured; or

(d) A preceding prescription drug or medical treatment is not in the best interest of the insured because the insured's use of such drug or treatment is expected to:

1. Cause a significant barrier to the insured's adherence to or compliance with the insured's plan of care;

2. Worsen an insured's medical condition that exists simultaneously but independently with the condition under treatment; or

3. Decrease the insured's ability to achieve or maintain his or her ability to perform daily activities.

(5) The health insurer may request a copy of relevant documentation from the insured's medical record in support of a protocol exception request.

Section 3. This act shall take effect July 1, 2017.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Innovation Subcommittee

Representative Harrison offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 627.42393, Florida Statutes, is created to read:

627.42393 Fail-first protocols.—

(1) As used in this section, the term:

(a) "Fail-first protocol" means a written policy that specifies the order in which a certain medical procedure, course of treatment, or prescription drug must be used to treat an insured's condition.

(b) "Health insurer" means an authorized insurer offering health insurance as defined in s. 624.603 or a health maintenance organization as defined in s. 641.19(12).

(c) "Preceding prescription drug or medical treatment" means a medical procedure, course of treatment, or prescription drug that must be used to treat an insured's condition pursuant to a health insurer's fail-first protocol as a condition of coverage under a health insurance policy or a health maintenance contract.

(d) "Protocol exception" means a determination by a health insurer that a fail-first protocol is not medically appropriate or indicated for treatment of an insured's condition and the health insurer authorizes the use of another medical procedure, course of treatment, or prescription drug prescribed or recommended by the treating health care provider.

(e) "Urgent care situation" means the standard timeframe to treat the insured's injury or condition would, based on the opinion of a treating health care provider:

1. Seriously jeopardize the insured's life, health, or ability to regain maximum function; or

2. Subject the insured to pain that cannot be adequately managed.

(2) A health insurer must publish on its website, and provide to an insured in writing, the procedure for an insured

or health care provider to request a protocol exception. The procedure must include:

(a) A description of the manner in which an insured or health care provider may request a protocol exception.

(b) The manner and timeframe in which the health insurer is required to authorize or deny a protocol exception request or respond to an appeal of a health insurer's authorization or denial of a request.

(c) Conditions in which the protocol exception request must be granted.

(3)(a) The health insurer must authorize or deny a protocol exception request or respond to an appeal of an authorization or denial of a request within:

1. Three business days of obtaining a completed protocol exception request for a non-urgent care situation.

2. Twenty-four hours of obtaining a completed protocol exception request for an urgent care situation.

(b) An authorization of a protocol exception request must specify the approved medical procedure, course of treatment, or prescription drug benefits.

(c) A denial of a protocol exception request must include a detailed, written explanation of the reason for the denial, the clinical rationale that supports the denial, and the procedure to appeal the determination.

(4) A health insurer must grant a protocol exception request if:

(a) A preceding prescription drug or medical treatment is contraindicated or likely to cause an adverse reaction or physical or mental harm to the insured;

(b) A preceding prescription drug or medical treatment is expected to be ineffective, based on the medical history of the insured and the clinical evidence of the characteristics of the preceding prescription drug or medical treatment; or

(c) The insured has previously received a preceding prescription drug or medical treatment that is in the same pharmacologic class or has the same mechanism of action, and such drug or treatment lacked efficacy or effectiveness or adversely affected the insured.

(5) The health insurer may request a copy of relevant documentation from the insured's medical record in support of a protocol exception request.

Section 2. This act shall take effect July 1, 2017.

T I T L E A M E N D M E N T

Remove everything before the enacting clause and insert: An act relating to fail-first protocols; creating s. 627.42393, F.S.; providing definitions; requiring health insurers to provide a procedure to obtain protocol exceptions on its website

and in writing; providing information that must be included in the procedure; providing a timeframe in which health insurers must make a determination to protocol exception requests; providing notification requirements for such determination; providing circumstances in which health insurers must grant a protocol exception request; authorizing health insurers to request for certain medical records; providing an effective date

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1077 Trauma Services
SPONSOR(S): Trumbull
TIED BILLS: **IDEN./SIM. BILLS:** SB 746

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Siples	Poche
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The Department of Health (DOH) is responsible overseeing of the statewide inclusive trauma system which ensures that all injured trauma victims have access to the resources needed for care and treatment. Currently, DOH designates trauma centers in regional trauma services areas, but may designate no more than 44 trauma centers in the state, to ensure access to trauma services. Over the years, there has been extensive litigation related to DOH's apportionment of trauma centers needed in a particular trauma service area, as well as litigation related to the designation of specific hospitals as trauma centers.

HB 1077 restructures how trauma centers are designated in the state by:

- Eliminating the statewide limit on the number of trauma centers;
- Eliminating trauma service areas and trauma regions;
- Eliminating DOH's responsibility to set the standards for trauma centers or perform the necessary site surveys to ensure compliance with the standards;
- Authorizing DOH to designate a hospital as a trauma center if it holds a certificate of verification issued by a national trauma accreditation body, completes a DOH-approved application, and provides copies of certain documents submitted to and received from the national trauma accreditation body; and
- Allowing DOH to only deny an application for designation for failure to submit required application materials.

Current provisional and verified trauma centers must obtain the certificate of verification by July 1, 2022, to maintain designations. DOH may take action against a trauma center if it fails to maintain its certification or the standards required to obtain the certificate of verification. DOH may also revoke a trauma center designation if it fails to provide or withholds the information it supplied to the national trauma center accreditation body.

The bill requires DOH to coordinate the development of a state trauma plan to serve as the basis for the statewide inclusive trauma system. The plan must be updated by December 31 of every odd year.

The bill prohibits more than one trauma agency in a county. The bill grandfathers the trauma agencies that exist before July 1, 2018. The bill requires trauma agencies, which serve regional areas or counties, to submit a regional trauma plan biennially rather than every 5 years as required in existing law. The bill requires all emergency medical services providers to submit and obtain approval of their trauma transport protocol, regardless of whether it operates in conjunction with a trauma agency that has DOH-approved trauma transport protocols.

The bill will have a significant, positive indeterminate fiscal impact on DOH and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

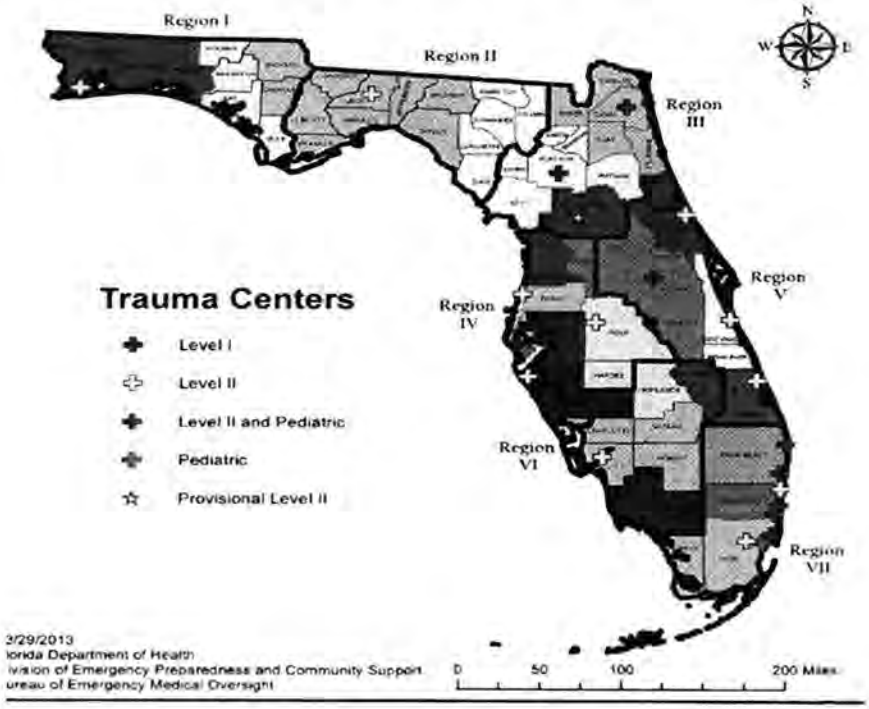
Current Situation

Florida Trauma System

The regulation of trauma centers in Florida is governed by Part II of Chapter 395, F.S., and administered by the Department of Health (DOH) by rule in chapter 64J-2, F.A.C. A trauma center is a type of hospital that provides trauma surgeons, neurosurgeons, and other surgical and non-surgical specialists and medical personnel, equipment, and facilities for immediate or follow-up treatment of severely injured patients who have sustained a single or multisystem injury due to blunt or penetrating means or burns. As part of the state trauma system plan, DOH is required to establish trauma regions which cover all geographical areas of the state and have boundaries that align with the state's seven Regional Domestic Security Task Force regions.[1] These regions may serve as the basis for the development of department-approved local or regional trauma plans.

Florida Trauma Service Areas, Agencies and Regions

Florida's trauma system is comprised of seven trauma regions and nineteen trauma service areas (TSAs). The trauma system also includes local and regional trauma agencies, but at any one time there have been four agencies in existence - the North Central Florida Trauma Agency, Hillsborough County Trauma Agency, Palm Beach Trauma Agency and Broward County Trauma Agency. The impact of trauma agencies in the current trauma system is unknown. The seven trauma regions, which match the Regional Domestic Security Task Force regions established by the Department of Law Enforcement (FDLE) pursuant to s. 943.0312(1), F.S., are illustrated below.[2]



[1] S. 395.4015, F.S.,

[2] Florida Department of Health, Division of Emergency Preparedness and Community Support, Bureau of Emergency Medical Oversight, *Trauma Centers*, March 29, 2013 (on file with Health and Human Services Committee staff).

Florida is divided into nineteen TSAs, detailed below:[3]

TRAUMA SERVICE AREAS (TSAs) IN FLORIDA	
TSA	COUNTIES IN TSA
1	Escambia, Okaloosa, Santa Rosa, Walton
2	Bay, Gulf, Holmes, Washington
3	Calhoun, Franklin, Gadsden, Jackson, Jefferson, Leon, Liberty, Madison, Taylor, Wakulla
4	Alachua, Bradford, Columbia, Dixie, Gilchrist, Hamilton, Lafayette, Levy, Putnam, Suwannee, Union
5	Baker, Clay, Duval, Nassau, St. Johns
6	Citrus, Hernando, Marion
7	Flagler, Volusia
8	Lake, Orange, Osceola, Seminole, Sumter
9	Pasco, Pinellas
10	Hillsborough
11	Hardee, Highlands, Polk
12	Brevard, Indian River
13	Desoto, Manatee, Sarasota
14	Martin, Okeechobee, St. Lucie
15	Charlotte, Glades, Hendry, Lee
16	Palm Beach
17	Collier
18	Broward
19	Dade, Monroe

For purposes of medical response times, the TSAs are designed to provide the best and fastest services to the state's population. Each TSA should have at least one Level I or Level II trauma center and there may be no more than 44 trauma centers in the state.[4] Each Level I and Level II trauma center must be capable of annually treating a minimum of 1,000 and 500 patients, respectively, with an injury severity score of 9 or greater.[5] A Level II trauma center in a county with a population of more than 500,000 must have the capacity to care for 1,000 patients per year.[6] Currently, TSA 17 (Collier) is not directly covered by a trauma center.[7]

DOH is required to apportion, by rule, the number of trauma centers needed for each TSA.[8] Additionally, DOH is required to adopt rules based on standards for verification of trauma centers based on national guidelines, to include those established by the American College of Surgeons (ACS) entitled "Hospital and Pre-hospital Resources for Optimal Care of the Injured Patient" and standards specific to pediatric trauma centers are to be developed in conjunction with the DOH Division of Children's Medical Services.[9]

[3] S. 395.402(4)(a), F.S.
[4] S. 395.402(4)(b) and (c), F.S.
[5] S. 395.402(1), F.S.
[6] Id.
[7] Florida Department of Health, *Amended Trauma Service Area Assessment*, January 6, 2016, page 23, available at www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/trauma-area-service-assessment.pdf (last visited on March 7, 2017).
[8] S. 395.402(4)(b), F.S., and Rule 64J-2.010, F.A.C.
[9] S. 395.401(2), F.S., and Rule 64J-2.011, F.A.C.

A trauma agency[10] develops a plan for its local and regional trauma services system. The plan, which must be submitted to DOH for approval, must include:

- The organizational structure of the trauma system;
- Prehospital care management guidelines for triage and transportation of trauma cases;
- The flow patterns of trauma cases and transportation system design and resources;
- The number and location of needed trauma centers based on local needs, population, and location and distribution of resources;
- Data collection regarding system operation and patient outcomes;
- Periodic performance evaluation of the trauma system and its components;
- The use of air transport services within the jurisdiction of the trauma agency;
- Public information and education about the trauma system;
- Emergency medical services communication system usage and dispatching;
- The coordination and integration between the trauma center and other acute care hospitals;
- Medical control and accountability; and
- Quality control and system evaluation.

Florida only has one regional trauma agency and three local trauma agencies. Although, by rule,[11] trauma agency boundaries are to be aligned with the Regional Domestic Security Task Force regions, none of regional or local trauma agencies have boundaries that align with these regions.[12]

Trauma Centers

A hospital may receive a designation as a Level I, Level II, pediatric, or provisional trauma center if DOH verifies that the hospital is in substantial compliance with s. 395.4025, F.S., and the relevant trauma center standards.[13] A trauma center may have more than one designation; for example, Sacred Heart Hospital in Pensacola carries both a Level II and a pediatric trauma center designation. As of July 29, 2016, the following hospitals are designated trauma centers:[14]

TRAUMA CENTER	LEVEL	COUNTY
Aventura Hospital and Medical Center	Level II	Miami-Dade
Baptist Hospital, Inc.	Level II	Escambia
Bay County Health Systems, LLC Bay Medical Center Sacred Heart Health System	Level II	Bay
Bayfront HMA Medical Center, LLC Bayfront Medical Center	Level II	Pinellas
Central Florida Regional Hospital	Level II	Seminole
Delray Medical Center, Inc.	Level I	Palm Beach
Florida Health Sciences, Inc.Tampa General Hospital	Level I	Hillsborough
Halifax Hospital Medical Center / Halifax Health	Level II	Volusia
HCA Health Services of Florida, Inc. Blake Medical Center	Level II	Manatee
HCA Health Services of Florida, Inc. Regional Medical Center Bayonet Point	Level II	Pasco
Holmes Regional Medical Center, Inc.	Level II	Brevard
Jackson South Community Hospital	Provisional Level II	Miami-Dade
Johns Hopkins All Children's Hospital, Inc.	Pediatric	Pinellas
Kendall Healthcare Group, LTD	Provisional Level I	Miami-Dade

[10] A trauma agency is a DOH-approved agency established and operated by one or more counties, or a DOH-approved entity with which one or more counties contract, for the purpose of administering an inclusive regional trauma system. (S. 395.4001(11), F.S.)
[11] Rule 64J-2.007, F.A.C.
[12] Supra, FN 7, at pg. 5.
[13] The trauma center standards are provided in DH Pamphlet 150-9 and codified in Rule 64J-2.011, F.A.C. The standards were last updated in January 2010.
[14] Florida Department of Health, *Florida Trauma Centers*, available at http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/traumacenterlisting2016.pdf (last visited on March 7, 2017).

Kendall Regional Medical Center		
Lakeland Regional Medical Center, Inc.	Level II	Polk
Lawnwood Medical Center, Inc. Lawnwood Regional Medical Center & Heart Institute	Level II	St. Lucie
Lee Memorial Health System	Level II	Lee
Marion Community Hospital, Inc. Ocala Regional Medical Center/ West Marion Community	Level II	Marion
North Broward Hospital District Broward Health Medical Center	Level I	Broward
North Broward Hospital District Broward Health North	Level II	Broward
Orlando Health, Inc.(Orlando Regional Medical Center)	Level I	Orange
Orange Park Medical Center	Provisional Level II	Clay
Osceola Regional Medical Center	Level II	Osceola
Sacred Heart Health System, Inc.	Level II / Pediatric	Escambia
Sarasota Memorial Hospital	Level II	Sarasota
Shands Jacksonville Medical Center, Inc. Shands Jacksonville/ UF Health Jacksonville	Level I	Duval
Shands Teaching Hospital and Clinics, Inc. Shands UF (Gainesville)	Level I	Alachua
South Broward Hospital District Memorial Regional Hospital	Level I	Broward
St. Joseph's Hospital, Inc.	Level II / Pediatric	Hillsborough
St. Mary's Medical Center, Inc.	Level I	Palm Beach
Tallahassee Memorial Healthcare, Inc.	Level II	Leon
The Public Health Trust of Miami-Dade County, Florida Jackson Health System Jackson Memorial Hospital / Ryder Trauma Center	Level I	Miami-Dade
Variety Children's Hospital, Inc. Nicklaus Children's Hospital	Pediatric	Dade

A provisional trauma center is a hospital that has been verified to be in substantial compliance with the requirements in s. 395.4025, is approved by DOH to operate as a provisional Level I, Level II or pediatric trauma center, and has applied to be a verified trauma center.[15] A hospital that is granted provisional status operates as a provisional trauma center for up to one year while DOH conducts an in-depth review and a provisional onsite survey prior to deciding to approve or deny verification.[16] Currently, there is one provisional Level I trauma center, Kendal Regional Medical Center in Miami, and two provisional Level II trauma centers, Jackson South Community Hospital in Miami and Orange Park Medical Center in Orange Park.

A Level I trauma center serves as a resource facility to Level II trauma centers, pediatric trauma referral-centers, and general hospitals through shared outreach, education, and quality-improvement activities.[17] A Level I trauma center must have:[18]

- A minimum of five qualified trauma surgeons, assigned to the trauma service, with at least two trauma surgeons available to provide in-hospital trauma services and backup trauma coverage 24 hours a day, when summoned.
- Twelve surgical specialties and eleven non-surgical specialties. These specialties must be available to provide in-hospital trauma services and backup trauma coverage 24 hours, when summoned.

[15] S. 395.4001(10), F.S.
[16] S. 395.4025(3), (5), and (6), F.S.
[17] S. 395.4001(6)(b), F.S.
[18] Florida Department of Health, *Trauma Center Standards*, Pamphlet 150-9, January 2010, pages 2.1-2.38, available at http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/traumacntrstandpamphlet150-9-2009rev1-14-10.pdf (last visited on March 7, 2017).

- Formal research and education programs for the enhancement of both adult and pediatric trauma care.

A Level II trauma center serves as a resource facility to general hospitals through shared outreach, education, and quality improvement activities.[19] A Level II trauma center must have:[20]

- A minimum of five qualified trauma surgeons, assigned to trauma service, with at least two trauma surgeons available to arrive promptly to the trauma center to provide trauma services within 30 minutes from inside or outside of the hospital, and backup trauma coverage 24 hours a day, when summoned.
- Nine surgical specialties and nine non-surgical specialties available to provide trauma services and arrive promptly to provide trauma coverage 24 hours a day, when summoned.

In contrast to the requirements of a Level I or Level II trauma center, a pediatric trauma center must have:[21]

- A minimum of five qualified trauma surgeons[22], assigned to the trauma service, with at least two trauma surgeons available to provide trauma services and backup trauma coverage 24-hours a day, when summoned. If the trauma medical director is not a pediatric surgeon, then at least one of the five must be a pediatric surgeon.
- Ten surgical specialties and eight non-surgical specialties available 24 hours a day to arrive promptly when summoned.
- Formal research and education programs for the enhancement of pediatric trauma care.

All trauma centers are required to submit quality indicator data to the Florida Trauma Registry.[23]

Florida Trauma System Reforms

During the 2003-2004 legislative interim, the Florida Senate's Committee on Home Defense, Public Security, and Ports conducted a study to review Florida's hospital response capacity and examine the disparity of available trauma centers across the state.[24] The study recommended adopting the borders of the seven Regional Domestic Security Task Force regions as the state trauma regions and maintaining the nineteen TSAs.[25]

Following the interim study, numerous bills were filed during the 2004 Legislative Session to amend the trauma system. Senate Bill 1762 (2004) was the only law enacted following that Session.[26] The law required the boundaries of the trauma regions to be coterminous with the boundaries of the Regional Domestic Security Task Force regions established within FDLE. The law included a grandfather clause to allow the delivery of trauma services coordinated with a trauma agency pursuant to a public or private agreement established before July 1, 2004. DOH was also directed to complete an assessment

[19] S. 395.4001(7)(b), F.S.
[20] Supra, FN 18 at pages 3.2-3.33.
[21] Id. at pages 4.2-4.36
[22] A trauma surgeon is required to be board certified or a trauma surgeon actively participating in the certification process within a specified timeframe may fill the requirement for pediatric surgery if the following conditions are met:
- The trauma medical director attests in writing that the substitute trauma surgeon has competency in the care of pediatric trauma; and
- A hospital grants privileges to the trauma surgeon to provide care to the injured child.

[23] S. 395.404(1)(a), F.S.
[24] The Florida Senate, Committee on Home Defense, Public Security, and Ports, *Hospital Response Capacity*, Report Number 2004-148, available at http://archive.flsenate.gov/data/Publications/2004/Senate/reports/interim_reports/pdf/2004-148hp.pdf (last visited on March 7, 2017).
[25] Id. at page 11.
[26] Ch. 2004-259, Laws of Fla.

of the effectiveness of the trauma system and report its findings to the Governor and Legislature by February 1, 2005. The assessment included:[27]

- Consideration of aligning trauma service areas within the trauma region boundaries as established in July 2004.
- Review of the number and level of trauma centers needed for each TSA to provide a statewide, integrated trauma system.
- Establishment of criteria for determining the number and level of trauma centers needed to serve the population in a defined TSA or region.
- Consideration of a criterion within trauma center verification standards based on the number of trauma victims served within a service area.
- Review of the Regional Domestic Security Task Force structure to determine whether integrating the trauma system planning with interagency regional emergency and disaster planning efforts is feasible and to identify any duplication of effort between the two entities.

In conducting the assessment and subsequent annual reviews, the law required DOH to consider the following:[28]

- The recommendations made as a part of the regional trauma system in plans submitted by regional trauma agencies.
- Stakeholder recommendations.
- Geographical composition of an area to ensure rapid access to trauma care.
- Historical patterns of patient referral and transfer in an area.
- Inventories of available trauma care resources, including professional medical staff.
- Population growth characteristics.
- Transportation capabilities, including ground and air transport.
- Medically appropriate ground and air travel times.
- Recommendations of the Regional Domestic Security Task Force.
- The actual number of trauma victims currently being served by each trauma center.
- Other appropriate criteria.

In February 2005, DOH submitted the report to the Legislature, which included the findings of an assessment conducted by a group of researchers from the University of South Florida and the University of Florida. The report made numerous recommendations, including a recommendation to amend the TSAs to align them with the Regional Domestic Security Task Force regions. To date, the Legislature has not amended the structure of the trauma system to incorporate the recommendations of the report.

In 2013, the Legislature passed, and the Governor signed into law, House Bill 1159 which, among other provisions, amended s. 395.4025(14), F.S., to require DOH to designate a hospital in an area with limited access to trauma center services as a Level II trauma center if the hospital provided a valid certificate of trauma center verification from the ACS.[29] An area with limited access to trauma center services is defined by the following criteria:

- The hospital is located in a TSA with a population greater than 600,000 persons but a population density of less than 225 persons per square mile;
- The hospital is located in a county with no verified trauma center; and
- The hospital is located at least 15 miles or 20 minutes travel time by ground transport from the nearest verified trauma center.

[27] S. 395.402(2), F.S.
[28] S. 395.402(3), F.S.
[29] S. 3, ch. 2013-153, Laws of Fla.

Florida Trauma System Administrative Rule Challenge and Associated Litigation

In 2011, four not-for-profit hospitals[30] challenged DOH approval of new trauma centers in Pasco,[31] Manatee,[32] and Clay[33] counties by initiating a formal challenge to Rule 64J-2.010, F.A.C. ("the Rule"). The Rule sets the number of trauma centers in the state at 42 and apportions to each TSA the number of trauma centers permitted therein.[34] The hospitals argued that, since the Rule was promulgated in 1992, substantial amendments to part II of chapter 395, F.S., effectively repealed and invalidated the Rule. In addition, the hospitals argued that 2004 amendments to s. 395.4015, F.S., required DOH to establish trauma regions coterminous with the boundaries of the seven Regional Domestic Security Task Force regions established in s. 943.0312, F.S. However, the Rule establishes 19 TSAs that are not coterminous with the seven regions. Lastly, the hospitals argued that the 2005 assessment found that it would be feasible to reduce the TSAs to match the seven regions, yet the Rule was never amended to adopt this recommendation. In July 2011, due to the rule challenge, DOH initiated a special study using national trauma experts and state and local stakeholders to develop evidenced-based guidelines to be used by DOH in the determination of new trauma center locations.

In September 2011, the Division of Administrative Hearings (DOAH) issued an administrative order finding that the Rule was invalid, as alleged. DOH appealed the ruling and the State Surgeon General suspended the special study and the planning efforts of the trauma program until the rule challenge and resulting litigation was resolved. DOH continued the trauma program's application, verification, and quality assurance activities pending the outcome of the appeal.

On November 30, 2012, the First District Court of Appeal held that the Rule was an invalid exercise of delegated legislative authority, finding:[35]

- The trauma statutes were substantially amended in 2004, yet the rule remained unchanged since 1992. As such, the rule continues to implement outdated provisions of the statutes, without implementing any of the enumerated statutes.
- DOH has not updated the rule to conform to the 2004 amendments or the 2005 Assessment.
- The rule does not implement the 2004 amendment to section 395.4015, which governs state regional trauma planning and trauma regions.
- Both the pre-and post-2004 versions of the statute require DOH to establish trauma regions that "cover all geographic areas of the state." However, the 2004 amendment requires that the trauma regions both "cover all geographical areas of the state and have boundaries that are coterminous with the boundaries of the regional domestic security task forces established under s. 943.0312."
- Because the rule continues to set forth nineteen trauma service areas that are not coterminous with the boundaries of the seven regional domestic security taskforces, it does not implement the changes in the 2004 version of section 395.4015, F.S.

Instead of appealing the decision, DOH initiated the rulemaking process to develop an inclusive, sustainable trauma system that distributes trauma centers throughout the state. The rulemaking process is discussed in detail below.

In May 2016, Shands Jacksonville Medical Center, Inc., d/b/a UF Health Jacksonville, challenged DOH's approval of Orange Park Medical Center, Inc., as a provisional Level II trauma center.[36] At the time of submission of its intent to establish a Level II trauma center in October 2015 and throughout the

[30] Bayfront Medical Center in St. Petersburg, Tampa General Hospital, St. Joseph's Hospital in Tampa, and Shands Jacksonville.
[31] Blake Medical Center in Bradenton.
[32] Regional Medical Center Bayonet Point in Hudson.
[33] Orange Park Medical Center in Orange Park.
[34] For example, Rule 64J-2.010(3), F.A.C., limits the number of trauma centers in TSA 9 (Pasco, Pinellas) to 3 and in TSA 16 (Palm Beach) to 2.
[35] See *Department of Health v. Bayfront Medical Center*, 2012 WL 5971201 (Fla.App. 1 Dist.).
[36] *Shands Jacksonville Medical Center, Inc., d/b/a UF Health Jacksonville v. Department of Health*, DOAH Case No. 16-3369 (Jan. 27, 2017).

application and review process, TSA 5, where Orange Park Medical Center is located, was allocated one trauma center for the area.[37] In 2015, DOH proposed an amendment to the rule governing the allocation of trauma centers that would have increased the number of trauma centers in TSA 5 to two, but the proposed rule was challenged and eventually withdrawn by DOH.[38] The rule had not been adopted at the time DOH approved Orange Park Medical Center to operate as a provisional Level II trauma center. The court ultimately ruled that the provisional Level II trauma center designation was awarded in error because there was not a slot available in TSA 5, and DOH relied on an unadopted rule that permitted DOH to accept a letter of intent regardless of whether there was a slot available in the affected TSA.[39]

Rulemaking Process to Amend the Rule on Apportionment of Trauma Centers

In December 2012, DOH held its first rule development workshop to gather input from the trauma system providers and partners on how the Rule could be amended to ensure an inclusive trauma system in Florida. At least 10 rulemaking workshops were held through 2013 in an effort to reach agreement, but no consensus on rule language was reached.

A negotiated rulemaking proceeding was held on January 23, 2014, to draft a mutually acceptable proposed rule addressing the appropriate distribution of trauma centers in Florida. No consensus on draft rule language was reached at the meeting. Subsequently, DOH published a Notice of Proposed Rule on February 3, 2014, which detailed substantive changes to the Rule governing the allocation of trauma centers in the TSAs. The final rule was adopted on July 29, 2014. Although a number of cases were filed challenging the validity of the rule, an administrative law judge upheld the validity of rule.[40]

In May 2015, DOH sought to amend the trauma system rules and held a workshop on the proposed changes. The workshop included a discussion of the changes, including changes to the allocation of trauma centers in two TSAs in northeast Florida and two TSAs in south Florida. An additional workshop was held in August 2015, to discuss issues related to guidelines for triage and trauma center standards. In December 2015, DOH withdrew proposed amendments to rule 64J-2.010, F.A.C., which specifically addressed the allocation of the trauma centers.

In February 2016, DOH once again published a proposed rule amendment impacting the allocation of trauma centers among the TSAs. DOH held a rule hearing in March 2016, on the proposed amendment, which again changed the allocation of trauma centers in two TSAs in northeast Florida and two TSAs in south Florida. Challenges to the rule were filed with DOAH by The Public Health Trust of Miami-Dade County, which operates the Jackson Memorial Health System, Broward County, which operates three trauma centers, and Shands Jacksonville Medical Center, Inc., d/b/a UF Health of Jacksonville. On April 12, 2016, DOH withdrew the rule; and with that withdrawal, the plaintiffs' challenges were moot.

In June and July 2016, DOH held a series of workshops in Tallahassee, West Palm Beach, and Orlando to work with stakeholders on proposed amendments to the trauma rules, again addressing the allocation of trauma centers. On September 26, 2016, DOH published proposed amendments to the trauma rule and held a rule hearing. Several hospitals filed petitions with DOAH to determine the validity of the proposed rules.[41] The primary concern of this litigation, as with previous litigation, is the allocation of trauma centers, as well as the methodology used by DOH to determine the allocation. A

[37] Rule 64J-2.010, F.A.C. TSA 5 includes Baker, Clay, Duval, Nassau, and St. John's County.
[38] See below for further discussion of the rulemaking process.
[39] Supra, FN 36.
[40] Id.
[41] According to the DOAH's website, there are active rule challenges by St. Joseph's Hospital, Inc., d/b/a St. Joseph's Hospital (Tampa); Bayfront HMA Medical Center, LLC, d/b/a Bayfront Heath – St. Petersburg; Lee Memorial Health System, d/b/a Lee Memorial Hospital; Florida Health Sciences Center, Inc., d/b/a Tampa General Hospital; and Shands Jacksonville Medical Center, Inc. d/b/a U.F. Hospital Jacksonville. Intervenors include JFK Medical Center Limited Partnership, d/b/a JFK Medical Center (Atlantis); The Public Health Trust of Miami-Dade County, Florida, d/b/a Jackson South Community Hospital; and Orange Park Medical Center, Inc. d/b/a Orange Park Medical Center (last viewed March 25, 2017).

hearing on the rule challenge was held January 10 through 13, 2017, and a recommended order has not yet been issued.

American College of Surgeons (ACS)

The ACS is a scientific and educational association of surgeons established in 1913.[42] ACS works to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. ACS does not designate trauma centers; instead, it verifies the presence of the resources listed in a book, "Resources for Optimal Care of the Injured Patient,"[43] which is recognized as a guide to develop trauma centers in the United States. ACS site surveyors use the book to review trauma centers. Currently, ACS is the only national trauma accreditation body to offer verification services.

According to ACS, the consultation and verification process helps hospitals to evaluate and improve trauma care by providing an objective, external review of a trauma center's resources and performance. A team of ACS trauma experts complete an on-site review of a hospital to assess relevant features of a trauma program, including commitment, readiness, resources, policies, patient care, and performance improvement. The fee for the initial verification consultation is $18,000,[44] and the annual fee ranges from $17,000 to $34,000 depending on the level of verification the hospital holds.[45] The certification process is voluntary and only those trauma centers that have successfully completed a verification visit are awarded a certificate.[46] ACS awards Level I through IV verifications:[47]

- A Level I facility is a regional resource trauma center that is a tertiary care facility central to the trauma system. The facility must have the capability of providing leadership and total care for every aspect of injury, from prevention through rehabilitation, and must have the depth of resources and personnel. A Level I center is usually a university-based teaching hospital due to the large number of personnel and resources required for patient care, education, and research.
- A Level II facility may not be able to provide the same comprehensive care as a Level I trauma center and more complex injuries may need to be transferred to a Level I center. The Level II trauma center is required to provide initial definitive trauma care regardless of the severity of the injury. A Level II trauma center may be an academic institution or a public or private community facility located in an urban, suburban, or rural area.
- A Level III facility is required to provide prompt assessment, resuscitation, emergency operations, and stabilization for a patient, arrange for possible transfer to another facility that can provide definitive care, and maintain transfer agreements and standardized treatment protocols. General surgeons are required in a Level III trauma center. A Level III trauma center is generally not appropriate in urban or suburban areas with adequate Level I or Level II resources.
- A Level IV facility provides advanced trauma life support before a patient is transferred to another facility for additional care. A Level IV trauma center is located in a remote area where no higher level of care is available and the trauma center serves as the de facto primary care

[42] American College of Surgeons, *History of the American College of Surgeons*, available at https://www.facs.org/about-acs/archives/acshistory (last visited on March 7, 2017).
[43] A copy of this publication is on file with Health Innovation Subcommittee staff.
[44] If the consultation is for a Level II Pediatric with a Level I or II Adult, the total fee is $21,500. Additional fees may apply if other visits are needed. The cost of the initial consultation will increase to $19,000 in July 2018. See ACS, *Fees and Invoices*, available at https://www.facs.org/quality-programs/trauma/vrc/fees (last visited on March 9, 2017).
[45] The fees will increase in July 2019, and will range from $19,000 to $38,000. See ACS, *Fees and Invoices*, available at https://www.facs.org/quality-programs/trauma/vrc/fees (last visited on March 9, 2017).
[46] As of March 28, 2014, ACS verifies trauma centers in 47 states. The hospitals with ACS verification in Florida are Blake Medical Center in Bradenton (Level II trauma center), Jackson Memorial Hospital in Miami (Level I trauma center), Kendall Regional Medical Center in Miami (Level II trauma center), Lawnwood Regional Medical Center in Fort Pierce (Level II trauma center), Ocala Regional Medical Center (Level II trauma center), Tampa General Hospital (Level I trauma center), and Tampa General Hospital Children's Medical Center (Level I and pediatric trauma center). See American College of Surgeons, *Searching for Verified Trauma Centers*, available at: https://www.facs.org/search/trauma-centers (last visited on March 7, 2017).
[47] American College of Surgeons, *Description of Hospital Levels*, available at: http://www.facs.org/trauma/hospitallevels.pdf (last visited on March 7, 2017).

provider. Such a facility may be a clinic rather than a hospital and a physician may not be available.

According to DOH, several of the trauma centers in this state have started or completed ACS verification.[48] Three trauma centers have scheduled on-site visits and seven have scheduled consultation visits for 2017.[49]

In February 2013, the ACS Committee on Trauma (COT), at the request of the State Surgeon General, conducted a system consultation and review of Florida's trauma system. The final report from ACS was released to the DOH in May 2013. The following are some of the priority recommendations contained in the report:[50]

- Appoint a new Florida Trauma System Advisory Council to provide input to policy development for the trauma system.
- Revise immediately the Florida trauma system plan to address key issues necessary for the further development of the regional and statewide trauma system.[51]
- Use the Regional Domestic Security Task Force regions as the TSA regions, which will enable the integration of trauma centers with emergency medical services, disaster preparedness, and other regional activities.
- Revise the distribution method of the trauma center fund to ensure designated trauma centers receive level-appropriate support for the "cost of readiness."
- Conduct an assessment of the current trauma system to inform decisions regarding the location and level of new trauma center designations.
- Establish a transparent, broadly accepted process for future provisional trauma center designation based upon both capacity and trauma system need.
- Impose a moratorium on any new provisional or verified trauma center designation until new processes are in place.
- Evaluate the content, implementation, and method of enforcement of trauma transport protocols to assure uniformity and efficiency of patient flow both within trauma regions as well as statewide.[52]

Trauma Transport Protocols

Emergency medical service (EMS) providers must transport trauma alert victims[53] to approved trauma centers, except as provided for in either a DOH-approved trauma transport protocol[54] of the local or regional trauma agency, or if none exists, the DOH-approved trauma transport protocol of the EMS provider. A local or regional trauma agency[55] may develop a uniform trauma transport protocol that is applicable to all licensed EMS providers operating within its geographical area.

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[48] Department of Health, *2017 Agency Bill Analysis for HB 1077*, (February 14, 2017), on file with the Health Innovation Subcommittee.
[49] Id.
[50] American College of Surgeons Committee on Trauma, Trauma Systems Evaluation and Planning Committee, *Trauma System Consultation Report-State of Florida*, Tallahassee, FL, February 2-5, 2013, available at http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/fl-report-final-5-6-13.pdf (last viewed on March 7, 2017).
[51] On March 3, 2014 and updated on April 21, 2015, the DOH released the State Trauma System Plan, a document that laid out strategic priorities for the Florida trauma system based, in part, on the priority recommendations from the ACS, and set goals to be achieved by December 31, 2016. The Plan focused on tasks associated with developing Regional Trauma Agencies statewide and establishing benchmarking and ensuring data quality for performance improvement. The Plan is available at http://www.floridahealth.gov/licensing-and-regulation/trauma-system/_documents/state-trauma-system-plan-final.pdf. (last visited on March 7, 2017).
[52] Supra, FN 50 at pages 12-14.
[53] A trauma alert victim is a person who has incurred a single or multiple injury due to blunt or penetrating means or burns, who requires immediate medical intervention or treatment, and who meets one or more of the adult or pediatric scorecard criteria established by DOH by rule. S. 395.4001(12), F.S.
[54] A trauma transport protocol is a document that describes the policies, processes, and procedures governing the dispatch of vehicles, triage, prehospital transport, and interfacility trauma transfer of trauma victims.
[55] A trauma agency is a DOH-approved agency established or operated by one or more counties, or a DOH-approved entity with which one or more counties contract to administer an inclusive regional trauma center.

In a TSA in which air ambulance services are available, the trauma transport protocol may not permit an EMS provider to transport outside the TSA. However, if there is no air ambulance service available and there is no agreement between adjacent local or regional trauma agencies, an EMS provider must transport a patient with life-threatening injuries to the most appropriate trauma center as defined by DOH-approved trauma transport protocols.

Effect of Proposed Changes

HB 1077 redesigns the process by which trauma centers are designated by repealing the statewide limitation on the number of trauma centers, eliminating the regional trauma service areas, repealing DOH's duty to set standards for designation, and requiring trauma centers seeking designation to meet standards established by a national trauma accreditation body. Under the bill, DOH is responsible for planning, coordinating, and overseeing the statewide trauma system. Those duties include:

- Designating trauma centers;
- Publishing and maintaining a state trauma plan;
- Establishing and maintaining a statewide trauma registry to monitor, evaluate, and enforce the requirements of the state trauma plan;
- Soliciting input from stakeholders and subject matter experts for the enhancement of a coordinated approach to the care of trauma victims, including the movement of a trauma victim through the system of care and the defined role of acute care hospitals; and
- Actively fostering provision of trauma care and serving as a catalyst for improvements in the outcomes and treatment of trauma patients in an inclusive trauma system.

The bill repeals a requirement that DOH coordinate with the Agency for Health Care Administration, the Board of Medicine, and the Board of Nursing to develop guidelines, standards, and rules related to an inclusive trauma system. The bill also repeals the designation of TSAs.

Designation of Trauma Centers

The bill eliminates the statewide limit on the number of trauma centers, as well as the limit on the number of trauma centers that may be located in each of the 19 TSAs.

The bill repeals the current system of designating trauma centers and establishes a new procedure. The verification process for which DOH is currently responsible will shift from DOH to a national trauma center accreditation body. A hospital seeking verification must pay for any fees associated with obtaining such verification.

Any hospital may apply for designation as a trauma center if it submits an application to DOH which includes:

- The name and physical address of the hospital;
- The name, telephone number, and e-mail address of the hospital's chief executive officer, trauma medical director, and trauma program manager. Level I trauma center applicants must include information for both adult and pediatric services;
- A list of all trauma victim-related interfacility transfer agreements with other designated trauma centers, acute care hospitals, burn centers, and rehabilitation facilities;
- A description of the hospital's trauma surge capacity in the event of a natural disaster or mass casualty event;
- A copy of the application materials submitted to the national trauma center accreditation body[56] for verification as a trauma center;

[56] The bill defines "national trauma center accreditation body" as an organization with optimal trauma center accreditation standards, approved by DOH, that publishes national guidelines for trauma center verification, has an active national trauma center verification program that has verified trauma centers in at least 25 states, and is not affiliated with any entity that is engaged in the delivery of

- A copy of reports and evaluations issued to the hospital by the national trauma center accreditation body relating to verification as a trauma center; and
- The certificate of trauma center verification.[57]

DOH will designate a hospital as a trauma center upon receipt of a completed application for designation as a trauma center and a valid certificate of trauma center verification. The designation as a Level I, Level II, or pediatric trauma center must correspond to the certificate of trauma center verification. DOH may only deny an application if it is missing any of the required information listed above.

If a hospital has received provisional or verified status as a trauma center before July 1, 2016, it may continue its current operation as such, but must obtain a certificate of trauma center verification by July 1, 2022, to maintain its designation as a trauma center by DOH.

DOH may take corrective action against a trauma center, including revocation of the designation, if the trauma center fails to maintain its certification or the standards required to obtain verification from the national trauma center accreditation body as determined by DOH, its subcontractor, or the national trauma center accreditation body. A trauma center's designation is not valid if it does not hold a certificate of trauma center verification or the standards required to obtain verification from the national trauma center verification. DOH may also revoke a trauma center's designation if it fails to provide or withholds the information it supplied to any national trauma center accreditation body, at any time.

The bill abolishes DOH's responsibility to determine the number of trauma centers needed, to conduct a review of an applicant for designation as a trauma center to determine if the hospital has the critical elements required for a trauma center, to have a review team of out of state experts[58] perform onsite visits of provisional trauma centers, to grant provisional status to a trauma center awaiting full approval, and adopt rules for the procedure and process by which it will select trauma centers.

The bill retains but relocates provisions that require a designated trauma center to accept all trauma victims regardless of race, sex, creed, or ability to pay, and prohibits a hospital or other facility from representing itself as a trauma center unless it has been designated as such by DOH.

Trauma Funding

The bill retains the eligibility of designated trauma centers to receive state funds, in equal amounts, when such funds are appropriated. However, the bill repeals a requirement that the trauma center comply with all DOH rules that ensure high quality trauma services.

State Trauma Plan

The bill requires DOH to coordinate the development of the state trauma plan, which serves as the basis for the statewide inclusive trauma system. The bill repeals requirements for the establishment of trauma regions based on the regions established by FDLE for the Regional Domestic Security Task Force. DOH is responsible for updating the state trauma system plan by December 31 of each odd numbered year.

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health care services. The accreditation body must have standards relating to facilities, trauma system integration, equipment, staffing, physician response requirements, interfacility transfer, education, and performance improvement. Currently, only the American College of Surgeons meets these criteria.

[57] The bill defines "certificate of trauma center verification" as the documentation issued by a national trauma center accreditation body that certifies a hospital's compliance with published standards for the administration of trauma care and the treatment of injured patients.

[58] Under s. 395.402(5), F.S., these out of state experts are considered agents of DOH and are exempt from civil liability for actions taken within the scope of the authority and responsibility assigned by DOH.

Trauma Agency Plans

To operate as a trauma agency, DOH must approve a trauma agency plan submitted by the entity. The bill retains many of the requirements for the trauma agency plan that exist under current law for a local and regional trauma agency plan. However, the trauma agency plan required under the bill does not require the number and location of needed trauma centers based on local needs, population, and location and distribution of resources. In addition to the requirements in current law, the trauma agency plan must include:

- An annual performance evaluation of the trauma system, rather than the nonspecific periodic evaluations are required in current law;
- A uniform trauma transport protocol or approved trauma transport protocols from each emergency medical services provider in the geographic area served by the trauma agency, that incorporates all trauma centers and resources required to implement an inclusive trauma system; and
- A list of all participating healthcare facilities, organizations, and emergency medical services providers.

DOH must approve the trauma agency application within 120 days after notifying the developer of the trauma agency plan that the plan is complete. Under the bill, a trauma agency plan is not subject to the provisions of law that govern the approval or denial of applications. Under s. 120.60, F.S., an agency must approve or deny an application for a license[59] within 90 days of receipt of a completed application; and if it is not acted on within the 90 days, the license application is approved. Since the trauma agency plan is not a license, the trauma agency plan is not considered approved without department approval.

After the initial submission of a trauma system plan, a trauma agency must submit an updated plan by July 1 of each even-numbered year, which is more often than every five years as mandated under current law. The trauma agency plan must be consistent with the state trauma plan and must coordinate trauma care on a county level.

The bill allows a coordinated delivery of trauma services established before July 1, 2018, to continue in accordance with the public and private agreements and operational procedures previously established and in accordance with law.

The bill prohibits DOH from designating more than one trauma agency per county.

Trauma Transport Protocols

The bill requires each EMS provider license applicant to submit and obtain approval of its trauma transport protocol, regardless of whether the applicable trauma agency has DOH-approved trauma transport protocols. A trauma patient must be transported to the most appropriate trauma center as defined by DOH-approved trauma transport protocols. The trauma transport protocols are no longer limited by whether there is an air ambulance available, as they are under current law.

Public records

Under current law, DOH has a public records exemption for all patient care, transport, or treatment records or reports, or patient care quality assurance proceedings, records, or reports obtained or made pursuant to its responsibility to plan, coordinate, and oversee the trauma system in this state.[60] The bill

[59] A "license" is defined as a franchise, permit, certification, registration, charter, or similar form of authorization required by law, but does not include a license required primarily for revenue purposes when issuance of the license is merely a ministerial act. S. 120.52(10), F.S.

[60] S. 395.4025(10), F.S. The sections of law covered by this provision include ss. 395.3025(4)(f), 395.401, 395.4015, 395.402, 395.403, 395.404, 395.4045, 395.405, 395.50, and 395.51, F.S.

clarifies that emergency medical service transport and treatment records obtained by DOH are exempt, but does not expand the existing public records exemption.

Rulemaking Authority

The bill repeals various grants of DOH's rulemaking authority located in the statutes relating to the trauma system. Currently, DOH has authority under s. 395.405, F.S., to adopt rules related to trauma care and therefore, the elimination of these individual, specific grants of rulemaking authority does not affect DOH's ability to adopt any necessary rules.

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Amends s. 395.40, F.S., relating to legislative findings and intent.
Section 2: Amends s. 395.4001, F.S., relating to definitions.
Section 3: Amends s. 395.401, F.S., relating to trauma services system plans; approval of trauma centers and pediatric trauma centers; procedures; renewal.
Section 4: Amends s 395.4015, F.S., relating to state regional trauma planning; trauma regions.
Section 5: Repeals s. 395.402, F.S., relating to trauma service areas; number and locations of trauma centers.
Section 6: Amends s. 395.4025, F.S., relating to trauma centers; selection; quality assurance; records.
Section 7: Amends s. 395.403, F.S., relating to reimbursement of trauma centers.
Section 8: Amends s. 395.4036, F.S., relating to trauma payments.
Section 9: Amends s. 395.404, F.S., relating to review of trauma registry data; report to central registry; confidentiality and limited release.
Section 10: Amends s. 395.4045, F.S., relating to emergency medical service providers; trauma transport protocols; transport of trauma alert victims to trauma centers; interfacility transfer.
Section 11: Amends s. 395.405, F.S., relating to rulemaking.
Section 12: Amends s. 395.50, F.S., relating to quality assurance activities of trauma agencies.
Section 13: Amends s. 320.0801, F.S.; relating to additional tax on certain vehicles.
Section 14: Amends s. 408.036, F.S.; relating to projects subject to review; exemptions.
Section 15: Amends s. 409.975, F.S.; relating to managed care plan accountability.
Section 16: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   DOH projects a reduction in expenditures of $1,348,641 through fiscal year 2022-2023, under the bill, since it will not be responsible for reviewing applications, performing site reviews, and providing a defense for litigation regarding apportionment and designation of trauma centers.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Hospitals that are designated trauma centers, as well as hospitals seeking to be designated as a trauma center, will incur costs associated with obtaining and maintaining the certificate of trauma center verification.

An unlimited number of new trauma centers may result in decreased patient volume and income for existing trauma centers or for trauma centers in close proximity to one another.

Consumers may have more choices on where to seek emergency medical services. Increased competition may affect the cost and quality of care for consumers.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides DOH sufficient rulemaking authority to implement its provisions.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to trauma services; amending s. 395.40, F.S.; providing duties of the Department of Health relating to the coordination and oversight of a statewide inclusive trauma system; deleting legislative findings and intent; amending s. 395.4001, F.S.; providing and revising definitions; amending s. 395.401, F.S.; designating statewide, rather than local and regional trauma agencies; requiring a trauma agency to submit plans to the department; revising minimum components for trauma agency plans; requiring the department to establish minimum requirements for a trauma agency to conduct annual performance evaluations and submit results therefrom to the department; prohibiting the designation of more than one trauma agency per county; amending s. 395.4015, F.S.; requiring the department to coordinate the development of a state trauma system plan; requiring periodic updates of the plan; repealing s. 395.402, F.S., relating to trauma service areas and the number and location of trauma centers; amending s. 395.4025, F.S.; requiring certain hospitals to obtain verification from a national trauma center verification body to be designated by the department; providing for contents of an application for

designation; providing criteria for designation; deleting provisions relating to the extension of provisional status of applicants for state-approved trauma centers; conforming provisions to changes made by the act; providing sanctions for withholding certain information; requiring the department to adopt rules; amending s. 395.403, F.S.; revising eligibility provisions for certain hospitals to receive funding as a trauma center from the Emergency Medical Services Trust Fund; amending s. 395.4036, F.S.; revising provisions for distribution of funds in the Emergency Medical Services Trust Fund to trauma centers; amending s. 395.404, F.S.; revising reporting requirements to the trauma registry data system maintained by the department; amending s. 395.4045, F.S.; revising requirements relating to trauma transport protocols; amending s. 395.50, F.S.; deleting a provision relating to admission of certain patient records into evidence in a civil or administrative action involving the department; amending s. 320.0801, F.S.; conforming cross-references and deleting an obsolete provision; amending ss. 395.405, 408.036, and 409.975, F.S.; conforming cross-references; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 395.40, Florida Statutes, is amended to read:

395.40 Department duties ~~Legislative findings and intent.~~—

~~(1) The Legislature finds that there has been a lack of timely access to trauma care due to the state's fragmented trauma system. This finding is based on the 1999 Trauma System Report on Timely Access to Trauma Care submitted by the department in response to the request of the Legislature.~~

~~(2) The Legislature finds that it is necessary to plan for and to establish an inclusive trauma system to meet the needs of trauma victims. An "inclusive trauma system" means a system designed to meet the needs of all injured trauma victims who require care in an acute-care setting and into which every health care provider or facility with resources to care for the injured trauma victim is incorporated. The Legislature deems the benefits of trauma care provided within an inclusive trauma system to be of vital significance to the outcome of a trauma victim.~~

~~(3) It is the intent of the Legislature to place~~ Primary responsibility for the planning, coordination, and oversight ~~establishment~~ of a statewide inclusive trauma system shall reside with the department. The department shall:

(1) Designate trauma centers in the state.

(2) Publish and update a statewide trauma plan in accordance with s. 395.4015.

(3) Establish and maintain a statewide trauma registry for monitoring, evaluating, and enforcing the requirements of the state's inclusive trauma system.

(4) Solicit input from stakeholders and subject matter experts for the enhancement of a coordinated approach to the care of trauma victims. Considerations shall include the movement of the trauma victim through the system of care and defined roles for acute care hospitals.

(5) Actively foster the provision of trauma care and serve as a catalyst for improvements in the outcomes and treatment of trauma patients in an inclusive trauma system ~~undertake the implementation of a statewide inclusive trauma system as funding is available~~.

~~(4) The Legislature finds that significant benefits are to be obtained by directing the coordination of activities by several state agencies, relative to access to trauma care and the provision of trauma care to all trauma victims. It is the intent of the Legislature that the department, the Agency for Health Care Administration, the Board of Medicine, and the Board of Nursing establish interagency teams and agreements for the development of guidelines, standards, and rules for those portions of the inclusive state trauma system within the~~

~~statutory authority of each agency. This coordinated approach will provide the necessary continuum of care for the trauma victim from injury to final hospital discharge. The department has the leadership responsibility for this activity.~~

~~(5) In addition, the agencies listed in subsection (4) should undertake to:~~

~~(a) Establish a coordinated methodology for monitoring, evaluating, and enforcing the requirements of the state's inclusive trauma system which recognizes the interests of each agency.~~

~~(b) Develop appropriate roles for trauma agencies, to assist in furthering the operation of trauma systems at the regional level. This should include issues of system evaluation as well as managed care.~~

~~(c) Develop and submit appropriate requests for waivers of federal requirements which will facilitate the delivery of trauma care.~~

~~(d) Develop criteria that will become the future basis for consultation between acute care hospitals and trauma centers on the care of trauma victims and the mandatory transfer of appropriate trauma victims to trauma centers.~~

~~(e) Develop a coordinated approach to the care of the trauma victim. This shall include the movement of the trauma victim through the system of care and the identification of medical responsibility for each phase of care for out-of-~~

~~hospital and in-hospital trauma care.~~

~~(f) Require the medical director of an emergency medical services provider to have medical accountability for a trauma victim during interfacility transfer.~~

~~(6) Furthermore, the Legislature encourages the department to actively foster the provision of trauma care and serve as a catalyst for improvements in the process and outcome of the provision of trauma care in an inclusive trauma system. Among other considerations, the department is required to:~~

~~(a) Promote the development of at least one trauma center in every trauma service area.~~

~~(b) Promote the development of a trauma agency for each trauma region.~~

~~(c) Update the state trauma system plan by February 2005 and at least annually thereafter.~~

Section 2. Section 395.4001, Florida Statutes, is amended to read:

395.4001 Definitions.—As used in this part, the term:

(1) "Agency" means the Agency for Health Care Administration.

(2) "Certificate of trauma center verification" means documentation issued by a national trauma center accreditation body that certifies a hospital's compliance with published standards for the administration of trauma care and the treatment of injured patients.

(3)~~(2)~~ "Charity care" or "uncompensated trauma care" means that portion of hospital charges reported to the agency for which there is no compensation, other than restricted or unrestricted revenues provided to a hospital by local governments or tax districts regardless of method of payment, for care provided to a patient whose family income for the 12 months preceding the determination is less than or equal to 200 percent of the federal poverty level, unless the amount of hospital charges due from the patient exceeds 25 percent of the annual family income. However, in no case shall the hospital charges for a patient whose family income exceeds four times the federal poverty level for a family of four be considered charity.

(4)~~(3)~~ "Department" means the Department of Health.

(5) "Designated" means approved by the department to operate as a Level I, Level II, or pediatric trauma center based on verification by a national trauma center accreditation body.

(6) "Inclusive trauma system" means a system designed to meet the needs of all injured trauma victims who require care in an acute-care setting and into which every health care provider or facility with the resources to care for the injured trauma victim is incorporated.

(7)~~(4)~~ "Interfacility trauma transfer" means the transfer of a trauma victim between two facilities licensed under this chapter, pursuant to this part.

(8)~~(5)~~ "International Classification Injury Severity Score" means the statistical method for computing the severity of injuries sustained by trauma patients. The International Classification Injury Severity Score shall be the methodology used by the department and trauma centers to report the severity of an injury.

(9)~~(6)~~ "Level I trauma center" means a trauma center that:

(a) ~~Has formal research and education programs for the enhancement of trauma care;~~ Is verified ~~by the department~~ to be in ~~substantial~~ compliance with Level I trauma center ~~and pediatric trauma center~~ standards~~;~~ and has been designated ~~approved~~ by the department to operate as a Level I trauma center.

(b) Serves as a resource facility to Level II trauma centers, pediatric trauma centers, and general hospitals through shared outreach, education, and quality improvement activities.

(c) Participates in an inclusive system of trauma care, including providing leadership, system evaluation, and quality improvement activities.

(10)~~(7)~~ "Level II trauma center" means a trauma center that:

(a) Is verified ~~by the department~~ to be in ~~substantial~~ compliance with Level II trauma center standards and has been designated ~~approved~~ by the department to operate as a Level II trauma center ~~or is designated pursuant to s. 395.4025(14)~~.

(b) Serves as a resource facility to general hospitals through shared outreach, education, and quality improvement activities.

(c) Participates in an inclusive system of trauma care.

(11)~~(8)~~ "Local funding contribution" means local municipal, county, or tax district funding exclusive of any patient-specific funds received pursuant to ss. 154.301-154.316, private foundation funding, or public or private grant funding of at least $150,000 received by a hospital or health care system that operates a trauma center.

(12) "National trauma center accreditation body" means an organization with optimal trauma center accreditation standards, approved by the department, that publishes national guidelines for trauma center verification, has an active national trauma center verification program that has verified trauma centers in at least 25 states, and is not affiliated with any entity that is engaged in the delivery of health care services. The accreditation body shall have standards relating to facilities, trauma system integration, equipment, staffing, physician response requirements, interfacility transfer, education, and performance improvement.

(13)~~(9)~~ "Pediatric trauma center" means a hospital that is verified ~~by the department~~ to be in ~~substantial~~ compliance with pediatric trauma center standards published by the accrediting body ~~as established by rule of the department~~ and has been

designated ~~approved~~ by the department to operate as a pediatric trauma center.

~~(10) "Provisional trauma center" means a hospital that has been verified by the department to be in substantial compliance with the requirements in s. 395.4025 and has been approved by the department to operate as a provisional Level I trauma center, Level II trauma center, or pediatric trauma center.~~

(14)~~(11)~~ "Trauma agency" means an entity established and operated by one or more counties and approved by the department ~~a department-approved agency established and operated by one or more counties, or a department-approved entity with which one or more counties contract,~~ for the purpose of administering an inclusive ~~regional~~ trauma system.

(15)~~(12)~~ "Trauma alert victim" means a person who has incurred a single or multisystem injury due to blunt or penetrating means or burns, who requires immediate medical intervention or treatment, and who meets one or more of the adult or pediatric scorecard criteria established by the department by rule.

(16)~~(13)~~ "Trauma caseload volume" means the number of trauma patients reported by designated ~~individual~~ trauma centers to the Trauma Registry and validated by the department.

(17)~~(14)~~ "Trauma center" means a hospital that has been designated ~~verified by the department to be in substantial compliance with the requirements in s. 395.4025 and has been~~

~~approved~~ by the department to operate as a Level I trauma center, Level II trauma center, or pediatric trauma center~~, or is designated by the department as a Level II trauma center pursuant to s. 395.4025(14)~~.

(18)~~(15)~~ "Trauma patient" means a person who has incurred a physical injury or wound caused by trauma and has accessed a trauma center.

(19)~~(16)~~ "Trauma scorecard" means a statewide methodology adopted by the department by rule under which a person who has incurred a traumatic injury is graded as to the severity of his or her injuries or illness and which methodology is used as the basis for making destination decisions.

(20)~~(17)~~ "Trauma transport protocol" means a document which describes the policies, processes, and procedures governing the dispatch of vehicles, the triage, prehospital transport, and interfacility trauma transfer of trauma victims.

(21)~~(18)~~ "Trauma victim" means any person who has incurred a single or multisystem injury due to blunt or penetrating means or burns and who requires immediate medical intervention or treatment.

(22) "Verified" means a hospital has received a certificate of verification issued by a national trauma center accreditation body and maintains compliance with all standards set forth as a condition of receiving the certificate.

Section 3. Section 395.401, Florida Statutes, is amended

to read:

395.401 Trauma agencies ~~services system plans; approval of trauma centers and pediatric trauma centers; procedures; renewal~~.—

(1)(a) A ~~The local and regional~~ trauma agency ~~agencies~~ shall plan, implement, and evaluate trauma services systems, in accordance with this section and ss. 395.4015, 395.404, and 395.4045, which consist of organized patterns of readiness and response services based on public and private agreements and operational procedures. ~~The department shall establish, by rule, processes and procedures for establishing a trauma agency and obtaining its approval from the department.~~

(b) A ~~The local and regional~~ trauma agency ~~agencies~~ shall develop and submit to the department the trauma agency plan ~~plans~~ for local and regional trauma services systems. The plans must include, at a minimum, the following components:

1. The organizational structure of the trauma system.

2. Prehospital care management guidelines for triage and transportation of trauma cases.

3. Flow patterns of trauma cases and transportation system design and resources, including air transportation services, provision for interfacility trauma transfer, and the prehospital transportation of trauma victims. The trauma agency shall plan for the development of a system of transportation of trauma alert victims to trauma centers where the distance or time to a

trauma center or transportation resources is in the best interest of the ~~diminish access by~~ trauma alert victims.

~~4. The number and location of needed trauma centers based on local needs, population, and location and distribution of resources.~~

4.~~5.~~ Data collection regarding system operation and patient outcome.

5.~~6.~~ Annual ~~Periodic~~ performance evaluations ~~evaluation~~ of the trauma system and its components.

6.~~7.~~ The use of air transport services within the jurisdiction of the local trauma agency.

7.~~8.~~ Public information and education about the trauma system.

8.~~9.~~ Emergency medical services communication system usage and dispatching.

9.~~10.~~ The coordination and integration between the trauma center and other acute care hospitals.

10.~~11.~~ Medical control and accountability.

11.~~12.~~ Quality control and system evaluation.

12. A uniform trauma transport protocol, or approved trauma transport protocols from each emergency medical service provider in the geographic area served by the trauma agency, that incorporates all trauma centers and other resources required to implement an inclusive trauma system.

13. List of all participating healthcare facilities,

organizations, and emergency medical providers.

(c) The department shall receive applications ~~plans~~ for the implementation of inclusive trauma systems from trauma agencies. The application shall be limited to the trauma agency plan and information about the plan's developer. The department shall ~~may~~ approve or deny ~~not approve~~ trauma agency plans based on the conformance of the plan with this section and ss. 395.4015, 395.404, and 395.4045 and the rules and definitions adopted by the department pursuant to those sections. Notwithstanding s. 120.60, the department shall approve or deny the applications ~~disapprove the plans~~ within 120 days after ~~the date the plans are submitted to~~ the department notifies the developer of the trauma agency plan that the plan is complete. For the purposes of s. 120.60, the plans do not constitute licensure and are not considered approved in the absence of department approval. ~~The department shall, by rule, provide an application process for establishing a trauma agency. The application must, at a minimum, provide requirements for the trauma agency plan submitted for review, a process for reviewing the application for a trauma agency, a process for reviewing the trauma transport protocols for the trauma agency, and a process for reviewing the staffing requirements for the agency.~~

(d) The department shall, by rule, establish minimum requirements for a trauma agency to conduct an annual performance evaluation and submit the results to the department.

(e)~~(d)~~ A trauma agency may ~~shall~~ not operate unless the department has approved the local or regional trauma services system plan of the agency.

~~(e) The department may grant an exception to a portion of the rules adopted pursuant to this section or s. 395.4015 if the local or regional trauma agency proves that, as defined in the rules, compliance with that requirement would not be in the best interest of the persons served within the affected local or regional trauma area.~~

~~(f) A local or regional trauma agency may implement a trauma care system only if the system meets the minimum standards set forth in the rules for implementation established by the department and if the plan has been submitted to, and approved by, the department. At least 60 days before the local or regional trauma agency submits the plan for the trauma care system to the department, the local or regional trauma agency shall hold a public hearing and give adequate notice of the public hearing to all hospitals and other interested parties in the area to be included in the proposed system.~~

~~(g) Local or regional trauma agencies may enter into contracts for the purpose of implementing the local or regional plan. If local or regional agencies contract with hospitals for trauma services, such agencies must contract only with hospitals which are verified trauma centers.~~

(f)~~(h)~~ A ~~Local or regional~~ trauma agency ~~agencies~~

providing service for more than one county shall, as part of their formation, establish interlocal agreements between or among the several counties in the trauma ~~regional~~ system.

(g) ~~(i)~~ This section does not restrict the authority of a health care facility to provide service for which it has received a license pursuant to this chapter.

~~(j) Any hospital which is verified as a trauma center shall accept all trauma victims that are appropriate for the facility regardless of race, sex, creed, or ability to pay.~~

~~(k) It is unlawful for any hospital or other facility to hold itself out as a trauma center unless it has been so verified or designated pursuant to s. 395.4025(14).~~

(h) ~~(l)~~ A county~~, upon the recommendations of the local or regional trauma agency,~~ may adopt ordinances governing the transport of a patient who is receiving care in the field from prehospital emergency medical personnel when the patient meets specific criteria for trauma, burn, or pediatric centers adopted by a ~~the local or regional~~ trauma agency. These ordinances must be consistent with s. 395.4045, ordinances adopted under s. 401.25(6), and a ~~the local or regional~~ trauma agency ~~system~~ plan and, to the furthest possible extent, must ensure that individual patients receive appropriate medical care while protecting the interests of the community at large by making maximum use of available emergency medical care resources.

(i) ~~(m)~~ A trauma agency plan shall be ~~The local or regional~~

~~trauma agency shall,~~ consistent with the state ~~regional~~ trauma system plan, coordinate trauma care at the county level, and ~~otherwise~~ facilitate arrangements necessary to develop an inclusive ~~a~~ trauma ~~services~~ system.

(j)~~(n)~~ After the submission of the initial trauma system plan, each trauma agency shall, every even-numbered ~~5th~~ year, submit to the department by July 1 ~~for approval~~ an updated plan that identifies the changes, if any, to be made in the plan ~~regional trauma system~~.

(k)~~(o)~~ This section does not preclude a ~~local or regional~~ trauma agency from adopting trauma care system protocols ~~standards~~.

(2) The delivery of trauma services in coordination with a trauma agency established before July 1, 2018, may continue in accordance with the public and private agreements and operational procedures entered into as provided in this section.

(3) The department shall designate only one trauma agency in any single county.

~~(2) The department shall 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 Injured Patient" and published appendices thereto. Standards specific to pediatric trauma referral centers shall be developed in conjunction with Children's Medical Services and adopted by~~

~~rule of the department.~~

~~(3) The department may withdraw local or regional agency authority, prescribe corrective actions, or use the administrative remedies as provided in s. 395.1065 for the violation of any provision of this section and ss. 395.4015, 395.402, 395.4025, 395.403, 395.404, and 395.4045 or rules adopted thereunder. All amounts collected pursuant to this subsection shall be deposited into the Emergency Medical Services Trust Fund provided in s. 401.34.~~

Section 4. Section 395.4015, Florida Statutes, is amended to read:

395.4015 State ~~regional~~ trauma planning~~; trauma regions~~.—

(1) The department shall coordinate the development of ~~establish~~ a state trauma system plan. ~~As part of the state trauma system plan, the department shall establish trauma regions that cover all geographical areas of the state and have boundaries that are coterminous with the boundaries of the regional domestic security task forces established under s. 943.0312. These regions may serve as the basis for the development of department-approved local or regional trauma plans. However, the delivery of trauma services by or in coordination with a trauma agency established before July 1, 2004, may continue in accordance with public and private agreements and operational procedures entered into as provided in s. 395.401.~~

(2) The department shall update the state trauma system plan by December 31 of each odd numbered year. The statewide trauma system plan shall serve ~~consider the advice and recommendations of any affected local or regional trauma agency in developing the state trauma system plan.~~

~~(3) The department shall use the state trauma system plan~~ as the basis for establishing a statewide inclusive trauma system.

Section 5. Section 395.402, Florida Statutes, is repealed.

Section 6. Section 395.4025, Florida Statutes, is amended to read:

395.4025 Trauma centers; selection; quality assurance; records.—

(1) A hospital that has received provisional or verified status as a trauma center from the department before July 1, 2016 shall have until July 1, 2022, to obtain verification from a national trauma center accreditation body and upon presentation of such verification shall be designated by the department. Notwithstanding any other law or s. 120.569, a hospital that has received provisional or verified status as a trauma center from the department before July 1, 2016, shall be approved to operate in accordance with this section.

(2) The department shall accept an application for the designation of a hospital as a trauma center which contains the following information:

(a) The name and physical address of the hospital seeking designation as a trauma center.

(b) The name, telephone number, and e-mail address of the hospital's chief executive officer, trauma medical director, and trauma program manager. Level I trauma centers shall include information for both adult and pediatric services.

(c) A list of all trauma victim-related interfacility transfer agreements with other designated trauma centers, acute care hospitals, burn centers, and rehabilitation facilities.

(d) A description of the hospital's trauma surge capacity in the event of a natural disaster or mass causality event.

(e) A copy of application materials submitted by the hospital to the national trauma center accreditation body for verification as a trauma center.

(f) A copy of reports and evaluations issued to the hospital by the national trauma center accreditation body relating to verification as a trauma center.

(g) The certificate of trauma center verification.

(3) The application for designation as a trauma center may only be denied by the department if information is missing.

(4) The department shall designate a hospital as a trauma center upon receipt of:

(a) A completed application for designation as a trauma center.

(b) A valid certificate of trauma center verification.

(5) The department's designation of a hospital as a Level I, Level II, or pediatric trauma center shall correspond with the certificate of trauma center verification.

(6) The designation of a hospital as a trauma center is valid only when the hospital holds a certificate of trauma center verification and maintains the standards required to obtain verification from the national trauma center accreditation body. If a trauma center fails to maintain its certification or maintain such standards as determined by the department, its subcontractor, or national trauma center accreditation body, the department may take corrective actions, including revocation of trauma center designation.

~~(1) For purposes of developing a system of trauma centers, the department shall use the 19 trauma service areas established in s. 395.402. Within each service area and based on the state trauma system plan, the local or regional trauma services system plan, and recommendations of the local or regional trauma agency, the department shall establish the approximate number of trauma centers needed to ensure reasonable access to high-quality trauma services. The department shall select those hospitals that are to be recognized as trauma centers.~~

~~(2)(a) The department shall annually notify each acute care general hospital and each local and each regional trauma agency in the state that the department is accepting letters of intent from hospitals that are interested in becoming trauma~~

~~centers. In order to be considered by the department, a hospital that operates within the geographic area of a local or regional trauma agency must certify that its intent to operate as a trauma center is consistent with the trauma services plan of the local or regional trauma agency, as approved by the department, if such agency exists. Letters of intent must be postmarked no later than midnight October 1.~~

~~(b) By October 15, the department shall send to all hospitals that submitted a letter of intent an application package that will provide the hospitals with instructions for submitting information to the department for selection as a trauma center. The standards for trauma centers provided for in s. 395.401(2), as adopted by rule of the department, shall serve as the basis for these instructions.~~

~~(c) In order to be considered by the department, applications from those hospitals seeking selection as trauma centers, including those current verified trauma centers that seek a change or redesignation in approval status as a trauma center, must be received by the department no later than the close of business on April 1. The department shall conduct a provisional review of each application for the purpose of determining that the hospital's application is complete and that the hospital has the critical elements required for a trauma center. This critical review will be based on trauma center standards and shall include, but not be limited to, a review of~~

~~whether the hospital has:~~

~~1. Equipment and physical facilities necessary to provide trauma services.~~

~~2. Personnel in sufficient numbers and with proper qualifications to provide trauma services.~~

~~3. An effective quality assurance process.~~

~~4. Submitted written confirmation by the local or regional trauma agency that the hospital applying to become a trauma center is consistent with the plan of the local or regional trauma agency, as approved by the department, if such agency exists.~~

~~(d)1. Notwithstanding other provisions in this section, the department may grant up to an additional 18 months to a hospital applicant that is unable to meet all requirements as provided in paragraph (c) at the time of application if the number of applicants in the service area in which the applicant is located is equal to or less than the service area allocation, as provided by rule of the department. An applicant that is granted additional time pursuant to this paragraph shall submit a plan for departmental approval which includes timelines and activities that the applicant proposes to complete in order to meet application requirements. Any applicant that demonstrates an ongoing effort to complete the activities within the timelines outlined in the plan shall be included in the number of trauma centers at such time that the department has conducted~~

~~a provisional review of the application and has determined that the application is complete and that the hospital has the critical elements required for a trauma center.~~

~~2. Timeframes provided in subsections (1)-(8) shall be stayed until the department determines that the application is complete and that the hospital has the critical elements required for a trauma center.~~

~~(3) After April 30, any hospital that submitted an application found acceptable by the department based on provisional review shall be eligible to operate as a provisional trauma center.~~

~~(4) Between May 1 and October 1 of each year, the department shall conduct an in-depth evaluation of all applications found acceptable in the provisional review. The applications shall be evaluated against criteria enumerated in the application packages as provided to the hospitals by the department.~~

~~(5) Beginning October 1 of each year and ending no later than June 1 of the following year, a review team of out-of-state experts assembled by the department shall make onsite visits to all provisional trauma centers. The department shall develop a survey instrument to be used by the expert team of reviewers. The instrument shall include objective criteria and guidelines for reviewers based on existing trauma center standards such that all trauma centers are assessed equally. The survey~~

~~instrument shall also include a uniform rating system that will be used by reviewers to indicate the degree of compliance of each trauma center with specific standards, and to indicate the quality of care provided by each trauma center as determined through an audit of patient charts. In addition, hospitals being considered as provisional trauma centers shall meet all the requirements of a trauma center and shall be located in a trauma service area that has a need for such a trauma center.~~

~~(6) Based on recommendations from the review team, the department shall select trauma centers by July 1. An applicant for designation as a trauma center may request an extension of its provisional status if it submits a corrective action plan to the department. The corrective action plan must demonstrate the ability of the applicant to correct deficiencies noted during the applicant's onsite review conducted by the department between the previous October 1 and June 1. The department may extend the provisional status of an applicant for designation as a trauma center through December 31 if the applicant provides a corrective action plan acceptable to the department. The department or a team of out-of-state experts assembled by the department shall conduct an onsite visit on or before November 1 to confirm that the deficiencies have been corrected. The provisional trauma center is responsible for all costs associated with the onsite visit in a manner prescribed by rule of the department. By January 1, the department must approve or~~

~~deny the application of any provisional applicant granted an extension. Each trauma center shall be granted a 7-year approval period during which time it must continue to maintain trauma center standards and acceptable patient outcomes as determined by department rule. An approval, unless sooner suspended or revoked, automatically expires 7 years after the date of issuance and is renewable upon application for renewal as prescribed by rule of the department.~~

~~(7) Any hospital that wishes to protest a decision made by the department based on the department's preliminary or in-depth review of applications or on the recommendations of the site visit review team pursuant to this section shall proceed as provided in chapter 120. Hearings held under this subsection shall be conducted in the same manner as provided in ss. 120.569 and 120.57. Cases filed under chapter 120 may combine all disputes between parties.~~

(7)~~(8)~~ Notwithstanding any provision of chapter 381, a hospital licensed under ss. 395.001-395.3025 that operates a trauma center may not terminate or substantially reduce the availability of trauma service without providing at least 180 days' notice of its intent to terminate such service. Such notice shall be given to the department, to all affected ~~local or regional~~ trauma agencies, and to all trauma centers, hospitals, and emergency medical service providers in the trauma service area. ~~The department shall adopt by rule the procedures~~

~~and process for notification, duration, and explanation of the termination of trauma services.~~

(8)~~(9)~~ Except as otherwise provided in this subsection, the department or its agent may collect trauma care and registry data, as prescribed by rule of the department, from trauma centers, hospitals, emergency medical service providers, ~~local or regional~~ trauma agencies, or medical examiners for the purposes of evaluating trauma system effectiveness, ensuring compliance with the standards, and monitoring patient outcomes. A trauma center, hospital, emergency medical service provider, medical examiner, or ~~local~~ trauma agency ~~or regional trauma agency~~, or a panel or committee assembled by such an agency under s. 395.50(1), may, but is not required to, disclose to the department patient care quality assurance proceedings, records, or reports. However, the department may require a ~~local~~ trauma agency ~~or a regional trauma agency~~, or a panel or committee assembled by such an agency, to disclose to the department patient care quality assurance proceedings, records, or reports that the department needs solely to conduct quality assurance activities under s. 395.4015, or to ensure compliance with the quality assurance component of a ~~the~~ trauma agency ~~agency's~~ plan approved under s. 395.401. The patient care quality assurance proceedings, records, or reports that the department may require for these purposes include, but are not limited to, the structure, processes, and procedures of the agency's quality

assurance activities, and any recommendation for improving or modifying the overall trauma system, if the identity of a trauma center, hospital, emergency medical service provider, medical examiner, or an individual who provides trauma services is not disclosed.

~~(10) Out-of-state experts assembled by the department to conduct onsite visits are agents of the department for the purposes of s. 395.3025. An out-of-state expert who acts as an agent of the department under this subsection is not liable for any civil damages as a result of actions taken by him or her, unless he or she is found to be operating outside the scope of the authority and responsibility assigned by the department.~~

(9)~~(11)~~ Onsite visits by the department or its agent may be conducted at any reasonable time and may include but not be limited to a review of records in the possession of trauma centers, hospitals, emergency medical service providers, local or regional trauma agencies, or medical examiners regarding the care, transport, treatment, or examination of trauma patients.

(10)~~(12)~~ Patient care, transport, or treatment records or reports, or patient care quality assurance proceedings, records, or reports obtained or made pursuant to this section, s. 395.3025(4)(f), s. 395.401, s. 395.4015, ~~s. 395.402,~~ s. 395.403, s. 395.404, s. 395.4045, s. 395.405, s. 395.50, or s. 395.51 must be held confidential by the department or its agent and are exempt from the provisions of s. 119.07(1). Patient care quality

assurance proceedings, records, or reports obtained or made pursuant to these sections are not subject to discovery or introduction into evidence in any civil or administrative action.

(11) A hospital that is designated as a trauma center shall accept all trauma victims that are appropriate for the facility regardless of race, sex, creed, or ability to pay.

(12) A hospital or other facility may not hold itself out as a trauma center unless it has been so designated by the department.

(13) Information supplied by a hospital to any national trauma center accreditation body, at any time, may not be withheld from the department. The department may revoke a hospital's designation as a trauma center for failure to provide such information to the department.

(14) The department shall adopt rules to implement this section.

~~(13) The department may adopt, by rule, the procedures and process by which it will select trauma centers. Such procedures and process must be used in annually selecting trauma centers and must be consistent with subsections (1)-(8) except in those situations in which it is in the best interest of, and mutually agreed to by, all applicants within a service area and the department to reduce the timeframes.~~

~~(14) Notwithstanding the procedures established pursuant~~

~~to subsections (1) through (13), hospitals located in areas with limited access to trauma center services shall be designated by the department as Level II trauma centers based on documentation of a valid certificate of trauma center verification from the American College of Surgeons. Areas with limited access to trauma center services are defined by the following criteria:~~

~~(a) The hospital is located in a trauma service area with a population greater than 600,000 persons but a population density of less than 225 persons per square mile;~~

~~(b) The hospital is located in a county with no verified trauma center; and~~

~~(c) The hospital is located at least 15 miles or 20 minutes travel time by ground transport from the nearest verified trauma center.~~

Section 7. Section 395.403, Florida Statutes, is amended to read:

395.403 Reimbursement of trauma centers.—

(1) All trauma centers shall be considered eligible to receive state funding when state funds are specifically appropriated for state ~~state-sponsored~~ trauma centers in the General Appropriations Act. ~~Effective July 1, 2010,~~ The department shall make payments from the Emergency Medical Services Trust Fund under s. 20.435 to the trauma centers. Payments shall be in equal amounts for the trauma centers designated ~~approved~~ by the department as of July 1 of the fiscal

year in which funding is appropriated. In the event a trauma center does not maintain its status as a trauma center for any state fiscal year in which such funding is appropriated, the trauma center shall repay the state for the portion of the year during which it was not a trauma center.

(2) Trauma centers eligible to receive distributions from the Emergency Medical Services Trust Fund under s. 20.435 in accordance with subsection (1) may request that such funds be used as intergovernmental transfer funds in the Medicaid program.

(3) In order to receive state funding, a hospital shall be a trauma center and shall:

~~(a) Agree to conform to all departmental requirements as provided by rule to assure high-quality trauma services.~~

(a)~~(b)~~ Agree to provide information concerning the provision of trauma services to the department, in a form and manner prescribed by rule of the department.

(b)~~(c)~~ Agree to accept all trauma patients, regardless of ability to pay, on a functional space-available basis.

(4) A trauma center that fails to comply with any of the conditions listed in subsection (3) may ~~or the applicable rules of the department shall~~ not receive payments under this section for the period in which it was not in compliance.

Section 8. Section 395.4036, Florida Statutes, is amended to read:

395.4036 Trauma payments.—

(1) ~~Recognizing the Legislature's stated intent to provide financial support to the current verified trauma centers and to provide incentives for the establishment of additional trauma centers as part of a system of state-sponsored trauma centers,~~ The department shall expend ~~utilize~~ funds collected under s. 318.18 and deposited into the Emergency Medical Services Trust Fund of the department to ensure the availability and accessibility of trauma services throughout the state as provided in this subsection.

(a) Funds collected under s. 318.18(15) shall be distributed as follows:

1. Twenty percent of the total funds collected during the state fiscal year shall be distributed to ~~verified~~ trauma centers that have a local funding contribution as of December 31. Distribution of funds under this subparagraph shall be based on trauma caseload volume for the most recent calendar year available.

2. Forty percent of the total funds collected shall be distributed to ~~verified~~ trauma centers based on trauma caseload volume for the most recent calendar year available. The determination of caseload volume for distribution of funds under this subparagraph shall be based on the department's Trauma Registry data.

3. Forty percent of the total funds collected shall be

distributed to ~~verified~~ trauma centers based on severity of trauma patients for the most recent calendar year available. The determination of severity for distribution of funds under this subparagraph shall be based on the department's International Classification Injury Severity Scores or another statistically valid and scientifically accepted method of stratifying a trauma patient's severity of injury, risk of mortality, and resource consumption as adopted by the department by rule, weighted based on the costs associated with and incurred by the trauma center in treating trauma patients. The weighting of scores shall be established by the department by rule.

(b) Funds collected under s. 318.18(5)(c) and (20) shall be distributed as follows:

1. Thirty percent of the total funds collected shall be distributed to Level II trauma centers operated by a public hospital governed by an elected board of directors as of December 31, 2008.

2. Thirty-five percent of the total funds collected shall be distributed to ~~verified~~ trauma centers based on trauma caseload volume for the most recent calendar year available. The determination of caseload volume for distribution of funds under this subparagraph shall be based on the department's Trauma Registry data.

3. Thirty-five percent of the total funds collected shall be distributed to ~~verified~~ trauma centers based on severity of

trauma patients for the most recent calendar year available. The determination of severity for distribution of funds under this subparagraph shall be based on the department's International Classification Injury Severity Scores or another statistically valid and scientifically accepted method of stratifying a trauma patient's severity of injury, risk of mortality, and resource consumption as adopted by the department by rule, weighted based on the costs associated with and incurred by the trauma center in treating trauma patients. The weighting of scores shall be established by the department by rule.

(2) Funds deposited in the department's Emergency Medical Services Trust Fund for ~~verified~~ trauma centers may be used to maximize the receipt of federal funds that may be available for such trauma centers. Notwithstanding this section and s. 318.14, distributions to trauma centers may be adjusted in a manner to ensure that total payments to trauma centers represent the same proportional allocation as set forth in this section and s. 318.14. For purposes of this section and s. 318.14, total funds distributed to trauma centers may include revenue from the Emergency Medical Services Trust Fund and federal funds for which revenue from the Administrative Trust Fund is used to meet state or local matching requirements. Funds collected under ss. 318.14 and 318.18 and deposited in the Emergency Medical Services Trust Fund of the department shall be distributed to trauma centers on a quarterly basis using the most recent

calendar year data available. Such data shall not be used for more than four quarterly distributions unless there are extenuating circumstances as determined by the department, in which case the most recent calendar year data available shall continue to be used and appropriate adjustments shall be made as soon as the more recent data becomes available.

(3)(a) Any trauma center not subject to audit pursuant to s. 215.97 shall annually attest, under penalties of perjury, that such proceeds were used in compliance with law. The annual attestation shall be made in a form and format determined by the department. The annual attestation shall be submitted to the department for review within 9 months after the end of the organization's fiscal year.

(b) Any trauma center subject to audit pursuant to s. 215.97 shall submit an audit report in accordance with rules adopted by the Auditor General.

(4) The department, working with the Agency for Health Care Administration, shall maximize resources for trauma services wherever possible.

Section 9. Section 395.404, Florida Statutes, is amended to read:

395.404 Review of trauma registry data; report to central registry; confidentiality and limited release.—

(1)(a) ~~Each~~ Trauma centers and ~~center shall furnish, and, upon request of the department, all~~ acute care hospitals shall

furnish ~~for department review~~ trauma registry data as prescribed by rule of the department for the purpose of monitoring patient outcomes ~~outcome~~ and ensuring compliance with the standards of verification published by a national trauma center accreditation body ~~approval~~.

(b) Trauma registry data obtained pursuant to this subsection and emergency medical service transport and treatment records of trauma alert victims obtained pursuant to s. 401.30 are confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution. However, the department may provide such trauma registry data to the person, trauma center, hospital, emergency medical service provider, ~~local or regional~~ trauma agency, medical examiner, or other entity from which the data were obtained. The department may also use or provide trauma registry data for purposes of research in accordance with the provisions of chapter 405.

(2) Each trauma center~~, pediatric trauma center,~~ and acute care hospital shall report to the department's brain and spinal cord injury central registry, consistent with the procedures and timeframes of s. 381.74, any person who has a moderate-to-severe brain or spinal cord injury, and shall include in the report the name, age, residence, and type of disability of the individual and any additional information that the department finds necessary.

Section 10. Section 395.4045, Florida Statutes, is amended

to read:

395.4045 Emergency medical service providers; trauma transport protocols; transport of trauma alert victims to trauma centers; interfacility transfer.—

(1) Each emergency medical services provider licensed under chapter 401 shall transport trauma alert victims to hospitals designated ~~approved~~ as trauma centers, except as may be provided for either in the department-approved trauma transport protocol of the trauma agency for the geographical area in which the emergency medical services licensee provides services or, if no such department-approved trauma transport protocol is in effect, as provided for in a department-approved provider's trauma transport protocol.

(2) A trauma agency may develop a uniform trauma transport protocol that is applicable to the emergency medical services licensees providing services within the geographical boundaries of a ~~the~~ trauma agency. Development of a uniform trauma protocol by a trauma agency shall be through consultation with interested parties, including, but not limited to, each approved trauma center; physicians specializing in trauma care, emergency care, and surgery in the geographical area served by a trauma agency ~~region~~; each trauma system administrator in the geographical area served by a trauma agency ~~region~~; each emergency medical service provider in the region licensed under chapter 401, and such providers' respective medical directors.

(3) Trauma alert victims shall be identified through the use of a trauma scoring system~~, including adult and pediatric assessment~~ as specified in rule of the department. The rule shall also include the requirements of licensed emergency medical services providers for performing and documenting these assessments.

(4) The department shall specify by rule the subjects and the minimum criteria related to prehospital trauma transport, trauma center or hospital destination determinations, and interfacility trauma transfer transport by an emergency medical services provider to be included in a trauma agency's or emergency medical service provider's trauma transport protocol and shall approve or disapprove each such protocol. ~~Trauma transport protocol rules pertaining to the air transportation of trauma victims shall be consistent with, but not limited to, applicable Federal Aviation Administration regulation.~~ Emergency medical services licensees and trauma agencies shall be subject to monitoring by the department, under ss. 395.401(2) ~~395.401(3)~~ and 401.31(1) for compliance with requirements, as applicable, regarding trauma transport protocols and the transport of trauma victims.

(5) ~~If there is no department-approved trauma agency trauma transport protocol for the geographical area in which the emergency medical services license applicant intends to provide services, as provided for in subsection (1),~~ Each applicant for

licensure as an emergency medical services provider, under chapter 401, must submit and obtain department approval of a trauma transport protocol prior to the department granting a license. The department shall prescribe by rule the submission and approval process for an applicant's trauma transport protocols ~~whether the applicant will be using a trauma agency's or its own trauma transport protocol~~.

(6) ~~If an air ambulance service is available in the trauma service area in which an emergency medical service provider is located, trauma transport protocols shall not provide for transport outside of the trauma service area unless otherwise provided for by written mutual agreement. If air ambulance service is not available and there is no agreement for interagency transport of trauma patients between two adjacent local or regional trauma agencies, both of which include at least one approved trauma center, then the transport of~~ A trauma patient with an immediately life-threatening condition shall be transported to the most appropriate trauma center as defined pursuant to trauma transport protocols approved by the department. ~~The provisions of this subsection shall apply only to those counties with a population in excess of 1 million residents.~~

(7) Prior to an interfacility trauma transfer, the emergency medical services provider's medical director or his or her designee must agree, pursuant to protocols and procedures in

the emergency medical services provider's trauma transport protocol, that the staff of the transport vehicle has the medical skills, equipment, and resources to provide anticipated patient care as proposed by the transferring physician. The emergency medical services provider's medical director or his or her designee may require appropriate staffing, equipment, and resources to ensure proper patient care and safety during transfer.

(8) The department shall adopt and enforce all rules necessary to administer this section. The department shall adopt and enforce rules to specify the submission and approval process for trauma transport protocols or modifications to trauma transport protocols by ~~trauma agencies and~~ licensed emergency medical services providers.

Section 11. Section 395.405, Florida Statutes, is amended to read:

395.405 Rulemaking.—The department shall adopt and enforce all rules necessary to administer ss. 395.401, 395.4015, ~~395.402,~~ 395.4025, 395.403, 395.404, and 395.4045.

Section 12. Section 395.50, Florida Statutes, is amended to read:

395.50 Quality assurance activities of trauma agencies.—

(1) As used in this section, the term "entity" means a ~~local~~ trauma agency ~~or a regional trauma agency~~ that performs quality assurance activities, or a panel or committee assembled

to assist a ~~local~~ trauma agency ~~or a regional trauma agency~~ in performing quality assurance activities in accordance with the trauma agency ~~a~~ plan ~~approved under s. 395.401~~.

(2) A hospital or an emergency medical services provider shall disclose records and reports of patient care, transport, and treatment to an entity, and a hospital or an emergency medical services provider may disclose to an entity and to one another its own quality assurance proceedings, records, or reports. However, this section does not require a hospital or an emergency medical services provider to disclose to an entity its own quality assurance proceedings, records, or reports prepared under s. 395.0191, s. 395.0193, s. 401.265, s. 401.30, s. 401.425, or s. 766.101.

(3) A ~~local~~ trauma agency ~~or regional trauma agency~~ may assemble a panel or committee to assist in performing the tasks authorized by an approved plan under s. 395.401.

(4) The investigations, proceedings, records, and reports obtained or made by any entity under this section are not subject to discovery or introduction into evidence in a civil or administrative action that arises out of a matter that is the subject of evaluation and review by the entity, and a person who attends a meeting of the entity may not testify in any such civil or administrative action as to any evidence or other matter produced or presented during the proceedings of the entity or as to any findings, recommendations, evaluations,

opinions, or other actions of the entity or any members thereof. However, information, documents, or records provided to the entity from a source external to the entity are not immune from discovery or use in a civil or administrative action, and a person who is a member of the entity may testify in such action as to matters within his or her knowledge, but may not be asked about his or her testimony before the entity or about information obtained from or opinions formed by him or her as a result of participating in activities conducted by the entity.

(5)(a) There is no monetary liability on the part of, and no cause of action arises against, any person, including a person who acts as a witness, incident reporter to, or investigator for an entity for any act or proceeding undertaken or performed within the scope of the functions of the entity if the action is taken without intentional fraud or malice.

(b) The provisions of this section do not supersede the provisions of s. 768.28.

(6) Except as provided in subsection (4), this section does not confer immunity from liability on a person for services performed outside his or her capacity as a member of an entity or upon a person who acts as a witness for, incident reporter to, or investigator for the entity for any act or proceeding undertaken or performed outside the scope of the functions of the entity.

(7) If the defendant prevails in an action brought by a

person against a person who initiated, participated in, was a witness in, or conducted any review as authorized by this section, the court shall award reasonable attorney's fees and costs to the defendant.

~~(8) Nothing in this section, ss. 395.4001-395.405, or s. 395.51 prohibits admitting into evidence patient care, transport, or treatment records or reports, or records or reports of the department in any civil or administrative action brought by or involving the department, excluding the name, residence or business address, telephone number, social security or other identifying number, or photograph of any person or the spouse, relative, or guardian of such person or other patient-specific information that otherwise identifies the patient, either directly or indirectly.~~

Section 13. Section 320.0801, Florida Statutes, is amended to read:

320.0801 Additional license tax on certain vehicles.—

(1) In addition to the license taxes specified in s. 320.08 and in subsection (2), there is hereby levied and imposed an annual license tax of 10 cents for the operation of a motor vehicle, as defined in s. 320.01, and moped, as defined in s. 316.003, which tax shall be paid to the department or its agent upon the registration or renewal of registration of the vehicle. Notwithstanding s. 320.20, revenues collected from the tax imposed in this subsection shall be deposited in the Emergency

Medical Services Trust Fund and used solely for the purpose of carrying out ss. 395.401, 395.4015, 395.4025, 395.404, and 395.4045 ~~and s. 11, chapter 87-399, Laws of Florida~~.

(2) In addition to the license taxes imposed by s. 320.08 and by subsection (1), there is imposed an additional surcharge of $10 on each commercial motor vehicle having a gross vehicle weight of 10,000 pounds or more, which surcharge must be paid to the department or its agent upon the registration or renewal of registration of the commercial motor vehicle. Notwithstanding the provisions of s. 320.20, 50 percent of the revenues collected from the surcharge imposed in this subsection shall be deposited into the State Transportation Trust Fund, and 50 percent shall be deposited in the General Revenue Fund.

Section 14. Paragraph (l) of subsection (3) of section 408.036, Florida Statutes, is amended to read:

408.036 Projects subject to review; exemptions.—

(3) EXEMPTIONS.—Upon request, the following projects are subject to exemption from the provisions of subsection (1):

(l) For the establishment of:

1. A Level II neonatal intensive care unit with at least 10 beds, upon documentation to the agency that the applicant hospital had a minimum of 1,500 births during the previous 12 months;

2. A Level III neonatal intensive care unit with at least 15 beds, upon documentation to the agency that the applicant

hospital has a Level II neonatal intensive care unit of at least 10 beds and had a minimum of 3,500 births during the previous 12 months; or

3. A Level III neonatal intensive care unit with at least 5 beds, upon documentation to the agency that the applicant hospital is a designated ~~verified~~ trauma center pursuant to s. 395.4001(17) ~~395.4001(14)~~, and has a Level II neonatal intensive care unit,

if the applicant demonstrates that it meets the requirements for quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency transportation, and data reporting found in agency certificate-of-need rules for Level II and Level III neonatal intensive care units and if the applicant commits to the provision of services to Medicaid and charity patients at a level equal to or greater than the district average. Such a commitment is subject to s. 408.040.

Section 15. Paragraph (a) of subsection (1) of section 409.975, Florida Statutes, is amended to read:

409.975 Managed care plan accountability.—In addition to the requirements of s. 409.967, plans and providers participating in the managed medical assistance program shall comply with the requirements of this section.

(1) PROVIDER NETWORKS.—Managed care plans must develop and maintain provider networks that meet the medical needs of their

enrollees in accordance with standards established pursuant to s. 409.967(2)(c). Except as provided in this section, managed care plans may limit the providers in their networks based on credentials, quality indicators, and price.

(a) Plans must include all providers in the region that are classified by the agency as essential Medicaid providers, unless the agency approves, in writing, an alternative arrangement for securing the types of services offered by the essential providers. Providers are essential for serving Medicaid enrollees if they offer services that are not available from any other provider within a reasonable access standard, or if they provided a substantial share of the total units of a particular service used by Medicaid patients within the region during the last 3 years and the combined capacity of other service providers in the region is insufficient to meet the total needs of the Medicaid patients. The agency may not classify physicians and other practitioners as essential providers. The agency, at a minimum, shall determine which providers in the following categories are essential Medicaid providers:

1. Federally qualified health centers.

2. Statutory teaching hospitals as defined in s. 408.07(45).

3. Hospitals that are trauma centers as defined in s. 395.4001(17) ~~395.4001(14)~~.

4. Hospitals located at least 25 miles from any other hospital with similar services.

Managed care plans that have not contracted with all essential providers in the region as of the first date of recipient enrollment, or with whom an essential provider has terminated its contract, must negotiate in good faith with such essential providers for 1 year or until an agreement is reached, whichever is first. Payments for services rendered by a nonparticipating essential provider shall be made at the applicable Medicaid rate as of the first day of the contract between the agency and the plan. A rate schedule for all essential providers shall be attached to the contract between the agency and the plan. After 1 year, managed care plans that are unable to contract with essential providers shall notify the agency and propose an alternative arrangement for securing the essential services for Medicaid enrollees. The arrangement must rely on contracts with other participating providers, regardless of whether those providers are located within the same region as the nonparticipating essential service provider. If the alternative arrangement is approved by the agency, payments to nonparticipating essential providers after the date of the agency's approval shall equal 90 percent of the applicable Medicaid rate. Except for payment for emergency services, if the alternative arrangement is not approved by the agency, payment

to nonparticipating essential providers shall equal 110 percent of the applicable Medicaid rate.

Section 16. This act shall take effect July 1, 2017.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1191 Medication Synchronization
SPONSOR(S): Cruz
TIED BILLS: **IDEN./SIM. BILLS:** SB 800

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Langston	Poche
2) Insurance & Banking Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Medication synchronization is the process of a pharmacy coordinating all of a patient's prescription medications to fill them on the same date each month. In order to achieve this, some medications may need an early or short refill to align all the prescription medications. Recently, several states have enacted laws that require health insurance plans to make partial supplies of prescriptions available to consumers at a reduced cost-sharing amount for medication synchronization purposes. Currently, Florida does not require health plans to make partial supplies of prescriptions available to consumers at a reduced cost-sharing amount for medication synchronization.

HB 1191 requires health insurers and HMOs to approve a partial supply of medication for the purpose of syncing an insured's medications and to apply a prorated daily cost-sharing rate. Health insurance policies and HMO contracts that provide prescription drug coverage must cover a partial supply of a medication dispensed by a network pharmacy at a prorated rate if the prescribing practitioner or pharmacist determines the fill or refill to be in the best interests of the insured, and the insured requests or agrees to a partial supply for the purpose of synchronizing his or her medications.

For the purposes of medication synchronization, the health insurance policy or HMO contract must allow a network pharmacy to override any denial code indicating that a prescription is being refilled too soon. Additionally, the health insurer or HMO must pay the pharmacy in full for each prescription dispensed, regardless of any prorated copay for the beneficiary or fee paid for alignment services.

The bill will have an indeterminate fiscal impact on the State Group Insurance Program and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2017.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Medication Synchronization

Medication synchronization is the process of a pharmacy coordinating all of a patient's prescription medications to fill them on the same date each month.[1] In order to achieve this, some medications may need an early or short refill to align all of the patient's prescription medications.[2] Without medication synchronization, pharmacy workflow operates around patients bringing in new prescriptions, calling for medication refills, and picking up their mediations at their convenience, with those who are on multiple medications often visiting the pharmacy many times a month, which creates inefficiency for the patient and the pharmacy.[3] Medication synchronization programs can reduce the administrative burden on patients who take multiple medications by centering all prescription refills to a common monthly or quarterly fill date.[4] Medication synchronization may also offer pharmacies a mechanism to improve workload and inventory control.[5]

Medication Synchronization in Other States

Recently, several states have enacted laws that require health insurance plans to make partial supplies of prescriptions available to consumers at a reduced cost-sharing amount for medication synchronization purposes. In 2015, Arizona enacted a law that requires pharmacies to dispense an early refill or a short fill and to prorate the cost for a refill for less than the standard refill amount if such a refill is for medication synchronization[6]. It defines medication synchronization as, "the coordination of medication refills for a patient taking two or more medications for a chronic condition that are being dispensed by a single contracted pharmacy to facilitate the synchronization of the patient's medications for the purpose of improving medication adherence." Maine,[7] New Mexico,[8] and Washington[9] enacted similar measures in 2015. Kentucky[10] and Oregon[11] also enacted similar measures in 2015; however, they placed limits on which medications were subject to the new laws, prohibiting early and short refills of Schedule II and certain Schedule III controlled substances.

In 2016, Missouri enacted similar medication synchronization legislation, which also required the health insurance carrier or managed care plan to pay a full dispensing fee to the pharmacy for any prescription dispensed in a quantity less than the prescribed amount to align prescriptions.[12] Ohio also enacted a medication synchronization law in 2016; in addition to prohibitions on Schedule II controlled

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[1] National Community Pharmacist Association, *Model Legislation: Patient Protection & Medication Synchronization*, available at: http://www.ncpa.co/pdf/state/med-synch-model-legislation.pdf (last visited March 25, 2017).
[2] Id.
[3] American Pharmacists Association Foundation, *Pharmacy's Appointment Based Model: A prescription synchronization program that improves adherence*, Jul. 2015, available at: https://naspa.us/wp-content/uploads/2015/07/ABMWhitePaper-FINAL-201309233.pdf (last visited March 22, 2017).
[4] Academy of Managed Care Pharmacy, *Medication Synchronization*, 2015, p. 1, available at: http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=20019 (last visited March 25, 2017).
[5] National Association of Boards of Pharmacy, *Report of the Task Force on Medication Synchronization*, 2016, p. 2, available at: https://nabp.pharmacy/wp-content/uploads/2016/07/MedSynchTFReport-Final.pdf (last visited March 25, 2017).
[6] Ariz. Rev. Stat. ss. 20-848; 20-1057.15; 20-1376.07; 20-1406.07.
[7] Me. Rev. Stat. tit. 24-A s. 2769.
[8] N.M. Stat. ss. 59A-22-1978; 59A-23-1978.
[9] Wash. Rev. Code ss. 48.43; 41.05.
[10] Ky. Rev. Stat. s. 304.17A-165.
[11] 2014 Or. Laws ch. 25, ss. 2; 4.
[12] Mo. Rev. Stat. s. 376.379.

substances, it also limits the number of times a consumer may synchronize his or her medications to once per year.[13]

Federal Health Care Requirements

Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act (PPACA)[14] created many new health insurance requirements, including required essential health benefits (EHB) and cost-sharing limits.[15] PPACA requires insurers and HMOs of qualified health plans (QHPs) to provide coverage of EHBs in at least 10 specified categories, including prescription drugs.[16] To be certified as a QHP, the insurer or HMO must submit an application, follow established limits on cost sharing, and be certified by the federal Health Insurance Marketplace.[17]

QHPs must provide access to prescription drug benefits. An individual or small group health plan[18] must allow enrollees to obtain prescription drug benefits at in-network retail pharmacies, unless a drug is subject to restricted distribution by the U.S. Food and Drug Administration; or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy. A QHP has the flexibility to charge a lower cost-sharing amount when obtaining the drug at an in-network retail pharmacy[19] and only needs to provide enrollees with the option to access drugs that are not exempted at a network retail pharmacy.[20]

Federal law does not require health insurers and HMOs to make partial supplies of prescriptions available to consumers at a reduced cost-sharing amount for medication synchronization.

Medicare Part D

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003[21] established a voluntary, outpatient, prescription drug benefit under Medicare Part D, effective January 1, 2006. Medicare Part D provides coverage through private prescription drug plans that offer only drug coverage, or through Medicare Advantage prescription drug plans that offer coverage as part of broader, managed care plans.

While federal law does not require medication synchronization by QHPs, beginning in 2014, the Centers for Medicare and Medicaid Services requires health plans administering Medicare Part D plans to apply a daily cost-sharing rate to most prescriptions that are dispensed for less than a 30-day supply.[22]

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[13] Oh. Rev. Stat. ss. 1751.68 and 3923.602.
[14] The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. P.L. 111-148. Most of the insurance regulatory provisions in PPACA amend Title XXVII of the Public Health Service Act, 42 U.S.C. s. 300gg et seq.
[15] 42 U.S.C. s. 18022; 45 CFR s. 156.110 et seq.
[16] Id., see also, Centers for Medicare and Medicaid Services, *Information on Essential Health Benefits (EHB) Benchmark Plans*, available at: https://www.cms.gov/cciio/resources/data-resources/ehb.html (last visited March 23, 2017).
[17] Center for Consumer Information & Insurance Oversight, *Qualified Health Plans*, available at: https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp.html (last visited March 25, 2017).
[18] The Patient Protection and Affordable Care Act (Pub. L. 111–148). This regulation does not apply to large group plans, self-insured plans, transitional plans, or grandfathered plans.
[19] 45 C.F.R. s. 156.135.
[20] 45 C.F.R. s. 156.122(e).
[21] P.L. 108-173.
[22] Centers for Medicare and Medicaid Services, *Medicare Part D Overutilization Monitoring System – Updates*, (Oct. 25, 2013), available at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoMedicare-Part-D-OMS-Updates-10-25-13.pdf (last visited March 25, 2017); Centers for Medicare and Medicaid Services, *Copayment/coinsurance in drug plans*, available at:https://www.medicare.gov/part-d/costs/copayment-coinsurance/drug-plan-copayments.html (last visited March 25, 2017).

Regulation of Insurance in Florida

Regulation of Health Insurers and Health Maintenance Organizations

The regulatory oversight of insurance companies is generally reserved to the states. In Florida, the Office of Insurance Regulation (OIR) is responsible for all activities concerning insurers and other risk bearing entities, as provided under the insurance code. OIR regulates health insurer provider contracts under part VI of ch. 627, F.S. and health maintenance organization (HMO) contracts and rates under part I of ch. 641, F.S. To operate in Florida, an HMO must obtain a certificate of authority from OIR.[23] The Agency for Health Care Administration (AHCA) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from OIR, an HMO must receive a Health Care Provider Certificate from AHCA.[24]

The Florida Insurance Code requires health insurers and HMOs to provide an outline of coverage or other information describing the benefits, coverages, and limitations of a policy or contract. This may include an outline of coverage, including prescription drug coverage, describing the principal exclusions and limitations of the policy.[25] Section 641.31(4), F.S., requires each contract, certificate, or member handbook of an HMO to delineate the services, including prescription drug coverage, for which a subscriber is entitled and any limitations under the contract.

Pharmacy Benefit Managers

Health insurers and HMOs contract with pharmacy benefit managers (PBMs) to help manage prescription drug benefits. PBMs are sometimes referred to as the middlemen in the prescription drug market because they act as intermediaries between health plan sponsors and drug manufacturers and pharmacies.[26] PBMs provide specified services, which may include developing and managing pharmacy networks, developing drug formularies, providing mail order and specialty pharmacy services, providing support services for physicians and beneficiaries, and processing claims.[27] Their contracts with PBMs also establish how pharmacies will be reimbursed for prescriptions they dispense to health plan sponsor beneficiaries.[28]

State Employees' Prescription Drug Program

The State Group Insurance Program (SGI Program) was created by s. 110.123, F.S., and is administered by the Division of State Group Insurance within the Department of Management Services (DMS). The SGI Program is an optional benefit for all state employees including all state agencies, state universities, the court system, and the Legislature, and includes health, life, dental, vision, disability, and other supplemental insurance benefits.

As part of the SGI Program, DMS is required to maintain the State Employees' Prescription Drug Program (Prescription Drug Plan).[29] DMS contracts with CVS/Caremark, a PBM, to administer the Prescription Drug Plan.[30] A member can receive up to a 30-day supply of prescription medication at a retail pharmacy in the Prescription Drug Plan network and up to a 90-day supply at a mail order pharmacy or at a participating 90-day retail pharmacy.

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[23] S. 641.21(1) and 641.49, F.S.
[24] S. 641.21(1) and 641.48, F.S.
[25] S. 627.642, F.S.
[26] Office of Program Policy Analysis & Government Accountability, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (Feb. 2007), available at: http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/0708rpt.pdf (last visited March 25, 2017).
[27] Id.
[28] Id.
[29] S. 110.12315, F.S.
[30] Department of Management Services, *myFlorida, Prescription Drug Plan*, available at: http://mybenefits.myflorida.com/health/health_insurance_plans/prescription_drug_plan (last visited March 25, 2017).

Currently, the SGI Program does not allow for the synchronization of medication if it requires an early refill.

Effect of Proposed Changes

HB 1191 requires certain health insurers and HMOs to approve a partial supply of medication for the purpose of syncing an insured's medications and to apply a prorated daily cost-sharing rate for such partial refills.

Health insurance policies and HMO contracts that provide prescription drug coverage must cover a partial supply of a medication dispensed by a network pharmacy at a prorated rate if:

- The prescribing practitioner or pharmacist determines the fill or refill to be in the best interests of the insured; and
- The insured requests or agrees to a partial supply for the purpose of synchronizing his or her medications.

This will allow patients to obtain a partial refill to align all their medications, without incurring any additional costs for refilling too soon or having to pay more than the prorated rate for a partial refill. Aligning prescription refill dates will necessitate fewer trips to the pharmacy for refills, which may reduce gaps in therapies because of improved adherence to prescription medication regimens.

For the purposes of medication synchronization, the health insurance policy or HMO contract must allow a network pharmacy to override any denial code indicating that a prescription is being refilled too soon. Additionally, the insurer or HMO must pay the pharmacy in full for each prescription dispensed, regardless of any prorated copay for the beneficiary or fee paid for alignment services. Insurers and HMOs may have to update their contracts with pharmacies or PBMs to allow network pharmacies to override the denial code; insurers and HMOs may also have to update their policies for how they reimburse for partial prescription refills to ensure that the pharmacy gets a full dispensing fee when the partial refill is for medication synchronization.

The bill provides an effective date of July 1, 2017.

B. SECTION DIRECTORY:

Section 1: Creates s. 627.64196, F.S., relating to requirements for the partial fill or refill of prescriptions for medication synchronization purposes.
Section 2: Amends s. 641.31, F.S., relating to health maintenance contracts.
Section 3: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   For each partial refill made for the purpose of medication synchronization, DMS expects an initial low-cost negative fiscal impact to the SGI Program. However DMS anticipates greater member adherence to prescription medication regimens for chronic conditions, which should result in overall lower medical spending in the SGI Program

DMS will need to make changes to the summary plan description currently used by the SGI Program's PBM to allow for prescriptions to be filled at any point for medication synchronization.[31] DMS would also need to develop and incorporate a proration schedule outlining and creating prorated copayment amounts for medication synchronization.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:
None.

2. Expenditures:
None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

There may be new administrative costs for insurers and pharmacies to institute daily cost sharing rates for partial fills and refills.[32] Some insurers may also incur costs to revise their forms to comply with the bill.[33] Insurers may have to renegotiate or amend their contracts with PBMs to take into account the bill's requirements.

D. FISCAL COMMENTS:

For SGI Program members with a Preferred Provider Organization plan filling maintenance medications at a retail pharmacy, any "partial" fill would count as one of their three 30-day fills at retail before being required to use 90-day retail refill or 90-day mail order refill.[34]

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The deadline for insurers and HMOs to submit their 2018 rates and forms for products on or off the exchange is May 3, 2017.[35] The effective date of the bill is in the middle of the plan year for most health

[31] Department of Management Services, *Agency Analysis of 2017 House Bill 1191* (Mar. 12, 2017) (on file with Health Innovation Subcommittee staff).
[32] Office of Insurance Regulation, *Agency Analysis of 2017 House Bill 1191* (Mar. 7, 2017) (on file with Health Innovation Subcommittee staff).
[33] Id.
[34] Supra, FN 31.

insurance plans. An effective date of January 1, 2018 may allow additional time for health insurers and HMOs to implement the provisions of the bill.

Additionally, s. 110.12315(11), F.S., may need to be amended to incorporate provisions regarding prorated member cost-share for medication synchronization in the Prescription Drug Plan.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[35] Office of Insurance Regulation, *Guidance to Insurers*, available at: http://www.floir.com/sitedocuments/PPACANoticetoIndustry201802032017.pdf (last visited March 25, 2017).

A bill to be entitled

An act relating to medication synchronization; creating s. 627.64196, F.S., and amending s. 641.31, F.S.; prohibiting, under certain circumstances, certain health insurance policies and health maintenance contracts, respectively, from denying coverage for partial supplies of medication dispensed by network pharmacies; requiring such policies and contracts to authorize and apply a prorated daily cost-sharing rate to certain prescriptions under certain circumstances; requiring such policies and contracts to allow network pharmacies to override denial codes under certain circumstances; prohibiting such policies and contracts from using payment structures incorporating prorated dispensing fees; providing requirements for dispensing fees for partially filled or refilled prescriptions; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 627.64196, Florida Statutes, is created to read:

627.64196 Requirements for the partial fill or refill of prescriptions for medication synchronization purposes.—

(1) An individual or group health insurance policy providing prescription drug coverage in this state may not deny coverage for a partial supply of medication dispensed by a network pharmacy and must authorize and apply a prorated daily cost-sharing rate to prescriptions that are dispensed by a network pharmacy for the partial supply if:

(a) The prescribing practitioner or pharmacist determines the fill or refill to be in the best interest of the insured; and

(b) The insured requests or agrees to a partial supply for the purpose of synchronizing his or her medications.

(2) An individual or group health insurance policy:

(a) Must allow, for the purposes of medication synchronization, a network pharmacy to override any denial code indicating that a prescription is being refilled too soon.

(b) May not use payment structures incorporating prorated dispensing fees. Dispensing fees for partially filled or refilled prescriptions must be paid in full for each prescription dispensed, regardless of any prorated copay for the beneficiary or fee paid for alignment services.

Section 2. Subsection (44) is added to section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(44)(a) A health maintenance contract providing prescription drug coverage in this state may not deny coverage

for the dispensing of a partial supply of medication by a network pharmacy and must authorize and apply a prorated daily cost-sharing rate to prescriptions that are dispensed by a network pharmacy for the partial supply if:

1. The prescribing practitioner or pharmacist determines the fill or refill to be in the best interest of the subscriber; and

2. The subscriber requests or agrees to a partial supply for the purpose of synchronizing his or her medications.

(b) A health maintenance contract:

1. Must allow, for the purposes of medication synchronization, a network pharmacy to override any denial code indicating that a prescription is being refilled too soon.

2. May not use payment structures incorporating prorated dispensing fees. Dispensing fees for partially filled or refilled prescriptions must be paid in full for each prescription dispensed, regardless of any prorated copay for the beneficiary or fee paid for alignment services.

Section 3. This act shall take effect July 1, 2017.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Innovation Subcommittee

Representative Cruz offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 627.64196, Florida Statutes, is created to read:

627.64196 Medication synchronization.—An individual or group health insurance policy issued or delivered in this state which provides prescription drug coverage shall offer medication synchronization services to allow an insured to align the refill dates for prescription drugs covered by the policy at least once in a plan year. The insurer shall implement a policy for dispensing prescription drugs to an insured for the purpose of aligning the refill dates of such drugs, and such medication

synchronization shall be available only through a network pharmacy. A controlled substance, a prescription drug dispensed in an unbreakable package, or a multi-dose unit of a prescription drug may not be partially filled for the purpose of aligning refill dates. The insurer shall pay a full dispensing fee to the network pharmacy for each partial refill of a covered prescription drug done for the purpose of aligning refill dates, unless otherwise agreed to by the plan and the network pharmacy at the time an insured requests medication synchronization. The insurer shall prorate the cost-sharing obligations of the insured for each partial refill of a covered prescription drug done for the purpose of aligning refill dates. This section applies to policies renewed or entered into on or after January 1, 2018.

Section 2. Subsection (44) is added to section 641.31, Florida Statutes, to read:

(44) A health maintenance contract issued or delivered in this state which provides prescription drug coverage shall offer medication synchronization services to allow a subscriber to align the refill dates for prescription drugs covered by the contract at least once in a plan year. The health maintenance organization shall implement a policy for dispensing prescription drugs to a subscriber for the purpose of aligning the refill dates of such drugs, and such medication synchronization shall be available only through a network

pharmacy. A controlled substance, a prescription drug dispensed in an unbreakable package, or a multi-dose unit of a prescription drug may not be partially filled for the purpose of aligning refill dates. The health maintenance organization shall pay a full dispensing fee to the network pharmacy for each partial refill of a covered prescription drug done for the purpose of aligning refill dates, unless otherwise agreed to by the health maintenance organization and the network pharmacy at the time a subscriber requests medication synchronization. The health maintenance organization shall prorate the cost-sharing obligations of the subscriber for each partial refill of a covered prescription drug done for the purpose of aligning refill dates. This subsection applies to contracts renewed or entered into on or after January 1, 2018.

Section 3. This act shall take effect July 1, 2017.

T I T L E A M E N D M E N T

Remove lines 4-17 and insert:

F.S.; requiring certain health insurance policies and health maintenance contracts, respectively, to provide medication synchronization services to allow an insured or subscriber to align refill dates of all covered prescription drugs no more than twice in a plan year; prohibiting a controlled substance, a prescription drug dispensed in an unbreakable package, or a

multi-dose unit of a prescription drug from being partially filled for the purpose of aligning refill dates; requiring a health insurer or health maintenance organization to pay a full dispensing fee to a network pharmacy for each partial refill of a covered prescription drug done for alignment purposes; providing for prorated cost-sharing obligations for each partially refilled prescription drug; applying the provisions of the bill to insurance policies and health maintenance contracts renewed or entered into on or after January 1, 2018 ; providing