HOUSE OF REPRESENTATIVES
FINAL BILL ANALYSIS

BILL #:	CS/CS/HB 1159	**FINAL HOUSE FLOOR ACTION:**	
SPONSOR(S):	Health & Human Services Committee; Health Innovation Subcommittee; O'Toole	103 **Y's**	13 **N's**
COMPANION BILLS:	(CS/CS/SB 1482)	**GOVERNOR'S ACTION:**	Approved

SUMMARY ANALYSIS

CS/CS/HB 1159 passed the House on April 29, 2013. The bill was amended by the Senate on May 3, 2013, and returned to the House. The House amended the Senate amendment. The Senate concurred with the House amendment to the Senate amendment and subsequently passed CS/CS/HB 1159 as amended on May 3, 2013. The bill amends laws related to nursing home Certificate of Need, trauma centers, health care clinic licensure, children's hospitals, cancer treatment, and the prescription drug monitoring program.

The bill provides an exemption from the moratorium on new nursing homes and an expedited review for Certificate of Need applicants for the construction of a community nursing home and the addition of a limited number of skilled nursing home beds within a retirement community that meets certain qualifications.

The bill allows hospitals located in areas with limited access to trauma services, as defined by the bill, to open a Level II trauma center by obtaining a valid certificate from the American College of Surgeons instead of completing the current application and review process performed by the Department of Health.

The bill creates exemptions from licensure under the Health Care Clinic Act for publicly traded pediatric cardiology, perinatology, or anesthesia clinical facilities. The bill amends an existing exemption for entities that are owned by a corporation that has $250 million or more in total annual sales of health care services allowing such entities to be operated by, rather than only owned by, a health care practitioner.

The bill allows specialty licensed children's hospitals that have licensed neonatal intensive care beds and are located in a county with a population of 1,750,000 or more, to have up to 10 beds for obstetrical services, including labor and delivery care for pregnant mothers with a fetus that has been diagnosed or identified as high risk or may require at least one perinatal intervention.

Effective July 1, 2014, the bill requires health insurance policies and contracts and HMO contracts that provide cancer treatment medication coverage to also provide coverage for oral cancer treatment medications. The bill requires policies and contracts to apply cost-sharing requirements for oral cancer treatment medications that are no less favorable than the cost-sharing requirements for non-oral cancer treatment medications. The bill prohibits insurers, HMOs, and their providers from taking specific actions designed to avoid the parity requirements of the bill.

Finally, the bill appropriates $500,000 in nonrecurring funds from the General Revenue Fund to the Department of Health for the administration of the prescription drug monitoring program (PDMP). Current law prohibits the use of state funds to maintain the PDMP; the bill makes an exception to that prohibition for Fiscal Year 2013-2014, only.

See fiscal comments.

The bill was approved by the Governor on June 7, 2013, ch. 2013-153, L.O.F., and became effective on that date, except as otherwise provided.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Present Situation

Skilled Nursing Facilities

A certificate of need (CON) is a written statement issued by the Agency for Health Care Administration (AHCA) evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility, health service, or hospice.[1] Under this regulatory program, AHCA must provide approval through the CON review and approval process prior to a provider establishing a new nursing home or adding nursing home beds.

Florida's CON program has been in operation since July 1973. From 1974 through 1986, the specifics of the program were largely dictated by the federal National Health Planning and Resources Development Act, which established minimum requirements regarding the type of services subject to CON review, review procedures, and review criteria. Each state was required to have a CON program in compliance with those standards as a condition for obtaining federal funds for health programs. The federal health planning legislation was repealed in 1986.

In 2001, the Legislature enacted the first moratorium on the issuance of CONs for additional community nursing home beds until July 1, 2006.[2] In 2006, the Legislature extended the moratorium until July 1, 2011.[3] In 2011, the Legislature again extended the moratorium, but provided that the moratorium will expire on June 30, 2016, or upon the statewide implementation of Medicaid managed care, whichever is earlier.[4] In addition, the Legislature provided for additional exceptions to the moratorium to address occupancy needs that might arise.

The Florida CON program has three levels of review: full, expedited, and exempt.[5]

Determination of Need

A CON is predicated on a determination of need. The future need for community nursing home beds is determined twice a year and published by the agency as a fixed bed need pool for the applicable planning horizon. The planning horizon for CON applications is 3 years. Need determinations are calculated for subdistricts within AHCA's 11 service districts[6] based on estimates of current and projected population as published by the Executive Office of the Governor.

The need formula[7] links the projected subdistrict need to a projected increase in the district need for nursing home beds. The district increase is based on the expected increase in the district population age 65 to 74 and age 75 and over, with the age group 75 and over given 6 times more weight in projecting the population increase. The projected district bed need total is then allocated to its subdistricts. The result for a given subdistrict is adjusted to reflect the current subdistrict occupancy of beds, and a desired standard of 94 percent occupancy. The subdistrict net need is the excess of the allocated beds over the licensed or approved beds in the subdistrict. If current occupancy of licensed beds is less than 85 percent, the net need in the subdistrict is zero regardless of whether the formula otherwise shows a net need.

[1] S. 408.032(3), F.S.
[2] S. 52, Ch. 2001-45, L.O.F.
[3] Chapter 2006-161, L.O.F.
[4] S. 4, Ch. 2011-135, L.O.F.
[5] S. 408.036, F.S.
[6] The nursing home subdistricts are set forth in Rule 59C-2.200, F.A.C.
[7] Rule 59C-1.036, F.A.C.

AHCA is required to issue a CON to the holder of a provisional certificate of authority to construct nursing home beds for the exclusive use of the prospective residents of the proposed continuing care facility under a different bed-need assessment scheme.[8] AHCA is required to approve at least one sheltered nursing home bed[9] for every four proposed residential units. Additional sheltered nursing home beds must be approved based on actual utilization and demand by current residents. Sheltered nursing home beds are not included in the need formula for community nursing home beds.

Full Review Process

Some nursing home projects are required to undergo a full comparative review under the statute. Adding beds in community nursing homes and constructing or establishing new skilled nursing facilities are both subject to full review.[10]

Nursing home bed projects subject to competitive review are included in the batching cycle for "other beds and programs." The review process takes approximately 120 days.[11] The fixed bed need determination is published in the Florida Administrative Weekly. A letter of intent describing the applicant, the project type including the number of beds, and its location must be submitted to AHCA at least 30 days prior to the applicable batching cycle application due date.[12] A grace period after the initial letter of intent deadline provides an opportunity for other applicants to compete with an initial letter of intent. The grace period extends this initial phase by an additional 16 days for the submission of a competitor's letter of intent.

The CON application must be submitted to AHCA by the date published for that batching cycle. AHCA must perform a completeness review of the application within 15 calendar days of the application submission deadline.[13] The applicant has 21 calendar days after receiving a request from AHCA for additional information, to provide the information, otherwise the application is withdrawn from further consideration. AHCA must determine whether the application is complete or withdrawn within 7 calendar days after receipt of the requested information.

AHCA will conduct public hearings on the applications, if requested, to determine that a proposed project involves issues of great local public interest.[14]

AHCA reviews CON applications for additional nursing home beds in context with the need for the health care facilities and health services being proposed.[15] An application for nursing facility beds will not be approved in the absence or insufficiency of a numeric need unless the absence or insufficiency of numeric need is outweighed by other information presented in a CON application showing special circumstances consistent with the following additional criteria;[16]

- The availability, quality of care, accessibility, and extent of utilization of existing health care facilities and health services in the service district of the applicant;

[8] S. 651.118, F.S.
[9] A sheltered nursing home bed is a nursing home bed located within a continuing care facility for which a CON is issued pursuant to s. 651.118(2), F.S. Generally these beds must be used for residents of the continuing care facility. However, the beds may be used for persons who are not residents of the continuing care facility for a period of up to 5 years after the date of issuance of the initial nursing home license. A continuing care community may request an extension of this timeframe for up to 30 percent of the sheltered nursing home beds based on demonstrated financial need.
[10] S. 408.032(16), F.S., defines an SNF as an institution, or a distinct part of an institution, which is primarily engaged in providing, to inpatients, skilled nursing care and related services for patients who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.
[11] Presentation by AHCA on Florida CONs to the House Health Quality Subcommittee on October 4, 2011, (on file with the Health Innovation Subcommittee).
[12] Rule 59C-1.008, F.A.C.
[13] Rule 59C-1.010, F.A.C.
[14] S. 408.039, F.S.
[15] S. 408.035, F.S.
[16] Rule 59C-1.036, F.A.C.

- The ability of the applicant to provide quality of care and the applicant's record of providing quality of care;
- The availability of resources, including health personnel, management personnel, and funds for capital and operating expenditures, for project accomplishment and operation;
- The extent to which the proposed services will enhance access to health care for residents of the service district;
- The immediate and long-term financial feasibility of the proposal;
- The extent to which the proposal will foster competition that promotes quality and cost-effectiveness;
- The costs and methods of the proposed construction, including the costs and methods of energy provision and the availability of alternative, less costly, or more effective methods of construction;
- The applicant's past and proposed provision of health care services to Medicaid patients and the medically indigent; and
- The applicant's designation as a Gold Seal Program nursing facility pursuant to s. 400.235, F.S., when the applicant is requesting additional nursing home beds at that facility.

AHCA issues a State Agency Action Report which states the intent to grant or deny a CON for projects in their entirety or for identifiable portions thereof and states the conditions required, if any, of the CON holder. If there is no challenge to all or any part of the decision embodied in the State Agency Action Report within 21 days after publication in the Florida Administrative Weekly, the decision becomes final and the CON is issued.[17]

Applicants in the same batching cycle and exiting health care facilities in the same district that will be substantially affected by the issuance of any CON may challenge the issuance or denial of a CON. The Division of Administrative Hearings conducts the hearing, which must commence within 60 days after the administrative law judge has been assigned except upon unanimous consent of the parties or pursuant to a motion of continuance granted by the administrative law judge.[18] A party to an administrative hearing for an application for a CON may seek judicial review of the final order issued by the administrative law judge to the District Court of Appeal.

Expedited Review

Expedited review exempts projects from the statutory review cycles, and the requirement to submit a letter of intent.[19] Certain exceptions to the moratorium allow existing nursing home beds to be moved from one facility to another within small geographic regions. Section 408.036(2), F.S., allows expedited review of applications for nursing home replacement and relocation of beds from one nursing home to another, as follows:

- Replacing a nursing home within the same district, if the proposed project site is located within a geographic area that contains at least 65 percent of the facility's current residents and is within a 30-mile radius of the replaced nursing home.
- Relocating a portion of a nursing home's licensed beds to a facility within the same district.

Review Exemptions

Section 408.036(3), F.S., provides several exemptions to CON review for skilled nursing facility projects, including:

[17] *Supra* fn. 12.
[18] *Supra* fn. 13.
[19] S. 408.032(7), F.S.

- Combining licensed beds from two or more licensed nursing homes within a district into a single nursing home within that district if 50 percent of the beds are transferred from the only nursing home in a county and that nursing home had less than a 75 percent occupancy rate;[20]
- State veteran's nursing homes operated by or on behalf of the Florida Department of Veterans' Affairs;
- Combining into one nursing home, the beds or services authorized by two or more CONs issued in the same planning subdistrict;
- Separating into two or more nursing homes in the subdistrict, the beds or services that are authorized by one CON;
- Adding the greater of no more than 10 total beds or 10 percent of the number of licensed nursing home beds if:[21]
    - The facility has not had any class I or class II deficiencies within the 30 months preceding the request for addition;
    - The prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 96 percent;
    - The prior 12-month occupancy rate for the nursing home beds in the subdistrict is 94 percent or greater; and
    - Any beds authorized for the facility under this exception in a prior request have been licensed and operational for at least 12 months.[22]
- Replacing a licensed nursing home on the same site, or within 3 miles, if the number of licensed beds does not increase.
- Adding the greater of no more than 10 total beds or 10 percent of the licensed nursing home beds of a nursing home located in a county having up to 50,000 residents, if:[23]
    - The nursing home has not had any class I or class II deficiencies[24] within the 30 months preceding the request for addition;
    - The prior 12-month average occupancy rate for the nursing home beds at the facility meets or exceeds 94 percent and the facility has not had any class I or class II deficiencies since its initial licensure; and
    - The prior 6-month average occupancy rate for the nursing home beds, at a facility that has been licensed for less than 24 months, meets or exceeds 94 percent and the facility has not had any class I or class II deficiencies since its initial licensure.

Florida Trauma System

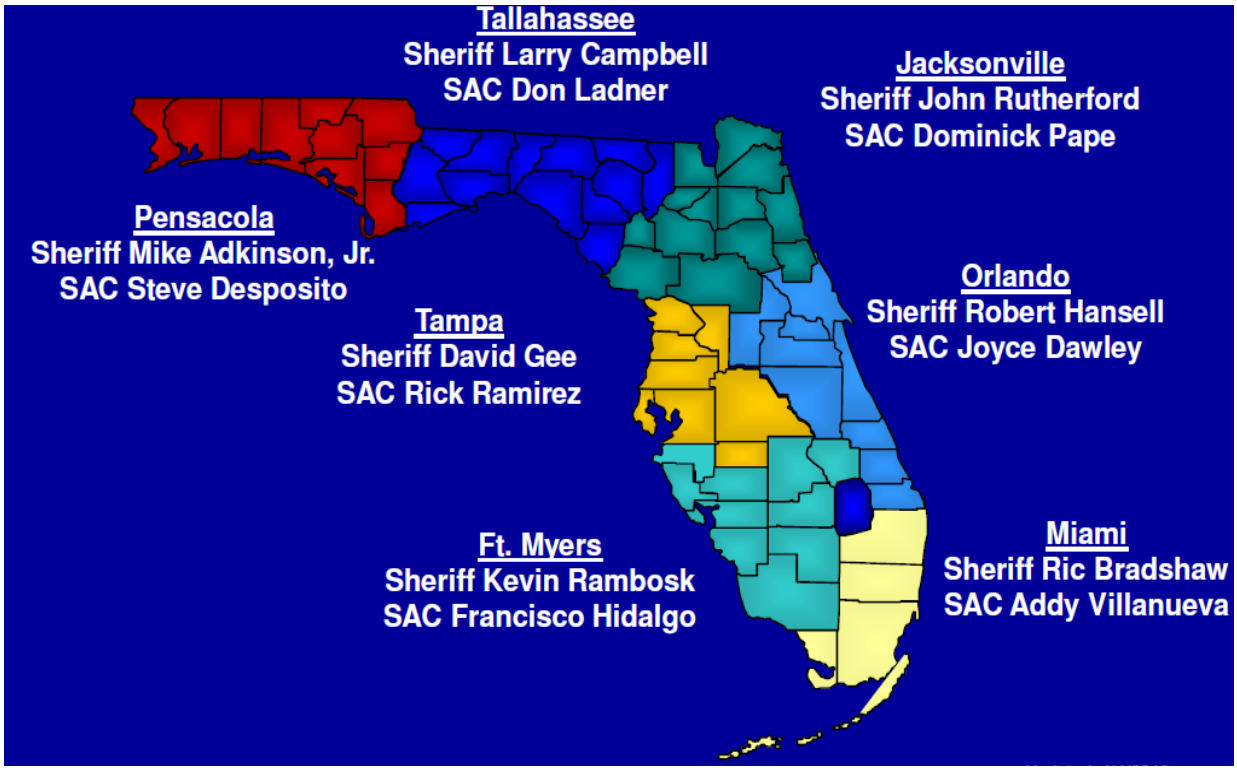
The regulation of trauma centers in Florida is established under Part II of Chapter 395, F.S. Trauma centers treat individuals who have incurred a single or multisystem injury due to blunt or penetrating means or burns and who require immediate medical intervention or treatment. In order to provide timely access to care, trauma standards are based on the "golden hour" principle, which is generally defined by emergency medical personnel as the first 60 minutes of intensive care during which it is possible to save the life of an injured or traumatized person.[25]

As part of the state trauma system plan, s. 395.4015, F.S., requires the Department of Health (DOH) to establish trauma regions which cover all geographical areas of the state and have boundaries that align

[20] This exemption is repealed upon the expiration of the moratorium by operation of s. 408.036(3)(f), F.S.
[21] S. 408.036(3)(k), F.S.
[22] The request to add beds under the exception to the moratorium is subject to the procedures related to an exemption to the CON requirements.
[23] S. 408.0435(5), F.S.
[24] Deficiencies in nursing homes are classified according to the nature and scope of the deficiency. A class I deficiency is a deficiency that the Agency determines presents a situation in which immediate corrective action is necessary because the facility's noncompliance has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident receiving care in a facility. A class II deficiency is a deficiency that the Agency determines has compromised a resident's ability to maintain or reach his or her highest practicable physical, mental, and psychosocial well-being, as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. *See* s. 400.23(8), F.S.
[25] Department of Health, Florida Trauma System: 2010 Annual Report, available at: http://www.doh.state.fl.us/demo/trauma/forms.htm (last viewed on April 22, 2013).

with the state's seven regional domestic security task forces. These regions may serve as the basis for the development of department-approved local or regional trauma plans.[26]

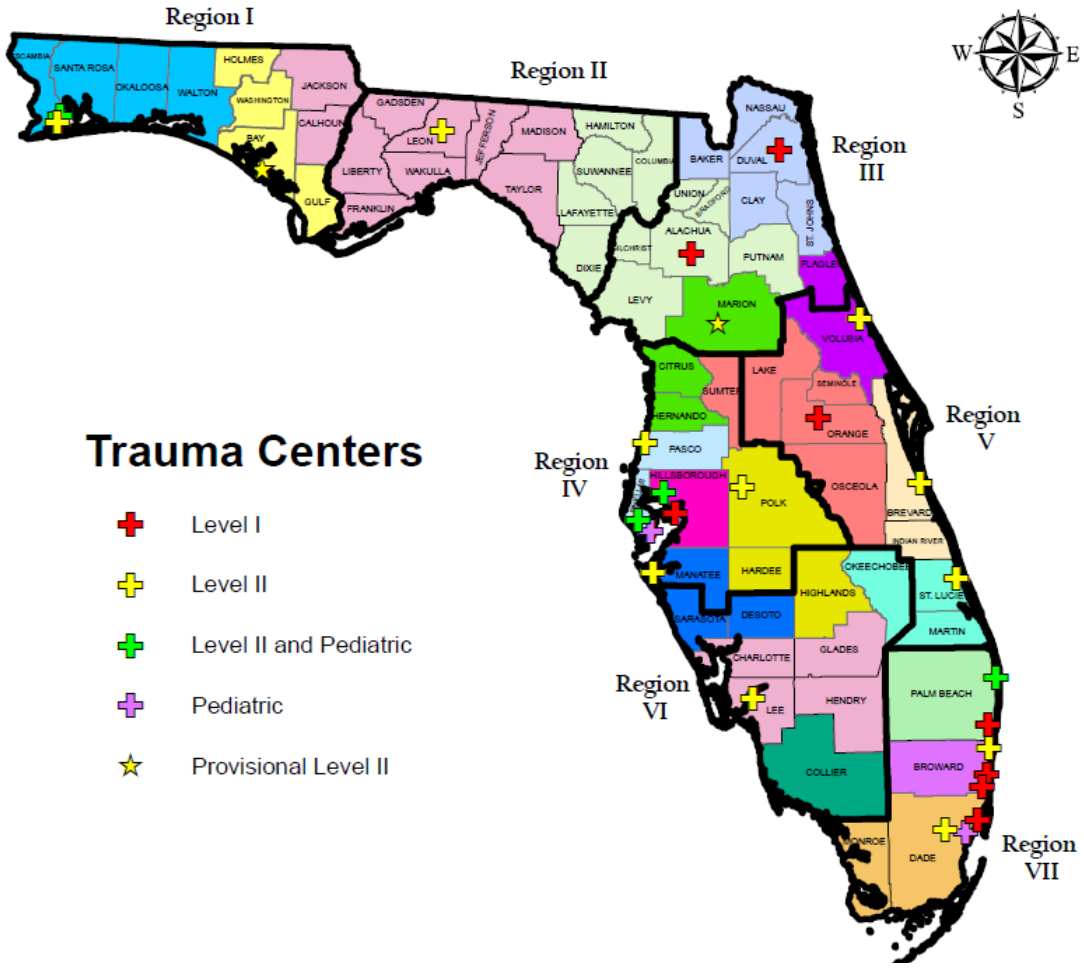
Florida Regional Domestic Security Task Forces



Florida's trauma system is comprised of four trauma agencies, seven trauma regions, and nineteen trauma service areas.

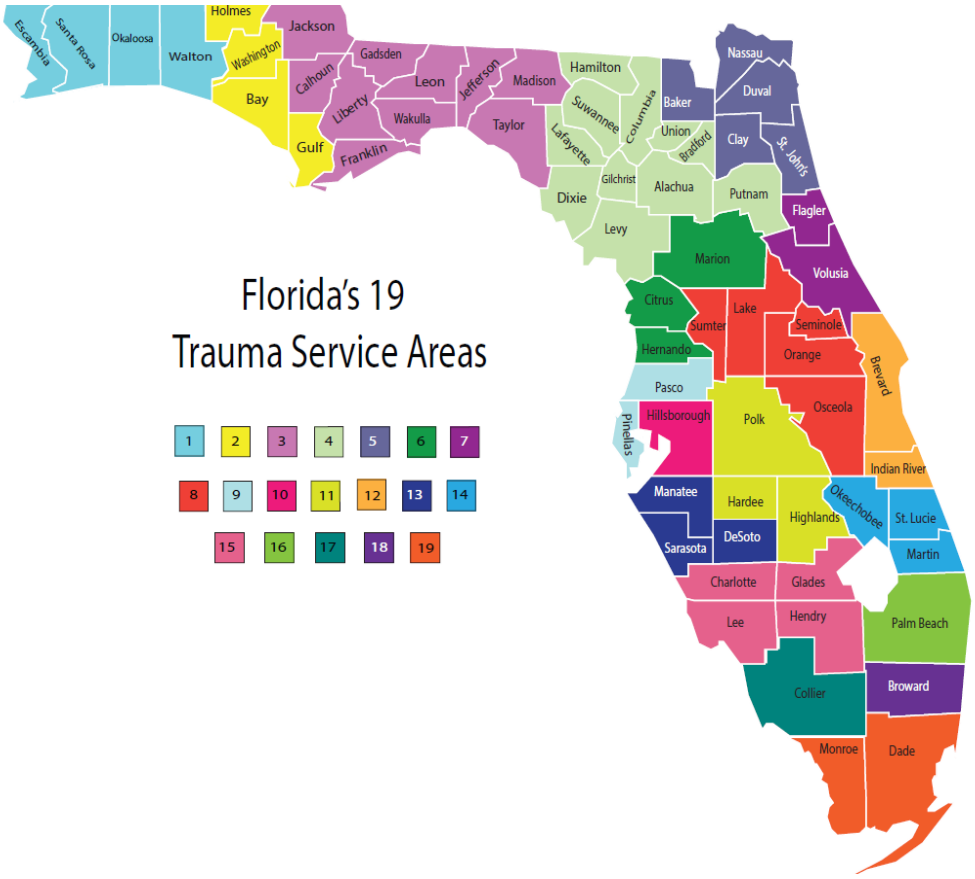
Trauma agencies are responsible for the development of department-approved local or regional trauma plans, administering an inclusive regional trauma system, coordinating arrangements to develop a trauma system, and updating an approved plan.[27] The four trauma agencies are: North Central Florida Trauma Agency, Hillsborough County Trauma Agency, Palm Beach Trauma Agency and Broward County Trauma Agency. The seven trauma regions are illustrated below.

[26] S. 395.4015(1), F.S.
[27] S. 395.401, F.S.



Pursuant to s. 395.402, F.S., Florida is divided into nineteen "trauma service areas." For purposes of medical response times, the trauma service areas are designed to provide the best and fastest services to the state's population. Each trauma service area 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.[28] Moreover, 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. Level II trauma centers in counties with a population of more than 500,000 must have the capacity to care for 1,000 patients per year.[29]

[28] S. 395.402(4), F.S.
[29] S. 395.402(1), F.S.



DOH is required to allocate, by rule, the number of trauma centers needed for each trauma service area. On October 8, 2008, DOH adopted these allocation requirements in Rule 64J-2.010, F.A.C.[30]

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 DOH's, Division of Children's Medical Services.[31]

Trauma Centers

Currently, 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.[32] A trauma center may have more than one designation; for example, St. Mary's Medical Center in Delray Beach carries both a Level I and a pediatric trauma center designation. As of April 22, 2013, the following hospitals are designated trauma centers:[33]

[30] Rule 64J-2.0101, F.A.C., which allocates a total of 42 trauma centers throughout the 19 trauma service areas, has been the subject of recent litigation. *See infra* fn 20 and the comments under the header "Trauma System Administrative Rule Challenge."
[31] S. 395.401(2), F.S. and Rule 64J-2.011, F.A.C.
[32] 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.
[33] Per email correspondence with DOH staff dated April 15, 2013, on file with the Health and Human Services Committee staff.

TRAUMA CENTER	LEVEL	DATE OF VERIFICATION OR PROVISIONAL	COUNTY	TRAUMA SERVICE AREA
Bayfront Medical Center and All Children's Bayfront	Joint Pediatric	1999	Pinellas	9
Baptist Hospital	Level II	1996	Escambia	1
Bay Medical Center	Provisional Level II	2012	Bay	2
Bayfront Medical Center	Level II	1984	Pinellas	9
Blake Medical Center	Level II	2013	Manatee	13
Broward General Medical Center	Level I	1998	Broward	18
Delray Medical Center	Level I	2012	Palm Beach	16
Halifax Medical Center	Level II	1985	Volusia	7
Holmes Regional Medical Center	Level II	2000	Brevard	12
Kendall Regional Medical Center	Level II	2013	Miami-Dade	19
Jackson Memorial Hospital/Ryder Trauma Center	Level I	1984	Miami-Dade	19
Lakeland Regional Medical Center	Level II	1998	Polk	11
Lawnwood Regional Medical Center	Level II	2010	St. Lucie	14
Lee Memorial Hospital	Level II	1994	Lee	15
Memorial Regional Hospital	Level I	1998	Broward	18
Miami Children's Hospital	Stand Alone Pediatric	1989	Miami-Dade	19
North Broward Medical Center	Level II	1993	Broward	18
Ocala Regional Medical Center/Marion Community Hospital	Provisional Level II	2012	Marion	6
Orlando Regional Medical Center	Level I	1982	Orange	8
Regional Medical Center Bayonet Point	Level II	2013	Pasco	9
Sacred Heart Hospital	Pediatric Level II	1996 2002	Escambia	1
St. Joseph's Hospital	Pediatric Level II	1997 1983	Hillsborough	10
St. Mary's Hospital	Pediatric Level I	1996 1992	Palm Beach	16
Shands Jacksonville	Level I	1982	Jacksonville	5
Shands at the University of Florida	Level I	2005	Gainesville	4
Tampa General	Level I	1984	Hillsborough	10
Tallahassee Memorial Hospital	Level II	2009	Leon	3

A provisional trauma center is an acute care hospital that has applied to become a Level I, Level II or pediatric verified trauma center.[34] Hospitals granted provisional status must operate as a provisional trauma center for a period of up to a year, while DOH conducts an in-depth review and a provisional onsite survey prior to DOH's determination to approve verification or deny a verification. Currently, there are two provisional Level II trauma centers: Bay Medical Center, Panama City, and Ocala Regional Medical Center, Ocala.[35]

Level I trauma centers serve as resource facilities to Level II trauma centers, pediatric trauma referral-centers, and general hospitals through shared outreach, education, and quality-improvement activities. Compared to other types of trauma centers, Level I trauma centers:[36]

- Must have 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 at the trauma center when summoned.
- Must have twelve surgical specialties and eleven non-surgical specialties (*see* the chart on page 8). These specialties must be available to provide in-hospital trauma services and backup trauma coverage 24-hours a day at the trauma center when summoned.
- Must have formal research and education programs for the enhancement of both adult and pediatric trauma care.

[34] S. 395.4001(10), F.S.
[35] Bay Medical Center received provisional status on May 2, 2012. Likewise, Ocala Regional Medical Center received provisional status on December 8, 2012. Per email correspondence with DOH staff dated April 9, 2013, on file with Health and Human Services Committee staff.
[36] S. 395.4025, F.S., and Rules 64J-2.011 - 64J-2.016, F.A.C.

Level II trauma centers serve as resource facilities to general hospitals through shared outreach, education, and quality improvement activities. Specific differences in the Level II standards and other verifications are that they:[37]

- Must have a minimum of five qualified trauma surgeons, assigned to the 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 at the trauma center when summoned.
- Must have nine surgical specialties and nine non-surgical specialties (*see* the chart below) available to provide trauma services and arrive promptly to provide trauma coverage 24 -hours a day at the trauma center when summoned.

Pediatric trauma centers serve as resource facilities to general hospitals through shared outreach, education, and quality improvement activities. Specific differences in the standards of a pediatric trauma center and other verifications are that they:[38]

- Must have a minimum of five qualified trauma surgeons, assigned to the trauma service, with at least two trauma surgeons available to provide trauma services and backup trauma coverage 24-hours a day at the trauma center when summoned. If the trauma medical director is not a pediatric surgeon, then at least one of the five must be a pediatric surgeon.
- Must have ten surgical specialties and eight non-surgical specialties (*see* the chart below) available 24-hours a day to arrive promptly at the trauma center when summoned.
- Must have formal research and education programs for the enhancement of pediatric trauma care.

Trauma Center Specialties by Trauma Center Type			
Surgical Specialties	**Level I**	**Level II**	**Pediatric**
Cardiac Surgery	×		×
Hand Surgery	×		×
Microsurgery capabilities	×		
Obstetric/gynecologic Surgery	×	×	
Ophthalmic Surgery	×	×	×
Oral/maxillofacial Surgery	×	×	×
Orthopedic Surgery	×	×	×
Otorhinolaryngologic Surgery	×	×	×
Pediatric Surgery	×	X***	×
Plastic surgery	×	×	×
Thoracic surgery	×	×	×
Urologic surgery	×	×	×
Non-Surgical Specialties	**Level I**	**Level II**	**Pediatric**
Cardiology	×	×	×
Gastroenterology	×		
Hematology	×	×	×
Infectious Disease	×	×	×
Internal Medicine	×	×	
Nephrology	×	×	×
Pathology	×	×	×
Pediatric	×	×	×
Psychiatry	×		
Pulmonary Medicine	×	×	×
Radiology	×	×	×

***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.

All trauma centers are required to submit quality indicator data to the Florida Trauma Registry.[39]

[37] *Id.*
[38] *Id.*
[39] S. 395.404, F.S. and Rule 64J-2.006, F.A.C.

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 which reviewed Florida's hospital response capacity and examined the disparity of available trauma centers across the state.[40] The study recommended adopting the borders of the seven regional domestic security task forces as the state trauma regions and maintaining the nineteen trauma service areas.

In response to the interim study, numerous bills were filed during the 2004 Legislative Session to amend Florida's trauma system. Only one, Senate Bill 1762 (2004), was ultimately enacted.[41] The new law required the boundaries of the trauma regions to be coterminous with the boundaries of the regional domestic security task forces established within the Florida Department of Law Enforcement. The law provided a grandfather clause to allow the continuation of the delivery of trauma services coordinated with a trauma agency pursuant to a public or private agreement established before July 1, 2004. Moreover, DOH was directed to complete an assessment of the effectiveness of the existing trauma system and report its findings to the Governor and Legislature by February 1, 2005. The assessment was to include:[42]

- Consideration of aligning trauma service areas within the trauma region boundaries as established July 2004.
- Review of the number and level of trauma centers needed for each trauma service area 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 trauma service area 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 Taskforce 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 this assessment and subsequent annual reviews, the law required DOH to consider the following:[43]

- The recommendations made as a part of the regional trauma system 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 Taskforce.
- The actual number of trauma victims currently being served by each trauma center.
- Other appropriate criteria.

In February 2005, DOH submitted to the Legislature a report, which included the findings of an assessment conducted by a group of researchers from the University of South Florida and the

[40] Hospital Response Capacity, Report Number 2004-148, Senate Committee on Home Defense, Public Security, and Ports, on file with the Health and Human Services Committee staff.
[41] Senate Bill 1762, Chapter 2004-259, L.O.F.
[42] S. 395.402(2), F.S.
[43] S. 395.402(3), F.S.

University of Florida. The 2005 report made numerous recommendations, including a recommendation to transform the Florida trauma service areas to align them with the boundaries utilized by the regional domestic security task forces.

To date, the Legislature has not amended the structure of the Florida trauma system to incorporate the recommendations of the 2005 report.

Trauma System Administrative Rule Challenge

The DOH trauma program is tasked with overseeing the development, implementation and monitoring of various patient care guidelines, criteria and protocols for trauma centers and emergency medical services. In 2008, DOH adopted Rule 64J-2.010, F.A.C., which allocates the number of trauma centers needed within each trauma service area. The trauma program held a series of rule development workshops and hearings on Rule 64J-2.010, F.A.C., from 2008 to 2009. These meetings generated no consensus on rule revisions.

In May 2011, DOH received a challenge to Rule 64J-2.010, F.A.C., from five of the existing 22 verified trauma centers. The rule challenge alleged that DOH's rule was invalid for it constituted an invalid exercise of delegated legislative authority and was arbitrary and capricious. 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 that DOH's Rule 64J-2.010, F.A.C., was invalid on both grounds. DOH appealed the administrative hearing officer's ruling. The 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, First District Court of Appeal held that Rule 64J-2.010, F.A.C., is an invalid exercise of delegated legislative authority:[44]

> The trauma statutes were substantially amended in 2004, yet the rule remains unchanged since 1992. As such, the rule continues to implement outdated provisions of these statutes, without implementing any of the enumerated statutes. The Department 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 the Department 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." §395.4015(1), Fla. Stat. (2004). 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.

The dissent, stated, in part:

> The order below [DOAH order] and the majority opinion find that because the Legislature, under section 395.4015(1), Florida Statutes, required the Department to change the

[44] *Department of Health v. Bayfront Medical Center*, 37 Fla. L. Weekly D2754 (Fla. 1st DCA November 30, 2012). The court did not uphold DOAH's finding, however, that the rule was arbitrary and capricious.

boundaries of trauma *regions* to be "coterminous with the boundaries of the regional domestic security taskforces established under s. 943.0312," the rule allocating trauma centers within *trauma service areas* is invalid. The flaw with this conclusion is that a trauma service area is not a trauma region; thus, the rule's allocation of trauma centers to trauma service areas cannot be invalid on this basis.

On December 21, 2012, DOH held its first rule development workshop to gather input from the trauma system providers and partners on how Rule 64J-2.010, F.A.C., could be amended to ensure an inclusive trauma system in Florida. A series of rule workshops have been held since then. No consensus on rule language has been reached.

In February 2013, the Surgeon General requested the American College of Surgeons (ACS) to conduct a systems consultation of Florida's trauma system. The final report from ACS is expected to be released to DOH in May.[45]

American College of Surgeons

The American College of Surgeons (ACS) is a scientific and educational association of surgeons that began in 1913. 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 called the "Resources for Optimal Care of the Injured Patient." ACS site surveyors use this book to review trauma centers and it is recognized as a guide to develop trauma centers in the United States.[46]

According to ACS, the consultation/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 to include: commitment, readiness, resources, policies, patient care, and performance improvement. The certification process is voluntary and only those trauma centers that have successfully completed a verification visit are awarded a certificate.[47] ACS awards Level I-IV verifications:[48]

- A *Level I* facility is a regional resource trauma center that is a tertiary care facility central to the trauma system. This type of 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. Level I centers are usually university-based teaching hospitals due to the large personnel and resources required for patient care, education (to include residency programs), 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, but the trauma center is required to provide initial definitive trauma care regardless of the severity of the injury. Level II centers may be an academic institution or a public or private community facility located in an urban, suburban, or rural area.

[45] Per telephone conversation with DOH staff on April 23, 2013.
[46] American College of Surgeons, About the ACS, available at: http://www.facs.org/about/corppro.html (last viewed April 22, 2013).
[47] ACS currently verifies trauma centers in the following states: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, Nevada, North Carolina, North Dakota, South Carolina, Ohio, Oklahoma, Oregon, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming. The hospitals with ACS verification in Florida are: 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, available at: http://www.facs.org/trauma/verified.html (last viewed April 22, 2013).
[48] American College of Surgeons, Description of Hospital Levels, available at: http://www.facs.org/trauma/sitepacket.html (last viewed April 22, 2013).

- A *Level III* facility is required to provide prompt assessment, resuscitation, emergency operations, and stabilization and also arrange for possible transfer to another facility that can provide definitive care and requires transfer agreements and standardized treatment protocols. General surgeons are required in a Level III facility. Level III trauma centers are 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. Level IV trauma centers are located in remote areas where no higher level of care is available and is the de facto primary care provider. Such a facility may be a clinic rather than a hospital and a physician may not be available.

ACS has a multistep application and review process for certification. The costs are delineated by the number of members of the review team.

ACS Fee Structure[49]			
	Two-person review team:	Three-person review team:	Four-person review team:
Verification	$13,000	$16,000	$19,000
Re-verification	$12,000	$15,000	$18,000
Consultation	---	$15,000	$18,000

The fees include ACS administrative fee, reviewers' honoraria, travel expenses and subsistence. The cost for each additional site reviewer is $3,000 (e.g. alternate pathway, trauma program manager, emergency physician, orthopedic surgeon, or neurosurgeon.)[50]

Health Care Clinics

Pursuant to the Health Care Clinic Act (Act), AHCA licenses entities that meet the definition of a "clinic"- an entity at which health care services are provided to individuals and which tenders charges for reimbursement for such services, including a mobile clinic and a portable equipment provider.[51] The biennial health care clinic license fee is $2,000.00.[52]

The statute creates a number of exemptions from the health care clinic licensure requirements, including, but not limited to:

- Entities licensed or registered by the state under chapter 395;[53]
- Clinical facilities affiliated with an accredited medical school at which training is provided for medical students, residents, or fellows;[54]
- Orthotic or prosthetic clinical facilities that are a publicly traded corporation or that are wholly owned, directly or indirectly, by a publicly traded corporation;[55]
- Entities that are owned by a corporation that has $250 million or more in total annual sales of health care services where one or more of the owners is a health care practitioner who is responsible for supervising the business activities of the entity; and
- Entities that employ 50 or more licensed health care practitioners licensed under chapter 458 or chapter 459 where the billing for medical services is under a single tax identification number.[56]

[49] American College of Surgeons, Application for a Site Visit, available at: http://www.facs.org/trauma/sitepacket.html (last viewed April 22, 2013).
[50] *Id.*
[51] S. 400.9905(4), F.S.
[52] Rule 59A-33.002(1)(a), F.A.C.
[53] S. 400.9905(4)(a), F.S.
[54] S. 400.9905(4)(h), F.S.
[55] S. 400.9905(4)(l), F.S.
[56] S. 400.9905(4)(n), F.S.

An entity exempt from the licensing requirements of the Act may submit an Application for Certificate of Exemption from Licensure as a Health Care Clinic to AHCA.[57] The certificate, however, is not required to be exempt from licensure.[58]

Applicants must provide proof of compliance with applicable rules and financial ability to operate. As an alternative to submitting certain detailed financial projections, an applicant may submit a surety bond, payable to AHCA, in the amount of $500,000.00.[59] A level two background screening is required of each applicant for clinic licensure, and certain criminal offenses bar licensure.[60] Each clinic must have a medical director or clinic director[61] who agrees in writing to accept legal responsibility pursuant to s. 400.9935, F.S., for the following activities on behalf of the clinic:

- Ensuring that all practitioners providing health care services or supplies to patients maintain a current, active, and unencumbered Florida license;
- Reviewing patient referral contracts or agreements made by the clinic;
- Ensuring that all health care practitioners at the clinic have active appropriate certification or licensure for the level of care being provided;
- Serving as the clinic records owner;
- Ensuring compliance with the recordkeeping, office surgery, and adverse incident reporting requirements of chapter 456, F.S., the respective practice acts, and rules adopted under the Health Care Clinic Act; and
- Conducting systematic reviews of clinic billings to ensure billings are not fraudulent or unlawful. If an unlawful charge is discovered, immediate corrective action must be taken.

As of March 2013, AHCA has issued 2,084 Health Care Clinic Licenses and 9,121 Certificates of Exemption.[62]

Specialty-Licensed Hospitals

Section 395.003, F.S., states that a specialty hospital may not provide any service or regularly serve any population group beyond those that are specified in its license. However, a specialty-licensed children's hospital may treat certain adult patients with cardiovascular issues that the hospital treated as children.

AHCA licenses all hospital types in Florida. Hospitals with a class II specialty license must be designated as either a women's hospital or a children's hospital. To offer services to women and children, a hospital must be licensed as a class I general acute care hospital. Currently, a licensed children's hospital wanting to offer services outside of its previously defined patient base would be required to obtain a Certificate of Need to establish a new hospital or apply to change its classification to a class I general acute care hospital. Currently, three hospitals[63] in Florida qualify as specialty-licensed children's hospitals, but only one, Miami Children's Hospital is located in a county with a population of 1,750,000 or more.[64,65]

[57] Rule 59A-33.006(1), F.A.C.; The Certificate of Exemption from Licensure as a Health Care Clinic carries a $100 fee. Rule 59A-33.006(7), F.A.C.
[58] Id.
[59] Rule 59A-33.002(1)(d), F.A.C.
[60] Rule 59A-33.002(1)(e), F.A.C.
[61] Rule 59A-33.008, F.A.C., contains additional details regarding the role and responsibilities of the medical director or clinic director.
[62] E-Mail correspondence from AHCA staff to Health Innovation subcommittee staff, March 11, 2013 (on file with Health Innovation subcommittee staff); staff also notes that there is no requirement that a Certificate of Exemption be updated or that a clinic advise AHCA when it goes out of business. Staff suspects that the number of Certificates of Exemption is inflated and may be much lower.
[63] The three specialty-licensed children's hospitals are: All Children's Hospital in Saint Petersburg, Miami Children's Hospital in Miami and Nemours Children's Hospital in Orlando.
[64] US Census Bureau, 2012 Population Estimates, found at: http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2012_PEPANNRES&prodType=table, last visited on April 3, 2013.
[65] Nemours Children's Hospital is located in Orange County which had a population of 1,202,234 in 2012, and All Children's Hospital is located in Pinellas County which had a population of 921,319 in 2012. Id.

Hospital obstetrical departments are regulated pursuant to AHCA Rule 59A-3.2085(8), F.A.C. The rule requires that if a hospital provides obstetrical services, the services must include labor and delivery. The hospital must have nursery facilities and must be formally organized and operated to provide complete and effective care for each patient. Also, except for in hospitals with 75 beds or less, the obstetrical department must be separated from other patient care rooms and have a separate nursing staff. The rule also includes provisions for ensuring that infants are identified at birth.

High-Risk Pregnancy

A high-risk pregnancy is one of greater risk to the mother or her fetus as compared to an uncomplicated pregnancy.[66] Factors contributing to high-risk pregnancies are existing health conditions, age, lifestyle, and conditions of pregnancy. The more risk factors a woman has, the more likely she and her fetus will be at risk during pregnancy and birth.

The American College of Obstetricians and Gynecologists

The National Guideline Clearinghouse (NGC) is an initiative of the Agency for Healthcare Research and Quality, within the U.S. Department of Health and Human Services. The NGC is a publicly available database of evidence-based practice guidelines and related documents.[67] Updated weekly with new content, the NGC provides physicians and other health care professionals an accessible mechanism for obtaining detailed information on clinical practice guidelines.[68] The American College (College) of Obstetricians and Gynecologists is an organization that provides guidelines to the NGC relating to women's health and pregnancy.[69] Currently, the College provides guidelines for 68 different topic areas relating to women's health and pregnancy.[70]

The Voluntary Review of Quality of Care Program

The Voluntary Review of Quality of Care Program (Program) provides peer consultations to departments of obstetrics and gynecology, assesses the quality of care provided, and provides suggestions for improvement.[71] Program reviews are voluntary and consist of a facility tour, interviews, and review of medical records. Upon completion of a review, the Program will issue the hospital a final report with findings and recommendations based on the College's guidelines. The hospital may not use any portion of the report for promotional purposes. It is the responsibility of the hospital to determine which recommendations, if any, to implement. Hospitals are charged a fee of $40,000 for a Program review.[72]

Cancer

Treatment Medications

The trend in the treatment of cancer has been towards the development of oral chemotherapy medications. Experts estimate that more than 25 percent of the 400 chemotherapy drugs in the development pipeline are planned as oral medications.[73]

---

[66] The National Institute of Child Health and Human Development, *High-Risk Pregnancy Condition Information*, available at http://www.nichd.nih.gov/health/topics/high-risk/conditioninfo/Pages/default.aspx (last visited April 18, 2013).
[67] The National Guideline Clearinghouse, available at http://guideline.gov/about/index.aspx (last visited April 18, 2013).
[68] *Id.*
[69] American College of Obstetricians and Gynecologists, *Guidelines*, available at http://guideline.gov/browse/by-organization.aspx?orgid=85 (last visited April 18, 2013).
[70] *Id.*
[71] The Voluntary Review of Quality of Care Program, *VRQC Program Overview*, available at http://www.acog.org/About_ACOG/ACOG_Departments/VRQC_and_SCOPE/VRQC_Pr (last visited April 18, 2013)
[72] *Id.*
[73] Weingart, S.N., Bach, P.B., et al., *NCCN task force report: oral chemotherapy*, Journal of the National Comprehensive Cancer Network, 2008;6: S1-S17.

There are a more than two dozen oral cancer treatment medications that do not have an intravenous or injectable equivalent, including tamoxifen, used to treat breast cancer, Gleevec, used to treat chronic myeloid leukemia, and anastrozole, used to treat prostate cancer.

There is a significant cost disparity to the patient between intravenous or injectable cancer treatment medications and oral cancer treatment medications. In most cases, intravenous or injectable cancer treatment medications are covered in the medical benefits portion of a health insurance plan. Due to the nature of the delivery system of the medication, a patient is required to go to the hospital, a clinic, or a doctor's office in order to have an intravenous line inserted and the medication dose administered or to have the medication injected. Because this form of treatment is covered under the medical benefits portion of insurance, the out-of-pocket expenses for the patient are limited to the office co-payment amount, which is normally a very reasonable cost, or are capped on an annual or lifetime basis.

Oral cancer treatment medications, however, are covered under the pharmacy benefits portion of health insurance coverage. Many pharmacy benefit designs assign medications into tiers based on cost. Each tier carries a co-payment amount, which significantly increases as the tier, and associated drug cost, increases. Also, pharmacy benefit designs may have unlimited out-of-pocket cost-sharing requirements, meaning patients can be required to pay significant co-payments for as long as the patient is required to take a certain medications. Oral cancer treatment medications can run into the thousands of dollars per month in out-of-pocket costs to the patient.

The following chart illustrates the cost of medications for serious illness, including oral oncology medications:[74]

Average Monthly Patient Out-of-Pocket Cost Per Prescription, 2011			
	Rheumatoid Arthritis	Multiple Sclerosis	Oral Oncology
Actual Out-of-Pocket (OOP) Cost	**$235**	**$227**	**$470**
Estimated OOP Cost (by Coinsurance Level)			
33% cost sharing	**$653**	**$1,100**	**$1,920**
25% cost sharing	**$495**	**$833**	**$1,454**
5% cost sharing	**$99**	**$167**	**$291**

Out-of-pocket costs for oral cancer medication treatments averaged $2,942 in 2009, which is a 17 percent increase over the costs in 2008.

Oral Cancer Treatment Parity

Between 2008 and January 2013, twenty-one states and the District of Columbia have enacted oral chemotherapy parity laws that require the same cost-sharing requirements for oral cancer treatment medications and intravenous or injectable cancer treatment medications.[75] It is anticipated that 16 states, including Florida, will have similar legislation introduced in 2013.[76]

In 2009, Milliman, Inc., in a study commissioned by GlaxoSmithKline, examined the average increase in insurance costs resulting from oral cancer treatment medication parity legislation. Such legislation requires state-regulated payers to cover oral cancer treatment medication with the same cost-sharing requirements as intravenous or injectable cancer treatment medications. Milliman found that, for most

[74] Pharmaceutical Executive, *Who Pays for Specialty Medicines?* (citing Healthcare Analytics 2011, Amundsen Group Analysis)(available at http://license.icopyright.net/user/viewFreeUse.act?fuid=MTY5MTg4MiA%3D).
[75] *Oral Chemotherapy Parity Legislative Landscape- January 2013* (on file with Health Innovation Subcommittee staff).
[76] *Id.*

benefit plans, parity will increase plan costs less than $0.50 per member per month (PMPM).[77] Parity for some benefit plans that carry very high cost-sharing requirements for oral specialty drugs and low medical benefits may see a cost of $1.00 PMPM or more.[78] Other benefit plans that have a low cost-sharing requirement in general could see parity costs of $0.05 to $0.10 PMPM.[79]

Patient Protection and Affordable Care Act

In March 2010, the Congress passed and the President signed the Patient Protection and Affordable Care Act (PPACA).[80] Under PPACA, qualified health plans (QHP) would be available from the state or federal Exchange beginning January 1, 2014. PPACA required the Secretary of Health and Human Services to establish for those QHP's a minimum package of essential health benefits (EHB).[81] The EHB package must cover benefits across ten general categories, including, but not limited to preventive services, maternity care, hospital services and prescription drugs.[82]

Section 1311(d)(3)(B) of PPACA allows a state to require QHPs to cover additional benefits above those required under the EHB; however, the law also directs the state to offset the costs of those supplemental benefits to the enrollee.[83] Under the final rule released on February 25, 2013, a distinction in the proposed rule's preamble is made between changes in benefits versus changes in cost sharing. The final rule limits the offset requirement only to "care, treatment and services," thereby excluding a state's obligations to defray costs relating to changes relating to provider types, cost-sharing or reimbursement.[84]

In addition to these provisions, certain plans under PPACA received "grandfather status." A grandfathered health plan is a plan that existed on March 23, 2010, the date that PPACA was enacted, and under which at least one person had been continuously covered for one year.[85] Some consumer protection elements in PPACA do not apply to grandfathered plans but others are applicable, regardless of the type of plan.[86]

The essential health benefits do not apply to grandfathered health plans.[87] A grandfathered plan can lose its status if significant changes to benefits or cost sharing changes are made to the plan since attaining its grandfathered status.[88] Grandfathered plans are required to disclose their status to their enrollees every time plan materials are distributed and to identify the consumer protections that are not available as a grandfathered plan.[89] Even though exempt from the EHB, a grandfathered plan could still be required to meet a new a requirement under state law if otherwise required under state requirements.[90] Depending on the impact, a new state benefit requirement could cause the loss of grandfathered status, such that all PPACA requirements would apply, likely resulting in higher costs for the consumer.

---

[77] Milliman, Client Report, Fitch, K., Iwasaki, K., Pyenson, B., *Parity for Oral and Intravenous/Injected Cancer Drugs*, page 1 (December 15, 2009).
[78] *Id*.
[79] *Id*.
[80] Pub. Law No. 111-148, H.R. 3590, 111th Cong. (Mar. 23, 2010).
[81] *Id.*
[82] Center for Consumer Information and Insurance Oversight, *Essential Health Benefits Coverage Bulletin*, (1), Dec. 16, 2011, available at: http://cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf (last viewed March 11, 2013).
[83] 78 Fed. Reg. 12,837, 12,837-12,838 (February 25, 2013).
[84] *Id.*
[85] Healthcare.gov, *Grandfathered Health Plans*, available at http://www.healthcare.gov/law/features/rights/grandfathered-plans/index.html (last viewed March 11, 2013).
[86] Healthcare.gov., *Factsheet,* available at http://www.healthcare.gov/news/factsheets/2012/11/ehb11202012a.html (last viewed March 11, 2013).
[87] Barr, S., *FAQ: Grandfathered Health Plans*, December 2012, available at http://www.kaiserhealthnews.org/stories/2012/december/17/grandfathered-plans-faq.aspx (last viewed March 11, 2013).
[88] Healthcare.gov, *Keeping the Health Plan You Have: The Affordable Care Act and "Grandfathered Health Plans*, June 14, 2010, available at http://www.healthcare.gov/news/factsheets/2010/06/keeping-the-health-plan-you-have-grandfathered.html (last viewed March 11, 2013).
[89] *Id.*
[90] 75 Fed. Reg. 34, 538, 34,540 (June 17, 2010).

The PPACA's provisions include annual limitations on cost sharing in section 1302(c)(1) and an annual limitation on deductibles in section 1302(c)(2) of the Affordable Care Act effective January 1, 2014. The type of plan an individual is enrolled in and the level of benefits selected or "medal plan," will determine the amount of out of pocket costs that an individual may incur.

The federal law further prohibits the imposition of annual and lifetime benefit limits, except for certain grandfathered plans, effective January 1, 2014. These protections went into effect for children earlier, September 23, 2010, and apply to grandfathered group health insurance plans. These restrictions would impact any out of pocket costs applied to prescription drug coverage whether delivered as an oral or an injectable medication.

Health Insurance Mandates and Mandated Offerings

A health insurance mandate is a legal requirement that an insurance company or health plan cover services by particular health care providers, specific benefits, or specific patient groups. Mandated offerings, on the other hand, do not mandate that certain benefits be provided. Rather, a mandated offering law can require that insurers offer an option for coverage for a particular benefit or specific patient groups, which may require a higher premium and which the insured is free to accept or reject. A mandated offering law in the context of mental health can require that insurers offer an option of coverage for mental illness, which may require a higher premium and which the insured is free to accept or reject or require that, if insurers offer mental illness coverage, the benefits must be equivalent to other types of benefits.

Florida currently has at least 59 mandates.[91] Higher costs resulting from mandates are most likely to be experienced in the small group market since these are the plans that are subject to state regulations. The national average cost of insurance for a family of four is $15,745.[92]

Health Insurance Mandate Report

Section 624.215, F.S., was enacted in 1987 to aid the Legislature in assessing the impact of health insurance mandates and mandated offerings on insurance policy premiums when considering proposed health insurance mandates. The statute requires that any proposal for legislation that mandates health benefit coverage or mandatorily offered health coverage must be submitted with a report to AHCA and to the legislative committees having jurisdiction over the issue. The report must assess the social and financial impact of the proposed coverage to the extent information is available, and shall include:

- To what extent is the treatment or service generally used by a significant portion of the population.[93]
- To what extent is the insurance coverage generally available.[94]
- If the insurance coverage is not generally available, to what extent does the lack of coverage result in persons avoiding necessary health care treatment.[95]
- If the coverage is not generally available, to what extent does the lack of coverage result in unreasonable financial hardship.[96]
- The level of public demand for the treatment or service.[97]
- The level of public demand for insurance coverage of the treatment or service.[98]

[91] Florida House of Representatives, Health and Human Services Quality Subcommittee, *Meeting Packet for November 15, 2011*, pages 7-9.
[92] The Henry J. Kaiser Family Foundation, Employer Health Benefits 2012 Annual Survey- Summary of Findings, page 1 (available at http://ehbs.kff.org/pdf/2012/8345.pdf) (last viewed March 11, 2013).
[93] S. 624.215(2)(a), F.S.
[94] S. 624.215(2)(b), F.S.
[95] S. 624.215(2)(c), F.S.
[96] S. 624.215(2)(d), F.S.
[97] S. 624.215(2)(e), F.S.

- The level of interest of collective bargaining agents in negotiating for the inclusion of this coverage in group contracts.[99]
- To what extent will the coverage increase or decrease the cost of the treatment or service.[100]
- To what extent will the coverage increase the appropriate uses of the treatment or service.[101]
- To what extent will the mandated treatment or service be a substitute for a more expensive treatment or service.[102]
- To what extent will the coverage increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.[103]
- The impact of this coverage on the total cost of health care.[104]

The International Myeloma Foundation (Foundation) delivered a report to the Senate Health Policy Committee on February 21, 2013, assessing SB 422 and HB 301 against the criteria of s. 624.215, F.S., while specifically not admitting that the bill's directives mandate any specific health coverage.[105] According to the Foundation, insurance coverage of oral cancer medications is not the precise issue. The issue is the out of pocket cost differential to patients between intravenous or injectables and oral treatments as most insurance plans already cover the medication.[106]

State Group Insurance Program

The State Group Insurance Program (program) is created by s. 110.123, F.S., and is administered by the Division of State Group Insurance (DSGI) within the Department of Management Services (DMS).

The program is an optional benefit for state employees including all state agencies, state universities, the court system, and the Legislature. The program includes health, life, dental, vision, disability, and other supplemental insurance benefits.

The health insurance benefit for active employees has premium rates for single, spouse, or family coverage regardless of plan selection. The state contributes approximately 90% toward the total annual premium for active employees for a total of $1.41 billion out of the total premium of $1.57 billion for FY 2012-13[107].

The program provides several options for employees to choose as their health plans. The preferred provider organization (PPO) plan is the statewide, self-insured health plan administered by Blue Cross Blue Shield of Florida. The administrator is responsible for processing health claims, providing access to a Preferred Provider Care Network, and managing customer service, utilization review, and case management functions. The standard health maintenance organization (HMO) plan is an insurance arrangement in which the state has contracted with multiple statewide and regional HMOs.

Each year the Legislature specifies in the General Appropriations Act the state program benefit design and the employer and employee premium contributions.

Currently, out-of-pocket costs for cancer treatment vary depending on the plan the employee is enrolled in and whether:

- The claim is for medical services or pharmacy;

---

[98] S. 624.215(2)(f), F.S.
[99] S. 624.215(2)(g), F.S.
[100] S. 624.215(2)(h), F.S.
[101] S. 624.215(2)(i), F.S.
[102] S. 624.215(2)(j), F.S.
[103] S. 624.215(2)(k), F.S.
[104] S. 624.215(2)(l), F.S.
[105] International Myeloma Foundation, *Health Insurance Mandate Report, Parity for Oral and Intravenous Cancer Medications*, page 1, February 2013 (on file with the Health Innovation Subcommittee).
[106] *Id.* at page 2.
[107] Fiscal information provided by DSGI.

- The medication is dispensed as a 30-day supply at a retail pharmacy or a 90-day supply at the mail order pharmacy;
- The medical services are inpatient services or outpatient services;
- The medical claim includes an office visit billing code;
- The services or drugs are obtained from an in-network or out-of-network provider or pharmacy; and
- The enrollee has met the applicable calendar year deductible and/or annual out-of-pocket maximum[108]

An enrollee in the program may have no cost sharing requirements for outpatient services that that include intravenously administered or injected cancer treatment medications or the copayment may be $40 depending the one enrollee's individual circumstances. The enrollee's cost for oral cancer medications is often $50 per month.[109]

Prescription Drug Monitoring Program

Chapter 2009-197, L.O.F, established the Prescription Drug Monitoring Program (PDMP) in s. 893.055, F.S. The PDMP uses a comprehensive electronic database to monitor the prescribing and dispensing of certain controlled substances.[110] Dispensers of controlled substances listed in Schedule II, III, or IV must report specified information to the PDMP database, including the name of the prescriber, the date the prescription was filled and dispensed, and the name, address, and date of birth of the person to whom the controlled substance is dispensed.[111] Dispensers must report the dispensing of a specified controlled substance to the PDMP database within seven days of dispensing the controlled substance.[112]

Direct access to the PDMP database is presently limited to medical doctors, osteopathic physicians, dentists, podiatric physicians, advanced registered nurse practitioners, physician assistants, and pharmacists.[113] Indirect access to the PDMP database is provided to:

- DOH or its relevant health care regulatory boards;
- The Attorney General for Medicaid fraud cases;
- A law enforcement agency; and
- A patient or the legal guardian, or designated health care surrogate of an incapacitated patient.[114]

Entities with indirect access to the PDMP database may request information from the PDMP manager that is confidential and exempt under s. 893.0551, F.S, which is discussed below. A law enforcement agency, for example, may request such information during an active investigation regarding potential criminal activity, fraud, or theft relating to prescribed controlled substances.[115]

Restrictions on how DOH may fund implementation and operation of the PDMP are also included in statute. DOH is prohibited from using state funds and any money received directly or indirectly from prescription drug manufacturers to implement the PDMP.[116] Funding for the PDMP comes from three funding sources:[117]

---

[108] Analysis of HB 301 by the Department of Management Services, February 27, 2013 (on file with the Health and Human Services Committee).
[109] Id.
[110] S. 893.055(2)(a), F.S.
[111] S. 893.055(3)(a)-(c), F.S.; controlled substances listed in Schedule II, III, or IV can be found in s. 893.03(2)-(4), F.S.
[112] S. 893.055(4), F.S.
[113] S. 893.055(7)(b), F.S.
[114] S. 893.055(7)(c)1.-4., F.S.
[115] S. 893.055(7)(c)3., F.S.; see also 64K-1.003(2)(c), F.A.C.
[116] S. 893.055(10) and (11)(c), F.S.
[117] Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), *2011-2012 Prescription Drug Monitoring Program Annual Report*, page 7 (available at www.eforcse.com/docs/2012AnnualReport.pdf) (on file with

1. Donations procured by the Florida PDMP Foundation, Inc. (Foundation), the direct-support organization authorized by s. 893.055, F.S., to fund the continuing operation of the PDMP.

PDMP Foundation Payments to DOH	
FY 2009-2010	$39,108
FY 2010-2011	$201,552
FY 2011-2012	$96,758
FY 2012-2013	$102,654
Total	**$440,072**

2. Federal Grants. The PDMP has been awarded three Harold Rogers Prescription Drug Monitoring Program grants from the U.S. Department of Justice and one additional federal grant. The award date and amount of each grant follows:

   - On May 19, 2010, DOH was awarded an "Implementation" grant of $400,000 to implement the prescription drug monitoring system.
   - On September 19, 2010, DOH was awarded an "Enhancement" grant of $400,000 for system enhancements.
   - On August 21, 2012, DOH was awarded a second "Enhancement" grant of $399,300 to enhance the PDMP.
   - On September 20, 2012, DOH was awarded a grant of $240,105 from the Substance Abuse and Mental Health Services Administration (SAMHSA) to integrate PDMP data into existing clinical workflow and technology and to expand interoperability.

   The total amount of federal grants received is $1,199,300. Of that amount, approximately $566,460 has been expended in operation of the PDMP.

3. Private grants and donations. DOH has been awarded three private grants from the National Association of State Controlled Substance Authorities. These grants, totaling $49,952, were used to create a website, to purchase office equipment, and to purchase promotional items.

The following chart illustrates the breakdown of costs for the PDMP for FY 2012-13 and FY 2013-14:

COST	FY 2012-13	FY 2013-14
Infrastructure	$240,086	$240,087
Personnel (2 FTEs)	$211,016	$211,016
Facilities	$26,186	$43,596
TOTAL	**$477,288**	**$494,699**

Section 893.0551, F.S., provides an exemption from public records for personal information of a patient and certain information concerning health care professionals outlined in the statute.[118] The statute details exceptions for disclosure of information after DOH ensures the legitimacy of the person's request for the information.[119]

The PDMP became operational on September 1, 2011, when it began receiving prescription data from pharmacies and dispensing practitioners.[120] Health care practitioners began accessing the PDMP on

---

Health Quality Subcommittee staff); information also came from Florida Department of Health document detailing the funding history of the PDMP, also on file with Health Quality Subcommittee staff.

[118] S. 893.0551(2)(a)-(h), F.S.

[119] S. 893.0551(3)(a)-(g), F.S.

[120] Florida Department of Health, Florida's Prescription Drug Monitoring Program, Presentation to the Senate Health Policy Committee, January 23, 2013, slide 5 (on file with Health Quality Subcommittee staff).

October 17, 2011.[121] Law enforcement began requesting data from the PDMP in support of active criminal investigations on November 14, 2011.[122]

Between 2011 and 2012, physicians and pharmacists used the PDMP database at least 2.6 million times.[123] Nearly 5,000 pharmacists entered 56 million prescriptions into the database.[124] Law enforcement queried the PDMP database more than 20,000 times in conjunction with active criminal investigations.[125]

The PDMP is currently funded through fiscal year 2012-2013.[126]

Effect of Proposed Changes

Skilled Nursing Facilities

The bill provides an exemption from the moratorium on new community nursing homes and an expedited review for CON applicants for the construction of a community nursing home and the addition of skilled nursing home beds within a retirement community that meets certain qualifications.

The request for expedited review must be submitted to AHCA, and include the number of beds to be added and evidence that the retirement community:

- Is deed restricted for older persons;
- Is located in a county that has 25 percent or more of its population consisting of persons aged 65 and older;
- Is located in a county that has a rate of no more than 16.1 community skilled nursing home beds per thousand persons aged 65 and older; and
- Has a population of at least 8,000 residents within the county.

Further, the bill requires all nursing homes approved for expedited review to be dually certified for participation in the Medicare and Medicaid programs and be no closer than one mile from an existing nursing home.

The bill limits the number of community nursing home beds that can be approved under each application for expedited review to 120, and the total number of community nursing home beds for any single deed restricted community CON is capped at 240, regardless of whether the retirement community is located in more than one qualifying county.

To determine the exact number of beds to be approved, AHCA must ensure that the rate of beds to thousand persons aged 65 and older does not exceed 16.1. In determining the number of beds to approve, the bill requires AHCA to use a prospective county population estimate three years into the future to demonstrate that the population of persons aged 65 and older will be at least 25 percent and that the rate of beds to thousand persons aged 65 and older will be no more than 16.1.

The bill requires AHCA, upon verification that the retirement community meets the criteria for expedited review, to publicly notice in the Florida Administrative Register that a request for an expedited review has been submitted and determined to be qualified and that the retirement community intends to make land available for the construction and operation of a community nursing home. The bill requires AHCA to include the following in the public notice:

---

[121] *Id.*
[122] *Id.*
[123] *Id.*
[124] *Id.*
[125] *Id.*
[126] Florida Department of Health, *Florida's Prescription Drug Monitoring Program*, Presentation to the Senate Health Policy Committee, January 23, 2013, slide 5 (on file with Health Quality Subcommittee staff).

- Information identifying where potential applicants can obtain information describing the sales price of, or terms of the land lease for the property on which the project will be located; and
- The deadline for submission of any CON application.

The bill requires CON applications to:

- Identify the intended site for the project within the retirement community and the anticipated costs for the project based on that site; and
- Include written evidence that the retirement community has determined that the provider submitting the application and the project proposed by that provider satisfies its requirements for the project.

The bill provides that if the retirement community determines that more than one provider satisfies their requirements for the project they are not prohibited from notifying AHCA of their provider of choice, and AHCA is required to review the competing applications.

Finally, the bill requires a qualified retirement community to make land available to applicants it deems to have met the requirements for the construction and operation of a community nursing home, only if the applicant has been issued a CON by AHCA.

Florida Trauma System

The bill allows hospitals located in areas with limited access to trauma services to open Level II trauma centers by obtaining valid certificates from ACS instead of completing the current application and review process performed by DOH.

The bill defines areas with limited access to trauma center services as a hospital located in a trauma service area having a population greater than 600,000, with a population density of less than 225 persons per square mile, in a county with no verified trauma center, and at least 15 miles or 20 minutes travel time by ground transport from the nearest verified trauma center. It appears that five counties, Okaloosa, Santa Rosa, Walton, Hardee, and Highlands fall under the definition of limited access areas.

Health Care Clinics

The bill amends s. 400.9905, F.S., to create exemptions from licensure under the Health Care Clinic Act for publicly traded pediatric cardiology, perinatology, or anesthesia clinical facilities.

The bill also amends an existing exemption for entities that are owned by a corporation that has $250 million or more in total annual sales of health care services allowing such entities to be operated by, rather than only owned by, a health care practitioner.

Specialty-Licensed Hospitals

The bill allows specialty-licensed children's hospitals that have licensed neonatal intensive care beds, and are located in a county with a population of 1,750,000 or more, to provide obstetrical services, including labor and delivery care, up to 10 patients, under the following conditions:

- The services must be restricted to the diagnosis, care, and treatment of pregnant women of any age;
- The patient must have documentation by an examining physician, including information regarding:
    - At least one fetal characteristic or condition that would characterize the pregnancy or delivery as high risk; or

- Medical advice or a diagnosis indicating that the fetus may require at least one perinatal intervention.

In addition, the bill requires qualifying hospitals to provide obstetrical services, as follows:

- In accordance with the pertinent guidelines promulgated by the American College of Obstetricians and Gynecologists;
- With verification of guidelines and compliance with internal safety standards by the Voluntary Review for Quality of Care Program of the American College of Obstetricians and Gynecologists; and
- In compliance with AHCA rules.

Cancer

Effective July 1, 2014, the bill requires health insurance policies and contracts and HMO contracts that provide cancer treatment medication coverage to also provide coverage for oral cancer treatment medications.

The bill requires policies and contracts to apply cost-sharing requirements for oral cancer treatment medications that are no less favorable than the cost-sharing requirements for other cancer treatment medications, such as intravenous and injectable medications. The bill exempts grandfathered health plans, Medicare supplement, dental, vision, long-term care, disability, accident only, specified disease policies, or other supplemental limited-benefit plans[127] from the oral cancer treatment medications coverage and cost-sharing parity requirements.

The bill permits a policy or contract with cost-sharing requirements for intravenous or injectable cancer medications less than $50 to apply cost-sharing requirements up to $50 to prescribed oral cancer treatment medications.[128]

The bill prohibits insurers, HMOs, and any participating entities through which the insurer or HMO offers health services from taking the following actions designed to avoid the parity requirements of the bill:

- Varying the terms of the policy in effect on July 1, 2014;
- Providing any incentive to a covered person to accept coverage that includes anything less than parity;
- Penalizing a provider for recommending or providing oral cancer treatment medications;
- Providing any incentive to a provider to not comply with the parity provisions; and
- Changing cost-sharing requirements or classification of intravenous or injectable cancer treatment medications in effect on July 1, 2014.

Prescription Drug Monitoring Program

The bill creates an exception to the prohibition of using state funds for the PDMP for Fiscal Year 2013-2014, only. The bill appropriates $500,000 in nonrecurring funds from the General Revenue Fund to DOH for the administration of the PDMP.

---

[127] Supplemental insurance products are offered and issued separately from comprehensive, major medical insurance. Major medical insurance reimburses for actual medical expenses and is generally payable directly to health care providers. Supplemental insurance generally pays direct cash benefits to the insured. Supplemental insurance is not intended to replace or be issued in lieu of comprehensive, major medical insurance and instead is designed to provide benefits not covered by comprehensive coverage. *America's Health Insurance Plans (AHIP) Board of Directors Statement on the Value of Supplemental Health Insurance*, March 8, 2011, available at: http://www.ahip.org/Issues/Documents/2011/AHIP-Board-of-Directors-Statement-on-the-Value-of-Supplemental-Health-Insurance.aspx (last viewed on May 10, 2013).

[128] This provision will mitigate the negative fiscal impact of the cancer medication cost sharing parity requirement to the State Group Issuance Program. See Fiscal Comments, infra.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

If a public hospital seeks verification as a Level II trauma center from ACS, the costs for such verification may impact local governments that utilize special tax districts to support that hospital.

Local governments may experience a negative fiscal impact if health insurance premiums increase as a result of the oral cancer provisions of the bill. The amount is indeterminate and will vary depending on plan attributes.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Currently, the cost for the application and verification of a Level II trauma center reviewed and approved by DOH is paid for by established state funding. The costs for an ACS verification certificate for a Level II trauma center will be borne by a hospital seeking such designation.[129]

Health insurers and HMOs may raise premiums to address the impact of oral cancer medication treatment coverage and cost-sharing parity under the bill. As a result, policyholders and contract holders for health care coverage may see an increase in monthly premiums for the same coverage for policies and contracts issued or renewed after the effective date of the bill.

Patients receiving oral cancer treatment medications may realize lower out-of-pocket expenses to obtain their medications.

D. FISCAL COMMENTS:

DOH projects an annual savings of $165,000 to the Emergency Medical Services Trust Fund from eliminating the need for DOH to hire out-of-state surveyors and decreasing administrative costs associated with processing Level II trauma center applications.

PPACA allows a state to require QHPs to cover additional benefits above those required under the EHB. The law also directs the state to offset the costs of those supplemental benefits to the enrollee. The bill creates a new coverage and parity requirement for oral cancer treatment medications. While

[129] Department of Health, Bill Analysis for CS/CS/HB 817 dated April 17, 2013, on file with the Health and Human Services Committee staff.

PPACA requires the state to be responsible for offsetting the cost of this additional coverage and parity requirement, there are no guidelines addressing how the total cost will be determined, how it will be paid by the state, and to whom the payments will be made. As a result, the bill presents a potential indeterminate negative fiscal impact to the state.

The Division of State Group Insurance (DSGI) projected a negative fiscal impact to the State Group Employees' Health Insurance Trust Fund for four fiscal years (Fiscal Year 2013-2014 through Fiscal Year 2016-2017) of approximately $420,000 per year, based on 2012 claims data, if the State Group Insurance Program implements the bill's cancer treatment parity requirements. However, since the provisions of the bill permit a policy or contract with cost-sharing requirements for intravenous or injectable cancer medications less than $50 to apply cost-sharing requirements up to $50 to prescribed oral cancer treatment medications, the costs to the program are mitigated. The requirements of the bill will have an indeterminate negative fiscal impact on the State Employees' Health Insurance Trust Fund; however, the impact will be significantly less than $420,000 per year.

The bill appropriates $500,000 in nonrecurring funds for Fiscal Year 2013-2014, from the General Revenue Fund to DOH for the administration of the prescription drug monitoring program.