Health & Human Services Committee

Thursday, January 21, 2016
11:30 AM – 1:30 PM
Morris Hall

Steve Crisafulli
Speaker

Jason Brodeur
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health & Human Services Committee

Start Date and Time: Thursday, January 21, 2016 11:30 am

End Date and Time: Thursday, January 21, 2016 01:30 pm

Location: Morris Hall (17 HOB)

Duration: 2.00 hrs

Consideration of the following proposed committee bill(s):

PCB HHSC 16-01 -- State Employee Group Health Plan

Consideration of the following bill(s):

HB 85 Recovery Care Services by Fitzenhagen
CS/HB 313 Prescription Drug Monitoring Program by Health Quality Subcommittee, Pilon
CS/HB 325 Involuntary Examinations under the Baker Act by Health Quality Subcommittee, Campbell, Plasencia
CS/HB 373 Mental Health Counseling Interns by Health Quality Subcommittee, Burgess
CS/HB 375 Physician Assistants by Health Care Appropriations Subcommittee, Steube
HB 423 Drug Prescription by Advanced Registered Nurse Practitioners & Physician Assistants by Pigman, Campbell
HB 437 Certificates of Need for Hospitals by Sprowls
HB 581 State Veterans' Nursing Homes by Magar
CS/HB 595 Reimbursement to Health Access Settings for Dental Hygiene Services for Children by Health Innovation Subcommittee, Plasencia
HB 7041 OGSR/Florida Center for Brain Tumor Research by Government Operations Subcommittee, Trumbull

Presentation by Healthcare Bluebook

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Wednesday, January 20, 2016.

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., Wednesday, January 20, 2016.

NOTICE FINALIZED on 01/19/2016 2:19PM by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HHSC 16-01 State Employee Group Health Plan
SPONSOR(S): Health & Human Services Committee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health & Human Services Committee		Poche	Calamas

SUMMARY ANALYSIS

The State Group Insurance Program (program), administered by the Department of Management Services (DMS), is an optional benefit for employees that includes health, life, dental, vision, disability, and other supplemental insurance benefits. The program offers employees a choice among a health maintenance organization (HMO) plan, prefer provider plan (PPO) plan, and a high-deductible health plan (HDHP) with a health saving account (HSA). However, only one benefit level is offered for each plan type. Additionally, the employee's premium for the HMO and PPO are the same, even though the HMO provides greater benefits.

PCB HHSC 16-01 adds new products and services to the program by giving DMS broad authority to contract for a wide variety of additional products and services. Employees will be able to purchase new products as optional benefits. DMS is directed to contract with at least one entity that provides comprehensive pricing and inclusive services for surgery and other types of medical procedures. The contract requires cost savings to the program, which will be shared by the state and the enrollee.

Beginning in 2017, DMS is directed to contract with at least one entity that provides online health care price and quality information, including the average price paid for health care services and providers by county. The contract requires the entity to allow enrollees to shop for health care using the information provided to select higher quality, lower cost services and providers. The contract also requires the entity to identify any savings realized by the enrollee, and share those savings with the enrollee

Beginning in the 2019 plan year, the bill provides that state employees will have health plan choices at four different benefit levels. If the state's contribution for premium is more than the cost of the plan selected by the employee, then the employee may use the remainder to:

- Fund a flexible spending arrangement or a health savings account.
- Purchase additional benefits offered through the state group insurance program.
- Increase the employee's salary.

The bill directs DMS to hire an independent benefits consultant (IBC). The IBC will assist DMS in developing a plan for the implementation of the new benefit levels in the program. The plan shall be submitted to the Governor, the President of the Senate and the Speaker of the House of Representatives no later than January 1, 2018. The IBC will also provide ongoing assessments and analysis for the program.

The bill directs DMS to recommend employee contribution rates for standard plans and high deductible health plans for the 2017 plan year reflecting the actuarial benefit difference between the HMO and the PPO plans for both self-insured and fully insured products. The proposed enrollee premium rates for the 2017 plan year must be submitted to the Legislative Budget Commission (LBC) for review and approval. If the LBC does not approve the proposed rates, the rates provided in the 2016-17 General Appropriations Act will apply.

The bill provides $151,216 in recurring trust fund and $507,546 in nonrecurring trust fund authority to the Department of Management Services, and 2 full-time equivalent positions to implement the administrative provision of the act. The provisions of the bill are expected to have a positive, but indeterminate, fiscal impact on the state. See fiscal comments.

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

State Group Insurance Program

Overview

The State Group Insurance Program (state 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 or department).

The state program is an optional benefit for all 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 program[1], or family coverage regardless of plan selection. The state contributed approximately 91% toward the total annual premium for active employees for a total of $1.68 billion out of total premium of $1.85 billion for active employees during FY 2014-15[2]. Retirees and COBRA participants contributed an additional $228.4 million in premiums, with $139.4 million more in other revenue for a total of $2.2 billion in total revenues.[3]

Cafeteria Plans

A cafeteria plan is a plan that offers flexible benefits under Section 125 of the Internal Revenue Code. Employees choose from a "menu" of benefits. The plan can provide a number of selections, including medical, accident, disability, vision, dental and group term life insurance. It can reimburse actual medical expenses or pay children's day care expenses.

A cafeteria plan reduces both the employer's and employee's tax burden. Contributions by the employer are not subject to the employer social security contribution. Contributions made by the employee are not subject to federal income or social security taxes.

The employer chooses the range of benefits it wishes to offer in a cafeteria plan. The plan can be a simple premium-only plan where only health insurance is offered. Full flex plans, which offer a wide variety of benefits and choices, are more often offered by large employers and allow for more consumer-directed consumption of benefits. In some full flex plans, the employee is offered the choice between receiving additional compensation in lieu of benefits.

The state program qualifies as a cafeteria plan[4] even though it offers relatively narrow health plan options compared to other cafeteria plans.

[1] The Spouse Program provides discounted rates for family coverage when both spouses work for the state.
[2] Florida Legislature, Office of Economic and Demographic Research, Self-Insurance Estimating Conference, *State Employees' Group Health Self-Insurance Trust Fund- Report on the Financial Outlook for Fiscal Years Ending June 30, 2015 through June 30, 2020*, adopted August 12, 2015, page 6, available at http://edr.state.fl.us/Content/conferences/healthinsurance/HealthInsuranceOutlook.pdf
[3] Id.
[4] 26 USC sec. 125 requires that a cafeteria plan allow its members to choose between two or more benefits "consisting of cash and qualified benefits." The proposed regulations define "cash" to include a "salary reduction arrangement" whereby salary is deducted pre-tax to pay the employee's share of the insurance premium. Since the state program allows a "salary reduction arrangement", the program qualifies as a cafeteria plan. 26 C.F.R. ss. 1.125-1, et seq.

Health Plan Options

The program provides limited options for employees to choose as their health plan. The preferred provider organization (PPO) plan is the statewide, self-insured health plan administered by Florida Blue, whose current contract is for the 2015 through 2018 plan years. 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[5].

Prior to the 2011 plan year, the participating HMOs were fully insured; in other words, the HMOs assumed all financial risk for the covered benefits. During the 2010 session, the Legislature enacted s. 110.12302, F.S., which directed DMS to require costing options for both fully insured and self-insured plan designs as part of the department's solicitation for HMO contracts for the 2012 plan year and beyond. The department included these costing options in its Invitation to Negotiate[6] to HMOs for contracts for plans years beginning January 1, 2012. The department entered into contracts for the 2012 and 2013 plan years with two HMOs with a fully insured plan design and four with a self-insured plan design. The contracts with the HMOs have been renewed for the 2015 plan year.[7]

Additionally, the program offers two high-deductible health plans (HDHP[8]) with health savings accounts (HSAs)[9]. The Health Investor PPO Plan is the statewide HDHP with an integrated HSA. It is also administered by Florida Blue. The Health Investor HMO Plan is an HDHP with an integrated HSA in which the state has contracted with multiple state and regional HMOs. Both have an individual deductible of $1,350 for individual and $2,600 for family for network providers. The state makes a $500 per year contribution to the HSA for single coverage and a $1,000 per year contribution for family coverage. The employee may make additional annual contributions[10] to a limit of $3,350 for single coverage and $6,650 for family coverage. Both the employer and employee contributions are not subject to federal income tax on the employee's income. Unused funds roll over automatically every year. An HSA is owned by the employee and is portable.

The following charts illustrate the benefit design of each of the plan choices.

	HMO Standard	PPO Standard	
	Network Only	Network	Out-of-Network
Deductible	None	$250 | $500 Single | Family	$750 | $1,500 Single | Family
Primary Care	$20 copayment	$15 copayment	40% of out-of-network allowance plus the amount between the charge and the allowance
Specialist	$40 copayment	$25 copayment	
Urgent Care	$25 copayment	$25 copayment	
Emergency Room	$100 copayment	$100 copayment	

[5] The HMOs include Aetna, AvMed, Capital Health Plan, Coventry Health Care of Florida, Florida Health Care Plans and UnitedHealthcare.
[6] ITN NO.: DMS 10/11-011
[7] DMS is currently procuring HMOs for the next contract period and expects to complete the procurement process and award contracts to the HMOs after the 2016 Regular Legislative Session.
[8] High-deductible health plans with linked HSAs are also call consumer-directed health plans (CDHP) because costs of health care are more visible to the enrollee.
[9] 26 USC sec. 223; To qualify as a high-deductible plan, the annual deductible must be at least $1,300 for single plans and $2,600 for family coverage, but annual out-of-pocket expenses cannot exceed $6,450 for individual and $12,900 for family coverage. These amounts are adjusted annually by the IRS.
[10] The IRS annually sets the contribution limit as adjusted by inflation.

Hospital Stay	$250 copayment	20% after $250 copayment	40% after $500 copayment plus the amount between the charge and the allowance
Generic | Preferred | Non-Preferred Prescriptions	$7 | $30 | $50 Retail $14 | $60 | $100 Mail Order	$7 | $30 | $50 Retail $14 | $60 | $100 Mail Order	Pay in full, file claim
Out-of-Pocket Maximum	$1,500 | $3,000 Single | Family	$2,500 | $5,000 (coinsurance only) Single | Family	

	PPO and HMO Health Investor	
	Network	Out-of-Network (PPO Only)
Deductible	$1,300 | $2,600 Single | Family	$2,500 | $5,000 Single | Family
Primary Care	After meeting deductible, 20% of network allowed amount	After meeting deductible, 40% of out-of-network allowance plus the amount between the charge and the allowance
Specialist		
Urgent Care		
Emergency Room		
Hospital Stay		After meeting deductible, 40% after $1,000 copayment plus the amount between the charge and the allowance
Generic | Preferred | Non-Preferred Prescriptions	After meeting deductible , 30% | 30% | 50% Retail and Mail Order	Pay in full, file claim
Out-of-Pocket Maximum	$3,000 | $6,000 (coinsurance only) Single | Family	$7,500 | $15,000 (coinsurance only) Single | Family

Flexible Spending Accounts

Currently, the state program offers flexible spending accounts (FSAs)[11] as an optional benefit for employees. The FSA is funded though pre-tax payroll deductions from the employee's salary[12]. The funds can be used to pay for medical expenses that are not covered by the employees' health plan. Prior to 2013, there was no limit on the contribution to a FSA; however, it is now limited to $2,500 and subsequently adjusted for inflation. Unlike a HSA, a FSA is a "use it or lose it" arrangement.[13] If the employee does not annually use the contributions to the FSA, the contributions are forfeited.

[11] Sec. 125 I.R.C.; *see* IRS Publication 969 (2014) available at https://www.irs.gov/pub/irs-pdf/p969.pdf (last viewed on January 15, 2016).
[12] Employers are also allowed to contribute to FSAs.
[13] Beginning in 2013, an employee may carryover up to $500 into the next calendar year.

Health Reimbursement Arrangements

Health reimbursement arrangements (HRAs) are defined contribution benefits established by an employer for their employees. Each year, an employer determines a specified amount, or a defined contribution benefit, of pre-tax dollars to assist employees with medical expenses. The employer can determine minimum and maximum contribution amounts; there are no federal limits. Typically associated with an HDHP, an HRA is entirely funded by the employer and provides tax-free reimbursements to employees for medical expenses.[14] Unlike a FSA, an HRA is not a "use it or lose it" arrangement, but the employer may cap the rollover amount. The state program does not currently offer HRAs.

The following chart shows the distinctions among FSAs, HSAs, and HRAs:

	FSA	HSA	HRA
Who funds the account?	Employee and employer (optional)	Employee, employer, and other individuals	Employer
How is it funded?	Employee payroll deduction; employer direct contribution - money is held by employer in "fund"	Cash contributions to bank account owned by employee	Employer pays up to promised amount
Account Owner	Employer	Employee	Employer
Contribution Limits	$2,550 annually	Single - $3,350 Family - $6,750 Over 55 - additional $1,000 for single coverage	Set by employer
Rollover of Funds?	Up to $500 (federal law)	Yes	Yes, as determined by employer
Medical Expenses Allowed	IRC 213(d) expenses;[15] No personal health insurance	IRC 213(d) expenses; No employer limitations	Health insurance premiums and IRC 213(d) expenses, as determined by employer
High Deductible Health Plan Required?	No	Yes Minimum deductible: Single - $1,300 Family - $2,600 Max out-of-pocket: Single - $6,550 Family - $13,100	No

Employer and Employee Contributions

The state program is considered employer-sponsored since the state contracts with providers and contributes a substantial amount on behalf of the employee toward the cost of the insurance premium. The state's employer contribution is part of a state employee's overall compensation. The state program is a defined-benefit program. In a defined-contribution program, the employer pays a set amount toward the monthly premium and the employee pays the remainder. The following chart shows the monthly contributions[16] of the state and the employee to employee health insurance premium.

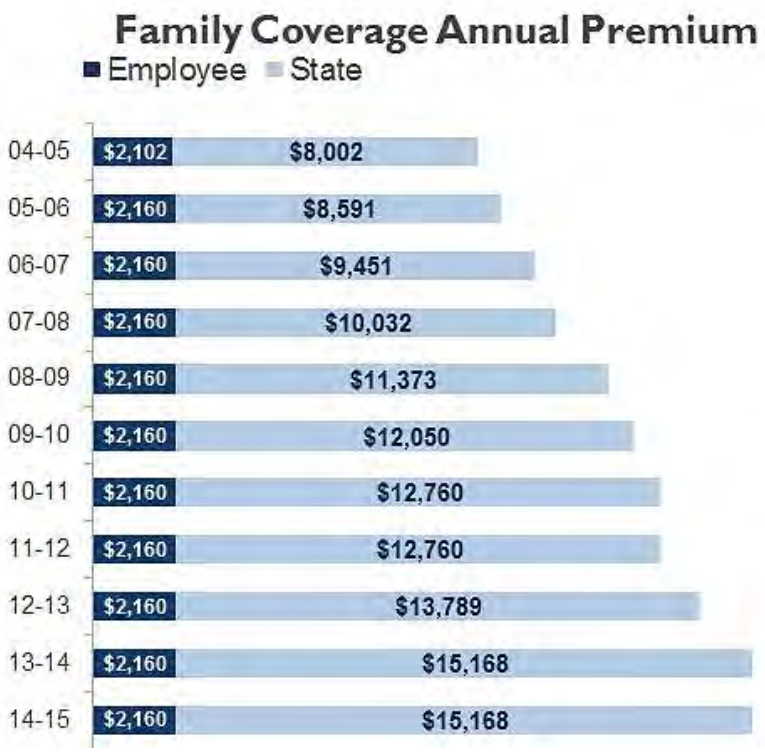
[14] An HRA can only be used for qualified medical expenses defined under s. 213(d), I.R.C., including health insurance and long-term care insurance.
[15] S. 213(d), I.R.C., permits the deduction of expenses paid for medical care of the taxpayer, his or her spouse, or a dependent. Medical care includes amounts paid for the diagnosis, cure, mitigation, treatment, or prevention of disease; transportation necessary for medical care; qualified long-term care services; and health insurance or long-term care insurance.
[16] Department of Management Services, State Employees' Group Health Self-Insurance Trust Fund, *Premium Rate Table Effective December 2015 for January 2016 Coverage,* available at http://mybenefits.myflorida.com/content/download/118950/652870/DSGI_-_Premium_Table_Effective_December_2015_for_January_2016_Coverage.pdf (last viewed on January 15, 2016).

Subscriber Category	Coverage Type	PPO and HMO Standard			PPO and HMO Health Investor		
		Employer	Enrollee	Total	Employer*	Enrollee	Total
Career Service/ OPS	Single	$591.52	$50.00	$641.52	$591.52	$15.00	$606.52
	Family	$1,264.06	$180.00	$1,444.06	$1,264.06	$64.30	$1,328.36
	Spouse	$1,429.08	$30.00	$1,459.08	$1,298.36	$30.00	$1,328.36
"Payalls" (SES/SMS)	Single	$637.34	$8.34	$645.68	$598.18	$8.34	$606.52
	Family	$1,429.06	$30.00	$1,459.06	$1,298.36	$30.00	$1,328.36

* Includes employer tax-free Health Savings Account (HSA) contribution - $41.66 and $83.33 per month ($500 and $1,000 annually) for single and family coverage, respectively

The state program is projected to spend $2.24 billion in FY 2015-2016 in health benefit costs.[17] The aggregate annual spending growth rate of the program is 9.5%. The state has absorbed almost all of the cost of the increase and employee contributions have remained the same for the last nine years as illustrated by the following charts.[18]

[17] Supra, FN 2, page 4.
[18] Department of Management Services, *Overview of the State Group Health Insurance Program,* presentation to the Health and Human Services Committee on March 12, 2015, slide 15 (on file with Committee staff).



Plan Enrollment

The state program has 360,821 covered lives and 171,794 policyholders.[19] Currently, 50.3% of enrollees chose the standard HMO and 48.3 % chose the standard PPO.[20] Only 1.4% of enrollees chose either HDHP.[21] During the open enrollment period for 2015, PPO enrollment increased slightly, by 0.05%, and HMO enrollment decreased by 0.46%.[22] Five year Open Enrollment trends show that annual enrollment in the PPO plans decreased.[23]

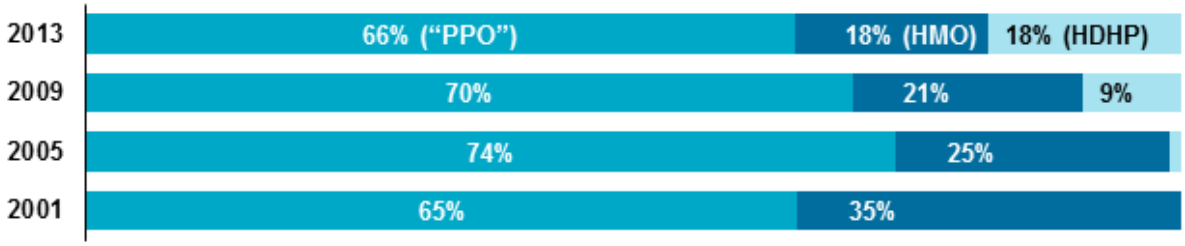
Employer Sponsored Insurance Trends

In 2010, DSGI contracted with Mercer Consulting to prepare a Benchmarking Report[24] (report) for the state. The report compares Florida's program to the programs of other large employers[25], both in the public and in the private sectors. The report found that the State of Florida contributes a higher percentage of the premium to employee health benefits than other states and private employers. At the time, Florida paid 84% of the monthly premium for a family PPO plan, but the average for large national employers was 69%. This results in Florida state employees paying less in monthly premiums than other states' employees and private employees. For example, the monthly premium for a family PPO plan for a Florida state employee is $180 and in 2011, the average premium for large national employers was $361.

[19] Supra, FN 2, page 1.
[20] Id.
[21] Id. at page 2.
[22] Florida Legislature, Office of Economic and Demographic Research, Self-Insurance Estimating Conference, State Employees' Group Health Self-Insurance Trust Fund, *Report on the Financial Outlook*, March 9, 2015, page 1, available at http://edr.state.fl.us/Content/conferences/healthinsurance/archives/150309healthins.pdf (last viewed on January 15, 2016).
[23] Id.
[24] Mercer Consulting, *State of Florida Benchmarking Report*, March 24, 2011, available at: http://www.dms.myflorida.com/content/download/81475/468865/version/1/file/2010+Small+Employer+Benchmarking+Report+for+State+of+Florida.pdf.
[25] For the purpose of the report, "large employers" had 500 or more employees.

Today, the monthly premium for a family PPO plan for a Florida state employee is still $180; however, the state now pays 88% of the premium[26] and the benchmark premium for large national employers ranges from $270 to $391 with the company paying 71% to 79% of the premium.[27]

The national trend among large employer health plans is increasing enrollment in high-deductible health plans (HDHP) and declining enrollment in HMOs as illustrated in the following chart[28]:



The state program's trend is the reverse of the national trend in HMO, PPO, and HDHP because of the HMO's high actuarial value and no difference in premiums between the HMO and PPO. The actuarial value (AV) measures the percentage of expected medical costs that a health plan will cover and is generally considered a measure of the health plan's generosity. The state program's standard HMO as an AV of 93%, the standard PPO has an AV of 86%, and the HDHP has an AV of 80%.[29] Accordingly, enrollees in the state program gravitate toward the high value, low cost HMO because they experience no price difference between the plans.

Employee Choice

The FY 2011-2012 General Appropriations Act directed DMS to develop a report of plan alternatives and options for the state program. DMS contracted with Buck Consultants which released its report[30] on September 29, 2011. The report concludes:

> The state's current approach to its health plan is best described as paternalistic, whereby the state serves as the architect/custodian of the plan, providing generous benefits and allowing employees to be passive and perhaps even entitled, with little concern about costs. Historically prevalent among large and governmental employers, this approach is rapidly being replaced by initiatives that focus on increasing and improving consumerism behaviors. In the consumerism approach the employer and employees maintain shared accountability, with the employer providing a supportive environment, partnering with employees and enabling them to make informed decisions, considering costs and outcomes of the health care services they seek and receive.

In a presentation before the Health and Human Services Committee on January 16, 2014, Mercer Health & Benefits (Mercer) reported that the state program is behind other large employers in key survey trends.[31] The state program has plans with lower employee premiums and higher benefits than industry benchmarks.[32] There is virtually no enrollment in HDHPs versus significant growth nationally.[33] Florida's plan costs and annual trend increase are higher than national survey data.[34] State employees have little real choice among health plan options since there is only a 4 percent difference in the

[26] The state contributes 92% of the premium for the individual PPO plan.
[27] *Market-Based Framework for Health Plan Program Changes*, Mercer Health & Benefits, presentation to the Health and Human Services Committee on January 16, 2014, at slide 18.
[28] Id. at slide 6.
[29] Id. at slide 20.
[30] Buck Consultants, *Strategic Health Plan Options for the State of Florida* (September 29, 2011), available at: http://www.dms.myflorida.com/content/download/81468/468856/version/1/file/Strategic+Health+Plan+Options+for+the+State+of+Florida+9-30-11+-+Final.pdf (last viewed on January 15, 2016).
[31] Supra, FN 24 at slide 5.
[32] Id.
[33] Id.
[34] Supra, FN 24 at slide 6.

"richness of the benefits" between the HMO and PPO, and the price is the same.[35] Consequently, 99 percent of enrollees chose the HMO or PPO with little to no incentive to choose the HDHP.[36]

Effect of the Bill

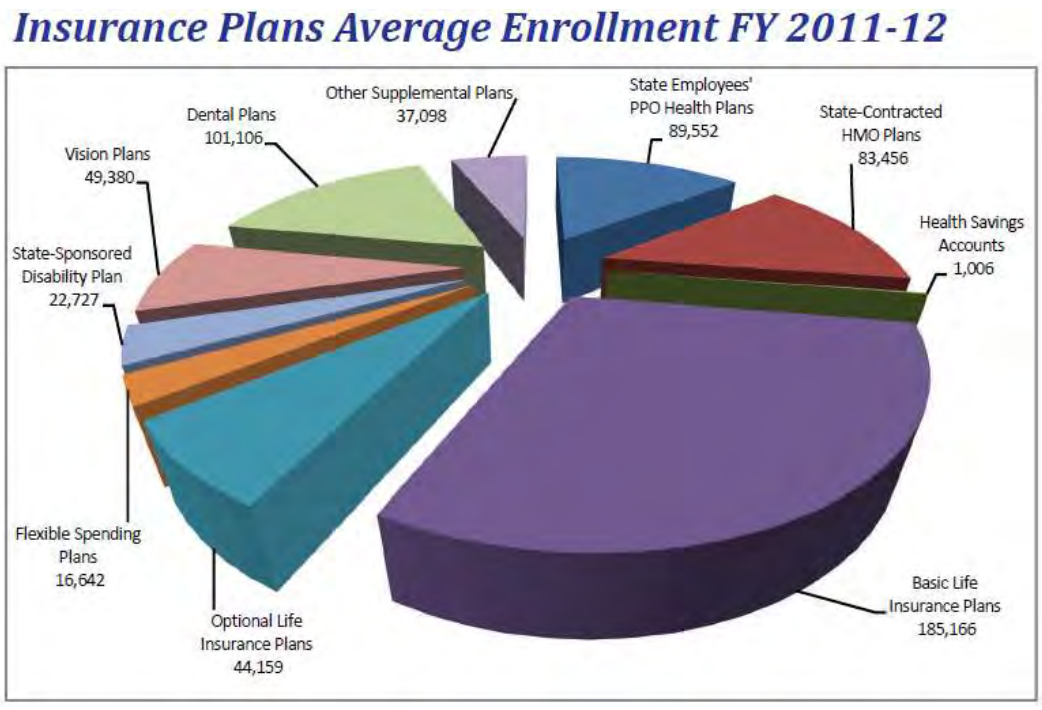
Premium Adjustments

Current law provides that "the state contribution toward the cost of any plan in the state group insurance program shall be uniform with respect to all state employees . . .participating in the same coverage tier[37] in the same plan."[38] Since there is a 4 percent difference in the actuarial value between the HMO and the PPO, the state currently pays more from the State Employees' Group Health Self-Insurance Trust Fund (Trust Fund) for the HMO benefits. However, each year the Legislature sets uniform premium amounts in the General Appropriations Act for state paid premiums. The premiums are deposited into the Trust Fund and used to pay the expenses of the state program.

Because DMS is currently procuring HMO contracts for the SGI program, the value of the benefits offered by the HMOs that will receive a contract is unknown. Employee contribution rates that reflect the different values of the HMO and the PPO cannot be determined until the conclusion of the procurement. The bill gives DMS authority to establish the employee contribution rates, and then seek approval from the Legislative Budget Commission. The bill directs DMS to determine and recommend employee contribution rates for standard plans and high deductible health plans for the 2017 plan year reflecting the actuarial benefit difference between the HMO and the PPO plans for both self-insured and fully insured products. The proposed enrollee premium rates for the 2017 plan year must be submitted to the Legislative Budget Commission (LBC) for review and approval. If the LBC does not approve the proposed rates, the rates provided in the 2016-17 General Appropriations Act will apply.

Additional Benefits

Many state employees enroll in products offered by the state program other than health insurance:



[35] Foster and Foster, *Actuarial Value Contribution Analysis,* March 20, 2015 at page 3.
[36] Supra, FN 24 at slide 9.
[37] The coverage tier is either individual or family.
[38] S. 110.123(3)(f), F.S.

The bill allows DMS to contract for additional products to be included in the state program. These include:

- Prepaid limited health service organizations as authorized under part I of chapter 636.
- Discount medical plan organizations as authorized under part II of chapter 636.
- Prepaid health clinic service providers licensed under part II of chapter 641.
- Health care providers, including hospitals and other licensed health facilities, health care clinics, licensed health professionals, and other licensed health care providers, who sell service contracts and arrangements for a specified amount and type of health services.
- Provider organizations, including service networks, group practices, professional associations, and other incorporated organizations of providers, who sell service contracts and arrangements for a specified amount and type of health services.
- Entities that provide specific health services in accordance with applicable state law and sell service contracts and arrangements for a specified amount and type of health services.
- Entities that provide health services or treatments through a bidding process.
- Entities that provide health services or treatments through bundling or aggregating the health services or treatments.
- Entities that provide other innovative and cost-effective health service delivery methods.

The bill also directs DMS to contract with at least one entity that provides comprehensive pricing and inclusive services for surgery and other medical procedures. These bundled services will be another option for state employees. The entity will be required to have procedures and evidence-based standards to assure only high quality health care providers are included. Assistance must be provided to the enrollee in accessing care and in the coordination of the care. The bundled services must provide cost savings to the state program and the enrollee, which will be shared by the state and the enrollee. The cost savings payable to an enrollee can be paid:

- To the enrollee's FSA;
- To the enrollee's HSA;
- To the enrollee's HRA; or
- To the enrollee as additional health plan reimbursements not exceeding the amount of the enrollee's out-of-pocket medical expenses.

The selected entity must provide an educational campaign for employees to learn about the offered services.

By January 15 of each year, DMS must report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the participation level and cost-savings to both the enrollee and the state resulting from contract.

Price Transparency and Cost Savings Sharing

The costs of health care procedures are often unknown and unknowable to consumers and can vary dramatically among providers.[39] The following chart shows the extreme price differences across the country of the average cost to Medicare for a joint replacement.

[39] *How to Bring the Price of Health Care Into the Open*, The Wall Street Journal, Melinda Beck, February 23, 2014, available at: http://online.wsj.com/news/articles/SB10001424052702303650204579375242842086688?mod=trending_now_5 (last viewed on January 15, 2016). *Does Knowing Medical Prices Save Money? CalPERS Experiment Says Yes*, Kaiser Health News, Ankita Rao, December 6, 2013, available at: http://capsules.kaiserhealthnews.org/index.php/2013/12/does-knowing-medical-prices-save-money-calpers-experiment-says-yes/ (last viewed on January 15, 2016).

	Hospital Charges	Actual Payment
Maryland	$21,230	$20,048
Delaware	$32,629	$14,765
Hawaii	$39,463	$18,512
Georgia	$46,856	$13,303
Pennsylvania	$51,014	$13,679
South Carolina	$57,557	$13,651
Arkansas	$63,290	$21,160
New Jersey	$66,639	$15,059
Nevada	$71,782	$13,621
California	$88,238	$17,187

Note: This includes all joints other than hips.
S*ource: Centers for Medicare & Medicaid Services, May 8, 2013*

The California Public Employees' Retirement System (CalPERS), the second largest benefits program in the country started a "reference pricing" initiative in 2011. CalPERS set a threshold of $30,000 for hospital payments for both for inpatient hip and knee replacements and designated certain hospitals where enrollees could get care at or below that price. If enrollees had surgery at designated hospitals, they paid only their plans' typical deductible and coinsurance up to the out-of-pocket maximum. Patients could go to other in-network hospitals for care but were responsible for both the typical cost sharing and all allowed amounts exceeding the $30,000 threshold, which were not subject to an out-of-pocket maximum. The initiative reportedly resulted in $2.8 million savings for CalPERS and $300,000 in savings for enrollees in 2011 without sacrificing quality.[40]

The bill directs DMS to contract with at least one contract with at least one entity that provides online health care price and quality information, including the average price paid for health care services and providers by county. The contract requires the entity to allow enrollees to shop for health care using the information provided to select higher quality, lower cost services and providers. The contract also requires the entity to identify any savings realized between what the enrollee pays for a service and provider and the average price paid for the same service or provider. The bill provides for the enrollee and state to share any savings generated by the enrollee's choice of providers.

If an enrollee selects a service or provider which results in savings to the state, the state shall pay to the employee fifty percent of the difference between the average price paid for the service or provider and the price paid. The amount payable to the employee can be paid:

- To the employee's FSA;
- To the employee's HSA;
- To the employee's HRA; or
- To the employee as additional health plan reimbursements not exceeding the amount of the enrollee's out-of-pocket medical expenses.

By January 1 of 2018, 2019, and 2020, the department shall report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the participation level, the amount paid to enrollees, and cost-savings to both the enrollees and the state resulting from the price transparency pilot project.

[40] *The Potential of Reference Pricing to Generate Health Care Savings: Lessons from a California Pioneer*, Center for Studying Health System Change, Amanda E. Lechner, Rebecca Gourevitch, Paul B. Ginsburg, Research Brief No. 30, December 2013, available at: http://www.hschange.org/CONTENT/1397/ (last viewed on January 15, 2016).

Additional Benefit Choices

Beginning in the 2019 plan year, the bill provides that state employees will have health plan choices at four different benefit levels. These levels are:

- Platinum Level (at least 90% AV)
- Gold Level (at least 80% AV)
- Silver Level (at least 70% AV)
- Bronze Level (at least 60% AV)

The state will make a defined contribution for each employee toward the cost of purchasing a health plan. Employees will have the following options:

- Use the entire employer contribution to pay for health insurance and pay any additional premium if the cost of the plan exceeds the employer contribution.
- Use part of the employer contribution to pay for health insurance and have the balance credited to a FSA.
- Use part of the employer contribution to pay for health insurance and have the balance credited to an HSA.
- Use part of the employer contribution to pay for health insurance and use the balance to purchase additional benefits offered through the state group insurance program.
- Use part of the employer contribution to pay for health insurance and have the balance used to increase the employees pay.[41]

The state currently pays 92 percent of the employee's premium for an individual plan and 88 percent for a family plan for a Platinum level plan (HMO) or a Gold level plan (PPO).

The following chart illustrates a hypothetical[42] example for a Career Service employee with a family plan and a defined contribution benchmarked using the current state contribution, current employee contribution, and the current plan cost:

Family Coverage	Current Plan 89% - 93% AV	80% AV Coverage	70% AV Coverage	60% AV Coverage
State Contribution	$15,168	$15,168	$15,168	$15,168
Plan Cost	$17,328	$14,344	$12,852	$11,361
Employee Contribution	$2,160	$0	$0	$0
Employee Receives	$0	$824	$2,316	$3,807

Under this hypothetical, the employee may choose the same value health plan as the employee has today and pay the same amount as today. Unlike today, the employee may also choose a different health plan and use the remainder toward other health benefits or receive additional salary.

Independent Benefits Consultant

The bill also directs DMS to competitively procure an independent benefits consultant (IBC). The IBC must not be or have a financial relationship in any HMO or insurer. Additionally, the IBC must have

[41] The employee must use part of the employer contribution to purchase health insurance. The employee may not receive pay in lieu of benefits.
[42] All examples must be hypothetical since the 2018 benefit structure and plan actuarial values cannot be known at this time.

substantial experience in designing and administering benefit plans for large employers and public employers.

The IBC will assist DMS in developing a plan for the implementation of the new benefit levels in the state program. The plan shall be submitted to the Governor, the President of the Senate and the Speaker of the House of Representatives no later than January 1, 2018, and include recommendations for:

- Employer and employee contribution policies.
- Steps necessary for maintaining or improving total employee compensation levels when the transition is initiated.
- An education strategy to inform employees on the additional choices available in the state program.

The ongoing duties of the IBC include:

- Providing assessments of trends in benefits and employer sponsored insurance that affect the state program.
- Conducting comprehensive analysis of the state program including available benefits, coverage options, and claims experience.
- Identifying and establishing appropriate adjustment procedures necessary to respond to any risk segmentation that may occur when increased choices are offered to employees.
- Assist the department with:
    - The submission of any necessary plan revisions for federal review.
    - Ensuring compliance with applicable federal and state regulations.
    - Monitoring the adequacy of funding and reserves for the state self-insured plan.

The IBC will assist DMS in preparing recommendations for any modifications to the state program no later than January 1 of each year which shall be submitted to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

B. SECTION DIRECTORY:

Section 1: Amends s. 110.123, F.S., relating to the State Group Insurance Program.
Section 2: Creates s. 110.12303, F.S., relating to the State Group Insurance Program; additional benefits; price transparency cost savings program; reporting.
Section 3: Creates s. 110.12304, F.S., relating to Independent Benefits Consultant.
Section 4: Creates an unnumbered section of law authorizing the Department of Management Services to determine and recommend premiums for employees in the state group insurance plan for the 2017 plan year, submit the proposed premium rates to the Legislative Budget Commission for approval, and providing for application of the premium rates in the 2016-17 General Appropriations Act if the Legislative Budget Commission does not approve the proposed premium rates.
Section 5: Appropriates $151,216 in recurring funds and $507,546 in nonrecurring funds and authorizes 2 full-time equivalent positions and 120,000 of associated salary rate for the 2015-2016 fiscal year to implement the act.
Section 6: Provides an effective date of July 1, 2016.

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:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill will provide additional opportunities for private companies to contract to provide services to the state and its employees.

D. FISCAL COMMENTS:

The bill appropriates $507,546 in nonrecurring trust funds and $151,216 in recurring trust funds and 2 FTEs to DMS to implement the administrative provisions of the bill. The positions and recurring funds are provided primarily for the implementation and continued administration of the price transparency pilot project, the administration of certain medical and surgical services provided for in the bill, and the implementation of communication and education components of the bill. The nonrecurring funds are provided to procure consulting services, conduct actuarial analysis, provide procurement support, assist in the development of the premium tiers and the reference pricing pilot project, and assist in the development of communication and education tools to provide employees with the means to make well-informed and educated choices.

The provision requiring DMS to determine and propose employee premium rates that reflect the actuarial benefit difference between the HMO, PPO and HDHPs for plan year 2017, if implemented, will be cost neutral to the state. Employees will generally have a choice between richer benefits and lower premiums.

DMS also indicated that the fiscal impact of the development of the tiered premium structure in plan year 2019 is indeterminate. The cost or savings to the state will be dependent on the specifics of the premium and cost-sharing arrangement ultimately established by the Legislature in implementing the tiered structure. The tiers and premium structure can be designed to be cost-neutral to the state.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DMS has sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the state group insurance program; amending s. 110.123, F.S.; revising applicability of certain definitions; defining the term "plan year"; authorizing the program to include additional benefits; authorizing an employee to use a certain portion of the state's contribution to purchase additional program benefits and supplemental benefits under specified circumstances; providing for the program to offer health plans in specified benefit levels; requiring the Department of Management Services to develop a plan for implementation of the benefit levels; providing reporting requirements; providing for expiration of the implementation plan; creating s. 110.12303, F.S.; authorizing additional benefits to be included in the program; requiring the department to contract with at least one entity that provides comprehensive pricing and inclusive services for surgery and other medical procedures; providing contract and reporting requirements; requiring the department to contract with an entity that provides health care service and provider cost and quality information online to allow program enrollees to shop for higher quality, lower cost health care; providing for the enrollee and state to share any savings realized from the enrollee's choice of health care

services or providers; providing contract and reporting requirements; creating s. 110.12304, F.S.; directing the department to contract with an independent benefits consultant; providing qualifications and duties of the independent benefits consultant; providing reporting requirements; providing that the Department of Management Services shall establish premiums for enrollees for the 2017 plan year that reflect the differences in benefit design and value among the health maintenance organization plan options and the preferred provider organization plan options; requiring the department to submit premium rates to the joint Legislative Budget Commission by a certain date for review and approval; requiring premium rates to be consistent with the total budgeted amount for the program in the General Appropriations Act for the 2016-17 fiscal year; prohibiting the department from implementing premium rates without the express approval of the commission; providing an appropriation and authorizing positions; providing an effective date.

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

Section 1. Subsection (2) and paragraphs (b), (f), (h), and (j) of subsection (3) of section 110.123, Florida Statutes,

are amended, and paragraph (k) is added to subsection (3) of that section, to read:

110.123 State group insurance program.—

(2) DEFINITIONS.—As used in ss. 110.123-110.1239 ~~this section~~, the term:

(a) "Department" means the Department of Management Services.

(b) "Enrollee" means all state officers and employees, retired state officers and employees, surviving spouses of deceased state officers and employees, and terminated employees or individuals with continuation coverage who are enrolled in an insurance plan offered by the state group insurance program. "Enrollee" includes all state university officers and employees, retired state university officers and employees, surviving spouses of deceased state university officers and employees, and terminated state university employees or individuals with continuation coverage who are enrolled in an insurance plan offered by the state group insurance program.

(c) "Full-time state employees" means employees of all branches or agencies of state government holding salaried positions who are paid by state warrant or from agency funds and who work or are expected to work an average of at least 30 or more hours per week; employees paid from regular salary appropriations for 8 months' employment, including university personnel on academic contracts; and employees paid from other-personal-services (OPS) funds as described in subparagraphs 1.

and 2. The term includes all full-time employees of the state universities. The term does not include seasonal workers who are paid from OPS funds.

1. For persons hired before April 1, 2013, the term includes any person paid from OPS funds who:

a. Has worked an average of at least 30 hours or more per week during the initial measurement period from April 1, 2013, through September 30, 2013; or

b. Has worked an average of at least 30 hours or more per week during a subsequent measurement period.

2. For persons hired after April 1, 2013, the term includes any person paid from OPS funds who:

a. Is reasonably expected to work an average of at least 30 hours or more per week; or

b. Has worked an average of at least 30 hours or more per week during the person's measurement period.

(d) "Health maintenance organization" or "HMO" means an entity certified under part I of chapter 641.

(e) "Health plan member" means any person participating in a state group health insurance plan, a TRICARE supplemental insurance plan, or a health maintenance organization plan under the state group insurance program, including enrollees and covered dependents thereof.

(f) "Part-time state employee" means an employee of any branch or agency of state government paid by state warrant from salary appropriations or from agency funds, and who is employed

for less than an average of 30 hours per week or, if on academic contract or seasonal or other type of employment which is less than year-round, is employed for less than 8 months during any 12-month period, but does not include a person paid from other-personal-services (OPS) funds. The term includes all part-time employees of the state universities.

(g) "Plan year" means a calendar year.

(h) ~~(g)~~ "Retired state officer or employee" or "retiree" means any state or state university officer or employee who retires under a state retirement system or a state optional annuity or retirement program or is placed on disability retirement, and who was insured under the state group insurance program at the time of retirement, and who begins receiving retirement benefits immediately after retirement from state or state university office or employment. The term also includes any state officer or state employee who retires under the Florida Retirement System Investment Plan established under part II of chapter 121 if he or she:

1. Meets the age and service requirements to qualify for normal retirement as set forth in s. 121.021(29); or

2. Has attained the age specified by s. 72(t)(2)(A)(i) of the Internal Revenue Code and has 6 years of creditable service.

(i) ~~(h)~~ "State agency" or "agency" means any branch, department, or agency of state government. "State agency" or "agency" includes any state university for purposes of this section only.

(j) ~~(i)~~ "Seasonal workers" has the same meaning as provided under 29 C.F.R. s. 500.20(s)(1).

(k) ~~(j)~~ "State group health insurance plan or plans" or "state plan or plans" mean the state self-insured health insurance plan or plans offered to state officers and employees, retired state officers and employees, and surviving spouses of deceased state officers and employees pursuant to this section.

(l) ~~(k)~~ "State-contracted HMO" means any health maintenance organization under contract with the department to participate in the state group insurance program.

(m) ~~(l)~~ "State group insurance program" or "programs" means the package of insurance plans offered to state officers and employees, retired state officers and employees, and surviving spouses of deceased state officers and employees pursuant to this section, including the state group health insurance plan or plans, health maintenance organization plans, TRICARE supplemental insurance plans, and other plans required or authorized by law.

(n) ~~(m)~~ "State officer" means any constitutional state officer, any elected state officer paid by state warrant, or any appointed state officer who is commissioned by the Governor and who is paid by state warrant.

(o) ~~(n)~~ "Surviving spouse" means the widow or widower of a deceased state officer, full-time state employee, part-time state employee, or retiree if such widow or widower was covered as a dependent under the state group health insurance plan, ~~a~~

TRICARE supplemental insurance plan, or a health maintenance organization plan established pursuant to this section at the time of the death of the deceased officer, employee, or retiree. "Surviving spouse" also means any widow or widower who is receiving or eligible to receive a monthly state warrant from a state retirement system as the beneficiary of a state officer, full-time state employee, or retiree who died prior to July 1, 1979. For the purposes of this section, any such widow or widower shall cease to be a surviving spouse upon his or her remarriage.

(p) ~~(o)~~ "TRICARE supplemental insurance plan" means the Department of Defense Health Insurance Program for eligible members of the uniformed services authorized by 10 U.S.C. s. 1097.

(3) STATE GROUP INSURANCE PROGRAM.—

(b) It is the intent of the Legislature to offer a comprehensive package of health insurance and retirement benefits and a personnel system for state employees which are provided in a cost-efficient and prudent manner, and to allow state employees the option to choose benefit plans which best suit their individual needs. ~~Therefore,~~ The state group insurance program ~~is established which~~ may include the state group health insurance plan or plans, health maintenance organization plans, group life insurance plans, TRICARE supplemental insurance plans, group accidental death and dismemberment plans, ~~and~~ group disability insurance plans, ~~.~~

~~Furthermore, the department is additionally authorized to establish and provide as part of the state group insurance program any~~ other group insurance plans or coverage choices, and other benefits authorized by law ~~that are consistent with the provisions of this section~~.

(f) Except as provided for in subparagraph (h)2., the state contribution toward the cost of any plan in the state group insurance program shall be uniform with respect to all state employees in a state collective bargaining unit participating in the same coverage tier in the same plan. This section does not prohibit the development of separate benefit plans for officers and employees exempt from the career service or the development of separate benefit plans for each collective bargaining unit. For the 2019 plan year and thereafter, if the state's contribution is more than the premium cost of the health plan selected by the employee, subject to federal limitation, the employee may elect to have the balance:

1. Credited to the employee's flexible spending account;

2. Credited to the employee's health savings account;

3. Used to purchase additional benefits offered through the state group insurance program; or

4. Used to increase the employee's salary.

(h)1. A person eligible to participate in the state group insurance program may be authorized by rules adopted by the department, in lieu of participating in the state group health insurance plan, to exercise an option to elect membership in a

health maintenance organization plan which is under contract with the state in accordance with criteria established by this section and by said rules. The offer of optional membership in a health maintenance organization plan permitted by this paragraph may be limited or conditioned by rule as may be necessary to meet the requirements of state and federal laws.

2. The department shall contract with health maintenance organizations seeking to participate in the state group insurance program through a request for proposal or other procurement process, as developed by the Department of Management Services and determined to be appropriate.

a. The department shall establish a schedule of minimum benefits for health maintenance organization coverage, and that schedule shall include: physician services; inpatient and outpatient hospital services; emergency medical services, including out-of-area emergency coverage; diagnostic laboratory and diagnostic and therapeutic radiologic services; mental health, alcohol, and chemical dependency treatment services meeting the minimum requirements of state and federal law; skilled nursing facilities and services; prescription drugs; age-based and gender-based wellness benefits; and other benefits as may be required by the department. Additional services may be provided subject to the contract between the department and the HMO. As used in this paragraph, the term "age-based and gender-based wellness benefits" includes aerobic exercise, education in alcohol and substance abuse prevention, blood cholesterol

screening, health risk appraisals, blood pressure screening and education, nutrition education, program planning, safety belt education, smoking cessation, stress management, weight management, and women's health education.

b. The department may establish uniform deductibles, copayments, coverage tiers, or coinsurance schedules for all participating HMO plans.

c. The department may require detailed information from each health maintenance organization participating in the procurement process, including information pertaining to organizational status, experience in providing prepaid health benefits, accessibility of services, financial stability of the plan, quality of management services, accreditation status, quality of medical services, network access and adequacy, performance measurement, ability to meet the department's reporting requirements, and the actuarial basis of the proposed rates and other data determined by the director to be necessary for the evaluation and selection of health maintenance organization plans and negotiation of appropriate rates for these plans. Upon receipt of proposals by health maintenance organization plans and the evaluation of those proposals, the department may enter into negotiations with all of the plans or a subset of the plans, as the department determines appropriate. Nothing shall preclude the department from negotiating regional or statewide contracts with health maintenance organization plans when this is cost-effective and when the department

determines that the plan offers high value to enrollees.

d. The department may limit the number of HMOs that it contracts with in each service area based on the nature of the bids the department receives, the number of state employees in the service area, or any unique geographical characteristics of the service area. The department shall establish by rule service areas throughout the state.

e. All persons participating in the state group insurance program may be required to contribute towards a total state group health premium that may vary depending upon the plan, coverage level, and coverage tier selected by the enrollee and the level of state contribution authorized by the Legislature.

3. The department is authorized to negotiate and to contract with specialty psychiatric hospitals for mental health benefits, on a regional basis, for alcohol, drug abuse, and mental and nervous disorders. The department may establish, subject to the approval of the Legislature pursuant to subsection (5), any such regional plan upon completion of an actuarial study to determine any impact on plan benefits and premiums.

4. In addition to contracting pursuant to subparagraph 2., the department may enter into contract with any HMO to participate in the state group insurance program which:

a. Serves greater than 5,000 recipients on a prepaid basis under the Medicaid program;

b. Does not currently meet the 25-percent non-

Medicare/non-Medicaid enrollment composition requirement established by the Department of Health excluding participants enrolled in the state group insurance program;

c. Meets the minimum benefit package and copayments and deductibles contained in sub-subparagraphs 2.a. and b.;

d. Is willing to participate in the state group insurance program at a cost of premiums that is not greater than 95 percent of the cost of HMO premiums accepted by the department in each service area; and

e. Meets the minimum surplus requirements of s. 641.225.

The department is authorized to contract with HMOs that meet the requirements of sub-subparagraphs a.-d. prior to the open enrollment period for state employees. The department is not required to renew the contract with the HMOs as set forth in this paragraph more than twice. Thereafter, the HMOs shall be eligible to participate in the state group insurance program only through the request for proposal or invitation to negotiate process described in subparagraph 2.

5. All enrollees in a state group health insurance plan, a TRICARE supplemental insurance plan, or any health maintenance organization plan have the option of changing to any other health plan that is offered by the state within any open enrollment period designated by the department. Open enrollment shall be held at least once each calendar year.

6. When a contract between a treating provider and the

state-contracted health maintenance organization is terminated for any reason other than for cause, each party shall allow any enrollee for whom treatment was active to continue coverage and care when medically necessary, through completion of treatment of a condition for which the enrollee was receiving care at the time of the termination, until the enrollee selects another treating provider, or until the next open enrollment period offered, whichever is longer, but no longer than 6 months after termination of the contract. Each party to the terminated contract shall allow an enrollee who has initiated a course of prenatal care, regardless of the trimester in which care was initiated, to continue care and coverage until completion of postpartum care. This does not prevent a provider from refusing to continue to provide care to an enrollee who is abusive, noncompliant, or in arrears in payments for services provided. For care continued under this subparagraph, the program and the provider shall continue to be bound by the terms of the terminated contract. Changes made within 30 days before termination of a contract are effective only if agreed to by both parties.

7. Any HMO participating in the state group insurance program shall submit health care utilization and cost data to the department, in such form and in such manner as the department shall require, as a condition of participating in the program. The department shall enter into negotiations with its contracting HMOs to determine the nature and scope of the data

submission and the final requirements, format, penalties associated with noncompliance, and timetables for submission. These determinations shall be adopted by rule.

8. The department may establish and direct, with respect to collective bargaining issues, a comprehensive package of insurance benefits that may include supplemental health and life coverage, dental care, long-term care, vision care, and other benefits it determines necessary to enable state employees to select from among benefit options that best suit their individual and family needs. Beginning with the 2017 plan year, the package of benefits may also include products and services described in s. 110.12303.

a. Based upon a desired benefit package, the department shall issue a request for proposal or invitation to negotiate for ~~health insurance~~ providers interested in participating in the state group insurance program, and the department shall issue a request for proposal or invitation to negotiate for ~~insurance~~ providers interested in participating in the non-health-related components of the state group insurance program. Upon receipt of all proposals, the department may enter into contract negotiations with ~~insurance~~ providers submitting bids or negotiate a specially designed benefit package. Insurance providers offering or providing supplemental coverage as of May 30, 1991, which qualify for pretax benefit treatment pursuant to s. 125 of the Internal Revenue Code of 1986, with 5,500 or more state employees currently enrolled may be included by the

department in the supplemental insurance benefit plan established by the department without participating in a request for proposal, submitting bids, negotiating contracts, or negotiating a specially designed benefit package. These contracts shall provide state employees with the most cost-effective and comprehensive coverage available; however, except as provided in subparagraph (f)3., no state or agency funds shall be contributed toward the cost of any part of the premium of such supplemental benefit plans. With respect to dental coverage, the division shall include in any solicitation or contract for any state group dental program made after July 1, 2001, a comprehensive indemnity dental plan option which offers enrollees a completely unrestricted choice of dentists. If a dental plan is endorsed, or in some manner recognized as the preferred product, such plan shall include a comprehensive indemnity dental plan option which provides enrollees with a completely unrestricted choice of dentists.

b. Pursuant to the applicable provisions of s. 110.161, and s. 125 of the Internal Revenue Code of 1986, the department shall enroll in the pretax benefit program those state employees who voluntarily elect coverage in any of the supplemental ~~insurance~~ benefit plans as provided by sub-subparagraph a.

c. Nothing herein contained shall be construed to prohibit insurance providers from continuing to provide or offer supplemental benefit coverage to state employees as provided under existing agency plans.

(j) For the 2019 plan year and thereafter, health plans shall be offered in the following benefit levels:

1. Platinum level, which shall have an actuarial value of at least 90 percent.

2. Gold level, which shall have an actuarial value of at least 80 percent.

3. Silver level, which shall have an actuarial value of at least 70 percent.

4. Bronze level, which shall have an actuarial value of at least 60 percent ~~Notwithstanding paragraph (f) requiring uniform contributions, and for the 2011-2012 fiscal year only, the state contribution toward the cost of any plan in the state group insurance plan is the difference between the overall premium and the employee contribution. This subsection expires June 30, 2012~~.

(k) In consultation with the independent benefits consultant described in s. 110.12304, the department shall develop a plan for implementation of the benefit levels described in paragraph (j). The plan shall be submitted to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than January 1, 2018, and include recommendations for:

1. Employer and employee contribution policies.

2. Steps necessary for maintaining or improving total employee compensation levels when the transition is initiated.

3. An education strategy to inform employees of the

additional choices available in the state group insurance program.

This paragraph expires July 1, 2018.

Section 2. Section 110.12303, Florida Statutes, is created to read:

110.12303 State group insurance program; additional benefits; price transparency pilot program; reporting.—Beginning with the 2017 plan year:

(1) In addition to the comprehensive package of health insurance and other benefits required or authorized to be included in the state group insurance program, the package of benefits may also include products and services offered by:

(a) Prepaid limited health service organizations as authorized by part I of chapter 636.

(b) Discount medical plan organizations as authorized by part II of chapter 636.

(c) Prepaid health clinics licensed under part II of chapter 641.

(d) Licensed health care providers, including hospitals and other health facilities, health care clinics, and health professionals, who sell service contracts and arrangements for a specified amount and type of health services.

(e) Provider organizations, including service networks, group practices, professional associations, and other incorporated organizations of providers, who sell service

contracts and arrangements for a specified amount and type of health services.

(f) Entities that provide specific health services in accordance with applicable state law and sell service contracts and arrangements for a specified amount and type of health services.

(g) Entities that provide health services or treatments through a bidding process.

(h) Entities that provide health services or treatments through the bundling or aggregating of health services or treatments.

(i) Entities that provide other innovative and cost-effective health service delivery methods.

(2)(a) The department shall contract with at least one entity that provides comprehensive pricing and inclusive services for surgery and other medical procedures which may be accessed at the option of the enrollee. The contract shall require the entity to:

1. Have procedures and evidence-based standards to ensure the inclusion of only high-quality health care providers.

2. Provide assistance to the enrollee in accessing and coordinating care.

3. Provide cost savings to the state group insurance program to be shared with both the state and the enrollee. Cost savings payable to an enrollee may be:

a. Credited to the enrollee's flexible spending account;

b. Credited to the enrollee's health savings account;

c. Credited to the enrollee's health reimbursement account; or

d. Paid as additional health plan reimbursements not exceeding the amount of the employee's out-of-pocket medical expenses.

4. Provide an educational campaign for enrollees to learn about the services offered by the entity.

(b) On or before January 15 of each year, the department shall report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the participation level and cost savings to both the enrollee and the state resulting from the contract or contracts described in this subsection.

(3) The department shall contract an entity that provides enrollees with online information on the cost and quality of health care services and providers, allows an enrollee to shop for health care services and providers, and rewards the enrollee by sharing any savings generated by the enrollee's choice of services or providers. The contract shall require the entity to:

(a) Establish an Internet-based, consumer friendly platform that educates and informs enrollees about the price and quality of health care services and providers, including the average amount paid in each county for health care services and providers. The average amounts paid for such services and

providers may be expressed for service bundles, which includes all products and services associated with a particular treatment or episode of care, or for separate and distinct products and services.

(b) Allow enrollees to shop for health care services and providers using the price and quality information provided on the platform.

(c) Identify the savings realized to the enrollee and state when the enrollee chooses high-quality, lower cost health care services or providers, and facilitate a shared savings payment to the enrollee. The amount of shared savings shall be determined by a methodology approved by the department with the goal of maximizing value-based purchasing by enrollees. The amount payable to the enrollee may be:

1. Credited to the enrollee's flexible spending account;

2. Credited to the enrollee's health savings account;

3. Credited to the enrollee's health reimbursement account; or

4. Paid as additional health plan reimbursements not exceeding the amount of the enrollee's out-of-pocket medical expenses.

(d) On or before January 1 of 2018, 2019, and 2020, the department shall report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the participation level, amounts paid to enrollees, and cost savings to both the enrollees and the state resulting from the

implementation of this subsection.

Section 3. Section 110.12304, Florida Statutes, is created to read:

110.12304 Independent benefits consultant.—

(1) The department shall competitively procure an independent benefits consultant.

(2) The independent benefits consultant may not:

(a) Be owned or controlled by a health maintenance organization or insurer.

(b) Have an ownership interest in a health maintenance organization or insurer.

(c) Have a direct or indirect financial interest in a health maintenance organization or insurer.

(3) The independent benefits consultant must have substantial experience in consultation and design of employee benefit programs for large employers and public employers, including experience with plans that qualify as cafeteria plans pursuant to s. 125 of the Internal Revenue Code of 1986.

(4) The independent benefits consultant shall:

(a) Provide an ongoing assessment of trends in benefits and employer-sponsored insurance that affect the state group insurance program.

(b) Conduct a comprehensive analysis of the state group insurance program, including available benefits, coverage options, and claims experience.

(c) Identify and establish appropriate adjustment

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 85 Recovery Care Services
SPONSOR(S): Fitzenhagen
TIED BILLS: **IDEN./SIM. BILLS:** SB 212

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Affordable Healthcare Access	10 Y, 4 N	Guzzo	Calamas
2) Health Care Appropriations Subcommittee	8 Y, 4 N	Clark	Pridgeon
3) Health & Human Services Committee		Guzzo	Calamas

SUMMARY ANALYSIS

Pursuant to s. 395.002, F.S., an ambulatory surgical center (ASC) is a facility, that is not part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.

Federal Medicare reimbursement is generally limited to stays of no more than 24 hours. The bill changes the allowable length of stay in an ASC from less than one working day to no more than 24 hours, which is the federal Medicare length of stay standard.

The bill creates a new license for a Recovery Care Center (RCC), defined as a facility the primary purpose of which is to provide recovery care services, to which a patient is admitted and discharged within 72 hours, and which is not part of a hospital. The bill defines recovery care services as:

- Postsurgical and post-diagnostic medical and general nursing care to patients for whom acute hospitalization is not required and an uncomplicated recovery is reasonably expected; and
- Postsurgical rehabilitation services.

Recovery care services do not include intensive care services, coronary care services, or critical care services.

The bill requires all patients to be certified as medically stable and not in need of acute hospitalization by their attending or referring physician prior to admission to a RCC. A patient may receive recovery care services in a RCC upon:

- Discharge from an ASC after surgery;
- Discharge from a hospital after surgery or other treatment; or
- Receiving out-patient medical treatment such as chemotherapy.

The new RCC license is modeled after the current licensing procedures for hospitals and ASCs, subjecting RCCs to similar regulatory standards, inspections, and rules. RCCs must have emergency care and transfer protocols, including transportation arrangements, and a referral or admission agreement with at least one hospital.

The bill has an indeterminate, but likely insignificant fiscal impact that can be managed within existing Agency for Health Care Administration resources.

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Ambulatory Surgical Centers (ASCs)

An ASC is a facility, that is not a part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.[1]

In Florida, outpatient surgery is performed in two settings, hospital outpatient surgery departments (HOPDs) and ASCs. Currently, there are 429 ASCs in Florida and 204 HOPDs.[2]

In 2014, there were 2,933,087 visits to ASCs and HOPDs in Florida.[3] HOPDs accounted for 46 percent and ASCs accounted for 54 percent of the total number of visits. Of the $33.8 billion in total combined charges in HOPDs and ASCs in 2014, HOPDs accounted for 77 percent of the charges, while ASCs accounted for 23 percent.[4] The average charge at the HOPDs ($19,140) was larger than the average charge at the ASCs ($5,018).[5] Two procedures, colonoscopy and gastrointestinal endoscopy, are consistently in the top 10 procedures performed by both facility types.[6] In 2014, the average charge for a colonoscopy by site was $6,694 for HOPDs and $2,391 for ASCs.[7] The average charge for gastrointestinal endoscopy by site was $9,537 for HOPDs and $2,269 for ASCs.[8] This data was not adjusted for acuity, so it may reflect higher acuity levels in hospital patients.

In 2014, the charges for visits to ASCs and HOPDs were paid mainly by commercial Insurance and Medicare. Commercial insurance paid for 40 percent of charges ($13.6 billion), while Medicare paid for 30 percent of charges ($10.1 billion).[9] The next three top payer groups (Medicare Managed Care, Medicaid, and Medicaid Managed Care) accounted for a combined 21.6 percent ($7.3 billion) of charges.[10]

ASC Licensure

ASCs are licensed and regulated by the Agency for Health Care Administration (AHCA) under the same regulatory framework as hospitals.[11] Applicants for ASC licensure must submit certain information to AHCA prior to accepting patients for care or treatment, including:

- An affidavit of compliance with fictitious name;
- Proof of registration of articles of incorporation; and
- A zoning certificate or proof of compliance with zoning requirements.[12]

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[1] S. 395.002(3), F.S.
[2] AHCA Agency Bill Analysis, dated September 18, 2015, pg. 3 (on file with Select Committee on Affordable Healthcare Access staff).
[3] Agency for Health Care Administration, *Ambulatory (Outpatient) Surgery Query Results; By Facility Type and Average Charges,* available at http://www.floridahealthfinder.gov/QueryTool/QTResults.aspx?T=O (last viewed on January 15, 2016).
[4] Id.
[5] Id.
[6] Agency for Health Care Administration, *Ambulatory (Outpatient) Surgery Query Results; By Current Procedural Terminology Code and Facility Type,* available at http://www.floridahealthfinder.gov/QueryTool/QTResults.aspx?T=O (last viewed on January 15, 2016).
[7] Id.
[8] Id.
[9] Agency for Health Care Administration, *Ambulatory (Outpatient) Surgery Query Results; By Patient, Primary Payer, and Average Charges* http://www.floridahealthfinder/gov/QueryTool/QTResults.aspx (last viewed on January 15, 2016).
[10] Id.
[11] SS. 395.001-1065, F.S., and Part II, Chapter 408, F.S.
[12] Rule 59A-5.003(4), F.A.C.

Upon receipt of an initial application, AHCA is required to conduct a survey to determine compliance with all laws and rules. ASCs are required to provide certain information during the initial inspection, including:

- Governing body bylaws, rules and regulations;
- A roster of registered nurses and licensed practical nurses with current license numbers;
- A fire plan; and
- The comprehensive Emergency Management Plan.[13]

AHCA is authorized to adopt rules for hospitals and ASCs.[14] Separate standards may be provided for general and specialty hospitals, ASCs, mobile surgical facilities, and statutory rural hospitals,[15] but the rules for all hospitals and ASCs must include minimum standards for ensuring that:

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards

The minimum standards for ASCs are contained in Chapter 59A-5, F.A.C.

Staff and Personnel Rules

ASCs are required to have written policies and procedures for surgical services, anesthesia services, nursing services, pharmaceutical services, and laboratory and radiologic services.[16] In providing these services, ACSs are required to have certain professional staff available, including:

- A registered nurse to serve as operating room circulating nurse;[17]
- An Anesthesiologist or other physician, or a certified registered nurse anesthetist under the on-site medical direction of a licensed physician in the ASC during the anesthesia and post-anesthesia recovery period until all patients are alert or discharged;[18] and
- A Registered professional nurse in the recovery area during the patient's recovery period.[19]

Infection Control Rules

ASCs are required to establish an infection control program, which must include written policies and procedures reflecting the scope of the program.[20] The written policies and procedures must be reviewed at least every two years by the infection control program members.[21] The infection control program must include:

[13] Rule 59A-5.003(5), F.A.C.
[14] S. 395.1055, F.S.
[15] S. 395.1055(2), F.S.
[16] Rule 59A-5.0085, F.A.C.
[17] Rule 59A-5.0085(3)(c), F.A.C.
[18] Rule 59A-5.0085(2)(b), F.A.C.
[19] Rule 59A-5.0085(3)(d), F.A.C.
[20] Rule 59A-5.011(1), F.A.C.
[21] Rule 59A-5.011(2), F.A.C.

- Surveillance, prevention, and control of infection among patients and personnel;[22]
- A system for identifying, reporting, evaluating and maintaining records of infections;[23]
- Ongoing review and evaluation of aseptic, isolation and sanitation techniques employed by the ASC;[24] and
- Development and coordination of training programs in infection control for all personnel.[25]

Emergency Management Plan Rules

ASCs are required to develop and adopt a written comprehensive emergency management plan for emergency care during an internal or external disaster or emergency.[26] The ASC must review the plan and update it annually.[27]

Accreditation

ASCs may seek voluntary accreditation by the Joint Commission for Health Care Organizations, the Accreditation Association for Ambulatory Health Care, and the American Osteopathic Association Healthcare Facilities Accreditation Program.[28] AHCA is required to conduct an annual licensure inspection survey for non-accredited ASCs.[29] AHCA must accept survey reports of accredited ASCs from accrediting organizations if the standards included in the survey report are determined to document that the ASC is in substantial compliance with state licensure requirements.[30] AHCA is required to conduct annual validation inspections on a minimum of 5 percent of the ASCs which were inspected by an accreditation organization.[31]

AHCA is required to conduct annual life safety inspections of all ASCs to ensure compliance with life safety codes and disaster preparedness requirements.[32] However, the life-safety inspection may be waived if an accreditation inspection was conducted on an ASC by a certified life safety inspector and the ASC was found to be in compliance with the life safety requirements.[33]

In 2014, 373 licensed ASCs in Florida were accredited by a national accrediting organization.[34]

Federal Requirements

Medicare

ASCs are required to have an agreement with the Centers for Medicare and Medicaid Services (CMS) to participate in Medicare. ASCs are also required to comply with specific conditions for coverage. CMS defines "ASC" as any distinct entity that operates exclusively for the purpose of providing surgical

[22] Rule 59A-5.011(1)(a), F.A.C.
[23] Rule 59A-5.011(1)(b), F.A.C.
[24] Rule 59A-5.011(1)(c), F.A.C.
[25] Rule 59A-5.011(1)(d), F.A.C.
[26] Rule 59A-5.018(1), F.A.C.
[27] Id.
[28] Rule 59A-5.004(3), F.A.C., and AHCA Ambulatory Surgical Center; *Accrediting Organizations for Ambulatory Surgical Centers,* available at http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/ambulatory.shtml (last viewed January 15, 2016).
[29] Rule 59A-5.004(1) and (2), F.A.C.
[30] Rule 59A-5.004(3), F.A.C.
[31] Rule 59A-5.004(5), F.A.C.
[32] Rule 59A-5.004(1), F.S., and s. 395.0161, F.S.
[33] S. 395.0161(2), F.S.
[34] Agency for Health Care Administration, *Ambulatory Surgical Center Regulatory Overview,* March 2015 (on file with Select Committee on Affordable Healthcare Access staff).

services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours[35] following an admission.[36]

CMS may deem an ASC to be in compliance with all of the conditions for coverage if the ASC is accredited by a national accrediting body, or licensed by a state agency, that CMS determines provides reasonable assurance that the conditions are met.[37] All of the CMS conditions for coverage requirements are included in Chapter 59A-5, F.A.C., and apply to all ASCs in Florida. The conditions for coverage require:

- A governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation;
- A quality assessment and performance improvement program;
- A transfer agreement with one or more acute care general hospitals, which will admit any patient referred who requires continuing care;
- A disaster preparedness plan;
- An organized medical staff;
- A fire control plan;
- A sanitary environment;
- An infection control program; and
- A procedure for patient admission, assessment and discharge.

OPPAGA Study on ASCs

In January, OPPAGA issued a study on ASCs.[38] The study reviewed research and literature related to ASCs in four categories: ASC health care in Florida; impact of ASCs on hospitals and cost; patient access to services and surgery location; and patient safety, clinical outcomes, and patient satisfaction.

The study used 2014 hospital discharge data collected by AHCA to compare the cost of procedures performed in ASCs to those performed in HOPDs in Florida. The study found that the average charge at HOPDs was more than three times that of the average charge at ASCs.[39]

The study found that while competition exists between ASCs and hospitals, the impact this competition has on hospitals may be limited and that ASCs can save money when performing certain procedures.[40] In determining the impact of ASCs on hospitals and costs, the OPPAGA study reviewed 23 academic studies. OPPAGA found that the research on the impact that ASCs have on hospitals varied. Eight studies indicated that ASCs had minimal impact on hospitals, and one study suggested that due to specialist referrals for complex procedures, some ASCs may generate admissions to hospitals. Three studies found that ASCs had a limited adverse effect on hospitals. One study found that in markets where an ASC opened for the first time, the adjusted HOPD surgery rates declined by 7 percent.[41]

The OPPAGA study was unable to identify patterns for patient access to services and surgery location because the studies they reviewed were not comparable due to the varying types of patients, procedures, and other data analyzed.[42]

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[35] State Operations Manual Appendix L, *Guidance for Surveyors: Ambulatory Surgical Centers* (Rev. 99, 01-31-14) exceeding the 24-hour time frame is expected to be a rare occurrence, and each rare occurrence is expected to be demonstrated to have been something which ordinarily could not have been foreseen. Not meeting this requirement constitutes condition-level noncompliance with §416.25. In addition, review of the cases that exceed the time frame may also reveal noncompliance with CfCs related to surgical services, patient admission and assessment, and quality assurance/performance improvement.
[36] 42 C.F.R. §416.2
[37] 42 C.F.R. §416.26(1)
[38] OPPAGA Research Memorandum, *Ambulatory Surgical Centers and Recovery Care Centers*, January 19, 2016 (on file with the Health & Human Services Committee).
[39] Id. at p. 2
[40] Id.
[41] Id. at p. 3
[42] Id.

In comparing patient safety, clinical outcomes, and patient satisfaction between ASCs and HOPDs, the OPPAGA study reviewed nine academic studies.[43] OPPAGA found that the studies largely agreed that ASCs provided more timely service and had low rates of unexpected safety events. Five studies found that the increase in surgeries being performed in ASCs was not associated with higher rates of hospital admission or mortality. Those five studies also found that ASCs had lower rates of unexpected safety events compared to hospitals. One study found that ASCs had a higher rate of unexpected hospitalization outcomes within the first week after release than HOPDs for some of the procedures studied, but, overall, OPPAGA concluded there was no appreciable difference in quality outcomes of procedures performed in both settings.[44]

Recovery Care Centers

Recovery care centers (RCCs) are entities that provide short-term nursing care, support, and pain control for patients that do not require acute hospitalization.[45] RCC patients are typically healthy persons that have had elective surgery. RCCs can be either freestanding or attached to an ASC or hospital. In practice, RCCs typically provide care to patients transferred from ASCs following surgery, which allows ASCs to perform more complex procedures.[46]

RCCs are not eligible for Medicare reimbursement.[47] However, RCCs may receive payments from Medicaid programs. One 1999 survey noted that RCCs received payment in the following breakdown: 41% from managed care plans, 29% from self-pay, 16% from indemnity plans, and 9% from workers' compensation.[48]

Three states, Arizona, Connecticut, and Illinois, have specific licenses for "recovery care centers."[49] Other states license RCCs as nursing facilities or hospitals.[50] One study found that eighteen states allow RCCs to have stays over 24 hours, usually with a maximum stay of 72 hours.[51]

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[43] Id.
[44] Id. at p. 4
[45] Medicare Payment Advisory Comm'n, Report to the Congress: Medicare Payment for Post-Surgical Recovery Care Centers, (2000).
[46] Id. at p. 4
[47] See Medicare Payment Advisory Comm'n, Supra FN 20.
[48] Medicare Payment Advisory Comm'n, Supra FN 20, at 6 (citing Federated Ambulatory Surgery Association, Post-Surgical Recovery Care, (2000)).
[49] Ariz. Rev. Stat. Ann.§§ 36-448.51-36-448.55; Conn. Conn. Agencies Regs § 19A-495-571; 210 Ill. Comp. Stat. Ann. 3/35.
[50] Sandra Lee Breisch, *Profits in Short Stays*, Am. Acad. of Orthopaedic Surgeons Bulletin (June, 1999), available at http://www2.aaos.org/bulletin/jun99/asc.htm (last viewed January 15, 2016).
[51] Medicare Payment Advisory Comm'n, supra FN 20, at 4 (citing Federated Ambulatory Surgery Association, Post-Surgical Recovery Care, (2000)).

Comparison of RCC Regulations in Arizona, Connecticut, and Illinois

Regulation	Arizona[52]	Connecticut[53]	Illinois[54]
Licensure Required	X	X	X
Written Policies	X	X	X
Maintain Medical Records	X	X	X
Patient's Bill of Rights	X	X	X
Allows Freestanding Facility or Attached	Not Addressed.	X	X
Length of Stay	Not Addressed.	Expected 3 days Maximum 21 days	Expected 48 hours Maximum 72 hours
Emergency Care Transfer Agreement	For care not provided by the recovery care center.	With a hospital and an ambulance service.	With a hospital within 15 minutes travel time.
Prohibited Patients	Patients needing: • Intensive care • Coronary care • Critical care	Patients needing: • Intensive care • Coronary care • Critical care	• Patients with chronic infectious conditions • Children under age 3
Prohibited Services	• Surgical • Radiological • Pediatric • Obstetrical	• Surgical • Radiological • Pre-adolescent pediatric • Hospice • Obstetrical services over 24 week gestation • Intravenous therapy for non-hospital based RCC	• Blood administration (only blood products allowed)
Required Services	• Laboratory • Pharmaceutical • Food	• Pharmaceutical • Dietary • Personal care • Rehabilitation • Therapeutic • Social work	• Laboratory • Pharmaceutical • Food • Radiological
Bed Limitation	Not Addressed.	Not Addressed.	20
Required Staff	• Governing authority • Administrator	• Governing body • Administrator	• Consulting committee
Required Medical Personnel	• At least two physicians • Director of nursing	• Medical advisory board • Medical director • Director of nursing	• Medical director • Nursing supervisor
Required Personnel When Patients Are Present	• Director of nursing 40 hours per week • One registered nurse • One other nurse	• Two persons for patient care	• One registered nurse • One other nurse

[52] Ariz. Rev. Stat. Ann. §§ 36-448.51-36-448.55; Ariz. Admin. Code §§ R9-10-501-R9-10-518 (updated in 2013, formerly R9-10-1401-R9-10-1412).
[53] Conn. Agencies Regs. § 19A-495-571.
[54] 210 Ill. Comp. Stat. Ann. 3/35; Ill. Admin. Code tit. 77, §§ 210.2500 & 210.2800.

Effect of Proposed Changes

Pursuant to s. 395.002(3), F.S., patients receiving services in an ASC must be discharged on the same working day that they were admitted and cannot stay overnight. Federal Medicare reimbursement policy limits the length of stay in an ASC to 24 hours following admission. The bill amends s. 395.002(3), F.S., to permit a patient to stay at an ASC for no longer than 24 hours. The change conforms to the Medicare length of stay requirement.

The bill creates a new license for a Recovery Care Center (RCC). The new RCC license is modeled after the current licensure program for hospitals and ASCs in Chapters 395 and 408, F.S. The bill adds RCCs to the list of facilities subject to the provisions of Chapter 395, Part I. An applicant for RCC licensure must follow the general licensing procedures in Chapter 408, Part II. Additionally, the applicant will be subject to the license, inspection, safety, facility and other requirements of Chapter 395, Part I.

The bill defines a RCC as a facility whose primary purpose is to provide recovery care services, to which the patient is admitted and discharged within 72 hours, and is not part of a hospital. The bill defines recovery care services as:

- Postsurgical and post-diagnostic medical and general nursing care to patients for whom acute hospitalization is not required and an uncomplicated recovery is reasonably expected; and
- Postsurgical rehabilitation services.

Recovery care services do not include intensive care services, coronary care services, or critical care services.

The bill requires all patients to be certified as medically stable and not in need of acute hospitalization by their attending or referring physician prior to admission to an RCC. A patient may receive recovery care services in an RCC upon:

- Discharge from an ASC after surgery;
- Discharge from a hospital after surgery or other treatment; or
- Receiving an out-patient medical treatment such as chemotherapy.

A RCC must have emergency care and transfer protocols, including transportation arrangements, and a referral or admission agreement with at least one hospital. Further, AHCA is authorized to adopt rules regarding RCC admission and discharge procedures.

Section 395.1055, F.S., directs AHCA to adopt rules for hospitals and ASCs that set standards to ensure patient safety. The bill directs AHCA to adopt rules for RCCs that address all the same regulatory areas currently addressed in rules for hospitals and ASCs, including requirements for:

- Staffing;
- Infection control;
- Housekeeping;
- Medical records;
- Emergency management;
- Inspections;
- Accreditation;
- Organization, including a governing body and organized medical staff;
- Departments and services;
- Quality assessment and improvement;
- Minimum space; and
- Equipment and furnishings.

In addition, the bill requires AHCA to adopt rules to set standards for dietetic departments, proper use of medications, and pharmacies in RCCs.

The license fee for a RCC will be set by rule by AHCA and must be at least $1,500.[55]

The bill provides an effective date of July 1, 2016.

B. SECTION DIRECTORY:

Section 1: Amends s. 395.001, F.S., related to legislative intent.
Section 2: Amends s. 395.002, F.S., related to definitions.
Section 3: Amends s. 395.003, F.S., related to licensure; denial, suspension, and revocation.
Section 4: Creates s. 395.0171, F.S., related to recovery care center admissions; emergency and transfer protocols; discharge planning and protocols.
Section 5: Amends s. 395.1055, F.S., related to rules and enforcement.
Section 6: Amends s. 395.10973, F.S., related to powers and duties of the agency.
Section 7: Amends s. 395.301, F.S., related to itemized patient bill; form and content prescribed by the agency.
Section 8: Amends s. 408.802, F.S., related to applicability.
Section 9: Amends s. 408.820, F.S., related to exemptions.
Section 10: Amends s. 394.4787, F.S., related to definitions.
Section 11: Amends s. 409.975, F.S., related to managed care plan accountability.
Section 12: Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Section 408.805, F.S., requires AHCA to set license fees that are reasonably calculated to cover the cost of regulation. AHCA estimates that five entities may apply for licensure. Applicants for licensure as a RCC will be subject to a Plans and Construction project review fee of $2,000 plus $100 per hour for building plan reviews, an application fee of at least $1,500, and a licensure inspection fee of $400.[56]

2. Expenditures:

The creation of the RCC license will require AHCA to regulate these facilities in accordance with Chapters 395 and 408, F.S., and any rules adopted by AHCA. The fees associated with the new license are anticipated to cover the expenses incurred by AHCA in enforcement and regulation of the new license. No additional staff will be required as existing regulatory staff is sufficient to absorb the workload associated with up to 10 licenses.[57]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

[55] Section 395.004, F.S.
[56] AHCA Agency Bill Analysis, dated September 18, 2015, pg. 3 (on file with Select Committee on Affordable Healthcare Access staff).
[57] Id.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Individuals needing surgery may save money by being able to stay longer in an ASC or stay in a RCC rather than having the original procedure in a hospital merely because the recovery time will be longer than the ASC limit would allow.

Being able to keep patients longer in an ASC may have a positive fiscal impact on the ASC by being able to perform more complex procedures.

Hospitals may experience a negative fiscal impact if more patients receive care in an ASC or RCC.

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:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to recovery care services; amending s. 395.001, F.S.; providing legislative intent regarding recovery care centers; amending s. 395.002, F.S.; revising and providing definitions; amending s. 395.003, F.S.; including recovery care centers as facilities licensed under chapter 395, F.S.; creating s. 395.0171, F.S.; providing admission criteria for a recovery care center; requiring emergency care, transfer, and discharge protocols; authorizing the Agency for Health Care Administration to adopt rules; amending s. 395.1055, F.S.; authorizing the agency to establish separate standards for the care and treatment of patients in recovery care centers; amending s. 395.10973, F.S.; directing the agency to enforce special-occupancy provisions of the Florida Building Code applicable to recovery care centers; amending s. 395.301, F.S.; providing for format and content of a patient bill from a recovery care center; amending s. 408.802, F.S.; providing applicability of the Health Care Licensing Procedures Act to recovery care centers; amending s. 408.820, F.S.; exempting recovery care centers from specified minimum licensure requirements; amending ss. 394.4787 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 395.001, Florida Statutes, is amended to read:

395.001 Legislative intent.—It is the intent of the Legislature to provide for the protection of public health and safety in the establishment, construction, maintenance, and operation of hospitals, ambulatory surgical centers, recovery care centers, and mobile surgical facilities by providing for licensure of same and for the development, establishment, and enforcement of minimum standards with respect thereto.

Section 2. Subsections (3), (16), and (23) of section 395.002, Florida Statutes, are amended, subsections (25) through (33) are renumbered as subsections (27) through (35), respectively, and new subsections (25) and (26) are added to that section, to read:

395.002 Definitions.—As used in this chapter:

(3) "Ambulatory surgical center" or "mobile surgical facility" means a facility the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility within 24 hours ~~the same working day and is not permitted to stay overnight,~~ and which is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy, an office maintained by a physician for the practice of medicine,

or an office maintained for the practice of dentistry shall not be construed to be an ambulatory surgical center, provided that any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003. Any structure or vehicle in which a physician maintains an office and practices surgery, and which can appear to the public to be a mobile office because the structure or vehicle operates at more than one address, shall be construed to be a mobile surgical facility.

(16) "Licensed facility" means a hospital, ambulatory surgical center, recovery care center, or mobile surgical facility licensed in accordance with this chapter.

(23) "Premises" means those buildings, beds, and equipment located at the address of the licensed facility and all other buildings, beds, and equipment for the provision of hospital, ambulatory surgical, recovery, or mobile surgical care located in such reasonable proximity to the address of the licensed facility as to appear to the public to be under the dominion and control of the licensee. For any licensee that is a teaching hospital as defined in s. 408.07(45), reasonable proximity includes any buildings, beds, services, programs, and equipment under the dominion and control of the licensee that are located at a site with a main address that is within 1 mile of the main address of the licensed facility; and all such buildings, beds, and equipment may, at the request of a licensee or applicant, be

included on the facility license as a single premises.

(25) "Recovery care center" means a facility the primary purpose of which is to provide recovery care services, to which a patient is admitted and discharged within 72 hours, and which is not part of a hospital.

(26) "Recovery care services" means postsurgical and postdiagnostic medical and general nursing care provided to patients for whom acute care hospitalization is not required and an uncomplicated recovery is reasonably expected. The term includes postsurgical rehabilitation services. The term does not include intensive care services, coronary care services, or critical care services.

Section 3. Subsection (1) of section 395.003, Florida Statutes, is amended to read:

395.003 Licensure; denial, suspension, and revocation.—

(1)(a) The requirements of part II of chapter 408 apply to the provision of services that require licensure pursuant to ss. 395.001-395.1065 and part II of chapter 408 and to entities licensed by or applying for such licensure from the Agency for Health Care Administration pursuant to ss. 395.001-395.1065. A license issued by the agency is required in order to operate a hospital, ambulatory surgical center, recovery care center, or mobile surgical facility in this state.

(b)1. It is unlawful for a person to use or advertise to the public, in any way or by any medium whatsoever, any facility as a "hospital," "ambulatory surgical center," "recovery care

center," or "mobile surgical facility" unless such facility has first secured a license under the provisions of this part.

2. This part does not apply to veterinary hospitals or to commercial business establishments using the word "hospital," "ambulatory surgical center," "recovery care center," or "mobile surgical facility" as a part of a trade name if no treatment of human beings is performed on the premises of such establishments.

(c) Until July 1, 2006, additional emergency departments located off the premises of licensed hospitals may not be authorized by the agency.

Section 4. Section 395.0171, Florida Statutes, is created to read:

395.0171 Recovery care center admissions; emergency and transfer protocols; discharge planning and protocols.—

(1) Admissions to a recovery care center shall be restricted to patients who need recovery care services.

(2) Each patient must be certified by his or her attending or referring physician or by a physician on staff at the facility as medically stable and not in need of acute care hospitalization before admission.

(3) A patient may be admitted for recovery care services upon discharge from a hospital or an ambulatory surgery center. A patient may also be admitted postdiagnosis and posttreatment for recovery care services.

(4) A recovery care center must have emergency care and

transfer protocols, including transportation arrangements, and referral or admission agreements with at least one hospital.

(5) A recovery care center must have procedures for discharge planning and discharge protocols.

(6) The agency may adopt rules to implement this section.

Section 5. Subsections (2) and (8) of section 395.1055, Florida Statutes, are amended, and subsection (10) is added to that section, to read:

395.1055 Rules and enforcement.—

(2) Separate standards may be provided for general and specialty hospitals, ambulatory surgical centers, recovery care centers, mobile surgical facilities, and statutory rural hospitals as defined in s. 395.602.

(8) The agency may not adopt any rule governing the design, construction, erection, alteration, modification, repair, or demolition of any public or private hospital, intermediate residential treatment facility, recovery care center, or ambulatory surgical center. It is the intent of the Legislature to preempt that function to the Florida Building Commission and the State Fire Marshal through adoption and maintenance of the Florida Building Code and the Florida Fire Prevention Code. However, the agency shall provide technical assistance to the commission and the State Fire Marshal in updating the construction standards of the Florida Building Code and the Florida Fire Prevention Code which govern hospitals, intermediate residential treatment facilities, recovery care

centers, and ambulatory surgical centers.

(10) The agency shall adopt rules for recovery care centers which include fair and reasonable minimum standards for ensuring that recovery care centers have:

(a) A dietetic department, service, or other similarly titled unit, either on the premises or under contract, which shall be organized, directed, and staffed to ensure the provision of appropriate nutritional care and quality food service.

(b) Procedures to ensure the proper administration of medications. Such procedures shall address the prescribing, ordering, preparing, and dispensing of medications and appropriate monitoring of the effects of such medications on the patient.

(c) A pharmacy, pharmaceutical department, or pharmaceutical service, or similarly titled unit, on the premises or under contract.

Section 6. Subsection (8) of section 395.10973, Florida Statutes, is amended to read:

395.10973 Powers and duties of the agency.—It is the function of the agency to:

(8) Enforce the special-occupancy provisions of the Florida Building Code which apply to hospitals, intermediate residential treatment facilities, recovery care centers, and ambulatory surgical centers in conducting any inspection authorized by this chapter and part II of chapter 408.

Section 7. Subsection (3) of section 395.301, Florida Statutes, is amended to read:

395.301 Itemized patient bill; form and content prescribed by the agency; patient admission status notification.—

(3) On each itemized statement submitted pursuant to subsection (1) there shall appear the words "A FOR-PROFIT (or NOT-FOR-PROFIT or PUBLIC) HOSPITAL (or AMBULATORY SURGICAL CENTER or RECOVERY CARE CENTER) LICENSED BY THE STATE OF FLORIDA" or substantially similar words sufficient to identify clearly and plainly the ownership status of the licensed facility. Each itemized statement must prominently display the phone number of the medical facility's patient liaison who is responsible for expediting the resolution of any billing dispute between the patient, or his or her representative, and the billing department.

Section 8. Subsection (30) is added to section 408.802, Florida Statutes, to read:

408.802 Applicability.—The provisions of this part apply to the provision of services that require licensure as defined in this part and to the following entities licensed, registered, or certified by the agency, as described in chapters 112, 383, 390, 394, 395, 400, 429, 440, 483, and 765:

(30) Recovery care centers, as provided under part I of chapter 395.

Section 9. Subsection (29) is added to section 408.820, Florida Statutes, to read:

408.820 Exemptions.—Except as prescribed in authorizing statutes, the following exemptions shall apply to specified requirements of this part:

(29) Recovery care centers, as provided under part I of chapter 395, are exempt from s. 408.810(7)-(10).

Section 10. Subsection (7) of section 394.4787, Florida Statutes, is amended to read:

394.4787 Definitions; ss. 394.4786, 394.4787, 394.4788, and 394.4789.—As used in this section and ss. 394.4786, 394.4788, and 394.4789:

(7) "Specialty psychiatric hospital" means a hospital licensed by the agency pursuant to s. 395.002(30) ~~395.002(28)~~ and part II of chapter 408 as a specialty psychiatric hospital.

Section 11. Paragraph (b) 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.

(b) Certain providers are statewide resources and

essential providers for all managed care plans in all regions. All managed care plans must include these essential providers in their networks. Statewide essential providers include:

1. Faculty plans of Florida medical schools.

2. Regional perinatal intensive care centers as defined in s. 383.16(2).

3. Hospitals licensed as specialty children's hospitals as defined in s. 395.002(30) ~~395.002(28)~~.

4. Accredited and integrated systems serving medically complex children that are comprised of separately licensed, but commonly owned, health care providers delivering at least the following services: medical group home, in-home and outpatient nursing care and therapies, pharmacy services, durable medical equipment, and Prescribed Pediatric Extended Care.

Managed care plans that have not contracted with all statewide essential providers in all regions as of the first date of recipient enrollment must continue to negotiate in good faith. Payments to physicians on the faculty of nonparticipating Florida medical schools shall be made at the applicable Medicaid rate. Payments for services rendered by regional perinatal intensive care centers shall be made at the applicable Medicaid rate as of the first day of the contract between the agency and the plan. Payments to nonparticipating specialty children's hospitals shall equal the highest rate established by contract between that provider and any other Medicaid managed care plan.

Section 12. This act shall take effect July 1, 2016.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 313 Prescription Drug Monitoring Program
SPONSOR(S): Health Quality Subcommittee; Pilon
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 0 N, As CS	Langston	O'Callaghan
2) Health & Human Services Committee		Langston	Calamas

SUMMARY ANALYSIS

Chapter 2009-197, Laws of Fla., established the Prescription Drug Monitoring Program (PDMP) within the Department of Health in s. 893.055, F.S. The PDMP uses a database to monitor the prescribing and dispensing of certain controlled substances.

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. Dispensers must report dispensing to the PDMP database within seven days of dispensing the controlled substance.

However, in certain instances, health care practitioners are exempt from the PDMP reporting requirements. Dispensing and administering controlled substances are exempt in certain health care settings where there is a low risk of controlled substances being overprescribed or diverted. Specifically, the following acts are not required to be reported:

- A health care practitioner administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.
- A pharmacist or health care practitioner administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.
- A practitioner administering or dispensing a controlled substance in the health care system of the Department of Corrections.
- A practitioner administering a controlled substance in the emergency room of a licensed hospital.
- A health care practitioner administering or dispensing a controlled substance to a person under the age of 16.
- A pharmacist or a dispensing practitioner dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient.

CS/HB 313 adds a PDMP reporting exemption for a rehabilitative hospital, an assisted living facility, or a nursing home when they dispense a controlled substance to a patient as ordered by the patient's treating physician. Consistent with current reporting exemptions, the bill exempts health care settings where there is a low risk of overprescribing or diverting controlled substances from the reporting requirements.

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

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Prescription Drug Monitoring Program

Prescription Drug Monitoring Programs (PDMPs) are state-run electronic databases used to track the prescribing and dispensing of certain controlled prescription drugs to patients.[1] PDMPs are designed to monitor this information for suspected abuse or diversion and provide prescribers and pharmacists with critical information regarding a patient's controlled substance prescription history.[2]

Chapter 2009-197, Laws of Fla., established Florida's PDMP within the Department of Health (DOH) in s. 893.055, F.S. The PDMP uses a database to monitor the prescribing and dispensing of certain controlled substances.[3] The PDMP database became operational on September 1, 2011, when it began receiving prescription data, retroactive to December 1, 2010, from pharmacies and dispensing practitioners.[4] By September 2013, 49 states either had an operational PDMP database or had adopted legislation authorizing the creation of one.[5]

PDMP Reporting Requirements

Dispensers of controlled substances listed in Schedule II, III, or IV of the Florida Comprehensive Drug Abuse Prevention and Control Act must report specified information to the PDMP database.[6] The following information is submitted for inclusion in the PDMP database:

- The name of the prescribing practitioner, the practitioners federal Drug Enforcement Administration (DEA) registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription;
- The date the prescription was filled and the method of payment, such as cash by an individual or third-party payment;
- The full name, address, and date of birth of the person for whom the prescription was written;
- The name, national drug code, quantity, and strength of the controlled substance dispensed;
- The full name, federal DEA registration number, and address of the pharmacy, other location, or other practitioner from which the controlled substance was dispensed;
- The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's NPI; and
- Other appropriate identifying information as determined by DOH rule.

Dispensers must report dispensing a specified controlled substance to the PDMP database within seven days.[7] By the end of February 2014, more than 90 percent of pharmacies required to report data to the PDMP had uploaded information into the system within the seven-day statutory limit.[8] By that

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[1] Centers for Disease Control and Prevention, *Prescription Drug Monitoring Programs*, http://www.cdc.gov/drugoverdose/pdmp/ (last visited January 14, 2016).
[2] Id.
[3] S. 893.055(2)(a), F.S.
[4] Florida Department of Health, *Overview and Status Update of the PDMP*, PowerPoint presentation before Health Quality Subcommittee, Sept. 24, 2013, page 3 (on file with Health Quality Subcommittee staff).
[5] Brandeis University, Institute of Behavioral Health, and the U.S. Department of Justice, Bureau for Justice Assistance, PDMP Center of Excellence, *Addressing the Problem*, http://pdmpexcellence.org/content/addressing-problem (last visited January 14, 2016).
[6] 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.
[7] S. 893.055(4), F.S.
[8] Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2013-2014 Prescription Drug Monitoring Program Annual Report, Dec. 1, 2014, available at http://www.floridahealth.gov/statistics-and-data/e-forcse/news-reports/2014-pdmp-annual-report-final.pdf (last visited January 18, 2016).

same time, more than 6,100 dispensers had reported over 100 million dispensing records to the PDMP since the program became operational.[9] On average, each month 5,585 pharmacy dispensers report controlled substance prescription information to the PDMP.[10]

Exemptions from PDMP Reporting Requirements

The purpose of the PDMP is to track the dispensing of prescribed controlled substances to provide information to subsequent prescribing physicians and prevent the overprescribing of such substances, and also to prevent the diversion of such substances. However, there are some circumstances in which there is inherently a low risk of controlled substances being overprescribed or diverted, and in those circumstances, the law exempts practitioners from having to report the dispensing of controlled substances. Specifically, the following acts are not required to be reported:

- A health care practitioner administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session;
- A pharmacist or health care practitioner administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state;
- A practitioner administering or dispensing a controlled substance in the health care system of the Department of Corrections;
- A practitioner administering a controlled substance in the emergency room of a licensed hospital;
- A health care practitioner administering or dispensing a controlled substance to a person under the age of 16; and
- A pharmacist or a dispensing practitioner dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient.[11]

Access to PDMP Database

Direct access to the PDMP database is presently limited by law to medical doctors, osteopathic physicians, dentists, podiatric physicians, advanced registered nurse practitioners, physician assistants, and pharmacists.[12] A pharmacy, prescriber, or dispenser has access to information in the PDMP database that relates to a patient of that pharmacy, prescriber, or dispenser, as needed, for reviewing the patient's controlled substance prescription history.[13]

Health care practitioners[14] began accessing the PDMP database on October 17, 2011.[15] From October 1, 2014 to September 30, 2015, 32,054 health care practitioners, or 20.7 percent of all licensed health care practitioners, were registered to use the PDMP Database.[16] Pharmacists have had the

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[9] Memorandum from Rebecca Poston, Program Manager for PDMP, and Bob MacDonald, Executive Director, The Florida PDMP Foundation, Inc., to Marco Paredes, Director of Legislative Planning, Florida Department of Health, Feb. 6, 2014, p. 1 (on file with Health Quality Subcommittee staff).

[10] Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2014-2015 Prescription Drug Monitoring Program Annual Report, Dec. 1, 2015, p. 5, available at http://www.floridahealth.gov/statistics-and-data/e-forcse/news-reports/_documents/2015-pdmp-annual-report.pdf (last visited January 18, 2016).

[11] S. 893.055(5), F.S.

[12] S. 893.055(7)(b), F.S.

[13] Id.

[14] S. 893.055(1)(d), F.S., defines health care practitioner for the purpose of the PDMP program as those practitioners who are subject to licensure or regulation by DOH under ch. 458, F.S., (Medicine), ch. 459, F.S., (Osteopathic Medicine), ch. 461, F.S., (Podiatric Medicine), ch. 462, F.S., (Naturopath), ch. 463, F.S., (Optometry), ch. 464, F.S., (Nursing), ch. 465, F.S., (Pharmacy), or ch. 466, F.S., (Dentistry).

[15] Florida Department of Health, Electronic-Florida Online Reporting of Controlled Substances Evaluation (E-FORCSE), 2012-2013 Prescription Drug Monitoring Program Annual Report, Dec. 1, 2013, available at www.floridahealth.gov/reports-and-data/e-forcse/news-reports/_documents/2012-2013pdmp-annual-report.pdf (last visited November 13, 2015).

[16] *Supra*, note 10, p. 12

highest utilization rate of the PDMP; from October 1, 2014 to September 30, 2015, 89.6 percent of licensed pharmacists were trained to use the PDMP, 51.4 percent of pharmacists were registered to use the PDMP, and 89.1 percent of pharmacists registered to use the PDMP had queried it.[17] From October 1, 2014 to September 30, 2015, in-state prescribers issued 36,491,586 controlled substance prescriptions to 7,359,995 Florida residents.[18] During that same timeframe, 25,833 registered health care practitioners queried the PDMP database 21,167,947 times.[19]

In Florida, indirect access to the PDMP database is provided to:

- DOH and its relevant health care regulatory boards;
- The Attorney General for Medicaid fraud cases involving prescribed controlled substances;
- A law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances; and
- A patient or the legal guardian, or designated health care surrogate of an incapacitated patient, for verifying the accuracy of database information.[20]

Entities with indirect access to the PDMP database may request information from the PDMP program manager that is otherwise confidential and exempt from public disclosure under s. 893.0551, F.S.[21] Prior to release, the PDMP program manager must verify that the request is authentic and authorized with the requesting organization.[22]

Public Records Exemption for Information in the PDMP Database

Section 893.0551, F.S.,[23] provides that personal information of a patient and certain information concerning health care practitioners contained in the PDMP database are confidential and exempt from s. 119.07(1), F.S., and article I, section 24 of the Florida Constitution.[24] The statute makes confidential and exempt identifying information, including, but not limited to, the name, address, telephone number, insurance plan number, government-issued identification number, provider number, Drug Enforcement Administration number, or any other unique identifying number of a patient, patient's agent, health care practitioner or practitioner as defined in s. 893.055, F.S., or an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy, which is contained in the PDMP database.

Any agency or person that obtains information pursuant to s. 893.0551, F.S., must maintain the confidential and exempt status of that information.[25]

Effect of Proposed Changes

CS/HB 313 adds a PDMP reporting exemption for a rehabilitative hospital, an assisted living facility (ALF), or a nursing home when they dispense a controlled substance to a patient as ordered by the patient's treating physician. Consistent with current law, which exempts dispensing and administering controlled substances from the PDMP reporting requirements in certain health care settings where there may be a lower risk of controlled substances being overprescribed or diverted, the bill exempts additional health care settings with similar risk levels from the PDMP reporting requirements.

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[17] Id. at p. 12, 19.
[18] Id. at p. 15-16.
[19] Id. at p. 19.
[20] S. 893.055(7)(c)1.-4., F.S.
[21] S. 893.055(7)(c), F.S.
[22] Id.
[23] The public records exemption was established in 2009 in conjunction with the PDMP. See s. 1, ch. 2009-197, Laws of Fla. Additionally, the public records exemption was reauthorized in 2014. See .s 1 ch. 2014-156, Laws of Fla.
[24] S. 893.0551(2)(a)-(h), F.S.
[25] S. 893.0551(5), F.S. However, a law enforcement agency with lawful access to such information is permitted to disclose confidential and exempt information received from the DOH to a criminal justice agency as part of an active investigation of a specific violation of law. S. 893.0551(4).

The bill provides an effective date of July 1, 2016.

B. SECTION DIRECTORY:

Section 1: Amends s. 893.055, F.S., relating to prescription drug monitoring program.
Section 2: Provides an effective date.

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:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On November 17, 2015, the Health Quality Subcommittee adopted an amendment to delete the bill's requirement that a patient be transferred to the a rehabilitative hospital, an ALF, or a nursing home after

surgery and the patient's physician directly order an advanced registered nurse practitioner at the facility to provide the controlled substance, if needed, to expand the exemption to the PDMP reporting requirements to include when a rehabilitative hospital, an ALF, or a nursing home dispenses a controlled substance, as needed, to a patient as ordered by the patient's treating physician.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.

A bill to be entitled

An act relating to the prescription drug monitoring program; amending s. 893.055, F.S.; providing that certain acts of dispensing controlled substances in specified facilities are not required to be reported to the prescription drug monitoring program; providing an effective date.

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

Section 1. Paragraph (g) is added to subsection (5) of section 893.055, Florida Statutes, to read:

893.055 Prescription drug monitoring program.—

(5) When the following acts of dispensing or administering occur, the following are exempt from reporting under this section for that specific act of dispensing or administration:

(g) A rehabilitative hospital, assisted living facility, or nursing home dispensing a certain dosage of a controlled substance, as needed, to a patient as ordered by the patient's treating physician.

Section 2. This act shall take effect July 1, 2016.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 325 Involuntary Examinations under the Baker Act
SPONSOR(S): Health Quality Subcommittee; Campbell; Plasencia and others
TIED BILLS: None **IDEN./SIM. BILLS:** SB 572

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 0 N, As CS	Siples	O'Callaghan
2) Civil Justice Subcommittee	12 Y, 0 N	Robinson	Bond
3) Health & Human Services Committee		Siples LS	Calamas CEC

SUMMARY ANALYSIS

In 1971, the Legislature passed the Florida Mental Health Act (also known as "The Baker Act") to address the mental health needs of individuals in the state. The Baker Act allows for voluntary and, under certain circumstances, involuntary, examinations of individuals suspected of having a mental illness, and establishes procedures for courts, law enforcement, and certain health care practitioners to initiate such examinations.

The bill adds advanced registered nurse practitioners and physician assistants to the list of health care practitioners who may initiate the involuntary examination of a person under the Baker Act.

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

The bill has an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Involuntary Examination under the Baker Act

In 1971, the Legislature passed the Florida Mental Health Act (also known as "The Baker Act"[1]), codified in part I of ch. 394, F.S., to address mental health needs in the state.[2] The Baker Act provides the authority and process for the voluntary and involuntary examination of persons with evidence of a mental illness and the subsequent inpatient or outpatient placement of such individuals for treatment.

The Department of Children and Families (DCF) administers The Baker Act through receiving facilities that examine persons with evidence of mental illness. Receiving facilities are designated by the DCF and may be public or private facilities that provide the examination and short-term treatment of persons who meet the criteria under The Baker Act.[3] Subsequent to examination at a receiving facility, a person who requires further treatment may be transported to a treatment facility. Treatment facilities designated by the DCF are state hospitals (e.g. Florida State Hospital) which provide extended treatment and hospitalization beyond what is provided in a receiving facility.[4]

Current law provides that an involuntary examination may be initiated if there is reason to believe a person has a mental illness and because of the illness:[5]

- The person has refused a voluntary examination after explanation of the purpose of the exam or is unable to determine for himself or herself that an examination is needed; and
- The person is likely to suffer from self-neglect or substantial harm to her or his well-being, or be a danger to himself or herself or others.

Courts, law enforcement officers, and certain health care practitioners are authorized to initiate such involuntary examinations.[6] A circuit court may enter an *ex parte* order stating a person meets the criteria for involuntary examination. A law enforcement officer[7] may take a person into custody who appears to meet the criteria for involuntary examination and transport them to a receiving facility for examination. Health care practitioners may initiate an involuntary examination by executing the *Certificate of a Professional Initiating an Involuntary Examination*, an official form adopted in rule by the

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[1] "The Baker Act" is named for its sponsor, Representative Maxine E. Baker, one of the first two women from Dade County elected to office in the Florida Legislature. As chair of the House Committee on Mental Health, she championed the treatment of mental illness in a manner that would not sacrifice a patient's rights and dignity. Baker served five terms as a member of the Florida House of Representatives from 1963-1972 and was instrumental in the passage of the Florida Mental Health Act. *See* University of Florida Smathers Libraries, *A Guide to the Maxine E. Baker Papers*, *available at* http://www.library.ufl.edu/spec/pkyonge/baker.htm (last visited December 1, 2015), and Department of Children and Families and University of South Florida, Department of Mental Health and Law, *Baker Act Handbook and User Reference Guide 2014* (2014), *available at* http://myflfamilies.com/service-programs/mental-health/baker-act (select "2014 Baker Act Manual) (last visited Jan. 15, 2014).

[2] Chapter 71-131, s. 1, Laws of Fla.

[3] Section 394.455(26), F.S.

[4] Section 394.455(32), F.S.

[5] Section 394.463(1), F.S.

[6] Section 394.463(2)(a)1.-3., F.S.

[7] "Law enforcement officer" means any person who is elected, appointed, or employed full time by any municipality or the state or any political subdivision thereof; who is vested with authority to bear arms and make arrests; and whose primary responsibility is the prevention and detection of crime or the enforcement of the penal, criminal, traffic, or highway laws of the state. This definition includes all certified supervisory and command personnel whose duties include, in whole or in part, the supervision, training, guidance, and management responsibilities of full-time law enforcement officers, part-time law enforcement officers, or auxiliary law enforcement officers but does not include support personnel employed by the employing agency. s. 943.10(1), F.S.

DCF.[8] The health care practitioner must have examined the person within the preceding 48 hours and state that the person meets the criteria for involuntary examination.[9] The Baker Act currently authorizes the following health care practitioners to initiate an involuntary examination by certificate:[10]

- A physician licensed under ch. 458, F.S., or ch. 459, F.S., who has experience in the diagnosis and treatment of mental and nervous disorders.
- A clinical psychologist, as defined in s. 490.003(7), F.S., with three years of postdoctoral experience in the practice of clinical psychology, inclusive of the experience required for licensure.
- A physician or psychologist employed by a facility operated by the United States Department of Veterans Affairs that qualifies as a receiving or treatment facility.
- A psychiatric nurse licensed under part I of ch. 464, F.S., who has a master's degree or a doctorate in psychiatric nursing, holds a national advanced practice certification as a psychiatric mental health advance practice nurse, and has two years of post-master's clinical experience under the supervision of a physician.
- A mental health counselor licensed under ch. 491, F.S.
- A marriage and family therapist licensed under ch. 491, F.S.
- A clinical social worker licensed under ch. 491, F.S.

In 2014, there were 181,471 involuntary examinations initiated in the state. Law enforcement initiated half of the involuntary examinations (50.18 percent), followed closely by mental health professionals (47.86 percent), with the remaining initiated pursuant to *ex parte* orders by judges (1.96 percent).[11]

Physician Assistants

Physician assistant (PA) licensure in Florida is governed by ss. 458.347(7) and 459.022(7), F.S. The Department of Health (DOH) licenses PAs and the Florida Council on Physician Assistants (Council) regulates them.[12] PAs are also regulated by either the Florida Board of Medicine for PAs licensed under ch. 458, F.S., or the Florida Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S. The duty of a board and its members is to make disciplinary decisions concerning whether a doctor or PA has violated the provisions of his or her practice act.[13] There are 7,987 PAs who hold active licenses in Florida.[14]

PAs may only practice under the direct or indirect supervision of a medical doctor or doctor of osteopathic medicine with whom they have a clinical relationship.[15] A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[16] The supervising physician is responsible and liable for any and all acts of the PA and may not supervise more than four PAs at any time.[17]

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[8] The *Certificate of a Professional Initiating an Involuntary Examination* is a form created by the DCF which must be executed by health care practitioners initiating an involuntary examination under The Baker Act. The form contains information related to the person's diagnosis and the health care practitioner's personal observations of statements and behaviors that support the involuntary examination of such person. *See* Florida Department of Children and Families, *CF-MH 3052b*, incorporated by reference in Rule 65E-5.280, F.A.C., and *available at* http://www.dcf.state.fl.us/programs/samh/MentalHealth/laws/3052b.pdf. (last visited January 15, 2016).

[9] Section 394.463(2)(a)3., F.S.

[10] *Id.*

[11] Annette Christy & Christina Guenther, Baker Act Reporting Center, College of Behavioral & Community Sciences, University of South Florida, *Annual Report of Baker Act Data: Summary of 2014 Data*, *available at* http://bakeract.fmhi.usf.edu/document/BA_Annual_2014.pdf (last visited Jan. 15, 2016).

[12] The Council consists of three physicians who are members of the Board of Medicine; one member who is a member of the Board of Osteopathic Medicine, and a physician assistant appointed by the State Surgeon General. (Sections 458.347(9) and 459.022(8), F.S.)

[13] Sections 458.347(12) and 459.022(12), F.S.

[14] Email correspondence with the Department of Health, Medical Quality Assurance staff on November 9, 2015. The number of active licensed PAs include both in-state and out-of-state licensees, as of November 9, 2015.

[15] Sections 458.347(2)(f) and 459.022(2)(f), F.S., define supervision as responsible supervision and control which requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.

[16] Rules 64B8-30.012 and 64B15-6.010, F.A.C.

[17] Sections 458.347(3) and 459.022(3), F.S.

To be licensed as a PA in Florida, an applicant must demonstrate to the Council:[18]

- Satisfactory passage of the National Commission on Certification of Physician Assistant exam;
- Completion of the application and remittance of the application fee;[19]
- Completion of an approved PA training program;
- A sworn statement of any prior felony convictions;
- A sworn statement of any previous revocation or denial of licensure in any state;
- Two letters of recommendation; and
- If the applicant wishes to apply for prescribing authority, a copy of course transcripts and a copy of the course description from a PA training program describing the course content in pharmacotherapy.

Licenses are renewed biennially.[20] At the time of renewal, a PA must demonstrate that he or she has met the continuing education requirements and must submit a sworn statement that he or she has not been convicted of any felony in the previous two years.[21]

Florida law does not expressly allow PAs to refer for or initiate involuntary examinations under the Baker Act, however, in 2008, Attorney General Bill McCollum issued an opinion stating:

> A physician assistant pursuant to Chapter 458 or 459, Florida Statutes, may refer a patient for involuntary evaluation pursuant to section 394.463, Florida Statutes, provided that the physician assistant has experience regarding the diagnosis and treatment of mental and nervous disorders and such tasks are within the supervising physician's scope of practice.[22]

However, PAs are not required by law to have experience in the diagnosis and treatment of mental and nervous disorders.

Advanced Registered Nurse Practitioners

Nurse licensure is governed by part I of ch. 464, F.S. Nurses are licensed by the DOH and regulated by the Board of Nursing. Licensure requirements to practice nursing include completion of an approved educational course of study, passage of an examination approved by the DOH, acceptable criminal background screening results, and payment of applicable fees.[23] There are 22,003 ARNPs who hold active licenses in Florida.[24]

A nurse who holds a current license to practice professional nursing may apply to be certified as an Advanced Registered Nurse Practitioner (ARNP), under s. 464.012, F.S., if the nurse meets one or more of the following requirements:

- Satisfactory completion of a formal postbasic educational program of at least one academic year that prepares nurses for advanced or specialized practice;

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[18] Sections 458.347(7) and 459.022(7), F.S.
[19] The application fee is $100 and the initial license fee is $205. *See* http://flboardofmedicine.gov/licensing/physician-assistant-licensure/ (last visited January 15, 2016).
[20] For timely renewed licenses, the renewal fee is $280 and the prescribing registration is $150. An applicant may be charged an additional fee if the license is renewed after expiration or is more than 120 days delinquent. *See* http://flboardofmedicine.gov/renewals/physician-assistants/ (last visited January 15, 2016).
[21] Sections 458.347(7)(c)-(d) and 459.022(7)(c)-(d), F.S.
[22] Op. Att'y Gen. Fla. 08-31 (2008), *available at* http://www.dcf.state.fl.us/programs/samh/MentalHealth/laws/agopinion.pdf (last visited January 15, 2016).
[23] Sections 464.008 and 464.009, F.S. As an alternative to licensure by examination, a nurse may also be eligible for licensure by endorsement.
[24] Email correspondence with the Department of Health, Medical Quality Assurance staff on November 9, 2015. The number of active licensed ARNPs include both in-state and out-of-state licensees, as of November 9, 2015.

- Certification by a specialty board; or
- Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills.

Current law defines three categories of ARNPs: certified registered nurse anesthetists, certified nurse midwives, and nurse practitioners.[25] All ARNPs, regardless of practice category, may only practice within the framework of an established protocol and under the supervision of an allopathic or osteopathic physician or dentist.[26] ARNPs may carry out treatments as specified in statute, including:[27]

- Monitoring and altering drug therapies;
- Initiating appropriate therapies for certain conditions;
- Ordering diagnostic tests and physical and occupational therapy; and
- Performing additional functions as maybe determined by rule in accordance with s. 464.003(2), F.S.[28]

In addition to the above-allowed acts, an ARNP may also perform other acts as authorized by statute and within his or her specialty.[29] Further, if it is within an ARNP's established protocol, the ARNP may establish behavioral problems and diagnosis and make treatment recommendations.[30]

Only ARNPs who are "psychiatric nurses" (who have a master's or doctoral degree in psychiatric nursing, hold a national advance practice certification as a psychiatric nurse, and two years post-master's clinical experience), may initiate involuntary examinations under the Baker Act.

Effect of Proposed Changes

The bill authorizes a PA or an ARNP to initiate an involuntary examination under The Baker Act by executing a certificate stating that a person he or she examined within the preceding 48 hours appears to meet the criteria for an involuntary examination for mental illness. Under current law, only a physician, clinical psychologist, psychiatric nurse, mental health counselor, marriage and family therapist or clinical social worker may initiate an involuntary examination by executing such a certificate.

The bill defines a "physician assistant" and an "advanced registered nurse practitioner" in the same manner as their respective practice acts (ss. 458.347, 459.022, and 464.003, F.S.).

The bill makes necessary conforming changes due to the statutory changes made by the bill.

The bill provides an effective date of July 1, 2016.

B. SECTION DIRECTORY:

Section 1: Amends s. 394.464, F.S., relating to involuntary examination.

Section 2: Amends s. 394.455, F.S., relating to definitions.

Section 3: Amends s. 394.407, F.S., relating to medical, psychiatric, and psychological examination and treatment of child; physical, mental, or substance abuse examination of person with or requesting child custody.

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[25] Section 464.012(2), F.S.
[26] Section 464.012(3), F.S.
[27] *Id.*
[28] Section 464.003(2), F.S., defines "advanced or specialized nursing practice" to include additional activities that an ARNP may perform as approved by the Board of Nursing.
[29] Section 464.012(4), F.S.
[30] Section 464.012(4)(c)1., F.S.

Section 4: Amends s. 394.495, F.S., relating to child and adolescent mental health system of care; programs and services.

Section 5: Amends s. 394.496, F.S., relating to service planning.

Section 6: Amends s. 394.9085, F.S., relating to behavioral provider liability.

Section 7: Amends s. 409.972, F.S., relating to mandatory and voluntary enrollment.

Section 8: Amends s. 744.704, F.S., relating to powers and duties.

Section 9: Provides an effective date of July 1, 2016.

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:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

No additional rule-making is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On November 17, 2015, the Health Quality Subcommittee adopted an amendment that incorporated, by reference, the definitions the definitions of physician in ss. 458.347(2)(e) and 459.022(2)(e), F.S.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.

A bill to be entitled

An act relating to involuntary examinations under the Baker Act; amending s. 394.463, F.S.; authorizing physician assistants and advanced registered nurse practitioners to initiate involuntary examinations under the Baker Act of persons believed to have mental illness; amending s. 394.455, F.S.; providing definitions; amending ss. 39.407, 394.495, 394.496, 394.9085, 409.972, and 744.704, F.S.; conforming cross-references; providing an effective date.

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

Section 1. Paragraph (a) of subsection (2) of section 394.463, Florida Statutes, is amended to read:

394.463 Involuntary examination.—

(2) INVOLUNTARY EXAMINATION.—

(a) An involuntary examination may be initiated by any one of the following means:

1. A court may enter an ex parte order stating that a person appears to meet the criteria for involuntary examination, giving the findings on which that conclusion is based. The ex parte order for involuntary examination must be based on sworn testimony, written or oral. If other less restrictive means are not available, such as voluntary appearance for outpatient evaluation, a law enforcement officer, or other designated agent

of the court, shall take the person into custody and deliver him or her to the nearest receiving facility for involuntary examination. The order of the court shall be made a part of the patient's clinical record. No fee shall be charged for the filing of an order under this subsection. Any receiving facility accepting the patient based on this order must send a copy of the order to the Agency for Health Care Administration on the next working day. The order shall be valid only until executed or, if not executed, for the period specified in the order itself. If no time limit is specified in the order, the order shall be valid for 7 days after the date that the order was signed.

2. A law enforcement officer shall take a person who appears to meet the criteria for involuntary examination into custody and deliver the person or have him or her delivered to the nearest receiving facility for examination. The officer shall execute a written report detailing the circumstances under which the person was taken into custody, and the report shall be made a part of the patient's clinical record. Any receiving facility accepting the patient based on this report must send a copy of the report to the Agency for Health Care Administration on the next working day.

3. A physician, physician assistant, clinical psychologist, psychiatric nurse, mental health counselor, marriage and family therapist, ~~or~~ clinical social worker, or advanced registered nurse practitioner may execute a certificate

stating that he or she has examined a person within the preceding 48 hours and finds that the person appears to meet the criteria for involuntary examination and stating the observations upon which that conclusion is based. If other less restrictive means are not available, such as voluntary appearance for outpatient evaluation, a law enforcement officer shall take the person named in the certificate into custody and deliver him or her to the nearest receiving facility for involuntary examination. The law enforcement officer shall execute a written report detailing the circumstances under which the person was taken into custody. The report and certificate shall be made a part of the patient's clinical record. Any receiving facility accepting the patient based on this certificate must send a copy of the certificate to the Agency for Health Care Administration on the next working day.

Section 2. Subsections (2) through (21) of section 394.455, Florida Statutes, are renumbered as subsections (3) through (22), respectively, present subsections (22) through (38) are renumbered as subsections (24) through (40), respectively, and new subsections (2) and (23) are added to that section, to read:

394.455 Definitions.—As used in this part, unless the context clearly requires otherwise, the term:

(2) "Physician assistant" has the same meaning as provided in s. 458.347(2)(e) or s. 459.022(2)(e).

(23) "Advanced registered nurse practitioner" means a

person licensed in this state to practice professional nursing and certified in advanced or specialized nursing practice, as defined in s. 464.003.

Section 3. Paragraph (a) of subsection (3) of section 39.407, Florida Statutes, is amended to read:

39.407 Medical, psychiatric, and psychological examination and treatment of child; physical, mental, or substance abuse examination of person with or requesting child custody.—

(3)(a)1. Except as otherwise provided in subparagraph (b)1. or paragraph (e), before the department provides psychotropic medications to a child in its custody, the prescribing physician shall attempt to obtain express and informed consent, as defined in s. 394.455(10) ~~394.455(9)~~ and as described in s. 394.459(3)(a), from the child's parent or legal guardian. The department must take steps necessary to facilitate the inclusion of the parent in the child's consultation with the physician. However, if the parental rights of the parent have been terminated, the parent's location or identity is unknown or cannot reasonably be ascertained, or the parent declines to give express and informed consent, the department may, after consultation with the prescribing physician, seek court authorization to provide the psychotropic medications to the child. Unless parental rights have been terminated and if it is possible to do so, the department shall continue to involve the parent in the decisionmaking process regarding the provision of psychotropic medications. If, at any time, a parent whose

parental rights have not been terminated provides express and informed consent to the provision of a psychotropic medication, the requirements of this section that the department seek court authorization do not apply to that medication until such time as the parent no longer consents.

2. Any time the department seeks a medical evaluation to determine the need to initiate or continue a psychotropic medication for a child, the department must provide to the evaluating physician all pertinent medical information known to the department concerning that child.

Section 4. Paragraphs (a) and (c) of subsection (3) of section 394.495, Florida Statutes, are amended to read:

394.495 Child and adolescent mental health system of care; programs and services.—

(3) Assessments must be performed by:

(a) A professional as defined in s. 394.455(3), (5), (22), (25), or (26) ~~394.455(2), (4), (21), (23), or (24)~~;

(c) A person who is under the direct supervision of a professional as defined in s. 394.455(3), (5), (22), (25), or (26) ~~394.455(2), (4), (21), (23), or (24)~~ or a professional licensed under chapter 491.

Section 5. Subsection (5) of section 394.496, Florida Statutes, is amended to read:

394.496 Service planning.—

(5) A professional as defined in s. 394.455(3), (5), (22), (25), or (26) ~~394.455(2), (4), (21), (23), or (24)~~ or a

professional licensed under chapter 491 must be included among those persons developing the services plan.

Section 6. Subsection (6) of section 394.9085, Florida Statutes, is amended to read:

394.9085 Behavioral provider liability.—

(6) For purposes of this section, the terms "detoxification services," "addictions receiving facility," and "receiving facility" have the same meanings as those provided in ss. 397.311(22)(a)4., 397.311(22)(a)1., and 394.455(28) ~~394.455(26)~~, respectively.

Section 7. Paragraph (b) of subsection (1) of section 409.972, Florida Statutes, is amended to read:

409.972 Mandatory and voluntary enrollment.—

(1) The following Medicaid-eligible persons are exempt from mandatory managed care enrollment required by s. 409.965, and may voluntarily choose to participate in the managed medical assistance program:

(b) Medicaid recipients residing in residential commitment facilities operated through the Department of Juvenile Justice or mental health treatment facilities as defined by s. 394.455(34) ~~394.455(32)~~.

Section 8. Subsection (7) of section 744.704, Florida Statutes, is amended to read:

744.704 Powers and duties.—

(7) A public guardian shall not commit a ward to a mental health treatment facility, as defined in s. 394.455(34)

~~394.455(32)~~, without an involuntary placement proceeding as provided by law.

Section 9. This act shall take effect July 1, 2016.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 373 Mental Health Counseling Interns
SPONSOR(S): Health Quality Subcommittee; Burgess, Jr.
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 0 N, As CS	Siples	O'Callaghan
2) Health & Human Services Committee		Siples	Calamas

SUMMARY ANALYSIS

The bill revises the requirements for registration as an intern in the fields of clinical social work, marriage and family therapy, and mental health counseling. The bill limits the length of time an intern may practice in one of these fields without obtaining full licensure.

The bill provides that an individual, who is registered to practice as an intern, must remain under supervision for clinical hours to count toward full licensure. When a registered intern is providing services in a private practice setting, the bill requires a licensed mental health professional to be on the premises. The bill provides that a registration issued on or before April 1, 2017, may not be renewed or reissued and expires March 31, 2022. Any registration issued after April 1, 2017, is valid for 5 years. The bill allows a subsequent intern registration only if the candidate passes a theory and practice examination.

The bill prohibits an individual who has held a provisional license to practice as a clinical social worker, marriage and family therapist, or mental health counselor from applying for intern registration in the same profession.

The bill deletes obsolete language and makes technical changes to the structure of existing law to clarify language.

The bill will have an insignificant, negative fiscal impact on the Department of Health and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling

The Board of Clinical Social Work, Marriage and Family Therapy, and Mental Health Counseling (the board) is located within the Department of Health (DOH), and implements and enforces rules that regulate the practice of clinical social work, marriage and family therapy, and mental health counseling pursuant to ch. 491, F.S. The board is composed of nine members appointed by the Governor and confirmed by the Senate.[1] Presently, the board regulates:

- 9,246 licensed clinical social workers;
- 1,866 marriage and family therapists; and
- 10,018 mental health counselors.[2]

Scope of Practice

Clinical Social Work

The practice of clinical social work uses scientific and applied knowledge, theories, and methods for the purpose of describing, preventing, evaluating, and treating individual, couple, marital, family, or group behavior to prevent and treat undesired behavior and enhance mental health. It includes methods of a psychological nature used to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders and dysfunctions (whether cognitive, affective, or behavioral, sexual dysfunction, behavioral disorders, alcoholism, and substance abuse. Clinical social work incorporates psychotherapy, hypnotherapy, sex therapy, counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients.[3]

Marriage and Family Therapy

The practice of marriage and family therapy uses scientific and applied marriage and family theories, methods, and procedures for the purpose of describing, evaluating, and modifying marital, family, and individual behavior, within the context of marital and family systems. The practice is based on marriage and family systems theory, marriage and family development, human development, normal and abnormal behavior, psychopathology, human sexuality, psychotherapeutic and marriage and family therapy theories and technique. The practice of marriage and family therapy include methods of a psychological nature to evaluate, assess, diagnose, treat, and prevent emotional and mental disorders or dysfunctions (whether cognitive, affective, or behavioral), sexual dysfunction, behavioral disorders, alcoholism, and substance abuse. Marriage and family therapy incorporates marriage and family therapy, psychotherapy, hypnotherapy, sex therapy, counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients.[4]

[1] Section 491.004(1), F.S.
[2] Email correspondence with the Department of Health, Medical Quality Assurance staff on November 9, 2015. The number of active licensed practitioners include both in-state and out-of-state licensees, as of November 9, 2015.
[3] Section 491.003(7), F.S.
[4] Section 491.003(8), F.S.

Mental Health Counseling

It uses scientific and applied behavioral science theories, methods, and techniques for the purpose of describing, preventing, and treating undesired behaviors and enhancing mental health and human development. The practice is based on the person-in-situation perspectives derived from research and theory in personality, family, group, and organizational dynamics and development, career planning, cultural diversity, human growth and development, human sexuality, normal and abnormal behavior, psychopathology, psychotherapy, and rehabilitation. The practice of mental health counseling includes methods of a psychological nature that are used to evaluate, assess, diagnose, and treat emotional and mental dysfunctions or disorders (whether cognitive, affective, or behavioral), behavioral disorders, interpersonal relationships, sexual dysfunctions, alcoholism, and substance abuse. Mental health counseling incorporates psychotherapy, hypnotherapy, sex therapy, counseling, behavior modification, consultation, client-centered advocacy, crisis intervention, and the provision of needed information and education to clients.[5]

Internship

To be licensed as a clinical social worker, marriage and family therapist, or mental health counselor, an applicant must meet educational requirements, complete at least 2 years of postgraduate or postmaster's clinical practice supervised by a licensed practitioner, and pass a theory and practice examination.[6] During the time in which an applicant is completing the required supervised clinical experience or internship, he or she must register with the DOH as an intern.[7] The supervised clinical experience may be met by providing at least 1,500 hours of face-to-face psychotherapy with clients, which may not be accrued in less than 100 weeks.[8]

An applicant seeking registration as an intern must:[9]

- Submit a completed application form and the nonrefundable fee to the DOH;
- Complete education requirements;
- Submit an acceptable supervision plan for meeting the practicum, internship, or field work required for licensure that was not satisfied by graduate studies; and
- Identify a qualified supervisor.

A registered intern may renew his or her registration every biennium, with no limit to the number of times it may be renewed.[10] Currently, there are 3,949 clinical social work interns; 1,039 marriage and family therapy interns; and 4,966 registered mental health counselor interns. More than 700 interns have continued to renew their intern registration for more than 10 years, and 150 of them have been renewing their registrations since the inception of this law in 1998.[11]

Recent disciplinary cases have shown that those interns who have held intern registrations for many years are no longer practicing under supervision as is required by law. The DOH receives complaints against registered interns for various infractions including filing false reports, failing to meet minimum standards, boundary violations, sexual misconduct, Medicaid fraud, false advertising, etc. Since 2007, the DOH has received 173 complaints against clinical social work interns, 72 complaints against marriage and family therapy interns, and 306 complaints against mental health counselor interns. Of

[5] Section 491.003(9), F.S.
[6] Section 491.005, F.S. A procedure for licensure by endorsement is provided in s. 491.006, F.S.
[7] Section 491.0045, F.S.
[8] Rule 64B4-2.001, F.A.C.
[9] Section 491.0045(2), F.S.
[10] Department of Health, *House Bill 373 Bill Analysis* (Oct. 20, 2015) (on file with House Health Quality Subcommittee). The registration renewal fee is $80.00 for a two-year period.
[11] *Id.*

these, 74 complaints have resulted in disciplinary actions and 4 resulted in emergency restriction orders signed.[12]

Provisional License

A provisional license allows an individual applying for licensure by examination or licensure by endorsement, who has satisfied the clinical experience requirements, to practice under supervision while meeting additional coursework or examination requirements for licensure.[13] Individuals must meet minimum coursework requirements and possess the respective graduate degree.[14] A provisional license is valid for 24 months, after which it may not be renewed or reissued.[15]

There are 53 provisionally licensed clinical social workers, 25 provisionally licensed marriage and family therapists, and 152 provisionally licensed mental health counselors.[16] The board has accepted applications for intern registrations from practitioners whose provisional licenses have expired. Currently, there is no prohibition against a provisional licensee applying for an intern registration.[17]

Effect of Proposed Changes

The bill provides that a registered intern must practice under the supervision of a licensed clinical social worker, marriage and family therapist, or mental health counselor for clinical hours to count toward full licensure. Additionally, this bill limits the time period for registered internship to 5 years (60 months) from the date the intern registration is issued and provides that a registration may not be renewed or reissued. Any intern registration issued on or before April 1, 2017, will expire on March 31, 2022. Registrations issued after April 1, 2017, expire 60 months after the date of issue and may only be renewed if the candidate has passed the theory and practice examination required for full licensure.

Under current law, an intern may perform work on or off the premises of the supervising mental health professional provided the off-premises work is not the independent private practice of unlicensed health services on the premises at the same time the intern is providing services. The bill clarifies that a licensed clinical social worker, marriage and family therapist, or mental health counselor is required to be on the premises when a registered intern provides clinical services in a private practice setting.

The bill prohibits a person who has held a provisional license from applying for an intern registration in the same profession. Under current law, there is no such provision, thus allowing individuals to lengthen the time period to practice in the fields of clinical social work, marriage and family therapy, and mental health counseling without obtaining full licensure.

The bill deletes obsolete language and makes technical grammatical and conforming changes.

The bill provides an effective date of July 1, 2016.

B. SECTION DIRECTORY:

Section 1. Amends s. 491.0045, F.S., relating to intern registration and requirements.

Section 2. Amends s. 491.005, F.S., relating to licensure by examination.

Section 3. Provides an effective date of July 1, 2016.

[12] *Id.*
[13] Section 491.0046(1), F.S., and Rule 64B4-3.0075, F.A.C.
[14] Section 491.0046(2), F.S.
[15] Section 491.0046(4), F.S.
[16] *Supra* note 10.
[17] *Id.*

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   The DOH will experience a decrease in revenues due to the elimination of the biennial renewal fee for interns. However, with internships limited to a 5-year duration, it is anticipated that interns will apply for full licensure which will offset the decrease in the intern renewal revenue.[18]

2. Expenditures:

   The DOH will need to update its licensure system to accommodate the 5-year registration period for internships. The DOH advises its current resources are sufficient to absorb the costs associated with the update.[19]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Interns of clinical social work, marriage and family therapy, and mental health counseling will no longer have to pay the biennial renewal fee, yet will be required to pay initial fees and renewal for full licensure after 5 years of internship to continue to practice in these professions.[20]

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The DOH has sufficient rule-making authority to implement the provisions of the bill.

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[18] *Id.*
[19] *Id.*
[20] *Id.*

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On November 17, 2015, the Health Quality Subcommittee adopted an amendment to change the date of application of certain registration requirements in the bill to after the effective date of the bill, thereby requiring registrations issued on or before April 1, 2017, to expire on March 31, 2022, and applying the 5-year time limit to all registrations issued after April 1, 2017.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.

A bill to be entitled

An act relating to mental health counseling interns; amending s. 491.0045, F.S.; revising mental health intern registration requirements; revising requirements for supervision of registered interns; deleting specified education and experience requirements; establishing a validity period and providing for expiration of intern registrations; amending s. 491.005, F.S.; requiring a licensed mental health professional to be on the premises when a registered intern provides services in clinical social work, marriage and family therapy, and mental health counseling; deleting a clinical experience requirement for such registered interns; deleting a provision requiring that certain registered interns meet educational requirements for licensure; providing an effective date.

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

Section 1. Section 491.0045, Florida Statutes, is amended to read:

491.0045 Intern registration; requirements.—

(1) ~~Effective January 1, 1998,~~ An individual who has not satisfied ~~intends to practice in Florida to satisfy~~ the postgraduate or post-master's level experience requirements, as

specified in s. 491.005(1)(c), (3)(c), or (4)(c), must register as an intern in the profession for which he or she is seeking licensure before ~~prior to~~ commencing the post-master's experience requirement or an individual who intends to satisfy part of the required graduate-level practicum, internship, or field experience, outside the academic arena for any profession, and must register as an intern in the profession for which he or she is seeking licensure before ~~prior to~~ commencing the practicum, internship, or field experience.

(2) The department shall register as a clinical social worker intern, marriage and family therapist intern, or mental health counselor intern each applicant who the board certifies has:

(a) Completed the application form and remitted a nonrefundable application fee not to exceed $200, as set by board rule;

(b)1. Completed the education requirements as specified in s. 491.005(1)(c), (3)(c), or (4)(c) for the profession for which he or she is applying for licensure, if needed; and

2. Submitted an acceptable supervision plan, as determined by the board, for meeting the practicum, internship, or field work required for licensure that was not satisfied in his or her graduate program.

(c) Identified a qualified supervisor.

(3) An individual registered under this section must remain under supervision while practicing under registered

intern status ~~until he or she is in receipt of a license or a letter from the department stating that he or she is licensed to practice the profession for which he or she applied~~.

~~(4) An individual who has applied for intern registration on or before December 31, 2001, and has satisfied the education requirements of s. 491.005 that are in effect through December 31, 2000, will have met the educational requirements for licensure for the profession for which he or she has applied.~~

(4)~~(5) Individuals who have commenced the experience requirement as specified in s. 491.005(1)(c), (3)(c), or (4)(c) but failed to register as required by subsection (1) shall register with the department before January 1, 2000.~~ Individuals who fail to comply with this section may ~~subsection shall~~ not be granted a license under this chapter, and any time spent by the individual completing the experience requirement as specified in s. 491.005(1)(c), (3)(c), or (4)(c) before ~~prior to~~ registering as an intern does ~~shall~~ not count toward completion of the ~~such~~ requirement.

(5) An intern registration is valid for 5 years.

(6) An intern registration issued on or before April 1, 2017, expires March 31, 2022, and may not be renewed or reissued. A registration issued after April 1, 2017, expires 60 months after the date of issuance. No subsequent intern registration may be issued unless the candidate has passed the theory and practice examination described in s. 491.005 (1)(d), (3)(d), and (4)(d).

(7) A person who has held a provisional license issued by the board may not apply for an intern registration in the same profession.

Section 2. Paragraphs (a) and (c) of subsection (1), paragraphs (a) and (c) of subsection (3), paragraphs (a) and (c) of subsection (4), and subsections (5) and (6) of section 491.005, Florida Statutes, are amended to read:

491.005 Licensure by examination.—

(1) CLINICAL SOCIAL WORK.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, plus the actual per applicant cost to the department for purchase of the examination from the American Association of State Social Worker's Boards or a similar national organization, the department shall issue a license as a clinical social worker to an applicant who the board certifies:

(a) Has submitted an ~~made~~ application ~~therefor~~ and paid the appropriate fee.

(c) Has had at least ~~not less than~~ 2 years of clinical social work experience, which took place subsequent to completion of a graduate degree in social work at an institution meeting the accreditation requirements of this section, under the supervision of a licensed clinical social worker or the equivalent who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy clinical experience requirements must register pursuant to s. 491.0045 before ~~prior to~~ commencing practice. If the

applicant's graduate program was not a program which emphasized direct clinical patient or client health care services as described in subparagraph (b)2., the supervised experience requirement must take place after the applicant has completed a minimum of 15 semester hours or 22 quarter hours of the coursework required. A doctoral internship may be applied toward the clinical social work experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting. ~~The experience requirement may be met by work performed on or off the premises of the supervising clinical social worker or the equivalent, provided the off-premises work is not the independent private practice rendering of clinical social work that does not have a licensed mental health professional, as determined by the board, on the premises at the same time the intern is providing services~~.

(3) MARRIAGE AND FAMILY THERAPY.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, plus the actual cost to the department for the purchase of the examination from the Association of Marital and Family Therapy Regulatory Board, or similar national organization, the department shall issue a license as a marriage and family therapist to an applicant who the board certifies:

(a) Has submitted an ~~made~~ application ~~therefor~~ and paid the appropriate fee.

(c) Has had at least ~~not less than~~ 2 years of clinical

experience during which 50 percent of the applicant's clients were receiving marriage and family therapy services, which must be at the post-master's level under the supervision of a licensed marriage and family therapist with at least 5 years of experience, or the equivalent, who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy the clinical experience requirements must register pursuant to s. 491.0045 before ~~prior to~~ commencing practice. If a graduate has a master's degree with a major emphasis in marriage and family therapy or a closely related field that did not include all the coursework required under sub-subparagraphs (b)1.a.-c., credit for the post-master's level clinical experience shall not commence until the applicant has completed a minimum of 10 of the courses required under sub-subparagraphs (b)1.a.-c., as determined by the board, and at least 6 semester hours or 9 quarter hours of the course credits must have been completed in the area of marriage and family systems, theories, or techniques. Within the 3 years of required experience, the applicant shall provide direct individual, group, or family therapy and counseling, to include the following categories of cases: unmarried dyads, married couples, separating and divorcing couples, and family groups including children. A doctoral internship may be applied toward the clinical experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting.

~~The clinical experience requirement may be met by work performed on or off the premises of the supervising marriage and family therapist or the equivalent, provided the off-premises work is not the independent private practice rendering of marriage and family therapy services that does not have a licensed mental health professional, as determined by the board, on the premises at the same time the intern is providing services~~.

(4) MENTAL HEALTH COUNSELING.—Upon verification of documentation and payment of a fee not to exceed $200, as set by board rule, plus the actual per applicant cost to the department for purchase of the examination from the Professional Examination Service for the National Academy of Certified Clinical Mental Health Counselors or a similar national organization, the department shall issue a license as a mental health counselor to an applicant who the board certifies:

(a) Has submitted an ~~made~~ application ~~therefor~~ and paid the appropriate fee.

(c) Has had at least ~~not less than~~ 2 years of clinical experience in mental health counseling, which must be at the post-master's level under the supervision of a licensed mental health counselor or the equivalent who is a qualified supervisor as determined by the board. An individual who intends to practice in Florida to satisfy the clinical experience requirements must register pursuant to s. 491.0045 before ~~prior to~~ commencing practice. If a graduate has a master's degree with a major related to the practice of mental health counseling that

did not include all the coursework required under sub-subparagraphs (b)1.a.-b., credit for the post-master's level clinical experience shall not commence until the applicant has completed a minimum of seven of the courses required under sub-subparagraphs (b)1.a.-b., as determined by the board, one of which must be a course in psychopathology or abnormal psychology. A doctoral internship may be applied toward the clinical experience requirement. A licensed mental health professional must be on the premises when clinical services are provided by a registered intern in a private practice setting. ~~The clinical experience requirement may be met by work performed on or off the premises of the supervising mental health counselor or the equivalent, provided the off-premises work is not the independent private practice rendering of services that does not have a licensed mental health professional, as determined by the board, on the premises at the same time the intern is providing services.~~

~~(5) INTERNSHIP.—An individual who is registered as an intern and has satisfied all of the educational requirements for the profession for which the applicant seeks licensure shall be certified as having met the educational requirements for licensure under this section.~~

(5)~~(6)~~ RULES.—The board may adopt rules necessary to implement any education or experience requirement of this section for licensure as a clinical social worker, marriage and family therapist, or mental health counselor.

Section 3. This act shall take effect July 1, 2016.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 375 Physician Assistants
SPONSOR(S): Health Care Appropriations Subcommittee; Steube
TIED BILLS: **IDEN./SIM. BILLS:** SB 748

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	11 Y, 0 N	Siples	O'Callaghan
2) Health Care Appropriations Subcommittee	12 Y, 0 N, As CS	Garner	Pridgeon
3) Health & Human Services Committee		Siples	Calamas

SUMMARY ANALYSIS

A physician assistant (PA) is a person licensed to perform health care services delegated by a supervising physician, in the specialty areas in which he or she has been trained. PAs are governed by the respective physician practice acts for medical doctors (MDs) and doctors of osteopathic medicine (DOs). A physician may supervise up to four PAs and is responsible and liable for the performance and the acts and omissions of the PA. Upon submission of required paperwork to the Department of Health (DOH), a supervising physician may delegate the authority to prescribe or dispense medicinal drugs used in the supervisory physician's practice to a PA.

The bill requires a PA to have a supervising physician, or designated supervising physician in a practice with multiple supervisory physicians. The PA must notify the DOH of changes in the supervising physician within 30 days after the change. The requirement to have a designated supervising physician does not prevent a PA from practicing under multiple supervising physicians. The designated supervising physician must maintain a current list of all supervising physicians within the practice or facility.

The bill expressly authorizes a PA to perform any duties or services he or she has been delegated by a supervising physician unless such duties or services are expressly prohibited by a statute or rule.

The bill amends chapters 458 and 459, F.S., to streamline the requirements for PA licensure by allowing the applicant to submit an acknowledgement of prior felony convictions and disciplinary action taken against a license from another state, rather than submitting a sworn statement attesting to such information. The bill also repeals a requirement that a PA licensure applicant submit two letters of recommendation.

Currently, all PA licensure applicants must successfully pass an examination offered by the National Commission on Certification of Physician Assistants prior to being licensed. The bill deletes obsolete provisions relating to a licensure examination administered by the DOH for certain foreign-trained PA licensure applicants. The bill also repeals a provision that allows the DOH to issue temporary licenses to PA licensure applicants awaiting the results of the DOH-administered examination.

The bill allows a PA with prescribing authority to acknowledge completion of the required continuing medical education hours, rather than submitting a signed affidavit attesting to the completion of the requirement at the time of license renewal. The bill allows a PA's prescriptions to be in written or electronic form, as long as they are in compliance with prescription labeling information requirements.

The bill has an insignificant, indeterminate, negative fiscal impact on the DOH. The agency's current resources can absorb any additional workload.

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Physician Assistants

A physician assistant (PA) is an individual who has completed an approved medical training program and is licensed to perform medical services as delegated by a supervising physician.[1] Currently, there are 7,987 PAs who hold active licenses in Florida.[2]

Licensure

PA licensure is governed by ss. 458.347(7) and 459.022(7), F.S. The Department of Health (DOH) licenses PAs and the Florida Council on Physician Assistants (Council) regulates them.[3] PAs are also regulated by either the Florida Board of Medicine for PAs licensed under ch. 458, F.S., or the Florida Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S.

To become licensed as a PA in Florida, an applicant must demonstrate to the Council that he or she has met the following requirements:[4]

- Satisfactory passage of the National Commission on Certification of Physician Assistant exam;
- Completion of the application and remittance of the application fee;[5]
- Completion of an approved PA training program;
- Submission of a sworn statement of any prior felony convictions;
- Submission of a sworn statement of any previous revocation or denial of licensure in any state;
- Submission of two letters of recommendation; and
- If the applicant wishes to apply for prescribing authority, submission of a copy of course transcripts and a copy of the course description from a PA training program describing the course content in pharmacotherapy.

Licenses are renewed biennially.[6] At the time of renewal, a PA must demonstrate that he or she has met the continuing medical education requirements and must submit a sworn statement that he or she has not been convicted of any felony in the previous two years.[7]

Supervision of PAs

A PA may only practice under the supervision of a medical doctor or a doctor of osteopathic medicine with whom they have a clinical relationship. A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[8] Supervision is defined as responsible supervision and control that requires the easy availability or physical presence

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[1] Sections 458.347(2)(e), F.S. and 459.022(2)(e), F.S.
[2] Email correspondence with the Department of Health, Medical Quality Assurance staff on November 9, 2015. The number of active licensed PAs include both in-state and out-of-state licensees, as of November 9, 2015.
[3] The council consists of three physicians who are members of the Board of Medicine; one member who is a member of the Board of Osteopathic Medicine, and a physician assistant appointed by the State Surgeon General. (Sections 458.347(9) and 459.022(8), F.S.)
[4] Sections 458.347(7) and 459.022(7), F.S.
[5] The application fee is $100 and the initial license fee is $200. Applicants must also pay an unlicensed activity fee of $5. *See* Rules 64B8-30.019 and 64B15-6.013, F.A.C.
[6] For timely renewed licenses, the renewal fee is $275 and the prescribing registration is $150. Additionally, at the time of renewal, the PA must pay an unlicensed activity fee of $5. *See* Rules 64B8-30.019 and 64B15-6.013, F.A.C.
[7] Sections 458.347(7)(c)-(d) and 459.022(7)(c)-(d), F.S.
[8] Rules 64B8-30.012 and 64B15-6.010, F.A.C.

of the licensed physician for consultation and direction of the PA.[9] In providing supervision, the supervising physician is required to periodically review the PA's performance.[10] A physician may not supervise more than four PAs at any time.[11]

The Board of Medicine and the Osteopathic Board have prescribed by rule what constitutes adequate responsible supervision. Responsible supervision is the ability of the supervising physician to reasonably exercise control and provide direction over the services or tasks performed by the PA.[12] In determining whether supervision is adequate, the following factors must be considered:[13]

- The complexity of the task;
- The risk to the patient;
- The background, training, and skill of the PA;
- The adequacy of the manner in which direction is provided;
- The setting in which the tasks are performed;
- The availability of the supervising physician;
- The necessity for immediate attention; and
- The number of other persons that the supervising physician must supervise.

Under current regulations, a physician may decide, based on his or her reasonable medical judgment regarding the probability of morbidity to the patient, whether to supervise a PA directly or indirectly in the performance of a task or procedure.[14] The supervising physician must be certain that the PA has the knowledge and skill to perform the tasks and procedures assigned. A physician or a group of physicians supervising PAs are individually or collectively liable for the performance of the acts and omissions of the PA.[15]

Scope of Practice

PAs are regulated through the respective physician practice acts.[16] The Board of Medicine and the Osteopathic Board have adopted rules that set out the general principles a supervising physician must use in the development of the scope of practice of a PA under both direct and indirect supervision.[17] A physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[18]

Rules of both the Board of Medicine and the Osteopathic Board prohibit the delegation of prescribing, dispensing, or compounding of medicinal drugs, or final diagnosis, except as authorized by statute.[19] Current law allows a supervising physician to delegate authority to prescribe or dispense any medication used in the physician's practice, except controlled substances, general anesthetics, and radiographic contrast materials.[20] A supervising physician is prohibited from delegating certain duties under indirect supervision, such as the insertion chest tubes, cardiac stress testing, insertion of central

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[9] Sections 458.347(2)(f) and 459.022(2)(f), F.S.
[10] Rules 64B8-30.001(3) and 64B15-6.001(3), F.A.C.
[11] Sections 458.347(3) and 459.022(3), F.S.
[12] *Supra* note10.
[13] *Id.*
[14] Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.
[15] Sections 458.347(3) and 459.022(3), F.S.
[16] Chapters 458 and 459, F.S.
[17] Sections 458.347(4) and 459.022(4), F.S.
[18] Rules 64B8-30.012(1) and 64B15-6.010(1), F.A.C. The term "scope of practice" refers to those tasks and procedures which the supervision physician is qualified by training or experience to perform.
[19] *Supra* note 14.
[20] Sections 458.347(4)(e) and (f)1. and 459.022(4)(e), F.S. However, a PA is allowed to order medications for the supervisory physician's patient during his or her care in a facility under ch. 395, F.S., such as hospitals. (*See* ss. 458.347(4)(g) and 459.022(4)(f), F.S.).

venous catheters, interpretation of laboratory tests, X-rays, and EKGs, and the administration of certain anesthetics.[21]

In regulating the practice of PAs, it is the duty of the Board of Medicine and the Osteopathic Board to make disciplinary decisions concerning whether a doctor or PA has violated the provisions of his or her practice act.[22]

Effect of Proposed Changes

Licensure

The bill amends the documentation that a PA must provide at the time of his or her initial application for licensure. Currently, an applicant for a PA license must submit sworn statements of any prior felony convictions and any previous revocation or denial of licensure or certification in any state; however, the bill changes the requirement to acknowledgements of such actions.[23] The bill also removes the requirement that a PA applicant submit two letters of recommendation at the time of application. Repealing this requirement will expedite the licensure process.[24]

For license renewals, current law requires a PA to submit a signed affidavit attesting that he or she has completed at least 10 hours of continuing education in the specialty practice in which he or she will have prescriptive privileges.[25] The bill requires that a PA acknowledge that he or she has met the required continuing education rather than submit a signed affidavit.

The bill repeals an obsolete provision that requires the DOH to administer a written, objective examination to certain PA licensure applicants, such as foreign-trained physicians who are not licensed to practice medicine. Eligibility to take the DOH-administered exam was limited to individuals who initially applied for licensure between July 1, 1990, and June 30, 1991. The DOH was limited to administering the examination five times. The DOH no longer administers a PA licensure examination.[26] The bill also repeals a provision that allows the DOH to grant temporary licenses to individuals who were awaiting scores from this licensure examination. The DOH has not issued a temporary license under this provision since 1998.[27] Under current law, an applicant must satisfactorily pass a proficiency exam administered by the National Commission on Certification of Physician Assistants.[28] All PA licensure applicants will be subject to the same licensure examination.

Supervision of PAs

Under current law, a PA must notify the DOH of his or her employment and the name of the supervising, within 30 days of commencing such employment or at any time his or her employment changes. The bill clarifies that the PA must report, within 30 days, the name of any new supervising physician or designated supervising physician. The bill defines "designated supervising physician" as a physician designated by the facility or practice to be the primary contact and supervising physician for the PAs in the practice where PAs are supervised by multiple supervising physicians. The requirement to have a designated supervising physician does not prevent a PA from practicing under multiple supervising physicians.

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[21] *Supra* note 14.
[22] Sections 458.347(12) and 459.022(12), F.S.
[23] Pursuant to s. 456.0135, F.S., all practitioners licensed under ch. 458 and 459, including PAs, are subject to a background screening and retention of fingerprints.
[24] Florida Dep't of Health, *Bill Analysis of House Bill 375* (Oct. 27, 2015) (on file with the Health Quality Subcommittee).
[25] Sections 458.347(4)(e) 3. and 459.022(4)(e)3., F.S.
[26] *Supra* note 24.
[27] Email correspondence with the Department of Health, Medical Quality Assurance staff on November 17, 2015.
[28] *See* ss. 458.347(7)(a)2. and 459.022(7)(a)2., F.S.

The designated supervising physician must maintain a list of all approved supervising physicians at the practice or facility, which includes each supervising physician's name and area of practice. This list must be kept current and must be available upon request by the DOH.

Scope of Practice

The bill clarifies that a PA may perform any duty or service delegated by a supervising physician unless the PA is expressly prohibited by statute or rule from providing such duty or service. This provision delineates the scope of practice of a PA while providing that there may be express limitations on the scope under the practice acts and board rules.[29]

The bill allows a PA's prescriptions to be in written or electronic form, as long as they comply with prescription labeling information requirements.[30]

The bill provides an effective date of July 1, 2016.

B. SECTION DIRECTORY:

Section 1. Amends s. 458.347, F.S., relating to physician assistants.
Section 2. Amends s. 459.022, F.S., relating to physician assistants.
Section 3. Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The DOH indicates that it may experience a recurring increase in workload associated with additional complaints and investigations that may occur due to the new requirements created under the provisions of the bill. Although indeterminate at this time, current resources are adequate to absorb any fiscal impact.[31]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

[29] *Supra* note 24.
[30] Section 456.0392(1), F.S., provides that a practitioner who does not have authority to prescribe control substance must list his or her name and professional license number on a prescription. Section 456.42(1), F.S., provides that a written prescription must be legibly printed or typed; contain the name of the prescribing practitioner; contain the name, strength, and quantity of the drug prescribed and directions for use; and dated and signed by the prescribing practitioner of the day of issue. Electronic prescriptions must contain the name of the prescribing practitioner, name, strength, and quantity of the drug prescribed and directions for use; and dated and signed by the prescribing practitioner only on the day issued.
[31] *Supra* note 24.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Since the bill deletes the requirements for sworn statements or affidavits, to the extent that a PA incurs costs associated with obtaining such statements, the costs associated with applying for licensure or renewing licensure may be reduced.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On December 2, 2015, the Healthcare Appropriations Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The amendment:

- Required that a PA must acknowledge that he or she has met the required continuing education rather than certify; and
- Required that a PA must report, within 30 days, the name of any new a supervising physician, as well as any new "designated" supervising physician.

The analysis is drafted to the committee substitute as passed by the Health Care Appropriations Subcommittee.

A bill to be entitled

An act relating to physician assistants; amending s. 458.347, F.S.; authorizing a licensed physician assistant to perform certain services as delegated by a supervisory physician; revising circumstances under which a physician assistant may prescribe medication; revising physician assistant licensure and license renewal requirements; deleting provisions related to examination by the Department of Health; defining the term "designated supervising physician"; requiring licensed physician assistants to report any changes in the designated supervising physician within a specified time; requiring a designated supervising physician to maintain a list of approved supervising physicians at the practice or facility; amending s. 459.022, F.S.; authorizing a licensed physician assistant to perform certain services as delegated by a supervisory physician; revising circumstances under which a physician assistant may prescribe medication; revising physician assistant licensure and license renewal requirements; defining the term "designated supervising physician"; requiring licensed physician assistants to report any changes in the designated supervising physician within a specified time; requiring a designated supervising physician to maintain a list of approved supervising physicians at

the practice or facility; providing an effective date.

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

Section 1. Paragraph (e) of subsection (4) of section 458.347, Florida Statutes, is amended, paragraph (h) is added to that subsection, paragraphs (c) through (h) of subsection (7) are redesignated as paragraphs (b) through (g), respectively, and present paragraphs (a), (b), (c), (e), and (f) of that subsection are amended, to read:

458.347 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that he or she is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician before ~~prior to~~ any prescription is ~~being~~ prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must acknowledge ~~file~~ with the department ~~a signed affidavit~~ that he or she has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant shall not be required to independently register pursuant to s. 465.0276.

5. The prescription may ~~must~~ be written or electronic but must be in a form that complies with ss. 456.0392(1) and 456.42(1) ~~chapter 499~~ and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the

prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

(h) A licensed physician assistant may perform services related to his or her practice, in accordance with his or her education and training, as delegated by the supervisory physician unless expressly prohibited under this chapter or chapter 459 or rules adopted thereunder.

(7) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met the following requirements:

1. Is at least 18 years of age.

2. Has satisfactorily passed a proficiency examination by an acceptable score established by the National Commission on Certification of Physician Assistants. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants to be eligible for licensure.

3. Has completed the application form and remitted an application fee not to exceed $300 as set by the boards. An application for licensure made by a physician assistant must include:

a. A certificate of completion of a physician assistant training program specified in subsection (6).

b. Acknowledgment ~~A sworn statement~~ of any prior felony convictions.

c. Acknowledgment ~~A sworn statement~~ of any previous revocation or denial of licensure or certification in any state.

~~d. Two letters of recommendation.~~

d.~~e.~~ A copy of course transcripts and a copy of the course description from a physician assistant training program describing course content in pharmacotherapy, if the applicant wishes to apply for prescribing authority. These documents must meet the evidence requirements for prescribing authority.

~~(b)1. Notwithstanding subparagraph (a)2. and sub-subparagraph (a)3.a., the department shall examine each applicant who the Board of Medicine certifies:~~

~~a. Has completed the application form and remitted a nonrefundable application fee not to exceed $500 and an examination fee not to exceed $300, plus the actual cost to the department to provide the examination. The examination fee is refundable if the applicant is found to be ineligible to take the examination. The department shall not require the applicant to pass a separate practical component of the examination. For~~

~~examinations given after July 1, 1998, competencies measured through practical examinations shall be incorporated into the written examination through a multiple-choice format. The department shall translate the examination into the native language of any applicant who requests and agrees to pay all costs of such translation, provided that the translation request is filed with the board office no later than 9 months before the scheduled examination and the applicant remits translation fees as specified by the department no later than 6 months before the scheduled examination, and provided that the applicant demonstrates to the department the ability to communicate orally in basic English. If the applicant is unable to pay translation costs, the applicant may take the next available examination in English if the applicant submits a request in writing by the application deadline and if the applicant is otherwise eligible under this section. To demonstrate the ability to communicate orally in basic English, a passing score or grade is required, as determined by the department or organization that developed it, on the test for spoken English (TSE) by the Educational Testing Service (ETS), the test of English as a foreign language (TOEFL) by ETS, a high school or college level English course, or the English examination for citizenship, Bureau of Citizenship and Immigration Services. A notarized copy of an Educational Commission for Foreign Medical Graduates (ECFMG) certificate may also be used to demonstrate the ability to communicate in basic English; and~~

~~b. Is an unlicensed physician who graduated from a foreign medical school listed with the World Health Organization who has not previously taken and failed the examination of the National Commission on Certification of Physician Assistants and who has been certified by the Board of Medicine as having met the requirements for licensure as a medical doctor by examination as set forth in s. 458.311(1), (3), (4), and (5), with the exception that the applicant is not required to have completed an approved residency of at least 1 year and the applicant is not required to have passed the licensing examination specified under s. 458.311 or hold a valid, active certificate issued by the Educational Commission for Foreign Medical Graduates; was eligible and made initial application for certification as a physician assistant in this state between July 1, 1990, and June 30, 1991; and was a resident of this state on July 1, 1990, or was licensed or certified in any state in the United States as a physician assistant on July 1, 1990.~~

~~2. The department may grant temporary licensure to an applicant who meets the requirements of subparagraph 1. Between meetings of the council, the department may grant temporary licensure to practice based on the completion of all temporary licensure requirements. All such administratively issued licenses shall be reviewed and acted on at the next regular meeting of the council. A temporary license expires 30 days after receipt and notice of scores to the licenseholder from the first available examination specified in subparagraph 1.~~

~~following licensure by the department. An applicant who fails the proficiency examination is no longer temporarily licensed, but may apply for a one-time extension of temporary licensure after reapplying for the next available examination. Extended licensure shall expire upon failure of the licenseholder to sit for the next available examination or upon receipt and notice of scores to the licenseholder from such examination.~~

~~3. Notwithstanding any other provision of law, the examination specified pursuant to subparagraph 1. shall be administered by the department only five times. Applicants certified by the board for examination shall receive at least 6 months' notice of eligibility prior to the administration of the initial examination. Subsequent examinations shall be administered at 1-year intervals following the reporting of the scores of the first and subsequent examinations. For the purposes of this paragraph, the department may develop, contract for the development of, purchase, or approve an examination that adequately measures an applicant's ability to practice with reasonable skill and safety. The minimum passing score on the examination shall be established by the department, with the advice of the board. Those applicants failing to pass that examination or any subsequent examination shall receive notice of the administration of the next examination with the notice of scores following such examination. Any applicant who passes the examination and meets the requirements of this section shall be~~

~~licensed as a physician assistant with all rights defined thereby.~~

(b)~~(c)~~ The license must be renewed biennially. Each renewal must include:

1. A renewal fee not to exceed $500 as set by the boards.

2. Acknowledgment ~~A sworn statement~~ of no felony convictions in the previous 2 years.

(d)1.~~(c)~~ Upon employment as a physician assistant, a licensed physician assistant must notify the department in writing within 30 days after such employment or after any subsequent change ~~changes~~ in the supervising physician or designated supervising physician. The notification must include the full name, Florida medical license number, specialty, and address of the supervising physician or designated supervising physician. For purposes of this paragraph, the term "designated supervising physician" means a physician designated by the facility or practice to be the primary contact and supervising physician for the physician assistants in a practice where physician assistants are supervised by multiple supervising physicians.

2. Assignment of a designated supervising physician does not preclude a physician assistant from practicing under the supervision of a physician other than the designated supervising physician.

3. The designated supervising physician shall maintain a list of all approved supervising physicians at the practice or

facility. Such list must include the name of each supervising physician and his or her area of practice, must be kept up to date with respect to additions and terminations, and must be provided, in a timely manner, to the department upon written request.

(e) ~~(f)~~ Notwithstanding subparagraph (a)2., the department may grant to a recent graduate of an approved program, as specified in subsection (6), who expects to take the first examination administered by the National Commission on Certification of Physician Assistants available for registration after the applicant's graduation, a temporary license. The temporary license shall expire 30 days after receipt of scores of the proficiency examination administered by the National Commission on Certification of Physician Assistants. Between meetings of the council, the department may grant a temporary license to practice based on the completion of all temporary licensure requirements. All such administratively issued licenses shall be reviewed and acted on at the next regular meeting of the council. The recent graduate may be licensed before ~~prior to~~ employment~~,~~ but must comply with paragraph (d) ~~(c)~~. An applicant who has passed the proficiency examination may be granted permanent licensure. An applicant failing the proficiency examination is no longer temporarily licensed~~,~~ but may reapply for a 1-year extension of temporary licensure. An applicant may not be granted more than two temporary licenses and may not be licensed as a physician assistant until he or she

passes the examination administered by the National Commission on Certification of Physician Assistants. As prescribed by board rule, the council may require an applicant who does not pass the licensing examination after five or more attempts to complete additional remedial education or training. The council shall prescribe the additional requirements in a manner that permits the applicant to complete the requirements and be reexamined within 2 years after the date the applicant petitions the council to retake the examination a sixth or subsequent time.

Section 2. Paragraph (e) of subsection (4) of section 459.022, Florida Statutes, is amended, paragraph (g) is added to that subsection, and paragraphs (a), (b), and (d) of subsection (7) of that section are amended, to read:

459.022 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to s. 458.347. A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:

1. A physician assistant must clearly identify to the patient that she or he is a physician assistant. Furthermore, the physician assistant must inform the patient that the patient has the right to see the physician before ~~prior to~~ any

prescription is ~~being~~ prescribed or dispensed by the physician assistant.

2. The supervisory physician must notify the department of her or his intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervisory physician who is registered as a dispensing practitioner in compliance with s. 465.0276.

3. The physician assistant must acknowledge ~~file~~ with the department ~~a signed affidavit~~ that she or he has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.

4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant shall not be required to independently register pursuant to s. 465.0276.

5. The prescription may ~~must~~ be written or electronic but must be in a form that complies with ss. 456.0392(1) and 456.42(1) ~~chapter 499~~ and must contain, in addition to the supervisory physician's name, address, and telephone number, the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under

chapter 465, and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.

(g) A licensed physician assistant may perform services related to his or her practice, in accordance with his or her education and training, as delegated by the supervisory physician unless expressly prohibited under chapter 458 or this chapter or rules adopted thereunder.

(7) PHYSICIAN ASSISTANT LICENSURE.—

(a) Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met the following requirements:

1. Is at least 18 years of age.

2. Has satisfactorily passed a proficiency examination by an acceptable score established by the National Commission on Certification of Physician Assistants. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission

on Certification of Physician Assistants to be eligible for licensure.

3. Has completed the application form and remitted an application fee not to exceed $300 as set by the boards. An application for licensure made by a physician assistant must include:

a. A certificate of completion of a physician assistant training program specified in subsection (6).

b. Acknowledgment ~~A sworn statement~~ of any prior felony convictions.

c. Acknowledgment ~~A sworn statement~~ of any previous revocation or denial of licensure or certification in any state.

~~d. Two letters of recommendation.~~

d.~~c.~~ A copy of course transcripts and a copy of the course description from a physician assistant training program describing course content in pharmacotherapy, if the applicant wishes to apply for prescribing authority. These documents must meet the evidence requirements for prescribing authority.

(b) The licensure must be renewed biennially. Each renewal must include:

1. A renewal fee not to exceed $500 as set by the boards.

2. Acknowledgment ~~A sworn statement~~ of no felony convictions in the previous 2 years.

(d)1. Upon employment as a physician assistant, a licensed physician assistant must notify the department in writing within 30 days after such employment or after any subsequent change

~~changes~~ in the supervising physician or designated supervising physician. The notification must include the full name, Florida medical license number, specialty, and address of the supervising physician or designated supervising physician. For purposes of this paragraph, the term "designated supervising physician" means a physician designated by the facility or practice to be the primary contact and supervising physician for the physician assistants in a practice where physician assistants are supervised by multiple supervising physicians.

2. Assignment of a designated supervising physician does not preclude a physician assistant from practicing under the supervision of a physician other than the designated supervising physician.

3. The designated supervising physician shall maintain a list of all approved supervising physicians at the practice or facility. Such list must include the name of each supervising physician and his or her area of practice, must be kept up to date with respect to additions and terminations, and must be provided, in a timely manner, to the department upon written request.

Section 3. This act shall take effect July 1, 2016.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 423 Drug Prescription by Advanced Registered Nurse Practitioners & Physician Assistants
SPONSOR(S): Pigman and others
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 1 N	Siples	O'Callaghan
2) Health Care Appropriations Subcommittee	11 Y, 2 N	Garner	Pridgeon
3) Health & Human Services Committee		Siples	Calamas

SUMMARY ANALYSIS

Unlike all other states in the U.S., Florida does not allow advanced registered nurse practitioners (ARNPs) to prescribe controlled substances and is one of two states that does not allow physician assistants (PAs) to prescribe controlled substances.

The bill authorizes ARNPs to prescribe, dispense, order, and administer controlled substances, but only to the extent authorized under a supervising physician's protocol. The bill also authorizes PAs to prescribe controlled substances that are not listed on the formulary established by the Council on Physician Assistants, under current supervisory standards. The bill subjects ARNPs and PAs to administrative disciplinary actions, such as fines or license suspensions, for violating standards of practice in law relating to prescribing and dispensing controlled substances. The bill adds specific prohibited acts related to the prescribing of controlled substances, which constitute grounds for denial of license or disciplinary action, into the Nurse Practice Act.

The bill requires ARNPs and PAs who prescribe controlled substances for the treatment of chronic nonmalignant pain to meet certain registration and prescribing requirements, but prevents ARNPs and PAs from prescribing controlled substances in registered pain management clinics.

The bill adds ARNPs and PAs into the definition of "practitioner" in the Florida Comprehensive Drug Abuse Prevention and Control Act (Act) requiring compliance with the prescribing and dispensing requirements and limitations under the Act.

The bill makes several technical and conforming changes and amends several statutes to recognize that an ARNP or a PA may be a prescriber of controlled substances. These include statutes relating to pilot licensure, criminal probation, and the state employees' prescription drug program.

The bill may have an insignificant, negative fiscal impact on the Department of Health; however, current resources are adequate to absorb it.

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Physician Assistants

Licensure and Regulation

A physician assistant (PA) is a person who has completed an approved medical training program and is licensed to perform medical services, as delegated by a supervising physician.[1] PAs licensure is governed by ss. 458.347(7) and 459.022(7), F.S. The Department of Health (DOH) licenses PAs, and the Florida Council on Physician Assistants (Council) regulates the practice of PAs in conjunction with either the Florida Board of Medicine (Board of Medicine) for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine (Osteopathic Board) for PAs licensed under ch. 459, F.S. Currently, 7,987 PAs hold active licenses in Florida.[2]

To be licensed as a PA , an applicant must demonstrate to the Council that he or she has met the following requirements:

- Satisfactory passage of the proficiency examination administered by the National Commission on Certification of Physician Assistants;
- Completion of an application and remittance of the applicable fees to the DOH; [3]
- Completion of an approved PA training program;
- Submission of a sworn statement of any prior felony convictions;
- Submission of a sworn statement of any revocation or denial of licensure or certification in any state;
- Submission of two letters of recommendation; and
- If the applicant is seeking prescribing authority, a submission of a copy of course transcripts and the course description from a PA training program describing the course content in pharmacotherapy.[4]

Licenses are renewed biennially.[5] At the time of renewal, a PA must demonstrate that he or she has met the continuing medical education requirements of 100 hours and must submit a sworn statement that he or she has not been convicted of any felony in the previous two years.[6] If a PA is licensed as a prescribing PA, an additional 10 hours of continuing medical education in the specialty areas of his or her supervising physician must be completed.[7]

Education of PAs

According to the American Academy of Physician Assistants, all accredited PA educational programs include pharmacology courses, and the average amount of formal classroom instruction in

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[1] Sections 458.347(2)(e) and 459.022(2)(e), F.S.
[2] Email correspondence with the Department of Health on November 9, 2015. The number of active-licensed PAs include both in-state and out-of-state licensees, as of November 9, 2015.
[3] The application fee is $100 and the initial license fee is $200. Applicants must also pay an unlicensed activity fee of $5. *See* Rules 64B8-30.019 and 64B15-6.013, F.A.C.
[4] Sections 458.347(7) and 459.022(7), F.S.
[5] For timely renewed licenses, the renewal fee is $275 and the prescribing registration fee is $150. Additionally, at the time of renewal, the PA must pay an unlicensed activity fee of $5. *See* Rules 64B8-30.019 and 64B15-6.013, F.A.C.
[6] Sections 458.347(7)(c)-(d) and 459.022(7)(c)-(d), F.S.
[7] Rules 64B8-30.005(6) and 64B15-6.0035(6), F.A.C.

pharmacology is 75 hours.[8] Course topics, include pharmacokintetics, drug interactions, adverse effects, contraindications, indications, and dosage, generally by doctoral-level pharmacologists or clinical pharmacists.[9] Additionally, pharmacology education occurs on all clinical clerkships or rotations.[10]

Supervision of PAs

A PA may only practice under the delegated authority of a supervising physician. A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.[11] Supervision is defined as responsible supervision and control that requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.[12] A physician may not supervise more than four PAs at any time.[13]

The Board of Medicine and the Osteopathic Board have prescribed by rule what constitutes adequate responsible supervision. Responsible supervision is the ability of a supervising physician to reasonably exercise control and provide direction over the services or tasks performed by the PA.[14] Whether the supervision of the PA is adequate is dependent on the:

- Complexity of the task;
- Risk to the patient;
- Background, training, and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.[15]

Direct supervision refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed.[16] Indirect supervision refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication.[17] The decision to permit a PA to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.[18]

Delegable Tasks

Rules of both the Board of Medicine and the Osteopathic Board place limitations on a supervising physician's ability to delegate certain tasks. Prescribing, dispensing, or compounding medicinal drugs and making a final diagnosis are not permitted to be delegated to a PA, except when specifically authorized by statute.[19]

A supervising physician may delegate authority to a PA the authority to:

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[8] American Academy of Physician Assistants, *PAs as Prescribers of Controlled Medications*, Professional Issues – Issue Brief (Dec. 2013), (on file with the staff of the Health and Human Services committee).
[9] *Id.*
[10] *Id.*
[11] Rules 64B8-30.012(1) and 64B15-6.010(1), F.A.C. The term "scope of practice" refers to those tasks and procedures that the supervising physician is qualified by training or experience to support.
[12] Sections 458.347(2)(f) and 459.022(2)(f), F.S.
[13] Sections 458.347(3) and 459.022(3), F.S.
[14] Rules 64B8-30.001(3) and 64B15-6.001(3), F.A.C.
[15] *Id.*
[16] Rules 64B8-30.001(4) and 64B15-6.001(4), F.A.C.
[17] Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.
[18] Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.
[19] *Supra* note 12.

- Prescribe or dispense any medicinal drug used in the supervising physician's practice;[20]
- Order medicinal drugs for a hospitalized patient of the supervising physician;[21] and
- Administer a medicinal drug under the direction and supervision of the physician.

Currently, PAs are prohibited from prescribing controlled substances, anesthetics, and radiographic contrast materials.[22] However, physicians may delegate the authority to order controlled substances in facilities licensed under ch. 395, F.S.[23]

Regulation of Advanced Registered Nurse Practitioners

Part I of ch. 464, F.S., governs the licensure and regulation of advanced registered nurse practitioners (ARNPs) in Florida. Nurses are licensed by the DOH and are regulated by the Board of Nursing.[24] There are 22,003 actively licensed ARNPs in Florida.[25]

In Florida, an ARNP is a licensed nurse who is certified in advanced or specialized nursing practice and may practice as a certified registered nurse anesthetist, a certified nurse midwife, or a nurse practitioner.[26] Section 464.003(2), F.S., defines "advanced or specialized nursing practice" to include the performance of advanced-level nursing acts approved by the Board of Nursing, which by virtue of postbasic specialized education, training, and experience are appropriately performed by an ARNP.[27]

Florida recognizes three types of ARNPs: nurse anesthetist, certified nurse midwife, and nurse practitioner. The Board of Nursing, created by s. 464.004, F.S., establishes the eligibility criteria for an applicant to be certified as an ARNP and the applicable regulatory standards for ARNP nursing practices.[28] To be certified as an ARNP, the applicant must:

- Have a registered nurse license;
- Have earned, at least, a master's degree; and
- Submit proof to the Board of Nursing of holding a current national advanced practice certification obtained from a board-approved nursing specialty board.[29]

All ARNPs must carry malpractice insurance or demonstrate proof of financial responsibility.[30] An applicant for certification is required to submit proof of coverage or financial responsibility within sixty

[20] Sections 458.347(4)(f)1., F.S., and 459.022(4)(e), F.S., directs the Council to establish a formulary listing the medical drugs that a PA may not prescribe. The formulary in Rules 64B8-30.008 and 64B15-6.0038, F.A.C., prohibits PAs from prescribing controlled substances, as defined in Chapter 893, F.S., general, spinal, or epidural anesthetics, and radiographic contrast materials.
[21] Sections 458.347(4)(g), and 459.022(4)(f), F.S., provides that an order is not a prescription.
[22] Rules 64B8-30.008, F.A.C., and 64B15-6.0038, F.A.C.
[23] Sections 458.347(4)(g), F.S., and 459.022(4)(f), F.S.; the facilities licensed in ch. 395, F.S., include hospitals, ambulatory surgical centers, and mobile surgical facilities.
[24] Pursuant to s. 464.004, F.S., the Board of Nursing is comprised of 13 members appointed by the Governor and confirmed by the Senate who serve 4-year terms. The Board is comprised of three licensed practical nurses who have practiced for at least four years, seven members who are registered numbers who have practiced for at least 4 years; three Florida residents who have never been licensed as nurses, are not connected to the practice of nursing, and have no financial interest in any health care facility, agency, or insurer; and seven members who are registered nurses who have practiced at least four years. Among the seven members who are registered nurses, there must be at least one must be an ARNP, one nurse educator of an approved program, and one nurse executive.
[25] E-mail correspondence with the Department of Health (Nov. 9, 2015) (on file with the staff of the Health and Human Services Committee). This number includes all active licenses, including out of state practitioners.
[26] Section 464.003(3), F.S.
[27] Section 464.003(2), F.S.
[28] Section 464.012(2), F.S.
[29] Section 464.012(1), F.S., and Rule 64B9-4.002, F.A.C. A nursing specialty board must attest to the competency of nurses in a clinical specialty area, require nurses to take a written examination prior to certification, require nurses to complete a formal program prior to eligibility of examination, maintain program accreditation, and identify standards or scope of practice statements appropriate for each nursing specialty.
[30] Section 456.048, F.S.

days of certification and with each biennial renewal.[31] An ARNP must have professional liability coverage of at least $100,000 per claim with a minimum annual aggregate of at least $300,000, or an unexpired irrevocable letter of credit, which is payable to the ARNP as beneficiary, in the amount of at least $100,000 per claim with a minimum aggregate availability of at least $300,000.[32]

Supervision of ARNPs

Pursuant to s. 464.012(3), F.S., ARNPs may only perform nursing practices delineated in an established protocol filed with the Board of Nursing that is filed within 30 days of entering into a supervisory relationship with a physician and upon biennial license renewal.[33] Florida law allows a primary care physician to supervise ARNPs in up to four offices, in addition to the physician's primary practice location.[34] If the physician provides specialty health care services, then only two medical offices, in addition to the physician's primary practice location, may be supervised.

The supervision limitations do not apply in the following facilities:

- Hospitals;
- Colleges of medicine or nursing;
- Nonprofit family-planning clinics;
- Rural and federally qualified health centers;
- Nursing homes;
- Assisted living facilities;
- Student health care centers or school health clinics; and
- Other government facilities.[35]

To ensure appropriate medical care, the number of ARNPs a supervising physician may supervise is limited based on consideration of the following factors:

- Risk to the patient;
- Educational preparation, specialty, and experience in relation to the supervising physician's protocol;
- Complexity and risk of the procedures;
- Practice setting; and
- Availability of the supervising physician or dentist.[36]

Delegable Tasks

Within the framework of a written physician protocol, an ARNP may:

- Monitor and alter drug therapies;
- Initiate appropriate therapies for certain conditions;
- Order diagnostic tests and physical and occupational therapy;
- Perform certain acts within his or her specialty;
- Perform medical acts authorized by a joint committee; and
- Perform additional functions determined by rule. [37]

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[31] Rule 64B9-4.002(5), F.A.C.
[32] *Id.*
[33] Physicians are also required to provide notice of the written protocol and the supervisory relationship to the Board of Medicine or Board of Osteopathic Medicine, respectively. *See* ss. 458.348 and 459.025, F.S.
[34] Sections 458.348(4) and 459.025(3), F.S.
[35] Sections 458.348(4)(e), and 459.025(3)(e), F.S.
[36] Rule 64B9-4.010, F.A.C.
[37] Section 464.012(3), F.S. Pursuant to s. 464.012(4), F.S., certified registered nurse anesthetists, certified nurse midwives, and certified nurse practitioners are authorized to perform additional acts that are within their specialty and authorized under an established supervisory protocol.

Florida law does not authorize ARNPs to prescribe, independently administer, or dispense controlled substances.[38]

Controlled Substances

Controlled substances are drugs with the potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act (Act) and classifies controlled substances into five categories, known as schedules.[39] The distinguishing factors between the different drug schedules are the "potential for abuse" of the substance and whether there is a currently accepted medical use for the substance. Schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances. The Act provides requirements for the prescribing and administering of controlled substances by health care practitioners and proper dispensing by pharmacists and health care practitioners.[40]

Controlled Substance Prescribing for Nonmalignant Pain in Florida

As of January 1, 2012, every physician, podiatrist, or dentist, who prescribes controlled substances in the state for the treatment of chronic nonmalignant pain,[41] must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.[42] Before prescribing controlled substances for the treatment of chronic nonmalignant pain, a practitioner must:

- Document certain characteristics about the nature of the patient's pain, success of past treatments, and a history of alcohol and substance abuse;
- Develop a written plan for assessing the patient's risk for aberrant drug-related behavior and monitor such behavior throughout the course of controlled substance treatment;
- Develop an written individualized treatment plan for each patient stating the objectives that will be used to determine treatment success; and
- Enter into a controlled substance agreement with each patient that must be signed by the patient or their legal representative and by the prescribing practitioner. Such agreements must include:
    - The number and frequency of prescriptions and refills;
    - A statement outlining expectations for patience compliance and reasons for which the drug therapy may be discontinued, such as violation of the agreement; and
    - An agreement that the patient's chronic nonmalignant pain only be treated by a single treating practitioner unless otherwise authorized and documented in the medical record.[43]

Patients being treated with controlled substances for chronic nonmalignant pain must be seen by their prescribing practitioners at least once every three months to monitor progress and compliance, and detailed medical records relating to such treatment must be maintained.[44] Patients at special risk for drug abuse or diversion may require consultation with or a referral to an addiction medicine physician or a psychiatrist.[45] Anyone with signs or symptoms of substance abuse must be immediately referred to a pain-management physician, an addiction medicine specialist, or an addiction medicine facility.[46]

[38] Sections 893.02(21) and 893.05(1), F.S. The definition of practitioner does not include ARNPs.
[39] *See* s. 893.03, F.S.
[40] Sections 893.04 and 893.05, F.S.
[41] "Chronic nonmalignant pain" is defined as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery. Section 456.44(1)(e), F.S.
[42] Chapter 2011-141, s. 3, Laws of Fla. (creating ss. 456.44, F.S., effective July 1, 2011).
[43] Section 465.44(3), F.S.
[44] Section 465.44(3)(d), F.S.
[45] Section 465.44(3)(e), F.S.
[46] Section 456.44(3)(g), F.S.

Drug Enforcement Administration

The Drug Enforcement Administration (DEA), housed within the U.S. Department of Justice, enforces the controlled substances laws and regulations of the United States, including preventing and investigating the diversion of controlled pharmaceuticals.[47]

Any health care professional wishing to prescribe controlled substances must apply for a registration number from the DEA. Registration numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee.[48] The DEA will grant registration numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only prescribe controlled substances as authorized under state law.[49] The DEA provides that a controlled substance prescription may only be issued by a registered practitioner who is:

- Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice; and
- Registered with the DEA, or exempt from registration (e.g., Public Health Service, Federal Bureau of Prisons, or military practitioners); or
- An qualified agent or employee of a hospital or other institution acting in the normal course of business or employment under the DEA registration number of the hospital or other institution which is registered in lieu of the individual practitioner being registered.[50]

The DEA's Practitioner Manual includes requirements for valid prescriptions. The DEA defines "prescription" as an order for medication which is dispensed to or for an ultimate user, but is not an order for a medication dispensed for immediate administration to the user, such as an order to dispense a drug to a patient in a hospital setting.[51]

Controlled Substance Prescriptive Authority for ARNPs and PAs in Other States

ARNPs

An ARNP's ability to prescribe, dispense, or administer controlled substances is dependent on his or her specific state's law. Forty-nine states authorize ARNPs to prescribe controlled substances.[52] Twenty-one states and the District of Columbia allow an ARNP to practice independently, including evaluating, diagnosing, ordering, and interpreting diagnostic tests, and managing treatment, including prescribing medications, of a patient without physician supervision.[53] Twenty-two states specifically prohibit certified registered nurse anesthetists from prescribing controlled substances.[54]

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[47] Drug Enforcement Administration, *About Us*, *available at* http://www.deadiversion.usdoj.gov/Inside.html (last visited January 15, 2016).

[48] Registration numbers must be renewed every three years. Drug Enforcement Administration, *Practitioners Manual*, 7(2006), *available at* http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf (last visited January 15, 2016).

[49] *Id.* at 7.

[50] DEA, *Practitioner Manual*, 18.

[51] *Id.*

[52] Drug Enforcement Agency, *Mid-Level Practitioners Authorization by State* (January 15, 2016), *available at* http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf (last visited January 15, 2016). The Commonwealth of Puerto Rico also prohibits ARNPs from prescribing controlled substances.

[53] Alaska, Arizona, Colorado, Connecticut, District of Columbia, Hawaii, Idaho, Iowa, Maine, Maryland, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Oregon, Rhode Island, Vermont, Washington, and Wyoming allow for independent practice. *See* American Association of Nurse Practitioners, *State Practice Environment*, *available at* https://www.aanp.org/legislation-regulation/state-legislation/state-practice-environment/66-legislation-regulation/state-practice-environment/1380-state-practice-by-type (last visited January 15, 2016).

[54] American Association of Nurse Anesthetists, AANA Journal, June 2011; 79(3):235, on file with committee staff.

Some states have specific limitations regarding ARNPs prescribing authority for Schedule II controlled substances.[55] For example, 7 states authorize ARNPs to prescribe all levels of scheduled drugs, except for Schedule II. Some states have specific education requirements for those ARNPs who wish to prescribe Schedule II substances or require additional registration for ARNPs to be authorized to prescribe.[56]

PAs

A PA's ability to prescribe, dispense, or administer controlled substances is dependent on their specific state's law. Forty-eight states authorize PAs to prescribe controlled substances within an agreement with a supervisory physician, with varying limitations on administration, dispensing, and independent prescribing.[57]

Of the 48 states, some have specific restrictions on PAs' prescribing authority for schedule II controlled substances; for example, Texas and Hawaii only authorize PAs to order schedule II controlled substances in an inpatient hospital setting. Some states have medication quantity restrictions on prescriptions for schedule II drugs and some states give PAs' prescriptive authority for all levels of scheduled drugs except for schedule II.[58] Some states also have a formulary determined by the relevant PA licensing board which identifies the controlled substances that PAs are authorized to prescribe.

Effect of Proposed Changes

The bill authorizes licensed PAs and licensed ARNPs to prescribe controlled substances under current supervisory standards for PAs and protocols for ARNPs.

Physician Assistants

The bill authorizes PAs to prescribe controlled substances by removing the requirement that the formulary of medicinal drugs that a PA may not prescribe include controlled substances. However, because the formulary is determined by the Council on Physician Assistants pursuant to s. 458.347(4)(f)1., F.S.,[59] the Council may elect to add controlled substances to the formulary, prohibiting PAs from prescribing them.

The bill subjects PAs to administrative disciplinary actions in s. 456.072, F.S., such as fines or license suspensions for violating standards of practice in law relating to prescribing and dispensing controlled substances.[60]

Advanced Registered Nurse Practitioners

The bill authorizes ARNPs to prescribe, dispense, order, or administer controlled substances, if allowed under a supervising physician's protocol. The bill adds additional acts related to the prescribing of controlled substances into s. 464.018, F.S., which an ARNP is prohibited from performing and which, if performed, constitute grounds for denial of license or disciplinary actions.

The bill revises s. 456.072(7), F.S., to include disciplinary actions against ARNPs, including specific fines and license suspension, which mirror actions against physicians for prescribing or dispensing a

[55] *Supra* note 51.
[56] *Id.*
[57] *Id.* Every state, except Florida and Kentucky, has some form of controlled substance prescriptive authority for PAs.
[58] *Id.*
[59] Section 459.022(4)(e), F.S., of the Osteopathic Medical Practice Act refers to the formulary in the Medical Practice Act.
[60] Disciplinary sanctions against physicians apply to PAs. Sections 458.347(7)(g) and 459.022(7)(g), F.S., state that the Board of Medicine or the Board of Osteopathic Medicine may impose any penalty authorized under ss. 456.072, 458.332(2), and 459.015(2), F.S., on a PA if the PA or the supervising physician has been found guilty of any prohibited acts.

controlled substance other than in the course of professional practice or for failing to meet practice standards.

Controlled Substances

The bill adds PAs and ARNPs to the definition of practitioner in ch. 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act (Act), thus requiring these practitioners to comply with the prescribing and dispensing requirements and limitations under the Act. This definition also requires practitioners to hold a valid federal DEA controlled substance registry number.

The bill amends s. 456.44, F.S., to require a PA or ARNP who prescribes any controlled substance that is listed in Schedule II, Schedule III, or Schedule IV, for the treatment of chronic nonmalignant pain to register as a controlled substance prescribing practitioner on the practitioner profile maintained by the DOH, and to meet other statutory requirements for such registrants.[61] The bill also replaces the terms physician and clinician with registrant throughout this section of law. The bill specifies that this registration is not required to order medication in a facility licensed under ch. 395, F.S.[62]

The bill amends sections regulating pain-management clinics under the Medical Practice Act and the Osteopathic Medical Practice Act to only authorize physicians licensed under ch. 458, F.S., or ch. 459, F.S., to prescribe controlled substances in a pain-management clinic. Accordingly, PAs and ARNPs are prohibited from prescribing controlled substances in pain-management clinics.

The bill makes several conforming changes to various statutes to recognize the new prescribing authority for PAs and ARNPs.

The bill provides an effective date of July 1, 2016.

B. SECTION DIRECTORY:

Section 1. Amends s. 110.12315, F.S., relating to prescription drug program.
Section 2. Amends s. 310.071, F.S., relating to deputy pilot certification.
Section 3. Amends s. 310.073, F.S., relating to state pilot licensing.
Section 4. Amends s. 310.081, F.S., relating to department examination and licensure of state pilots and certification of deputy pilots; vacancies.
Section 5. Amends s. 456.072, F.S., relating to grounds for discipline; penalties; enforcement.
Section 6. Amends s. 456.44, F.S., relating to controlled substance prescribing.
Section 7. Amends s. 458.3265, F.S., relating to pain-management clinics.
Section 8. Amends s. 458.347, F.S., relating to physician assistants.
Section 9. Amends s. 459.0137, F.S., relating to pain-management clinics.
Section 10. Amends s. 464.012, relating to certification of advanced registered nurse practitioners; fees; controlled substance prescribing.
Section 11. Amends s. 464.018, F.S., relating to disciplinary actions.
Section 12. Amends s. 893.02, F.S., relating to definitions.
Section 13. Amends s. 948.03, F.S., relating to terms and conditions of probation.
Section 14. Reenacts s. 310.071, F.S., relating to deputy pilot certification.
Section 15. Reenacts s. 458.331, F.S., relating to ground for discipline; action by the board and department; s. 458.347, F.S., relating to physician assistants; s. 459.022, F.S., relating to physician assistants; and s. 465.0158, relating to nonresident sterile compounding permit.
Section 16. Reenacts s. 456.072, F.S., relating to grounds for discipline; penalties; enforcement and s. 466.02751, F.S., relating to establishment of practitioner profile for designation as a controlled substance prescribing practitioner.

[61] Currently, PAs do not have practitioner profiles. Practitioner profiles contain information about a practitioner's education, training, and practice and are accessible to the public. If the bill is enacted, the Department will need to develop a profile for PAs.
[62] The facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgical centers, and mobile surgical facilities.

Section 17. Reenacts s. 458.303, F.S., relating to provisions not applicable to other practitioners; exceptions, etc.; s. 458.347, F.S., relating to physician assistants; s. 458.3475, F.S., relating to anesthesiologist assistants; s. 459.022, F.S., relating to physician assistants; and s. 459.023, F.S., relating to relating to anesthesiologist assistants.

Section 18. Reenacts s. 456.041, F.S., relating to practitioner profile; creation; s. 458.348, F.S., relating to formal supervisory relationships, standing orders, and established protocols; notice; standards; and s. 459.025, F.S., relating to relating to formal supervisory relationships, standing orders, and established protocols; notice; standards.

Section 19. Reenacts s. 464.008, F.S., relating to licensure by examination; s. 464.009, F.S., relating to licensure by endorsement; s. 464.018, F.S., relating to disciplinary actions; and s. 464.0205, F.S., relating to retired volunteer nurse certificate.

Section 20. Reenacts s. 775.051, F.S., relating to voluntary intoxication; not a defense; evidence not admissible for certain purposes; exceptions.

Section 21. Reenacts s. 944.17, F.S., relating to commitments and classification; transfers; s. 948.001, F.S., relating to definitions; and s. 948.101, F.S., relating to terms and conditions of community control.

Section 22. Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill may have an insignificant negative fiscal impact on the DOH associated with rulemaking, the creation of practitioner profiles for PAs, and workload impacts related to potential additional practitioner complaints and investigations. Current budget authority and revenues are adequate to absorb any additional workload.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Patients may see reduced health care costs and efficiencies in health care delivery as a result of having their health care needs more fully addressed by the PA or ARNP without specific additional involvement of a physician prescribing a needed controlled substance for treatment. Any such impacts are indeterminate.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

The Board of Nursing, Board of Medicine, Board of Osteopathic Medicine, and the DOH have sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to drug prescription by advanced registered nurse practitioners and physician assistants; amending s. 110.12315, F.S.; expanding the categories of persons who may prescribe brand drugs under the prescription drug program when medically necessary; amending ss. 310.071, 310.073, and 310.081, F.S.; exempting controlled substances prescribed by an advanced registered nurse practitioner or a physician assistant from the disqualifications for certification or licensure, and for continued certification or licensure, as a deputy or state pilot; amending s. 456.072, F.S.; applying existing penalties for violations relating to the prescribing or dispensing of controlled substances to an advanced registered nurse practitioner; amending s. 456.44, F.S.; deleting an obsolete date; requiring advanced registered nurse practitioners and physician assistants who prescribe controlled substances for certain pain to make a certain designation, comply with registration requirements, and follow specified standards of practice; providing applicability; amending ss. 458.3265 and 459.0137, F.S.; limiting the authority to prescribe a controlled substance in a pain-management clinic to a physician licensed under chapter 458 or chapter 459, F.S.; amending s. 458.347, F.S.;

expanding the prescribing authority of a licensed physician assistant; amending s. 464.012, F.S.; authorizing an advanced registered nurse practitioner to prescribe, dispense, administer, or order drugs, rather than to monitor and alter drug therapies; amending s. 464.018, F.S.; specifying acts that constitute grounds for denial of a license for or disciplinary action against an advanced registered nurse practitioner; amending s. 893.02, F.S.; redefining the term "practitioner" to include advanced registered nurse practitioners and physician assistants under the Florida Comprehensive Drug Abuse Prevention and Control Act; amending s. 948.03, F.S.; providing that possession of drugs or narcotics prescribed by an advanced registered nurse practitioner or physician assistant is an exception from a prohibition relating to the possession of drugs or narcotics during probation; reenacting s. 310.071(3), F.S., relating to deputy pilot certification, to incorporate the amendment made by the act to s. 310.071, F.S., in a reference thereto; reenacting ss. 458.331(10), 458.347(7)(g), 459.015(10), 459.022(7)(f), and 465.0158(5)(b), F.S., relating to grounds for disciplinary action against certain licensed health care practitioners or applicants, physician assistant licensure, the

imposition of penalties upon physician assistants by the Board of Osteopathic Medicine, and nonresident sterile compounding permits, respectively, to incorporate the amendment made by the act to s. 456.072, F.S., in references thereto; reenacting ss. 456.072(1)(mm) and 466.02751, F.S., relating to grounds for discipline of certain licensed health care practitioners or applicants and dentist practitioner profiles, respectively, to incorporate the amendment made by the act to s. 456.44, F.S., in references thereto; reenacting ss. 458.303, 458.347(4)(e) and (9)(c), 458.3475(7)(b), 459.022(4)(e) and (9)(c), and 459.023(7)(b), F.S., relating to the nonapplicability of certain provisions to specified health care practitioners, the prescribing or dispensing of medications by physician assistants, the duties of the Council on Physician Assistants, and the duties of the Board of Medicine and the Board of Osteopathic Medicine with respect to anesthesiologist assistants, respectively, to incorporate the amendment made by the act to s. 458.347, F.S., in references thereto; reenacting ss. 456.041(1)(a), 458.348(1) and (2), and 459.025(1), F.S., relating to practitioner profiles and notice and standards for formal supervisory relationships, standing orders, and established protocols, respectively, to incorporate the amendment

made by the act to s. 464.012, F.S., in references thereto; reenacting ss. 464.008(2), 464.009(5), 464.018(2), and 464.0205(1)(b), (3), and (4)(b), F.S., relating to licensure by examination of registered nurses and licensed practical nurses, licensure by endorsement to practice professional or practical nursing, disciplinary actions against nursing applicants or licensees, and retired volunteer nurse certifications, respectively, to incorporate the amendment made by the act to s. 464.018, F.S., in references thereto; reenacting s. 775.051, F.S., relating to the exclusion as a defense and nonadmissibility as evidence of voluntary intoxication, to incorporate the amendment made by the act to s. 893.02, F.S., in a reference thereto; reenacting ss. 944.17(3)(a), 948.001(8), and 948.101(1)(e), F.S., relating to the receipt by the state correctional system of certain persons sentenced to incarceration, the definition of the term "probation," and the terms and conditions of community control, respectively, to incorporate the amendment made by the act to s. 948.03, F.S., in references thereto; providing an effective date.

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

Section 1. Subsection (7) of section 110.12315, Florida Statutes, is amended to read:

110.12315 Prescription drug program.—The state employees' prescription drug program is established. This program shall be administered by the Department of Management Services, according to the terms and conditions of the plan as established by the relevant provisions of the annual General Appropriations Act and implementing legislation, subject to the following conditions:

(7) The department shall establish the reimbursement schedule for prescription pharmaceuticals dispensed under the program. Reimbursement rates for a prescription pharmaceutical must be based on the cost of the generic equivalent drug if a generic equivalent exists, unless the physician, advanced registered nurse practitioner, or physician assistant prescribing the pharmaceutical clearly states on the prescription that the brand name drug is medically necessary or that the drug product is included on the formulary of drug products that may not be interchanged as provided in chapter 465, in which case reimbursement must be based on the cost of the brand name drug as specified in the reimbursement schedule adopted by the department.

Section 2. Paragraph (c) of subsection (1) of section 310.071, Florida Statutes, is amended to read:

310.071 Deputy pilot certification.—

(1) In addition to meeting other requirements specified in this chapter, each applicant for certification as a deputy pilot

must:

(c) Be in good physical and mental health, as evidenced by documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician within the preceding 6 months. The board shall adopt rules to establish requirements for passing the physical examination, which rules shall establish minimum standards for the physical or mental capabilities necessary to carry out the professional duties of a certificated deputy pilot. Such standards shall include zero tolerance for any controlled substance regulated under chapter 893 unless that individual is under the care of a physician, advanced registered nurse practitioner, or physician assistant and that controlled substance was prescribed by that physician, advanced registered nurse practitioner, or physician assistant. To maintain eligibility as a certificated deputy pilot, each certificated deputy pilot must annually provide documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician. The physician must know the minimum standards and certify that the certificateholder satisfactorily meets the standards. The standards for certificateholders shall include a drug test.

Section 3. Subsection (3) of section 310.073, Florida Statutes, is amended to read:

310.073 State pilot licensing.—In addition to meeting other requirements specified in this chapter, each applicant for license as a state pilot must:

(3) Be in good physical and mental health, as evidenced by documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician within the preceding 6 months. The board shall adopt rules to establish requirements for passing the physical examination, which rules shall establish minimum standards for the physical or mental capabilities necessary to carry out the professional duties of a licensed state pilot. Such standards shall include zero tolerance for any controlled substance regulated under chapter 893 unless that individual is under the care of a physician, advanced registered nurse practitioner, or physician assistant and that controlled substance was prescribed by that physician, advanced registered nurse practitioner, or physician assistant. To maintain eligibility as a licensed state pilot, each licensed state pilot must annually provide documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician. The physician must know the minimum standards and certify that the licensee satisfactorily meets the standards. The standards for licensees shall include a drug test.

Section 4. Paragraph (b) of subsection (3) of section 310.081, Florida Statutes, is amended to read:

310.081 Department to examine and license state pilots and certificate deputy pilots; vacancies.—

(3) Pilots shall hold their licenses or certificates pursuant to the requirements of this chapter so long as they:

(b) Are in good physical and mental health as evidenced by documentary proof of having satisfactorily passed a physical examination administered by a licensed physician or physician assistant within each calendar year. The board shall adopt rules to establish requirements for passing the physical examination, which rules shall establish minimum standards for the physical or mental capabilities necessary to carry out the professional duties of a licensed state pilot or a certificated deputy pilot. Such standards shall include zero tolerance for any controlled substance regulated under chapter 893 unless that individual is under the care of a physician, advanced registered nurse practitioner, or physician assistant and that controlled substance was prescribed by that physician, advanced registered nurse practitioner, or physician assistant. To maintain eligibility as a certificated deputy pilot or licensed state pilot, each certificated deputy pilot or licensed state pilot must annually provide documentary proof of having satisfactorily passed a complete physical examination administered by a licensed physician. The physician must know the minimum standards and certify that the certificateholder or licensee satisfactorily meets the standards. The standards for certificateholders and for licensees shall include a drug test.

Upon resignation or in the case of disability permanently affecting a pilot's ability to serve, the state license or certificate issued under this chapter shall be revoked by the

department.

Section 5. Subsection (7) of section 456.072, Florida Statutes, is amended to read:

456.072 Grounds for discipline; penalties; enforcement.—

(7) Notwithstanding subsection (2), upon a finding that a physician has prescribed or dispensed a controlled substance, or caused a controlled substance to be prescribed or dispensed, in a manner that violates the standard of practice set forth in s. 458.331(1)(q) or (t), s. 459.015(1)(t) or (x), s. 461.013(1)(o) or (s), or s. 466.028(1)(p) or (x), or that an advanced registered nurse practitioner has prescribed or dispensed a controlled substance, or caused a controlled substance to be prescribed or dispensed, in a manner that violates the standard of practice set forth in s. 464.018(1)(n) or (p)6., the physician or advanced registered nurse practitioner shall be suspended for a period of not less than 6 months and pay a fine of not less than $10,000 per count. Repeated violations shall result in increased penalties.

Section 6. Subsections (2) and (3) of section 456.44, Florida Statutes, are amended to read:

456.44 Controlled substance prescribing.—

(2) REGISTRATION. ~~Effective January 1, 2012,~~ A physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466, a physician assistant licensed under chapter 458 or chapter 459, or an advanced registered nurse practitioner certified under part I of chapter 464 who prescribes any controlled

substance, listed in Schedule II, Schedule III, or Schedule IV as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must:

(a) Designate himself or herself as a controlled substance prescribing practitioner on his or her ~~the physician's~~ practitioner profile.

(b) Comply with the requirements of this section and applicable board rules.

(3) STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(a) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the registrant ~~clinician~~ who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each

registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

(b) Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the registrant ~~physician~~ shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

(c) The registrant ~~physician~~ shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The registrant ~~physician~~ shall use a written controlled substance agreement between the registrant ~~physician~~ and the patient outlining the patient's responsibilities,

including, but not limited to:

1. Number and frequency of controlled substance prescriptions and refills.

2. Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.

3. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating registrant ~~physician~~ unless otherwise authorized by the treating registrant ~~physician~~ and documented in the medical record.

(d) The patient shall be seen by the registrant ~~physician~~ at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the registrant's ~~physician's~~ evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the registrant ~~physician~~ shall reevaluate the appropriateness of continued treatment. The registrant ~~physician~~ shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-month intervals.

(e) The registrant ~~physician~~ shall refer the patient as necessary for additional evaluation and treatment in order to

achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or psychiatrist.

(f) A registrant ~~physician~~ registered under this section must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:

1. The complete medical history and a physical examination, including history of drug abuse or dependence.

2. Diagnostic, therapeutic, and laboratory results.

3. Evaluations and consultations.

4. Treatment objectives.

5. Discussion of risks and benefits.

6. Treatments.

7. Medications, including date, type, dosage, and quantity prescribed.

8. Instructions and agreements.

9. Periodic reviews.

10. Results of any drug testing.

11. A photocopy of the patient's government-issued photo identification.

12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.

13. The registrant's ~~physician's~~ full name presented in a legible manner.

(g) Patients with signs or symptoms of substance abuse shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the registrant is a physician who is board certified ~~board-certified~~ or board eligible ~~board-eligible~~ in pain management. Throughout the period of time before receiving the consultant's report, a prescribing registrant ~~physician~~ shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing registrant ~~physician~~ shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the

registrant ~~physician~~ shall be documented in the patient's medical record.

This subsection does not apply to a board-eligible or board-certified anesthesiologist, physiatrist, rheumatologist, or neurologist, or to a board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a board-eligible or board-certified medical specialist who has also completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is board eligible or board certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes. This subsection does not apply to a registrant, physician, advanced registered nurse practitioner, or physician assistant who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395.

Section 7. Paragraph (b) of subsection (2) of section 458.3265, Florida Statutes, is amended to read:

458.3265 Pain-management clinics.—

(2) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any physician who provides professional services in a

pain-management clinic that is required to be registered in subsection (1).

(b) A person may not dispense any medication on the premises of a registered pain-management clinic unless he or she is a physician licensed under this chapter or chapter 459. A person may not prescribe any controlled substance regulated under chapter 893 on the premises of a registered pain-management clinic unless he or she is a physician licensed under this chapter or chapter 459.

Section 8. Paragraph (f) of subsection (4) of section 458.347, Florida Statutes, is amended to read:

458.347 Physician assistants.—

(4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

(f)1. The council shall establish a formulary of medicinal drugs that a fully licensed physician assistant having prescribing authority under this section or s. 459.022 may not prescribe. The formulary must include ~~controlled substances as defined in chapter 893,~~ general anesthetics~~,~~ and radiographic contrast materials.

2. In establishing the formulary, the council shall consult with a pharmacist licensed under chapter 465, but not licensed under this chapter or chapter 459, who shall be selected by the State Surgeon General.

3. Only the council shall add to, delete from, or modify the formulary. Any person who requests an addition, deletion, or modification of a medicinal drug listed on such formulary has

the burden of proof to show cause why such addition, deletion, or modification should be made.

4. The boards shall adopt the formulary required by this paragraph, and each addition, deletion, or modification to the formulary, by rule. Notwithstanding any provision of chapter 120 to the contrary, the formulary rule shall be effective 60 days after the date it is filed with the Secretary of State. Upon adoption of the formulary, the department shall mail a copy of such formulary to each fully licensed physician assistant having prescribing authority under this section or s. 459.022, and to each pharmacy licensed by the state. The boards shall establish, by rule, a fee not to exceed $200 to fund the provisions of this paragraph and paragraph (e).

Section 9. Paragraph (b) of subsection (2) of section 459.0137, Florida Statutes, is amended to read:

459.0137 Pain-management clinics.—

(2) PHYSICIAN RESPONSIBILITIES.—These responsibilities apply to any osteopathic physician who provides professional services in a pain-management clinic that is required to be registered in subsection (1).

(b) A person may not dispense any medication on the premises of a registered pain-management clinic unless he or she is a physician licensed under this chapter or chapter 458. A person may not prescribe any controlled substance regulated under chapter 893 on the premises of a registered pain-management clinic unless he or she is a physician licensed under

this chapter or chapter 458.

Section 10. Section 464.012, Florida Statutes, is amended to read:

464.012 Certification of advanced registered nurse practitioners; fees; controlled substance prescribing.—

(1) Any nurse desiring to be certified as an advanced registered nurse practitioner shall apply to the department and submit proof that he or she holds a current license to practice professional nursing and that he or she meets one or more of the following requirements as determined by the board:

(a) Satisfactory completion of a formal postbasic educational program of at least one academic year, the primary purpose of which is to prepare nurses for advanced or specialized practice.

(b) Certification by an appropriate specialty board. Such certification shall be required for initial state certification and any recertification as a registered nurse anesthetist or nurse midwife. The board may by rule provide for provisional state certification of graduate nurse anesthetists and nurse midwives for a period of time determined to be appropriate for preparing for and passing the national certification examination.

(c) Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills. For applicants graduating on or after October 1, 1998, graduation from a master's degree program

shall be required for initial certification as a nurse practitioner under paragraph (4)(c). For applicants graduating on or after October 1, 2001, graduation from a master's degree program shall be required for initial certification as a registered nurse anesthetist under paragraph (4)(a).

(2) The board shall provide by rule the appropriate requirements for advanced registered nurse practitioners in the categories of certified registered nurse anesthetist, certified nurse midwife, and nurse practitioner.

(3) An advanced registered nurse practitioner shall perform those functions authorized in this section within the framework of an established protocol that is filed with the board upon biennial license renewal and within 30 days after entering into a supervisory relationship with a physician or changes to the protocol. The board shall review the protocol to ensure compliance with applicable regulatory standards for protocols. The board shall refer to the department licensees submitting protocols that are not compliant with the regulatory standards for protocols. A practitioner currently licensed under chapter 458, chapter 459, or chapter 466 shall maintain supervision for directing the specific course of medical treatment. Within the established framework, an advanced registered nurse practitioner may:

(a) Prescribe, dispense, administer, or order any ~~Monitor and alter~~ drug ~~therapies~~.

(b) Initiate appropriate therapies for certain conditions.

(c) Perform additional functions as may be determined by rule in accordance with s. 464.003(2).

(d) Order diagnostic tests and physical and occupational therapy.

(4) In addition to the general functions specified in subsection (3), an advanced registered nurse practitioner may perform the following acts within his or her specialty:

(a) The certified registered nurse anesthetist may, to the extent authorized by established protocol approved by the medical staff of the facility in which the anesthetic service is performed, perform any or all of the following:

1. Determine the health status of the patient as it relates to the risk factors and to the anesthetic management of the patient through the performance of the general functions.

2. Based on history, physical assessment, and supplemental laboratory results, determine, with the consent of the responsible physician, the appropriate type of anesthesia within the framework of the protocol.

3. Order under the protocol preanesthetic medication.

4. Perform under the protocol procedures commonly used to render the patient insensible to pain during the performance of surgical, obstetrical, therapeutic, or diagnostic clinical procedures. These procedures include ordering and administering regional, spinal, and general anesthesia; inhalation agents and techniques; intravenous agents and techniques; and techniques of hypnosis.

5. Order or perform monitoring procedures indicated as pertinent to the anesthetic health care management of the patient.

6. Support life functions during anesthesia health care, including induction and intubation procedures, the use of appropriate mechanical supportive devices, and the management of fluid, electrolyte, and blood component balances.

7. Recognize and take appropriate corrective action for abnormal patient responses to anesthesia, adjunctive medication, or other forms of therapy.

8. Recognize and treat a cardiac arrhythmia while the patient is under anesthetic care.

9. Participate in management of the patient while in the postanesthesia recovery area, including ordering the administration of fluids and drugs.

10. Place special peripheral and central venous and arterial lines for blood sampling and monitoring as appropriate.

(b) The certified nurse midwife may, to the extent authorized by an established protocol which has been approved by the medical staff of the health care facility in which the midwifery services are performed, or approved by the nurse midwife's physician backup when the delivery is performed in a patient's home, perform any or all of the following:

1. Perform superficial minor surgical procedures.

2. Manage the patient during labor and delivery to include amniotomy, episiotomy, and repair.

3. Order, initiate, and perform appropriate anesthetic procedures.

4. Perform postpartum examination.

5. Order appropriate medications.

6. Provide family-planning services and well-woman care.

7. Manage the medical care of the normal obstetrical patient and the initial care of a newborn patient.

(c) The nurse practitioner may perform any or all of the following acts within the framework of established protocol:

1. Manage selected medical problems.

2. Order physical and occupational therapy.

3. Initiate, monitor, or alter therapies for certain uncomplicated acute illnesses.

4. Monitor and manage patients with stable chronic diseases.

5. Establish behavioral problems and diagnosis and make treatment recommendations.

(5) The board shall certify, and the department shall issue a certificate to, any nurse meeting the qualifications in this section. The board shall establish an application fee not to exceed $100 and a biennial renewal fee not to exceed $50. The board is authorized to adopt such other rules as are necessary to implement the provisions of this section.

Section 11. Paragraph (p) is added to subsection (1) of section 464.018, Florida Statutes, to read:

464.018 Disciplinary actions.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(p) For an advanced registered nurse practitioner:

1. Presigning blank prescription forms.

2. Prescribing for office use any medicinal drug appearing on Schedule II in chapter 893.

3. Prescribing, ordering, dispensing, administering, supplying, selling, or giving a drug that is an amphetamine or a sympathomimetic amine drug, or a compound designated pursuant to chapter 893 as a Schedule II controlled substance, to or for any person except for:

a. The treatment of narcolepsy; hyperkinesis; behavioral syndrome in children characterized by the developmentally inappropriate symptoms of moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity; or drug-induced brain dysfunction.

b. The differential diagnostic psychiatric evaluation of depression or the treatment of depression shown to be refractory to other therapeutic modalities.

c. The clinical investigation of the effects of such drugs or compounds when an investigative protocol is submitted to, reviewed by, and approved by the department before such investigation is begun.

4. Prescribing, ordering, dispensing, administering, supplying, selling, or giving growth hormones, testosterone or its analogs, human chorionic gonadotropin (HCG), or other

hormones for the purpose of muscle building or to enhance athletic performance. As used in this subparagraph, the term "muscle building" does not include the treatment of injured muscle. A prescription written for the drug products listed in this paragraph may be dispensed by a pharmacist with the presumption that the prescription is for legitimate medical use.

5. Promoting or advertising on any prescription form a community pharmacy unless the form also states: "This prescription may be filled at any pharmacy of your choice."

6. Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including a controlled substance, other than in the course of his or her professional practice. For the purposes of this subparagraph, it is legally presumed that prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the advanced registered nurse practitioner's professional practice, without regard to his or her intent.

7. Prescribing, dispensing, or administering a medicinal drug appearing on any schedule set forth in chapter 893 to himself or herself, except a drug prescribed, dispensed, or administered to the advanced registered nurse practitioner by another practitioner authorized to prescribe, dispense, or administer medicinal drugs.

8. Prescribing, ordering, dispensing, administering,

supplying, selling, or giving amygdalin (laetrile) to any person.

9. Dispensing a controlled substance listed on Schedule II or Schedule III in chapter 893 in violation of s. 465.0276.

10. Promoting or advertising through any communication medium the use, sale, or dispensing of a controlled substance appearing on any schedule in chapter 893.

Section 12. Subsection (21) of section 893.02, Florida Statutes, is amended to read:

893.02 Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(21) "Practitioner" means a physician licensed under ~~pursuant to~~ chapter 458, a dentist licensed under ~~pursuant to~~ chapter 466, a veterinarian licensed under ~~pursuant to~~ chapter 474, an osteopathic physician licensed under ~~pursuant to~~ chapter 459, an advanced registered nurse practitioner certified under chapter 464, a naturopath licensed under ~~pursuant to~~ chapter 462, a certified optometrist licensed under ~~pursuant to~~ chapter 463, ~~or~~ a podiatric physician licensed under ~~pursuant to~~ chapter 461, or a physician assistant licensed under chapter 458 or chapter 459, provided such practitioner holds a valid federal controlled substance registry number.

Section 13. Paragraph (n) of subsection (1) of section 948.03, Florida Statutes, is amended to read:

948.03 Terms and conditions of probation.—

(1) The court shall determine the terms and conditions of probation. Conditions specified in this section do not require oral pronouncement at the time of sentencing and may be considered standard conditions of probation. These conditions may include among them the following, that the probationer or offender in community control shall:

(n) Be prohibited from using intoxicants to excess or possessing any drugs or narcotics unless prescribed by a physician, advanced registered nurse practitioner, or physician assistant. The probationer or community controllee may ~~shall~~ not knowingly visit places where intoxicants, drugs, or other dangerous substances are unlawfully sold, dispensed, or used.

Section 14. Subsection (3) of s. 310.071, Florida Statutes, is reenacted for the purpose of incorporating the amendment made by this act to s. 310.071, Florida Statutes, in a reference thereto.

Section 15. Subsection (10) of s. 458.331, paragraph (g) of subsection (7) of s. 458.347, subsection (10) of s. 459.015, paragraph (f) of subsection (7) of s. 459.022, and paragraph (b) of subsection (5) of s. 465.0158, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 456.072, Florida Statutes, in references thereto.

Section 16. Paragraph (mm) of subsection (1) of s. 456.072 and s. 466.02751, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 456.44, Florida Statutes, in references thereto.

Section 17. Section 458.303, paragraph (e) of subsection (4) and paragraph (c) of subsection (9) of s. 458.347, paragraph (b) of subsection (7) of s. 458.3475, paragraph (e) of subsection (4) and paragraph (c) of subsection (9) of s. 459.022, and paragraph (b) of subsection (7) of s. 459.023, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 458.347, Florida Statutes, in references thereto.

Section 18. Paragraph (a) of subsection (1) of s. 456.041, subsections (1) and (2) of s. 458.348, and subsection (1) of s. 459.025, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 464.012, Florida Statutes, in references thereto.

Section 19. Subsection (2) of s. 464.008, subsection (5) of s. 464.009, subsection (2) of s. 464.018, and paragraph (b) of subsection (1), subsection (3), and paragraph (b) of subsection (4) of s. 464.0205, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s. 464.018, Florida Statutes, in references thereto.

Section 20. Section 775.051, Florida Statutes, is reenacted for the purpose of incorporating the amendment made by this act to s. 893.02, Florida Statutes, in a reference thereto.

Section 21. Paragraph (a) of subsection (3) of s. 944.17, subsection (8) of s. 948.001, and paragraph (e) of subsection (1) of s. 948.101, Florida Statutes, are reenacted for the purpose of incorporating the amendment made by this act to s.

948.03, Florida Statutes, in references thereto.

Section 22. This act shall take effect July 1, 2016.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 437 Certificates of Need for Hospitals
SPONSOR(S): Sprowls
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Select Committee on Affordable Healthcare Access	10 Y, 4 N	Guzzo	Calamas
2) Health Care Appropriations Subcommittee	9 Y, 4 N	Clark	Pridgeon
3) Health & Human Services Committee		Guzzo	Calamas

SUMMARY ANALYSIS

The certificate of need (CON) program, administered by the Agency for Health Care Administration (AHCA), requires certain health care facilities to obtain authorization from the state before offering certain new or expanded services. Health care facilities subject to CON review include hospitals, nursing homes, hospices, and intermediate care facilities for the developmentally disabled.

Florida's CON program was established in 1973, and has undergone several changes over the years. 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, but Florida retained its CON program. Nationally, 22 states do not require CON review to add hospital beds. Of those states, 14 have no CON requirements for any health care facility or service.

The Florida CON program has three levels of review: full, expedited and exempt. Expedited review is primarily targeted towards nursing home projects. Projects required to undergo full comparative review include:

- Construction of a new hospital;
- Replacement of a hospital if the proposed project site is more than one mile from the hospital being replaced;
- Conversion from one type of hospital to another, including the conversion between a general hospital, specialty hospital, or a long-term care hospital; and
- Establishment of tertiary health services and comprehensive rehabilitation services.

The CON program exempts from full CON review the addition of beds to certain existing services, including comprehensive rehabilitation, neonatal intensive care, and psychiatric and substance abuse services.

An applicant for CON review must submit a fee with the application. The minimum CON application filing fee is $10,000. In addition to the base fee, an applicant must pay a fee of 1.5 percent of each dollar of the proposed expenditure; however the total fee may not exceed $50,000. The fee for a CON exemption is $250.

HB 437 eliminates CON review requirements for hospitals and hospital services and makes necessary conforming changes throughout part I of chapter 408, F.S. The bill also removes the CON review requirement for increasing the number of comprehensive rehabilitation beds in a facility that offers comprehensive rehabilitation services.

The bill makes a conforming change to s. 395.1055, F.S., to ensure that AHCA has rulemaking authority, after the repeal of the CON review process for hospitals, to maintain licensure requirements and quality standards for tertiary health services offered by a hospital.

The bill is expected to have a negative fiscal impact on AHCA resulting from the loss of CON application and exemption fees; however, the loss will be offset by an increase in project and licensure fees for new hospitals and services.

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Hospital Licensure

Hospitals are regulated by the Agency for Health Care Administration (AHCA) under chapter 395, F.S., and the general licensure provisions of part II, of chapter 408, F.S. Hospitals offer a range of health care services with beds for use beyond 24 hours by individuals requiring diagnosis, treatment, or care.[1] Hospitals must make regularly available at least clinical laboratory services, diagnostic X-ray services, and treatment facilities for surgery or obstetrical care, or other definitive medical treatment.[2]

A specialty hospital, in addition to providing the same services as general hospitals, provides other services, including:

- A range of medical services restricted to a defined age or gender group;
- A restricted range of services appropriate to the diagnosis, care, and treatment of patients with specific categories of medical or psychiatric illnesses or disorders; or
- Intensive residential treatment programs for children and adolescents.[3]

AHCA must maintain an inventory of hospitals with an emergency department.[4] The inventory must list all services within the capability of each hospital, and such services must appear on the face of the hospital's license. As of November 13, 2015, 219 of the 306 licensed hospitals in the state have an emergency department.[5]

Hospitals must meet initial licensing requirements by submitting a completed application and required documentation, and the satisfactory completion of a facility survey. The license fee is $1,565.13 or $31.46 per bed, whichever is greater.[6] The survey fee is $400.00 or $12.00 per bed, whichever is greater.[7]

Section 395.1055, F.S., authorizes AHCA to adopt rules for hospitals. Separate standards may be provided for general and specialty hospitals.[8] The rules for general and specialty hospitals must include minimum standards to ensure:

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards.[9]

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[1] S.395.002(12), F.S.
[2] Id.
[3] S. 395.002(28), F.S.
[4] S. 395.1041(2), F.S.
[5] Agency for Health Care Administration, Facility/Provider Search Results, *Hospitals,* available at http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (report generated on November 13, 2015).
[6] Rule 59A-3.006(3), F.A.C.
[7] S. 395.0161(3)(a), F.S.
[8] S. 395.1055(2), F.S.
[9] S. 395.1055(1), F.S.

The minimum standards for hospital licensure are contained in Chapter 59A-3, F.A.C.

Certificate of Need (CON)

CON laws require approval by a state health planning agency before a health care facility may construct or expand, offer a new service, or purchase equipment exceeding a certain cost.

CON programs are designed to restrain health care costs and provide for directed, measured planning for new services and facilities.[10] Such programs were originally established to regulate the addition of new facilities, or new beds in hospitals and nursing homes, for example, and to prevent overbuying of expensive equipment, under the economic theory that excess capacity directly results in health care price inflation.[11] When a hospital or health care service provider cannot meet its obligations, fixed costs must be met through higher charges for the beds that are used or for the number of patients using the service.[12] Larger institutions have higher costs, so CON supporters say it makes sense to limit facilities to building only enough capacity to meet actual needs.[13]

In addition to cost containment, CON regulation is intended to create a "quid pro quo" in which profitability of covered medical services is increased by restricting competition and, in return, medical providers cross-subsidize specified amounts of indigent care, or medical services to the poor that are unprofitable to the provider.[14] Some states require facilities and providers that obtain a CON to provide a certain amount of indigent care to underinsured or uninsured patients.[15]

Studies have found that CON programs do not meet the goal of limiting costs in health care. A literature review conducted in 2004 by the Federal Trade Commission and the Department of Justice concluded that:

> [O]n balance, CON programs are not successful in containing health care costs, and that they pose serious anticompetitive risks that usually outweigh their purported economic benefits. Market incumbents can too easily use CON procedures to forestall competitors from entering an incumbent's market. [. . . .] Indeed, there is considerable evidence that CON programs can actually increase prices by fostering anticompetitive barriers to entry. Other means of cost control appear to be more effective and pose less significant competitive concerns.[16]

Studies are split, however, on whether CON regulation has improved access to care for the underinsured and uninsured.[17] While there is limited research on the subject, some studies have found

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[10] National Conference of State Legislators, Certificate of Need: State Laws and Programs, available at http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx (last viewed January 15, 2016).
[11] Id.
[12] Id.
[13] Id.
[14] Thomas Stratmann and Jacob Russ, "Do Certificate-of-Need Laws Increase Indigent Care?" Mercatus Center at George Mason University, July 2014, pg. 2, available at: http://mercatus.org/publication/do-certificate-need-laws-increase-indigent-care (last viewed January 15, 2016).
[15] For example, Delaware (Del. Code Ann. tit. 16 § 9303), Georgia (Ga. Code Ann. §111-2-2.40), Rhode Island (R.I. Code R. §6.2.4(B)), and Virginia (12 Va. Admin. Code §5-230-40 and §5-220-270) require CON applicants to comply with such provisions.
[16] "Improving Health Care: A Does of Competition: A Report by the Federal Trade Commission and the Department of Justice," July 2004, available at: https://www.ftc.gov/reports/improving-health-care-dose-competition-report-federal-trade-commission-department-justice (last viewed January 15, 2016): "[t]here is near universal agreement among the authors [of studies on the economic effects of CON programs] and other health economists that CON has been unsuccessful in containing health care costs"); Daniel Sherman, Federal Trade Comm'n, The Effect of State Certificate-of-Need Laws on Hospital Costs: An Economic Policy Analysis (1988) (concluding, after empirical study of CON programs' effects on hospital costs using 1983-84 data, that strong CON programs do not lead to lower costs but may actually increase costs); Monica Noether, Federal Trade Comm'n, Competition Among Hospitals 82(1987) (empirical study concluding that CON regulation led to higher prices and expenditures).
[17] Supra, FN 10 at pg. 18.

that access to care for the underserved populations has increased in states with CON programs,[18] while another has found little, if any, evidence to support such a conclusion.[19] In Florida, the Statewide Medicaid Managed Care (SMMC) program requires all managed care plans to comply with provider network standards to ensure access to care for beneficiaries and imposes significant penalties if access to care is impeded within the program. While Florida maintains a CON program for several types of health care facilities and services, accountability standards within the SMMC program would ensure access to care for Medicaid patients should the CON program be repealed.

According to one study, states with hospital CON regulations have 13 percent fewer hospital beds per 100,000 persons than states without hospital CON regulations.[20] The impact of CON regulations in Florida has been examined as well. A study found that, in Miami-Dade County, CON regulations result in approximately 3,428 fewer hospital beds, between 5 and 10 fewer hospitals offering MRI services, and 18 fewer hospitals offering CT scans.[21]

Florida's CON Program

Overview

Florida's CON program has existed 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 of 1974 (the "Act), which established minimum requirements regarding the type of services subject to CON review, review procedures, and review criteria.[22] Each state was required to have a CON program in compliance with the Act as a condition for obtaining federal funds for health programs. The Act was repealed in 1986.

In Florida, a CON is a written statement issued by AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service, including hospices. The Florida CON program has three levels of review: full, expedited and exempt.[23] Unless a hospital project is exempt from the CON program, it must undergo a full comparative review. Expedited review is primarily targeted towards nursing home projects.

Projects Subject to Full CON Review

Some hospital projects are required to undergo a full comparative CON review, including:

- New construction of general hospitals, long-term care hospitals, and freestanding specialty hospitals; and
- Replacement of a hospital if the proposed project site is not located on the same site or within one mile of the existing health care facility.[24]

The addition of certain new or expansion of certain existing hospital services are also required to undergo a full comparative CON review, including:

- Establishing comprehensive medical rehabilitation inpatient services or increasing the number of beds for comprehensive rehabilitation;[25] and

[18] Tracy Yee, Lucy B. Stark, et al, "Health Care Certificate-of-Need Laws: Policy or Politics?," Research Brief, National Institute for Health Care Reform, No. 4, May 2011, pg. 6, available at: http://www.nihcr.org/index.php?download=119ncfl17 (citing Elana C. Fric-Shamji and Mohammed F. Shamji, "Impact of U.S. Government Regulation on Access to Elective Surgical Care," Clinical & Investigative Medicine, vol. 31, no. 5 (October 2008) and Ellen S. Campbell and Gary M. Fournier, "Certificate-of-Need Deregulation and Indigent Hospital Care," Journal of Health Politics, Policy and Law, vol. 18, no. 4 (Winter 1993)).
[19] Christopher J. Conover and Frank A. Sloan, "Does Removing Certificate-of-Need Regulations Lead to a Surge in Health Care Spending?," Journal of Health Politics, Policy and Law, vol. 23, no. 3, pg. 478 (June 1998).
[20] Id.
[21] Christopher Koopman and Thomas Stratman, "Certificate-of-Need Laws: Implications for Florida," March 2015, pg. 2, available at: http://mercatus.org/sites/default/files/Koopman-Certficate-of-NeedFL-MOP.pdf. (last viewed January 15, 2016).
[22] Pub. L. No. 93-641, 42 U.S.C. §§ 300k et seq.
[23] S. 408.036, F.S.
[24] S. 408.036(1)(b), F.S.

- Establishing tertiary health services.[26]

Comprehensive medical rehabilitation inpatient services shape an organized program of intensive care services provided by a coordinated multidisciplinary team to patients with severe physical disabilities, including:

- Stroke;
- Spinal cord injury;
- Congenital deformity;
- Amputation;
- Major multiple trauma;
- Hip fracture;
- Brain injury;
- Rheumatoid arthritis;
- Neurological disorders;
- Burns; and
- Neurological disorders.[27]

Section 408.032(17), F.S., requires AHCA to establish by rule a list of all tertiary health services subject to CON review. The list of tertiary health services must be reviewed annually by AHCA to determine if services should be added or deleted.[28]

Hospitals must undergo full comparative CON review for the establishment of the following tertiary health services:

- Pediatric cardiac catheterization;
- Pediatric open-heart surgery;
- Neonatal intensive care units;
- Adult open heart surgery; and
- Organ transplantation; including
    - Heart;
    - Kidney;
    - Liver;
    - Bone marrow;
    - Lung; and
    - Pancreas.[29]

[25] S. 408.0361(1)(e), F.S.
[26] S. 408.036(1)(f), F.S., and s. 408.032(17), F.S., which defines "tertiary health service" as a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service. Examples of tertiary health services include pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care units, comprehensive rehabilitation, and medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service.
[27] Rule 59C-1.039(2)(c), F.A.C.
[28] Rule 59C-1.002(41), F.A.C.
[29] Rule 59C-1.002(41), F.A.C.

Projects Subject to Expedited CON Review

Certain projects are eligible for expedited CON review. Applicants for expedited review are not subject to the application deadlines associated with full comparative review and may submit an application at any time. Projects subject to an expedited review include:

- Transfer of a CON;
- Replacement of a nursing home within the same district;
- Replacement of a nursing home if the proposed site is within a 30-mile radius of the existing nursing home;
- Relocation of a portion of a nursing home's beds to another facility or to establish a new facility in the same district, or a contiguous district, if the relocation is within a 30-mile radius of the existing facility and the total number of nursing home beds in the state does not increase; and
- Construction of a new community nursing home in a retirement community under certain conditions.[30]

Exemptions from CON Review

Section 408.036(3), F.S., provides many exemptions to CON review for certain hospital projects, including:

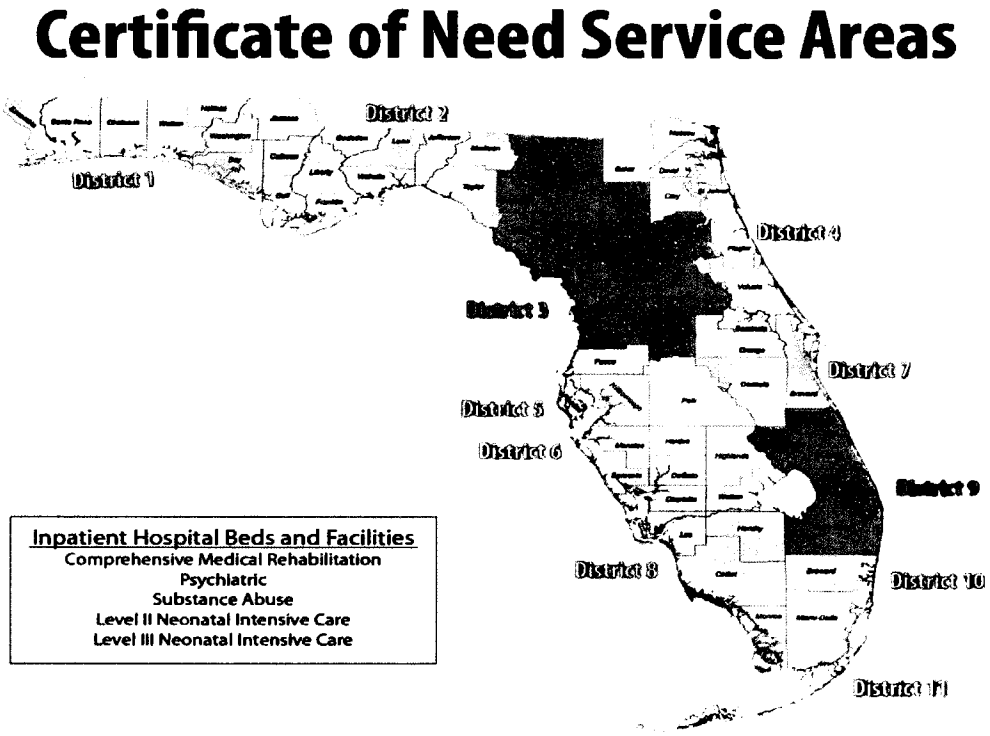
- Adding swing beds[31] in a rural hospital, the total of which does not exceed one-half of its licensed beds.
- Converting licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital, as defined in s. 395.602, F.S., so long as the conversion of the beds does not involve the construction of new facilities.
- Adding hospital beds licensed under chapter 395, F.S., for comprehensive rehabilitation, the total of which may not exceed 10 total beds or 10 percent of the licensed capacity, whichever is greater.
- Establishing a level II neonatal intensive care unit (NICU) if the unit has at least 10 beds, and if the hospital had a minimum of 1,500 births during the previous 12 months.
- Establishing a level III NICU if the unit has at least 15 beds, and if the hospital had a minimum of at least 3,500 births during the previous 12 months.
- Establishing a level III NICU if the unit has at least 5 beds, and is a verified trauma center,[32] and if the applicant has a level II NICU.
- Establishing an adult open heart surgery program in a hospital located within the boundaries of a health service planning district, which:
    - Has experienced an annual net out-migration of at least 600 open heart surgery cases for 3 consecutive years; and
    - Has a population that exceeds the state average of population per licensed and operational open-heart programs by at least 25 percent.
- For the provision of percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital that does not have an approved adult open-heart-surgery program.

[30] S. 408.036(2), F.S.
[31] S. 395.602(2)(g), F.S., defines "swing bed" as a bed which can be used interchangeably as either a hospital, skilled nursing facility (SNF), or intermediate care facility (ICF) bed pursuant to 42 C.F.R. parts 405, 435, 440, 442, and 447.
[32] S. 395.4001(14), F.S., defines "trauma center" as a hospital that has been verified by the Department of Health to be in substantial compliance with the requirements in s. 395.4025, F.S., and has been approved to operate as a Level I trauma center, Level II trauma center, or pediatric trauma center, or is designated as a Level II trauma center pursuant to s. 395.4025(14), F.S.

CON Determination of Need and Application and Review Process

A CON is predicated on a determination of need. The future need for services and projects is known as the "fixed need pool"[33], which AHCA publishes for each batching cycle. A batching cycle is a means of grouping of, for comparative review, CON applications submitted for beds, services or programs having a like CON need methodology or licensing category in the same planning horizon and the same applicable district or subdistrict.[34] Chapter 59C-1, F.A.C., provides need formulas[35] to calculate the fixed need pool for certain services, including NICU services[36], adult and child psychiatric services[37], adult substance abuse services[38], and comprehensive rehabilitation services.[39]

Upon determining that a need exists, AHCA accepts applications for CON based on batching cycles. Section 408.032(5), F.S., establishes the 11 district service areas in Florida, illustrated in the chart below.



[33] Rule 59C-1.002(19), F.A.C., defines "fixed need pool" as the identified numerical need, as published in the Florida Administrative Register, for new beds or services for the applicable planning horizon established by AHCA in accordance with need methodologies which are in effect by rule at the time of publication of the fixed need pools for the applicable batching cycle.

[34] Rule 59C-1.002(5), F.A.C.

[35] Rule 59C-1.039(5), F.A.C., provides the need formula for comprehensive medical rehabilitation inpatient beds as follows: ((PD/P) x PP / (365 x .85)) – LB – AB = NN where: 1. NN equals the net need for Comprehensive Medical Rehabilitation Inpatient Beds in a District. 2. PD equals the number of inpatient days in Comprehensive Medical Rehabilitation Inpatient Beds in a district for the 12-month period ending 6 months prior to the beginning date of the quarter of the publication of the Fixed Bed Need Pool.
3. P equals the estimated population in the district. For applications submitted between January 1 and June 30, P is the population estimate for January of the preceding year; for applications submitted between July 1 and December 31, P is the population estimate for July of the preceding year. The population estimate shall be the most recent estimate published by the Office of the Governor and available to the Department at least 4 weeks prior to publication of the Fixed Bed Need Pool.
4. PP equals the estimated population in the district for the applicable planning horizon. The population estimate shall be the most recent estimate published by the Office of the Governor and available to the Department at least 4 weeks prior to publication of the Fixed Bed Need Pool. 5. .85 equals the desired average annual occupancy rate for Comprehensive Medical Rehabilitation Inpatient Beds in the district. 6. LB equals the district's number of licensed Comprehensive Medical Rehabilitation Inpatient Beds as of the most recent published deadline for Agency initial decisions prior to publication of the Fixed Bed Need Pool.
7. AB equals the district's number of approved Comprehensive Medical Rehabilitation Inpatient Beds.

[36] Rule 59C-1.042(3), F.A.C.

[37] Rule 59C-1.040(4), F.A.C.

[38] Rule 59C-1.041(4), F.A.C.

[39] Rule 59C-1.039(5), F.A.C.

The CON review process consists of four batching cycles each year, including two batching cycles each year for each of two project categories: hospital beds and facilities, and other beds and programs.[40] The "hospital beds and facilities" batching cycle includes applicants for new or expanded:

- Comprehensive medical rehabilitation beds;
- Adult psychiatric beds;
- Child and adolescent psychiatric beds;
- Adult substance abuse beds;
- NICU level II beds; and
- NICU level III beds.[41]

The "other beds and programs" batching cycle includes:

- Nursing home beds;
- Hospice beds;
- Pediatric open heart surgery;
- Pediatric cardiac catheterization services; and
- Organ transplantation services.[42]

Hospital Beds & Facilities Applications for Last 4 Batching Cycles 2013-2015[43]

Proposed Project	*Applications Received*	*Applications Approved*
Establish a Comprehensive Medical Rehabilitation Unit	9	1
Establish an Acute Care Hospital	4	3
Establish an Adult Inpatient Psychiatric Hospital	4	3
Establish a Long-Term Care Hospital	2	2
Establish a Replacement Acute Care Hospital	2	2
Establish a Child/Adolescent Psychiatric Hospital	1	1
Total	**22**	**12**

At least 30 days prior to the application deadline for a batch cycle, an applicant must file a letter of intent with AHCA.[44] A letter of intent must describe the proposal, specify the number of beds sought, and identify the services to be provided and the location of the project.[45]

Applications for CON review must be submitted by the specified deadline for the particular batch cycle.[46] AHCA must review the application within 15 days of the filing deadline and, if necessary,

[40] Rule 59C-1.008(1)(g), F.A.C.
[41] Rule 59C-1.008(1), F.A.C.
[42] Id.
[43] AHCA, CON Decisions & State Agency Action Reports, Hospital Beds and Facilities, February 2015 batching cycle, August 2014 batching cycle, February 2014 batching cycle, and August 2013 batching cycle, available at http://ahca.myflorida.com/MCHQ/CON_FA/Batching/decisions.shtml (last viewed January 15, 2016). Pursuant to s. 408.036, F.S., and rule 59C-1.004(1), F.A.C., requests for an expedited review or exemption may be made at any time and are not subject to batching requirements.
[44] S. 408.039(2)(a), F.S.
[45] S. 408.039(2)(c), F.S.

request additional information for an incomplete application.[47] The applicant then has 21 days to complete the application or it is deemed withdrawn from consideration.[48]

Within 60 days of receipt of the completed applications for that batch, AHCA must issue a State Agency Action Report and Notice of Intent to Award a CON for a project in its entirety, to award a CON for identifiable portions of a project, or to deny a CON for a project.[49] AHCA must then publish the decision, within 14 days, in the Florida Administrative Weekly.[50] If no administrative hearing is requested within 21 days of the publication, the State Agency Action Report and the Notice of Intent to Award the CON become a final order of AHCA.[51]

CON Fees

An applicant for CON review must pay a fee to AHCA when the application is submitted. The minimum CON application filing fee is $10,000.[52] In addition to the base fee, an applicant must pay a fee of 1.5 percent of each dollar of the proposed expenditure; however, the total fee may not exceed $50,000.[53] A request for a CON exemption must be accompanied by a $250 fee payable to AHCA.[54]

CON Litigation

Florida law allows competitors to challenge CON decisions. A Notice of Intent to Award a CON may be challenged by a competing applicant in the same review cycle or an existing provider in the same district by submitting evidence that the challenge will be substantially affected if the CON is awarded.[55] A challenge to a CON decision is heard by an Administrative Law Judge under the Division of Administrative Hearings.[56] AHCA must render a Final Order within 45 days of receiving the Recommended Order of the Administrative Law Judge.[57] A party to an administrative hearing may challenge a Final Order to the District Court of Appeals for judicial review[58] within 30 days of receipt of a Final Order.[59]

CON Deregulation

Florida's CON program has been reformed several times over the course of the past 15 years. In 2000, CON review was eliminated for establishing a new home health agency.[60] The number of home health agencies doubled over the ten-year period immediately succeeding the elimination of CON review for establishing a new home health agency. Since 2010, the number of home health agencies has slowly declined.[61]

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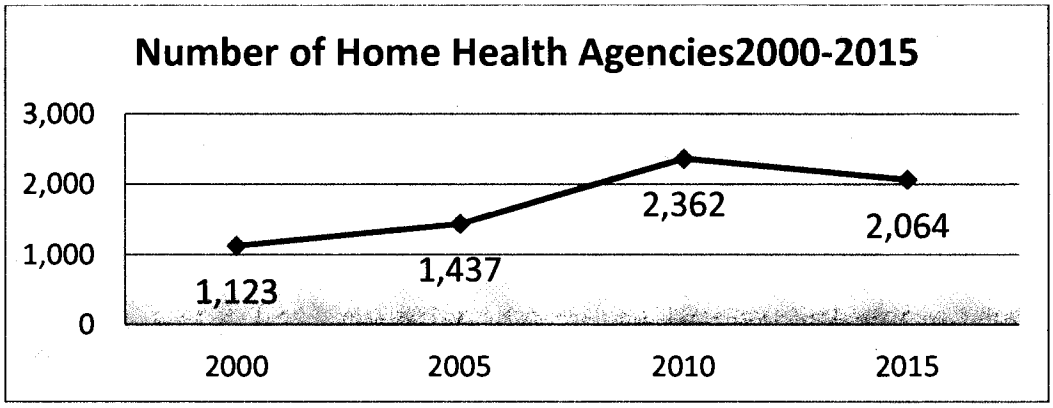
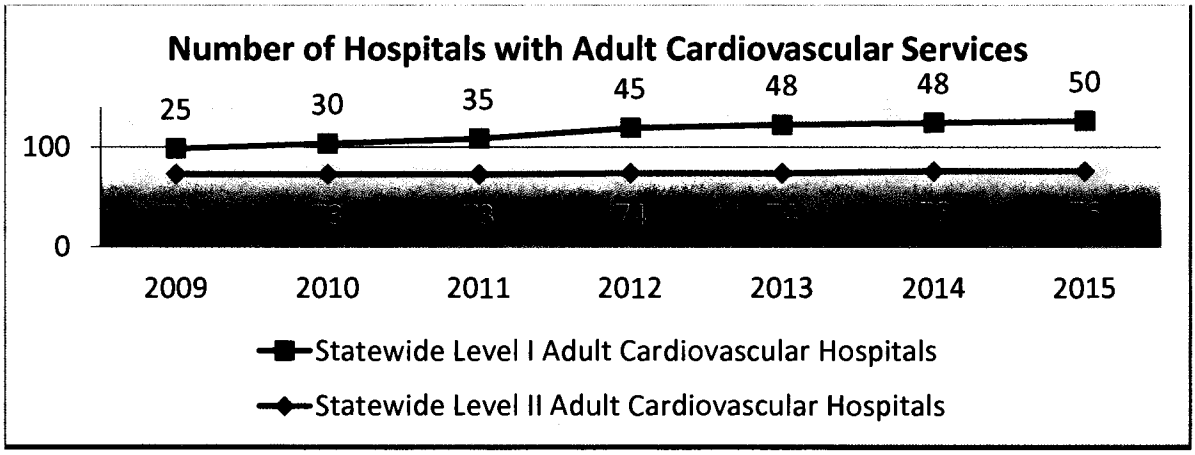
[46] Rule 59C-1.008(1)(g), F.A.C.
[47] S. 408.039(3)(a), F.S.
[48] Id.
[49] S. 408.039(4)(b), F.S.
[50] S. 408.039(4)(c), F.S.
[51] S. 408.039(4)(d), F.S.
[52] S. 408.038, F.S.
[53] Id.
[54] S. 408.036(4), F.S., and Rule 59C-1.005(2)(g), F.A.C.
[55] S. 408.039(5)(c), F.S.
[56] Id.
[57] S. 408.039(5)(e), F.S.
[58] S. 120.68(1), F.S., a party who is adversely affected by final agency action is entitled to judicial review. A preliminary, procedural, or intermediate order of the agency or of an administrative law judge of the Division of Administrative Hearings is immediately reviewable if review of the final agency decision would not provide an adequate remedy.
[59] S. 408.039(6), F.S.
[60] Ch. 2000-256, Laws of Fla.
[61] AHCA, Current Status of Certificate of Need, Effects of Deregulation, October 20, 2015, available at http://healthandhospitalcommission.com/Meetings.shtml (last viewed January 15, 2016).



In 2007, CON review was eliminated for adult cardiac catheterization and adult open heart surgery services.[62] Since the elimination of CON review for adult cardiovascular services, the number of hospitals with a Level I[63] adult cardiovascular services license has doubled while the number of hospitals with a Level II adult cardiovascular services license has only marginally increased.[64]



In 2014, the moratorium on the granting of CONs for additional community nursing home beds was repealed.[65] In addition to the repeal, the legislature imposed limitations on the issuance of CONs for community nursing home beds to limit the growth through July 1, 2017. AHCA may not approve a CON application for new community nursing home beds following the batching cycle in which the cumulative number of new community nursing home beds approved from July 1, 2014, to June 30, 2017, equals or exceeds 3,750.[66] As of October, 2015, 3,373 nursing home beds have been approved since the moratorium has been lifted.[67]

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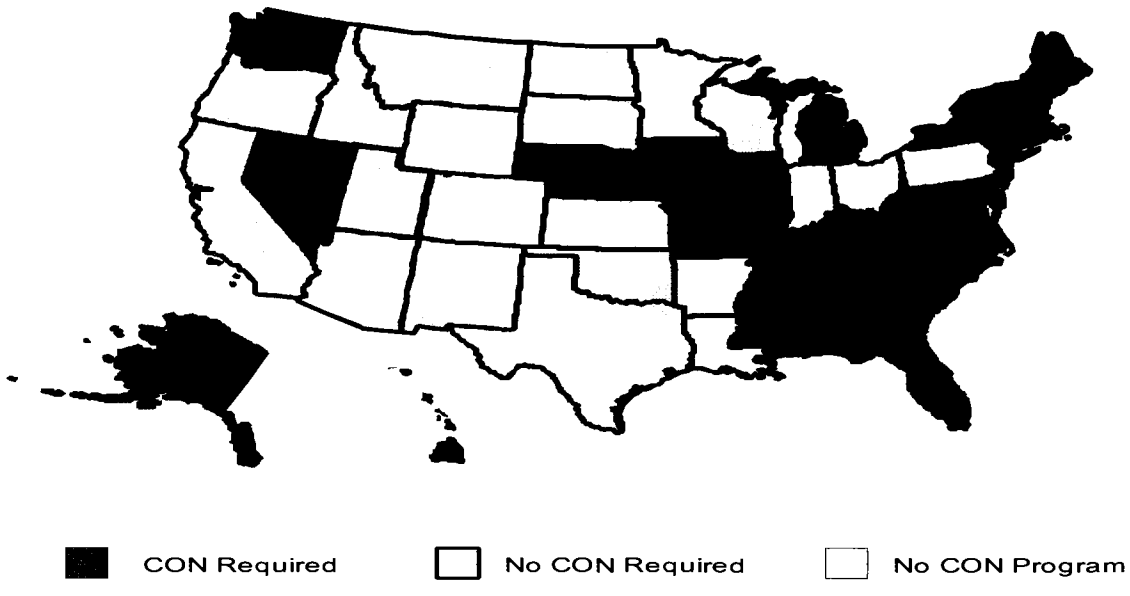
[62] Ch. 2007-214, Laws of Fla.
[63] S. 408.0361, F.S., requires AHCA to adopt rules for the establishment of two hospital program licensure levels: a Level I program authorizing the performance of adult percutaneous cardiac intervention without onsite cardiac surgery and a Level II program authorizing the performance of percutaneous cardiac intervention with onsite cardiac surgery. Rule 59A-3.2085(16) and (17), F.A.C., provides the licensure requirements for Level I and Level II adult cardiovascular services licensure.
[64] Supra, FN 62 at pg. 7.
[65] Ch. 2014-110, Laws of Fla.
[66] S. 408.0436, F.S.
[67] AHCA, Nursing Home Licensure and Regulation, Presentation to the Health Innovation Subcommittee, October 6, 2015, (on file with Select Committee on Affordable Healthcare Access staff).

	Oct. 2014[69]	April 2015[70]	Expedited Reviews	Exemptions	Total
Bed Need Published	3,115	657			3,772
Notices of Intent Filed	179	28			207
Applications Submitted	87	19			106
Approved Beds	2,447	381	240	305	3,373
Denied Beds	5,827	519			6,346
New Facilities	22	2	2		26
Additions to Existing Facilities	12	8			20

CON Nationwide

Fourteen states do not have CON requirements for any type of health care facility or service.[71] Eight additional states have CON laws for other facilities and services, but do not have CON requirements relating specifically to the addition of hospital beds.[72]

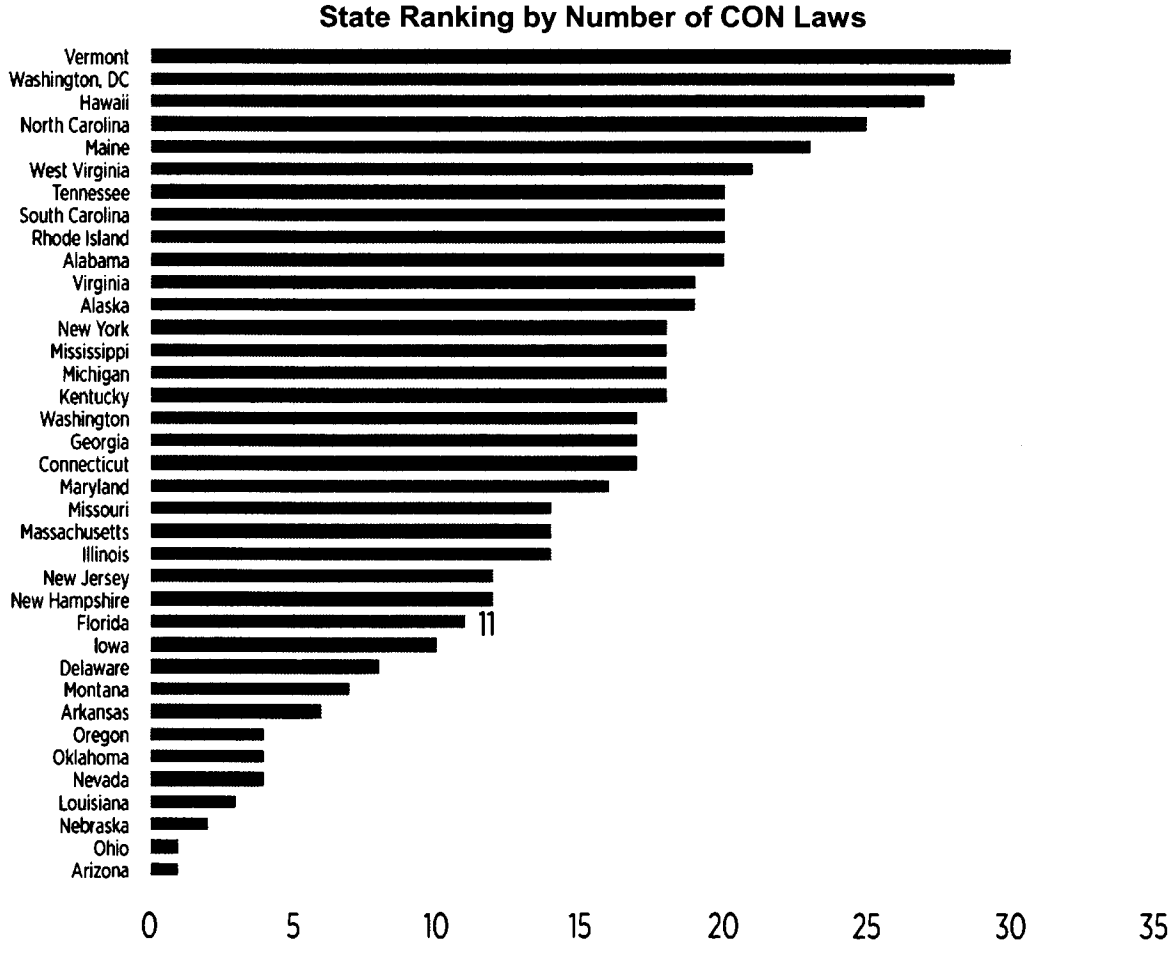


[68] Id.
[69] The decision date for this batching cycle was February 20, 2015.
[70] The decision date for this batching cycle was August 21, 2015.
[71] National Conference of State Legislators, Certificate of Need: State Laws and Programs, available at http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx (last viewed January 15, 2016).
[72] Id.

The states that have repealed their CON program, and the dates of repeal, are:

- Arizona (1985 – still retains CON requirements for ambulance service providers);
- California (1987);
- Idaho (1983);
- Indiana (1996);
- Kansas (1985);
- Minnesota (1985);
- New Mexico (1983);
- North Dakota (1995);
- Pennsylvania (1996);
- South Dakota (1988);
- Texas (1985);
- Utah (1984);
- Wisconsin (2011); and
- Wyoming (1989).[73]

On average, states with CON programs regulate 14 different services, devices, and procedures.[74] Florida's CON program currently regulates 11, which is slightly below the national average.[75] Vermont has the most CON laws in place. Arizona has the least number of CON laws.[76]



[73] Id.
[74] Supra, FN 18 at pg. 3.
[75] Id.
[76] Id.

CON Reform in Other States

Georgia

The State Commission on the Efficacy of the Certificate of Need Program recommended that CON be maintained and improved after spending 18 months examining the role of CON. The final Commission report, issued in 2006, recommended that Georgia maintain existing CON regulations for hospital beds, adult open heart surgery, and pediatric cardiac catheterization and open heart surgery.[77] The report did not recommend deregulation of any hospital CON project. The CON program for hospital facilities and services remains intact.

Illinois

In 2006, the Legislature passed a law requiring the Commission (Commission) on Government Forecasting and Accountability to "conduct a comprehensive evaluation of the Illinois Health Facilities Planning Act, including a review of the performance of the Illinois Health Facilities Planning Board, to determine if it is meeting the goals and objectives that were originally intended in the law...".[78] The Commission contracted with The Lewin Group to conduct a study on CON, which found that CONs rarely reduce health care costs and, on occasion, increase cost in some states. The study recommended that, while the traditional arguments for CON are empirically weak, based on the preponderance of hard evidence, the CON program should be allowed to sunset. However, the study cautioned that, given the potential for harm to specific critical elements of the health care system, the Legislature should move forward with an abundance of caution.[79]

In 2008, the Legislature decided to study the issue further and passed legislation to create the Task Force on Health Planning Reform (task force).[80] The task force evaluated the current CON program and recommended changes to the structure and function of both the Health Facilities Planning Board and the Department of Public Health in the review of applications to establish, expand, or modify health facilities and related capital expenditures.[81] The task force recommended that the state maintain the CON process and extend the sunset date.[82] Currently, the CON program is scheduled to sunset on December 31, 2019.

Washington State

In 1999, the Joint Legislative Audit Review Committee contracted with the Health Policy Analysis Program of the University of Washington to conduct a legislatively mandated study of the CON program.[83] The study examined the effects of CON, and its possible repeal, on the cost, quality, and availability health care. The results of the study were based on a literature review, information gathered from service providers and other experts in Washington, and analyses of states where CON has been completely or partially repealed.[84]

The study concluded that CON has not controlled overall health care spending or hospital costs and found conflicting or limited evidence of the effects of CON on the quality and availability of other health care services or of the effects of repealing CON. The study included three policy options for

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[77] Supra, FN 71 at pgs. 62 and 82.
[78] Ill. House Resolution 1497 (2006).
[79] The Lewin Group, An Evaluation of Illinois' Certificate of Need Program, Prepared for the State of Illinois Commission on Government Forecasting and Accountability, February 15, 2007, available at http://cgfa.ilga.gov/Upload/LewinGroupEvalCertOfNeed.pdf (last viewed January 15, 2016).
[80] Ill. Senate Bill 244 (PA 95-0005) of the 95th General Assembly, 2008
[81] The Illinois Task Force on Health Planning Reform, Final Report, December 31, 2008.
[82] Id.
[83] State of Washington, Senate Bill 6108, 55th Legislature, 1998 Regular Session.
[84] State of Washington Joint Legislative Audit and Review Committee, Effects of Certificate of Need and its Possible Repeal, Report 99-1, January 8, 1999, available at http://www.leg.wa.gov/JLARC/AuditAndStudyReports/1999/Documents/99-1.pdf (last viewed January 15, 2016).

consideration: reform CON to address its current weaknesses; repeal the program while taking steps to increase monitoring and ensure that relevant goals are being met; or conduct another study to identify more clearly the possible effects of repeal. Washington State decided to keep the CON program.

Virginia

The Virginia General Assembly adopted legislation during the 2015 legislative session requiring the Secretary of Health and Human Resources to convene a workgroup to review the state's Certificate of Public Need (COPN) process.[85]

The workgroup is required to develop specific recommendations for changes to the COPN process to be introduced during the 2016 Session of the General Assembly and any additional changes that may require further study or review.[86] In conducting its review and developing its recommendations, the work group must consider data and information about the current COPN process, the impact of such process, and any data or information about similar processes in other states.[87] A final report with recommendations was provided to the General Assembly on November 23, 2015.[88] The final report recommended repealing CON for lithotripsy, obstetrical services, magnetic source imaging, nuclear medicine imaging services, and replacement of a medical facility within the same primary service area.

In response to a request by the Virginia House of Delegates, the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice (the agencies) submitted a joint statement to the COPN workgroup.[89] The statement explains that the agencies historically have urged states to consider repeal or reform of their CON laws because they can prevent the efficient functioning of health care markets, and thus can harm consumers.[90] As the statement describes, CON laws create barriers to expansion, limit consumer choice, and stifle innovation.[91] Additionally, incumbent providers seeking to thwart or delay entry by new competitors may use CON laws to that end.[92] Finally, the statement asserts that CON laws can deny consumers the benefit of an effective remedy for antitrust violations and can facilitate anticompetitive agreements.[93] For these reasons, the agencies suggested that the workgroup and the General Assembly consider whether Virginia's citizens are well served by its COPN laws and, if not, whether they would benefit from the repeal or retrenchment of those laws.[94]

Currently, both North Carolina and South Carolina are considering legislation to repeal or limit their CON programs.[95]

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[85] SB 1283, Virginia General Assembly, 2015.
[86] 2015 Va. Acts Chapter 541.
[87] Id.
[88] Virginia Certificate of Public Need Workgroup, *Final Report,* available at http://www.vdh.state.va.us/Administration/COPN.htm (last viewed January 15, 2016).
[89] Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice to the Virginia Certificate of Public Need Work Group, October 26, 2015, available at http://www.vdh.state.va.us/Administration/documents/COPN/Federal%20Trade%20Commission%20and%20Department%20of%20Justice.pdf (last viewed January 15, 2016).
[90] Supra, FN 87 at pg. 2.
[91] Id.
[92] Id.
[93] Id.
[94] Supra, FN 87 at pg. 13.
[95] The North Carolina General Assembly is considering two bills to reform their CON program during the 2016 legislative session. Senate Bill 702 proposes to repeal the CON program in its entirety. House Bill 200 proposes to provide exemptions from CON review for diagnostic centers, ambulatory surgical centers, gastrointestinal endoscopy rooms, and psychiatric hospitals. The legislative session begins in April. The South Carolina General Assembly is also considering legislation during the 2016 legislative session to reform the CON program. Currently, South Carolina's CON program requires review for 20 different health care projects and services including hospitals. House Bill 3250 proposes to repeal the CON program effective January 1, 2018, and proposes to reduce CON regulations in the interim by providing several exemptions from CON review. The legislative session begins in January.

Effect of Proposed Changes

The bill eliminates CON review requirements for hospitals and hospital services and makes necessary conforming changes throughout part I of chapter 408, F.S. The bill also removes the CON review requirement for increasing the number of comprehensive rehabilitation beds in a facility that offers comprehensive rehabilitation services. Hospitals will be able to expand the number of beds and the types of services without seeking prior authorization from the state. Similarly, facilities that offer comprehensive rehabilitation services will be able to increase the number of beds to meet demand without first seeking prior authorization from the state.

The bill also makes a conforming change to s. 395.1055, F.S., to ensure that AHCA has rulemaking authority, after the repeal of the CON review requirements for hospitals, to maintain quality requirements for tertiary services that may be offered by a hospital. Current CON rules for tertiary services, such as comprehensive medical rehabilitation, neonatal intensive care services, organ transplantation, and pediatric cardiac catheterization, include quality standards for those programs.[96] The bill deletes the definition of "tertiary health service" in s. 408.032, F.S., to repeal the CON review requirement for a hospital to establish such services. This eliminates authority for CON rules, including quality standards. The conforming change transfers rulemaking authority for the quality standards from the CON law to the hospital licensure law. The change eliminates any implication or interpretation that AHCA loses rulemaking authority to impose and maintain licensure requirements for tertiary health services as a result of the repeal of the CON review requirements for hospitals.

B. SECTION DIRECTORY:

Section 1: Amends s. 408.032, F.S., relating to definitions relating to Health Facility and Services Development Act.
Section 2: Amends s. 408.034, F.S., relating to duties and responsibilities of the agency; rules.
Section 3: Amends s. 408.035, F.S., relating to review criteria.
Section 4: Amends s. 408.036, F.S., relating to projects subject to review; exemptions.
Section 5: Amends s. 408.037, F.S., relating to application content.
Section 6: Amends s. 408.039, F.S, relating to review process.
Section 7: Amends s. 408.043, F.S., relating to special provisions.
Section 8: Amends s. 395.1055, F.S., relating to rules and enforcement.
Section 9: Repeals s. 395.6025, F.S., relating to rural hospital replacement facilities.
Section 10: Amends s. 395.603, F.S., relating to deactivation of general hospital beds; rural hospital impact statement.
Section 11: Amends s. 395.604, F.S., relating to other rural hospital programs.
Section 12: Amends s. 395.605, F.S., relating to emergency care hospitals.
Section 13: Amends s. 408.0361, F.S., relating to cardiovascular services and burn unit licensure.
Section 14: Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

AHCA will experience a reduction in revenue resulting from the loss of CON application and exemption fees for hospital services which may be mitigated by a reduction in workload. Fees

[96] The current CON rules which include quality standards, in addition to the CON market-entry requirements, are 59C-1.039, F.A.C. (comprehensive medical rehabilitation); 59C-1.042, F.A.C. (neonatal intensive care services); 59C-1.044, F.A.C. (organ transplantation); 59C-1.032, F.A.C. (pediatric cardiac catheterization); 59C-1.033, F.A.C. (adult and pediatric open heart surgery programs); and 59A-3.2085(16)-(17), F.A.C. (adult cardiovascular services).

collected in Fiscal Year 2014-2015 resulted in revenue of approximately $450,000.[97] Any decrease in CON application fees will be offset by an approximate 10 percent increase in hospital projects resulting in almost $450,000 in new plans and construction fees.[98]

2. Expenditures:

AHCA will experience increased workload resulting from an increase in hospital licensure applications. The expenditure associated with any increase in workload is indeterminate yet likely insignificant; however, the increased workload will be offset by the reduced workload resulting from the repeal of the CON review process for hospitals.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Hospitals will experience a significant positive fiscal impact resulting from the elimination of CON fees, which range from $10,000 to $50,000.

By removing the CON review program for hospitals, the hospital industry is likely to realize increased competition in services offered by hospitals.

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:

No additional rulemaking authority is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[97] AHCA, Agency Bill Analysis of HB 437, October 26, 2015 (on file with the Select Committee on Affordable Healthcare Access staff).
[98] Id.

A bill to be entitled

An act relating to certificates of need for hospitals; amending s. 408.032, F.S.; revising definitions; amending s. 408.034, F.S.; revising duties and responsibilities of the Agency for Health Care Administration in the exercise of its authority to issue licenses to health care facilities and health service providers; amending s. 408.035, F.S.; revising review criteria for applications for certificate-of-need determinations for health care facilities and health services; excluding general hospitals from such review; amending s. 408.036, F.S.; revising health-care-related projects subject to review for a certificate of need and exemptions therefrom; amending s. 408.037, F.S.; revising content requirements with respect to an application for a certificate of need; amending s. 408.039, F.S.; revising the review process for certificates of need; amending s. 408.043, F.S.; revising special provisions to eliminate provisions relating to osteopathic acute care hospitals; amending s. 395.1055, F.S.; revising the agency's rulemaking authority with respect to minimum standards for hospitals; requiring hospitals that provide certain services to meet specified licensure requirements; deleting requirements for submitting data by hospitals for certificate-of-need reviews, to conform to changes

made by the act; repealing s. 395.6025, F.S., relating to rural hospital replacement facilities; amending ss. 395.603, 395.604, and 395.605, F.S.; conforming references; amending s. 408.0361, F.S.; deleting outdated licensure provisions for cardiovascular services and burn units; providing an effective date.

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

Section 1. Subsections (8) through (17) of section 408.032, Florida Statutes, are amended to read:

408.032 Definitions relating to Health Facility and Services Development Act.—As used in ss. 408.031-408.045, the term:

(8) "Health care facility" means a ~~hospital, long-term care hospital,~~ skilled nursing facility, hospice, or intermediate care facility for the developmentally disabled. A facility relying solely on spiritual means through prayer for healing is not included as a health care facility.

~~(9) "Health services" means inpatient diagnostic, curative, or comprehensive medical rehabilitative services and includes mental health services. Obstetric services are not health services for purposes of ss. 408.031-408.045.~~

(9)~~(10)~~ "Hospice" or "hospice program" means a hospice as defined in part IV of chapter 400.

~~(11) "Hospital" means a health care facility licensed~~

~~under chapter 395.~~

(10) ~~(12)~~ "Intermediate care facility for the developmentally disabled" means a residential facility licensed under part VIII of chapter 400.

~~(13) "Long-term care hospital" means a hospital licensed under chapter 395 which meets the requirements of 42 C.F.R. s. 412.23(e) and seeks exclusion from the acute care Medicare prospective payment system for inpatient hospital services.~~

~~(14) "Mental health services" means inpatient services provided in a hospital licensed under chapter 395 and listed on the hospital license as psychiatric beds for adults; psychiatric beds for children and adolescents; intensive residential treatment beds for children and adolescents; substance abuse beds for adults; or substance abuse beds for children and adolescents.~~

(11) ~~(15)~~ "Nursing home geographically underserved area" means:

(a) A county in which there is no existing or approved nursing home;

(b) An area with a radius of at least 20 miles in which there is no existing or approved nursing home; or

(c) An area with a radius of at least 20 miles in which all existing nursing homes have maintained at least a 95 percent occupancy rate for the most recent 6 months or a 90 percent occupancy rate for the most recent 12 months.

(12) ~~(16)~~ "Skilled nursing facility" means 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.

~~(17) "Tertiary health service" means a health service which, due to its high level of intensity, complexity, specialized or limited applicability, and cost, should be limited to, and concentrated in, a limited number of hospitals to ensure the quality, availability, and cost-effectiveness of such service. Examples of such service include, but are not limited to, pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care units, comprehensive rehabilitation, and medical or surgical services which are experimental or developmental in nature to the extent that the provision of such services is not yet contemplated within the commonly accepted course of diagnosis or treatment for the condition addressed by a given service. The agency shall establish by rule a list of all tertiary health services.~~

Section 2. Subsection (2) of section 408.034, Florida Statutes, is amended to read:

408.034 Duties and responsibilities of agency; rules.—

(2) In the exercise of its authority to issue licenses to health care facilities and health service providers, as provided under chapter ~~chapters~~ 393 ~~and 395~~ and parts II, IV, and VIII of

chapter 400, the agency may not issue a license to any health care facility or health service provider that fails to receive a certificate of need or an exemption for the licensed facility or service.

Section 3. Section 408.035, Florida Statutes, is amended to read:

408.035 Review criteria.—

~~(1)~~ The agency shall determine the reviewability of applications and shall review applications for certificate-of-need determinations for health care facilities and health services in context with the following criteria~~, except for general hospitals as defined in s. 395.002~~:

(1)~~(a)~~ The need for the health care facilities and health services being proposed.

(2)~~(b)~~ 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.

(3)~~(c)~~ The ability of the applicant to provide quality of care and the applicant's record of providing quality of care.

(4)~~(d)~~ The availability of resources, including health personnel, management personnel, and funds for capital and operating expenditures, for project accomplishment and operation.

(5)~~(e)~~ The extent to which the proposed services will enhance access to health care for residents of the service district.

(6) ~~(f)~~ The immediate and long-term financial feasibility of the proposal.

(7) ~~(g)~~ The extent to which the proposal will foster competition that promotes quality and cost-effectiveness.

(8) ~~(h)~~ 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.

(9) ~~(i)~~ The applicant's past and proposed provision of health care services to Medicaid patients and the medically indigent.

(10) ~~(j)~~ The applicant's designation as a Gold Seal Program nursing facility pursuant to s. 400.235, when the applicant is requesting additional nursing home beds at that facility.

~~(2) For a general hospital, the agency shall consider only the criteria specified in paragraph (1)(a), paragraph (1)(b), except for quality of care in paragraph (1)(b), and paragraphs (1)(e), (g), and (i).~~

Section 4. Section 408.036, Florida Statutes, is amended to read:

408.036 Projects subject to review; exemptions.—

(1) APPLICABILITY.—Unless exempt under subsection (3), all health-care-related projects, as described in this subsection ~~paragraphs (a)-(f)~~, are subject to review and must file an application for a certificate of need with the agency. The agency is exclusively responsible for determining whether a

health-care-related project is subject to review under ss. 408.031-408.045.

(a) The addition of beds in community nursing homes or intermediate care facilities for the developmentally disabled by new construction or alteration.

(b) The new construction or establishment of additional health care facilities, including a replacement health care facility when the proposed project site is not located on the same site as or within 1 mile of the existing health care facility, if the number of beds in each licensed bed category will not increase.

(c) The conversion from one type of health care facility to another~~, including the conversion from a general hospital, a specialty hospital, or a long-term care hospital~~.

(d) The establishment of a hospice or hospice inpatient facility, except as provided in s. 408.043.

~~(e) An increase in the number of beds for comprehensive rehabilitation.~~

~~(f) The establishment of tertiary health services, including inpatient comprehensive rehabilitation services.~~

(2) PROJECTS SUBJECT TO EXPEDITED REVIEW.—Unless exempt pursuant to subsection (3), the following projects are subject to expedited review:

(a) Transfer of a certificate of need~~, except that when an existing hospital is acquired by a purchaser, all certificates of need issued to the hospital which are not yet operational~~

~~shall be acquired by the purchaser without need for a transfer~~.

(b) Replacement of a nursing home, if the proposed project site is within a 30-mile radius of the replaced nursing home. If the proposed project site is outside the subdistrict where the replaced nursing home is located, the prior 6-month occupancy rate for licensed community nursing homes in the proposed subdistrict must be at least 85 percent in accordance with the agency's most recently published inventory.

(c) Replacement of a nursing home within the same district, if the proposed project site is outside a 30-mile radius of the replaced nursing home but within the same subdistrict or a geographically contiguous subdistrict. If the proposed project site is in the geographically contiguous subdistrict, the prior 6-month occupancy rate for licensed community nursing homes for that subdistrict must be at least 85 percent in accordance with the agency's most recently published inventory.

(d) Relocation of a portion of a nursing home's licensed beds to another facility or to establish a new facility within the same district or within a geographically contiguous district, if the relocation is within a 30-mile radius of the existing facility and the total number of nursing home beds in the state does not increase.

(e) New construction of a community nursing home in a retirement community as further provided in this paragraph.

1. Expedited review under this paragraph is available if

all of the following criteria are met:

a. The residential use area of the retirement community is deed-restricted as housing for older persons as defined in s. 760.29(4)(b).

b. The retirement community is located in a county in which 25 percent or more of its population is age 65 and older.

c. The retirement community is located in a county that has a rate of no more than 16.1 beds per 1,000 persons age 65 years or older. The rate shall be determined by using the current number of licensed and approved community nursing home beds in the county per the agency's most recent published inventory.

d. The retirement community has a population of at least 8,000 residents within the county, based on a population data source accepted by the agency.

e. The number of proposed community nursing home beds in an application does not exceed the projected bed need after applying the rate of 16.1 beds per 1,000 persons aged 65 years and older projected for the county 3 years into the future using the estimates adopted by the agency reduced by the agency's most recently published inventory of licensed and approved community nursing home beds in the county.

2. No more than 120 community nursing home beds shall be approved for a qualified retirement community under each request for expedited review. Subsequent requests for expedited review under this process may not be made until 2 years after

construction of the facility has commenced or 1 year after the beds approved through the initial request are licensed, whichever occurs first.

3. The total number of community nursing home beds which may be approved for any single deed-restricted community pursuant to this paragraph may not exceed 240, regardless of whether the retirement community is located in more than one qualifying county.

4. Each nursing home facility approved under this paragraph must be dually certified for participation in the Medicare and Medicaid programs.

5. Each nursing home facility approved under this paragraph must be at least 1 mile, as measured over publicly owned roadways, from an existing approved and licensed community nursing home.

6. A retirement community requesting expedited review under this paragraph shall submit a written request to the agency for expedited review. The request must include the number of beds to be added and provide evidence of compliance with the criteria specified in subparagraph 1.

7. After verifying that the retirement community meets the criteria for expedited review specified in subparagraph 1., the agency shall publicly notice in the Florida Administrative Register that a request for an expedited review has been submitted by a qualifying retirement community and that the qualifying retirement community intends to make land available

for the construction and operation of a community nursing home. The agency's notice must identify 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 requirements established by the retirement community. The agency notice must also specify the deadline for submission of the certificate-of-need application, which may not be earlier than the 91st day or later than the 125th day after the date the notice appears in the Florida Administrative Register.

8. The qualified retirement community shall make land available to applicants it deems to have met its requirements for the construction and operation of a community nursing home but may sell or lease the land only to the applicant that is issued a certificate of need by the agency under this paragraph.

a. A certificate-of-need application submitted under this paragraph must identify the intended site for the project within the retirement community and the anticipated costs for the project based on that site. The application must also include written evidence that the retirement community has determined that both the provider submitting the application and the project satisfy its requirements for the project.

b. If the retirement community determines that more than one provider satisfies its requirements for the project, it may notify the agency of the provider it prefers.

9. The agency shall review each submitted application. If

multiple applications are submitted for a project published pursuant to subparagraph 7., the agency shall review the competing applications.

The agency shall develop rules to implement the expedited review process, including time schedule, application content that may be reduced from the full requirements of s. 408.037(1), and application processing.

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

(a) For hospice services ~~or for swing beds in a rural hospital, as defined in s. 395.602, in a number that does not exceed one-half of its licensed beds~~.

~~(b) For the conversion of licensed acute care hospital beds to Medicare and Medicaid certified skilled nursing beds in a rural hospital, as defined in s. 395.602, so long as the conversion of the beds does not involve the construction of new facilities. The total number of skilled nursing beds, including swing beds, may not exceed one-half of the total number of licensed beds in the rural hospital as of July 1, 1993. Certified skilled nursing beds designated under this paragraph, excluding swing beds, shall be included in the community nursing home bed inventory. A rural hospital that subsequently decertifies any acute care beds exempted under this paragraph shall notify the agency of the decertification, and the agency shall adjust the community nursing home bed inventory~~

~~accordingly.~~

(b) ~~(e)~~ For the addition of nursing home beds at a skilled nursing facility that is part of a retirement community that provides a variety of residential settings and supportive services and that has been incorporated and operated in this state for at least 65 years on or before July 1, 1994. All nursing home beds must not be available to the public but must be for the exclusive use of the community residents.

(c) ~~(d)~~ For an inmate health care facility built by or for the exclusive use of the Department of Corrections as provided in chapter 945. This exemption expires when such facility is converted to other uses.

(d) ~~(e)~~ For mobile surgical facilities and related health care services provided under contract with the Department of Corrections or a private correctional facility operating pursuant to chapter 957.

(e) ~~(f)~~ For the addition of nursing home beds licensed under chapter 400 in a number not exceeding 30 total beds or 25 percent of the number of beds licensed in the facility being replaced under paragraph (2)(b), paragraph (2)(c), or paragraph (j) ~~(p)~~, whichever is less.

(f) ~~(g)~~ For state veterans' nursing homes operated by or on behalf of the Florida Department of Veterans' Affairs in accordance with part II of chapter 296 for which at least 50 percent of the construction cost is federally funded and for which the Federal Government pays a per diem rate not to exceed

one-half of the cost of the veterans' care in such state nursing homes. These beds shall not be included in the nursing home bed inventory.

(g) ~~(h)~~ For combination within one nursing home facility of the beds or services authorized by two or more certificates of need issued in the same planning subdistrict. An exemption granted under this paragraph shall extend the validity period of the certificates of need to be consolidated by the length of the period beginning upon submission of the exemption request and ending with issuance of the exemption. The longest validity period among the certificates shall be applicable to each of the combined certificates.

(h) ~~(i)~~ For division into two or more nursing home facilities of beds or services authorized by one certificate of need issued in the same planning subdistrict. An exemption granted under this paragraph shall extend the validity period of the certificate of need to be divided by the length of the period beginning upon submission of the exemption request and ending with issuance of the exemption.

~~(j) For the addition of hospital beds licensed under chapter 395 for comprehensive rehabilitation in a number that may not exceed 10 total beds or 10 percent of the licensed capacity, whichever is greater.~~

~~1. In addition to any other documentation otherwise required by the agency, a request for exemption submitted under this paragraph must:~~

~~a. Certify that the prior 12-month average occupancy rate for the licensed beds being expanded meets or exceeds 80 percent.~~

~~b. Certify that the beds have been licensed and operational for at least 12 months.~~

~~2. The timeframes and monitoring process specified in s. 408.040(2)(a)-(c) apply to any exemption issued under this paragraph.~~

~~3. The agency shall count beds authorized under this paragraph as approved beds in the published inventory of hospital beds until the beds are licensed.~~

(i) ~~(k)~~ For the addition of nursing home beds licensed under chapter 400 in a number not exceeding 10 total beds or 10 percent of the number of beds licensed in the facility being expanded, whichever is greater; or, for the addition of nursing home beds licensed under chapter 400 at a facility that has been designated as a Gold Seal nursing home under s. 400.235 in a number not exceeding 20 total beds or 10 percent of the number of licensed beds in the facility being expanded, whichever is greater.

1. In addition to any other documentation required by the agency, a request for exemption submitted under this paragraph must certify that:

a. The facility has not had any class I or class II deficiencies within the 30 months preceding the request.

b. The prior 12-month average occupancy rate for the

nursing home beds at the facility meets or exceeds 94 percent.

c. Any beds authorized for the facility under this paragraph before the date of the current request for an exemption have been licensed and operational for at least 12 months.

2. The timeframes and monitoring process specified in s. 408.040(2)(a)-(c) apply to any exemption issued under this paragraph.

3. The agency shall count beds authorized under this paragraph as approved beds in the published inventory of nursing home beds until the beds are licensed.

~~(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 verified trauma center pursuant to s. 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.~~

~~(m)1. For the provision of adult open-heart services in a hospital located within the boundaries of a health service planning district, as defined in s. 408.032(5), which has experienced an annual net out-migration of at least 600 open-heart-surgery cases for 3 consecutive years according to the most recent data reported to the agency, and the district's population per licensed and operational open-heart programs exceeds the state average of population per licensed and operational open-heart programs by at least 25 percent. All hospitals within a health service planning district which meet the criteria reference in sub-subparagraphs 2.a.-h. shall be eligible for this exemption on July 1, 2004, and shall receive the exemption upon filing for it and subject to the following:~~

~~a. A hospital that has received a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for the establishment of an open-heart-surgery program is entitled to receive a letter of exemption for the establishment of an adult open-heart-surgery~~

~~program upon filing a request for exemption and complying with the criteria enumerated in sub-subparagraphs 2.a.-h., and is entitled to immediately commence operation of the program.~~

~~b. An otherwise eligible hospital that has not received a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for the establishment of an open-heart-surgery program is entitled to immediately receive a letter of exemption for the establishment of an adult open-heart-surgery program upon filing a request for exemption and complying with the criteria enumerated in sub-subparagraphs 2.a.-h., but is not entitled to commence operation of its program until December 31, 2006.~~

~~2. A hospital shall be exempt from the certificate-of-need review for the establishment of an open-heart-surgery program when the application for exemption submitted under this paragraph complies with the following criteria:~~

~~a. The applicant must certify that it will meet and continuously maintain the minimum licensure requirements adopted by the agency governing adult open-heart programs, including the most current guidelines of the American College of Cardiology and American Heart Association Guidelines for Adult Open Heart Programs.~~

~~b. The applicant must certify that it will maintain sufficient appropriate equipment and health personnel to ensure quality and safety.~~

~~c. The applicant must certify that it will maintain~~

~~appropriate times of operation and protocols to ensure availability and appropriate referrals in the event of emergencies.~~

~~d. The applicant can demonstrate that it has discharged at least 300 inpatients with a principal diagnosis of ischemic heart disease for the most recent 12-month period as reported to the agency.~~

~~e. The applicant is a general acute care hospital that is in operation for 3 years or more.~~

~~f. The applicant is performing more than 300 diagnostic cardiac catheterization procedures per year, combined inpatient and outpatient.~~

~~g. The applicant's payor mix at a minimum reflects the community average for Medicaid, charity care, and self-pay patients or the applicant must certify that it will provide a minimum of 5 percent of Medicaid, charity care, and self-pay to open-heart-surgery patients.~~

~~h. If the applicant fails to meet the established criteria for open-heart programs or fails to reach 300 surgeries per year by the end of its third year of operation, it must show cause why its exemption should not be revoked.~~

~~3. By December 31, 2004, and annually thereafter, the agency shall submit a report to the Legislature providing information concerning the number of requests for exemption it has received under this paragraph during the calendar year and the number of exemptions it has granted or denied during the~~

~~calendar year.~~

~~(n) For the provision of percutaneous coronary intervention for patients presenting with emergency myocardial infarctions in a hospital without an approved adult open-heart surgery program. In addition to any other documentation required by the agency, a request for an exemption submitted under this paragraph must comply with the following:~~

~~1. The applicant must certify that it will meet and continuously maintain the requirements adopted by the agency for the provision of these services. These licensure requirements shall be adopted by rule and must be consistent with the guidelines published by the American College of Cardiology and the American Heart Association for the provision of percutaneous coronary interventions in hospitals without adult open-heart services. At a minimum, the rules must require the following:~~

~~a. Cardiologists must be experienced interventionalists who have performed a minimum of 75 interventions within the previous 12 months.~~

~~b. The hospital must provide a minimum of 36 emergency interventions annually in order to continue to provide the service.~~

~~c. The hospital must offer sufficient physician, nursing, and laboratory staff to provide the services 24 hours a day, 7 days a week.~~

~~d. Nursing and technical staff must have demonstrated experience in handling acutely ill patients requiring~~

~~intervention based on previous experience in dedicated interventional laboratories or surgical centers.~~

~~e. Cardiac care nursing staff must be adept in hemodynamic monitoring and Intra-aortic Balloon Pump (IABP) management.~~

~~f. Formalized written transfer agreements must be developed with a hospital with an adult open-heart-surgery program, and written transport protocols must be in place to ensure safe and efficient transfer of a patient within 60 minutes. Transfer and transport agreements must be reviewed and tested, with appropriate documentation maintained at least every 3 months. However, a hospital located more than 100 road miles from the closest Level II adult cardiovascular services program does not need to meet the 60-minute transfer time protocol if the hospital demonstrates that it has a formalized, written transfer agreement with a hospital that has a Level II program. The agreement must include written transport protocols that ensure the safe and efficient transfer of a patient, taking into consideration the patient's clinical and physical characteristics, road and weather conditions, and viability of ground and air ambulance service to transfer the patient.~~

~~g. Hospitals implementing the service must first undertake a training program of 3 to 6 months' duration, which includes establishing standards and testing logistics, creating quality assessment and error management practices, and formalizing patient-selection criteria.~~

~~2. The applicant must certify that it will use at all~~

~~times the patient-selection criteria for the performance of primary angioplasty at hospitals without adult open-heart-surgery programs issued by the American College of Cardiology and the American Heart Association. At a minimum, these criteria would provide for the following:~~

~~a. Avoidance of interventions in hemodynamically stable patients who have identified symptoms or medical histories.~~

~~b. Transfer of patients who have a history of coronary disease and clinical presentation of hemodynamic instability.~~

~~3. The applicant must agree to submit a quarterly report to the agency detailing patient characteristics, treatment, and outcomes for all patients receiving emergency percutaneous coronary interventions pursuant to this paragraph. This report must be submitted within 15 days after the close of each calendar quarter.~~

~~4. The exemption provided by this paragraph does not apply unless the agency determines that the hospital has taken all necessary steps to be in compliance with all requirements of this paragraph, including the training program required under sub-subparagraph 1.g.~~

~~5. Failure of the hospital to continuously comply with the requirements of sub-subparagraphs 1.c.-f. and subparagraphs 2. and 3. will result in the immediate expiration of this exemption.~~

~~6. Failure of the hospital to meet the volume requirements of sub-subparagraphs 1.a. and b. within 18 months after the~~

~~program begins offering the service will result in the immediate expiration of the exemption.~~

~~If the exemption for this service expires under subparagraph 5. or subparagraph 6., the agency may not grant another exemption for this service to the same hospital for 2 years and then only upon a showing that the hospital will remain in compliance with the requirements of this paragraph through a demonstration of corrections to the deficiencies that caused expiration of the exemption. Compliance with the requirements of this paragraph includes compliance with the rules adopted pursuant to this paragraph.~~

~~(o) For the addition of mental health services or beds if the applicant commits to providing services to Medicaid or charity care patients at a level equal to or greater than the district average. Such a commitment is subject to s. 408.040.~~

(j) ~~(p)~~ For replacement of a licensed nursing home on the same site, or within 5 miles of the same site if within the same subdistrict, if the number of licensed beds does not increase except as permitted under paragraph (e) ~~(f)~~.

(k) ~~(q)~~ For consolidation or combination of licensed nursing homes or transfer of beds between licensed nursing homes within the same planning district, by nursing homes with any shared controlled interest within that planning district, if there is no increase in the planning district total number of nursing home beds and the site of the relocation is not more

than 30 miles from the original location.

(l) ~~(r)~~ For beds in state mental health treatment facilities defined in s. 394.455 and state mental health forensic facilities operated under chapter 916.

(m) ~~(s)~~ For beds in state developmental disabilities centers as defined in s. 393.063.

(n) ~~(t)~~ For the establishment of a health care facility or project that meets all of the following criteria:

1. The applicant was previously licensed within the past 21 days as a health care facility or provider that is subject to subsection (1).

2. The applicant failed to submit a renewal application and the license expired on or after January 1, 2015.

3. The applicant does not have a license denial or revocation action pending with the agency at the time of the request.

4. The applicant's request is for the same service type, district, service area, and site for which the applicant was previously licensed.

5. The applicant's request, if applicable, includes the same number and type of beds as were previously licensed.

6. The applicant agrees to the same conditions that were previously imposed on the certificate of need or on an exemption related to the applicant's previously licensed health care facility or project.

7. The applicant applies for initial licensure as required

under s. 408.806 within 21 days after the agency approves the exemption request. If the applicant fails to apply in a timely manner, the exemption expires on the 22nd day following the agency's approval of the exemption.

Notwithstanding subparagraph 1., an applicant whose license expired between January 1, 2015, and the effective date of this act may apply for an exemption within 30 days of this act becoming law.

(4) REQUESTS FOR EXEMPTION.—A request for exemption under subsection (3) may be made at any time and is not subject to the batching requirements of this section. The request shall be supported by such documentation as the agency requires by rule. The agency shall assess a fee of $250 for each request for exemption submitted under subsection (3).

(5) NOTIFICATION.—Health care facilities and providers must provide to the agency notification of~~:~~

~~(a)~~ replacement of a health care facility when the proposed project site is located in the same district and on the existing site or within a 1-mile radius of the replaced health care facility, if the number and type of beds do not increase.

~~(b) The termination of a health care service, upon 30 days' written notice to the agency.~~

~~(c) The addition or delicensure of beds.~~

Notification under this subsection may be made by electronic,

facsimile, or written means at any time before the described action has been taken.

Section 5. Section 408.037, Florida Statutes, is amended to read:

408.037 Application content.—

(1) ~~Except as provided in subsection (2) for a general hospital,~~ An application for a certificate of need must contain:

(a) A detailed description of the proposed project and statement of its purpose and need in relation to the district health plan.

(b) A statement of the financial resources needed by and available to the applicant to accomplish the proposed project. This statement must include:

1. A complete listing of all capital projects, including new health facility development projects and health facility acquisitions applied for, pending, approved, or underway in any state at the time of application, regardless of whether or not that state has a certificate-of-need program or a capital expenditure review program pursuant to s. 1122 of the Social Security Act. The agency may, by rule, require less-detailed information from major health care providers. This listing must include the applicant's actual or proposed financial commitment to those projects and an assessment of their impact on the applicant's ability to provide the proposed project.

2. A detailed listing of the needed capital expenditures, including sources of funds.

3. A detailed financial projection, including a statement of the projected revenue and expenses for the first 2 years of operation after completion of the proposed project. This statement must include a detailed evaluation of the impact of the proposed project on the cost of other services provided by the applicant.

(c) An audited financial statement of the applicant or the applicant's parent corporation if audited financial statements of the applicant do not exist. In an application submitted by an existing health care facility, health maintenance organization, or hospice, financial condition documentation must include, but need not be limited to, a balance sheet and a profit-and-loss statement of the 2 previous fiscal years' operation.

~~(2) An application for a certificate of need for a general hospital must contain a detailed description of the proposed general hospital project and a statement of its purpose and the needs it will meet. The proposed project's location, as well as its primary and secondary service areas, must be identified by zip code. Primary service area is defined as the zip codes from which the applicant projects that it will draw 75 percent of its discharges. Secondary service area is defined as the zip codes from which the applicant projects that it will draw its remaining discharges. If, subsequent to issuance of a final order approving the certificate of need, the proposed location of the general hospital changes or the primary service area materially changes, the agency shall revoke the certificate of~~

~~need. However, if the agency determines that such changes are deemed to enhance access to hospital services in the service district, the agency may permit such changes to occur. A party participating in the administrative hearing regarding the issuance of the certificate of need for a general hospital has standing to participate in any subsequent proceeding regarding the revocation of the certificate of need for a hospital for which the location has changed or for which the primary service area has materially changed. In addition, the application for the certificate of need for a general hospital must include a statement of intent that, if approved by final order of the agency, the applicant shall within 120 days after issuance of the final order or, if there is an appeal of the final order, within 120 days after the issuance of the court's mandate on appeal, furnish satisfactory proof of the applicant's financial ability to operate. The agency shall establish documentation requirements, to be completed by each applicant, which show anticipated provider revenues and expenditures, the basis for financing the anticipated cash-flow requirements of the provider, and an applicant's access to contingency financing. A party participating in the administrative hearing regarding the issuance of the certificate of need for a general hospital may provide written comments concerning the adequacy of the financial information provided, but such party does not have standing to participate in an administrative proceeding regarding proof of the applicant's financial ability to operate.~~

~~The agency may require a licensee to provide proof of financial ability to operate at any time if there is evidence of financial instability, including, but not limited to, unpaid expenses necessary for the basic operations of the provider.~~

(2)~~(3)~~ The applicant must certify that it will license and operate the health care facility. For an existing health care facility, the applicant must be the licenseholder of the facility.

Section 6. Paragraphs (c) and (d) of subsection (3), paragraphs (b) and (c) of subsection (5), and paragraph (d) of subsection (6) of section 408.039, Florida Statutes, are amended to read:

408.039 Review process.—The review process for certificates of need shall be as follows:

(3) APPLICATION PROCESSING.—

~~(c) Except for competing applicants, in order to be eligible to challenge the agency decision on a general hospital application under review pursuant to paragraph (5)(c), existing hospitals must submit a detailed written statement of opposition to the agency and to the applicant. The detailed written statement must be received by the agency and the applicant within 21 days after the general hospital application is deemed complete and made available to the public.~~

~~(d) In those cases where a written statement of opposition has been timely filed regarding a certificate of need application for a general hospital, the applicant for the~~

~~general hospital may submit a written response to the agency. Such response must be received by the agency within 10 days of the written statement due date.~~

(5) ADMINISTRATIVE HEARINGS.—

(b) Hearings shall be held in Tallahassee unless the administrative law judge determines that changing the location will facilitate the proceedings. The agency shall assign proceedings requiring hearings to the Division of Administrative Hearings of the Department of Management Services within 10 days after the time has expired for requesting a hearing. Except upon unanimous consent of the parties or upon the granting by the administrative law judge of a motion of continuance, hearings shall commence within 60 days after the administrative law judge has been assigned. ~~For an application for a general hospital, administrative hearings shall commence within 6 months after the administrative law judge has been assigned, and a continuance may not be granted absent a finding of extraordinary circumstances by the administrative law judge.~~ All parties, except the agency, shall bear their own expense of preparing a transcript. In any application for a certificate of need which is referred to the Division of Administrative Hearings for hearing, the administrative law judge shall complete and submit to the parties a recommended order as provided in ss. 120.569 and 120.57. The recommended order shall be issued within 30 days after the receipt of the proposed recommended orders or the deadline for submission of such proposed recommended orders,

whichever is earlier. The division shall adopt procedures for administrative hearings which shall maximize the use of stipulated facts and shall provide for the admission of prepared testimony.

(c) In administrative proceedings challenging the issuance or denial of a certificate of need, only applicants considered by the agency in the same batching cycle are entitled to a comparative hearing on their applications. Existing health care facilities may initiate or intervene in an administrative hearing upon a showing that an established program will be substantially affected by the issuance of any certificate of need, whether reviewed under s. 408.036(1) or (2), to a competing proposed facility or program within the same district. ~~With respect to an application for a general hospital, competing applicants and only those existing hospitals that submitted a detailed written statement of opposition to an application as provided in this paragraph may initiate or intervene in an administrative hearing. Such challenges to a general hospital application shall be limited in scope to the issues raised in the detailed written statement of opposition that was provided to the agency. The administrative law judge may, upon a motion showing good cause, expand the scope of the issues to be heard at the hearing. Such motion shall include substantial and detailed facts and reasons for failure to include such issues in the original written statement of opposition.~~

(6) JUDICIAL REVIEW.—

~~(d) The party appealing a final order that grants a general hospital certificate of need shall pay the appellee's attorney's fees and costs, in an amount up to $1 million, from the beginning of the original administrative action if the appealing party loses the appeal, subject to the following limitations and requirements:~~

~~1. The party appealing a final order must post a bond in the amount of $1 million in order to maintain the appeal.~~

~~2. Except as provided under s. 120.595(5), in no event shall the agency be held liable for any other party's attorney's fees or costs.~~

Section 7. Subsection (1) of section 408.043, Florida Statutes, is amended to read:

408.043 Special provisions.—

~~(1) OSTEOPATHIC ACUTE CARE HOSPITALS. When an application is made for a certificate of need to construct or to expand an osteopathic acute care hospital, the need for such hospital shall be determined on the basis of the need for and availability of osteopathic services and osteopathic acute care hospitals in the district. When a prior certificate of need to establish an osteopathic acute care hospital has been issued in a district, and the facility is no longer used for that purpose, the agency may continue to count such facility and beds as an existing osteopathic facility in any subsequent application for construction of an osteopathic acute care hospital.~~

Section 8. Paragraph (f) of subsection (1) of section

395.1055, Florida Statutes, is amended to read:

395.1055 Rules and enforcement.—

(1) The agency shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this part, which shall include reasonable and fair minimum standards for ensuring that:

(f) All hospitals providing pediatric cardiac catheterization, pediatric open-heart surgery, organ transplantation, neonatal intensive care services, psychiatric services, or comprehensive medical rehabilitation meet the minimum licensure requirements adopted by the agency. Such licensure requirements shall include quality of care, nurse staffing, physician staffing, physical plant, equipment, emergency transportation, and data reporting standards ~~submit such data as necessary to conduct certificate-of-need reviews required under part I of chapter 408. Such data shall include, but shall not be limited to, patient origin data, hospital utilization data, type of service reporting, and facility staffing data. The agency may not collect data that identifies or could disclose the identity of individual patients. The agency shall utilize existing uniform statewide data sources when available and shall minimize reporting costs to hospitals~~.

Section 9. Section 395.6025, Florida Statutes, is repealed.

Section 10. Subsection (1) of section 395.603, Florida Statutes, is amended to read:

395.603 Deactivation of general hospital beds; rural hospital impact statement.—

(1) The agency shall establish, by rule, a process by which a rural hospital, as defined in s. 395.602, that seeks licensure as a rural primary care hospital or as an emergency care hospital, or becomes a certified rural health clinic as defined in Pub. L. No. 95-210, or becomes a primary care program such as a county health department, community health center, or other similar outpatient program that provides preventive and curative services, may deactivate general hospital beds. Rural primary care hospitals and emergency care hospitals shall maintain the number of actively licensed general hospital beds necessary for the facility to be certified for Medicare reimbursement. Hospitals that discontinue inpatient care to become rural health care clinics or primary care programs shall deactivate all licensed general hospital beds. All hospitals, clinics, and programs with inactive beds shall provide 24-hour emergency medical care by staffing an emergency room. Providers with inactive beds shall be subject to the criteria in s. 395.1041. The agency shall specify in rule requirements for making 24-hour emergency care available. ~~Inactive general hospital beds shall be included in the acute care bed inventory, maintained by the agency for certificate-of-need purposes, for 10 years from the date of deactivation of the beds. After 10 years have elapsed, inactive beds shall be excluded from the inventory.~~ The agency shall, at the request of the licensee,

reactivate the inactive general beds upon a showing by the licensee that licensure requirements for the inactive general beds are met.

Section 11. Subsection (1) of section 395.604, Florida Statutes, is amended to read:

395.604 Other rural hospital programs.—

(1) The agency may license rural primary care hospitals subject to federal approval for participation in the Medicare and Medicaid programs. Rural primary care hospitals shall be treated in the same manner as emergency care hospitals and rural hospitals with respect to ss. 395.605(2)-(7)(a) ~~395.605(2)-(8)(a)~~, 408.033(2)(b)3., and 408.038.

Section 12. Subsection (5) of section 395.605, Florida Statutes, is amended to read:

395.605 Emergency care hospitals.—

~~(5) Rural hospitals that make application under the certificate-of-need program to be licensed as emergency care hospitals shall receive expedited review as defined in s. 408.032. Emergency care hospitals seeking relicensure as acute care general hospitals shall also receive expedited review.~~

Section 13. Subsections (2) and (4) of section 408.0361, Florida Statutes, are amended to read:

408.0361 Cardiovascular services and burn unit licensure.—

(2) Each provider of adult cardiovascular services or operator of a burn unit shall comply with rules adopted by the agency that establish licensure standards that govern the

provision of adult cardiovascular services or the operation of a burn unit. Such rules shall consider, at a minimum, staffing, equipment, physical plant, operating protocols, the provision of services to Medicaid and charity care patients, accreditation, licensure period and fees, and enforcement of minimum standards. ~~The certificate-of-need rules for adult cardiovascular services and burn units in effect on June 30, 2004, are authorized pursuant to this subsection and shall remain in effect and shall be enforceable by the agency until the licensure rules are adopted.~~ Existing providers and any provider with a notice of intent to grant a certificate of need or a final order of the agency granting a certificate of need for adult cardiovascular services or burn units shall be considered grandfathered and receive a license for their programs effective on the effective date of this act. The grandfathered licensure shall be for at least 3 years or until July 1, 2008, whichever is longer, but shall be required to meet licensure standards applicable to existing programs for every subsequent licensure period.

~~(4) In order to ensure continuity of available services, the holder of a certificate of need for a newly licensed hospital that meets the requirements of this subsection may apply for and shall be granted Level I program status regardless of whether rules relating to Level I programs have been adopted. To qualify for a Level I program under this subsection, a hospital seeking a Level I program must be a newly licensed hospital established pursuant to a certificate of need in a~~

~~physical location previously licensed and operated as a hospital, the former hospital must have provided a minimum of 300 adult inpatient and outpatient diagnostic cardiac catheterizations for the most recent 12-month period as reported to the agency, and the newly licensed hospital must have a formalized, written transfer agreement with a hospital that has a Level II program, including written transport protocols to ensure safe and efficient transfer of a patient within 60 minutes. A hospital meeting the requirements of this subsection may apply for certification of Level I program status before taking possession of the physical location of the former hospital, and the effective date of Level I program status shall be concurrent with the effective date of the newly issued hospital license.~~

Section 14. This act shall take effect July 1, 2016.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 581 State Veterans' Nursing Homes
SPONSOR(S): Magar
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	10 Y, 0 N	Guzzo	Poche
2) Health Care Appropriations Subcommittee	13 Y, 0 N	Garner	Pridgeon
3) Health & Human Services Committee		Guzzo	Calamas

SUMMARY ANALYSIS

HB 581 creates a site selection process for new state veterans' nursing homes to be administered by the Florida Department of Veterans' Affairs (FDVA).

The State Veterans' Homes Program, administered by FDVA, provides care to eligible veterans in need of either long-term skilled nursing care or assisted living services. Currently, there are six state veterans' nursing homes in Florida. Because of the size and age of the veteran population, Florida is near the top of the list of states with a "Great Need" for veterans' nursing home beds as determined by the U.S. Department of Veterans' Affairs (VA). As a result, Florida will receive priority over other states applying to the VA for grants for the construction of new state veterans' nursing homes.

Currently, no Florida law governs FDVA's site selection process. FDVA's current process is two-tiered. First, FDVA contracts for a Site Selection Study (Study) to rank each county based on greatest need using certain measureable criteria. Second, FDVA sends applications to the top ten counties identified in the Study. Each county that wishes to be considered in the selection process must submit an application, which includes other measureable criteria, to FDVA by a specified date. The application is scored by a Site Selection Committee appointed by the Executive Director of FDVA. The county with the highest score is awarded the site, subject to approval by the Governor and the Cabinet.

The bill creates a single-step site selection process, in new s. 296.42, F.S. The bill requires FDVA to contract for a study to determine the most appropriate county for construction of a nursing home based on the greatest level of need. The study must be delivered to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1, 2016, and a new study must be conducted and submitted every 4 years thereafter.

The bill requires that the study rank each county using the following criteria:

- The distance from the geographic center of the county to the nearest existing state veterans' nursing home;
- The number of veterans aged 65 years and older living in the county;
- The availability of emergency health care in the county;
- The presence of an existing Veterans' Health Administration Medical Center or Outpatient Clinic in the county;
- The number of existing nursing home beds per 1,000 elderly male residents of the county;
- The presence of accredited education institutions with health care programs in the county; and
- The county poverty rate.

FDVA must select the county with the highest ranking as the site for the new home, subject to approval by the Governor and the Cabinet. The bill requires the next highest ranked county to be selected if a higher ranked county cannot participate. The study must be used to determine the site of any new veterans' nursing home authorized before July 1, 2020. The bill requires the Site Selection Study dated February 7, 2014, to be used to select a county for a new veterans' nursing home before November 1, 2016, if authorized.

The bill requires the FDVA to contract for a Site Selection Study which was competitively procured in previous years at the cost of $38,692. This additional cost can be absorbed with existing appropriations.

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

State Veterans' Homes Program

The Florida Department of Veterans' Affairs (FDVA) operates the State Veterans' Homes Program (Program) as authorized by Chapters 292 and 296, F.S.[1] The Program provides care to eligible veterans in need of either long-term skilled nursing care or assisted living services. Care is provided to veterans with qualifying war or peacetime service, who are residents of Florida and who require skilled care as certified by a U.S. Department of Veterans' Affairs (USDVA) physician.[2] There are over 700,000 veterans aged 65 years and older in the state.[3]

Currently, there are six state veterans' nursing homes in Florida. Five of the six homes have dementia-specific care.[4] The six nursing homes are located in Daytona Beach, Land O' Lakes, Pembroke Pines, Panama City, Port Charlotte, and St. Augustine. Currently, the Program has a total of 720 skilled-nursing beds and an average occupancy rate of 99%.[5] In 2014, St. Lucie County was selected as the site for the seventh nursing home. The home is currently in the initial planning stages.[6]

Funding

The construction of a new nursing home is subject to approval by the Governor and Cabinet. Funding is based on a 65% / 35% federal/state split of the cost.[7] Florida is near the top of the list of states with a "Great Need" for veterans' nursing home beds as determined by the USDVA.[8] As a result, Florida will receive priority over other states applying to USDVA for grants for the construction of new state veterans' nursing homes. The estimated cost to build a new nursing home can range from $37 million to $50 million, depending on style, land condition, materials used, weather resistance and energy efficiency.[9]

According to FDVA, the total cost of the seventh nursing home in St. Lucie County is $39.8 million.[10] The state pro-rata share of cost is $13.9 million and will be paid from the FDVA Operations and Maintenance Trust Fund.[11] Funding for future nursing homes will need to be supported by General Revenue funding.[12]

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[1] S. 292.05(7), F.S. "The Department shall administer this chapter and shall have the authority and responsibility to apply for and administer any federal programs and develop and coordinate such state programs as may be beneficial to the particular interests of the veterans of this state."; part II of ch. 296, F.S., titled "The Veterans' Nursing Home of Florida Act" provides for the establishment of basic standards by FDVA for the operation of veteran's nursing homes for eligible veterans in need of such services.
[2] S. 296.36, F.S.
[3] Florida Department of Veterans' Affairs, *Long Range Program Plan Fiscal Years 2016-17 through 2020-21,* page 10, available at http://floridavets.org/about-us/long-range-program-plan/ (last viewed on January 15, 2016).
[4] AHCA, Florida Health Finder.gov, *Facility Provider Locator; General Search by Nursing Home; Advanced Search (Special Programs and Services) by Alzheimer's,* available at http://www.floridahealthfinder.gov/facilitylocator/FacilitySearch.aspx (last viewed January 15, 2016).
[5] FDVA, Presentation to the House Health Care Appropriations Committee on November 3, 2015, *State Veterans' Homes Program and Fixed Capital Outlay Projects,* at pg. 3 (on file with Health Innovation Subcommittee staff).
[6] FDVA, *Fourth Quarter Report, Administrative Highlights, Current Issues Concerns, New State Veterans' Nursing Home,* (April 1 – June 30, 2015).
[7] 38 CFR §59.80
[8] 38 CFR §59.50(1)(iii); *see also* 38 CFR §§59.40 and .50.
[9] E-mail correspondence, FDVA, February 12, 2015, (on file with Health Innovation Subcommittee staff).
[10] Supra, FN 5 at pg. 10, "Changes in the construction schedule of state veteran' home number 7 may result in differences in actual expenditures by fiscal year. However, total cost of the project is not expected to vary from the total amount of $39.75 million.
[11] Id.
[12] Supra, at FN 8.

Site Selection Process for Recently Authorized State Veterans' Nursing Homes

State Veterans' Nursing Home Seven (St. Lucie County)

In 2013, the Legislature appropriated funds for FDVA to contract with a private entity to conduct a Site Selection Study (Study).[13] The purpose of the Study was to identify five communities, defined as single-county or multi-county areas, to be given priority for development of a new state veterans' nursing home.

Counties that did not meet certain minimum threshold criteria, including access to emergency care and the availability of health care professionals, were eliminated from consideration before the Study began. Counties with an existing state veterans' nursing home and those located within 25 miles of an existing home were also eliminated from consideration.

The Study used the following criteria to score the counties, rank ordered from greatest to least value assigned:

- Number of elderly veterans in the county;
- Ratio of existing nursing home beds per/1,000 elderly male residents in the county;
- County poverty rate;
- Distance to an existing state veterans' nursing home;
- Presence of an existing veterans' health care facility in the county; and
- Presence of nursing education programs in the county.

The Study identified the following top ten counties with the greatest need for a new state veterans' nursing home, ranked in order of greatest need based on the scoring criteria:

Study Ranking	County
1	Collier
2	Lee
3	Polk
4	Manatee
5	Marion
6	Putnam
7	St. Lucie
8	Hillsborough
9	Palm Beach
10	Sumter

FDVA sent applications to all ten counties listed in the Study. Six of the counties submitted applications: Collier County, Polk County, Manatee County, Marion County, Putnam County, and St. Lucie County. A Site Selection Committee (Committee) was created by the Executive Director of FDVA to evaluate each application.

The Committee established factors for consideration, and assigned a score of 0 to 50 points for each of the following criteria:

- Number of veterans aged 65 or older living within a 75 mile radius of the proposed site;
- Number of nursing home beds and assisted living facility beds located within 10 miles of the proposed site;

[13] Hoy & Stark Architects, *Site Selection Study; Phase I State Veterans' Nursing Homes Statewide*, February 7, 2014, (on file with the Health Innovation Subcommittee staff).

- Suitability of the donated site in terms of its general surroundings and support capabilities;
- Availability of emergency health care, as determined by:
  - Number of hospitals and/or emergency care centers within 25 miles of the proposed site;
  - Number of emergency room holding beds per facility;
  - Presence of in-house physicians on staff in the emergency room 24 hours/day, 7 days/week; and
  - The nursing workforce.
- Availability of health care professionals, as determined by the number of accredited educational institutions located within 50 miles of the proposed site; and
- Availability of infrastructure at the site, including roads, water, sewer, telephone lines, and electricity/natural gas services, all of which must link to the property line of the proposed site at no cost to the state.

The Committee's final rankings were:

Committee Ranking	County	Study Ranking
1	St. Lucie	7
2	Marion	5
3	Collier Site B	1
4	Collier Site A	1
5	Polk Site A	3
6	Polk Site B	3

St. Lucie County was selected as the site for the seventh nursing home, and approved by the Governor and Cabinet on September 23, 2014.

State Veterans' Nursing Home Six (St. Johns County)

The same site selection process was used to determine the site of the sixth nursing home. A Study[14] was conducted in 2004 and the home was built in 2010. The extended length of time between site selection and construction of the nursing home was due to a lack of funds caused by the economic recession in the mid-2000s.

The Study identified the following top twelve areas, which included counties and multi-county groups, with the greatest need for a veterans' nursing home:

Study Ranking	County or Area
1	Lake/Marion/Sumter
2	Duval
3	Brevard
4	Escambia/Santa Rosa/Okaloosa
5	Indian River/Martin/St. Lucie
6	Orange/Seminole
7	Collier/Lee
8	Palm Beach
9	Sarasota/Manatee
10	Polk
11	Citrus/Hernando
12	Pinellas

The Committee selected St. Johns County as the site for sixth veterans' nursing home. St. Johns County was not identified in the Study as an area of need.

[14] Health Strategies, Inc., *Nursing Home Site Selection Study*, February 2004, (on file with the Health Innovation Subcommittee staff).

Site Selection Process Workshop

In February 2015, FDVA conducted a state veterans' nursing home site selection process workshop (workshop). The goal of the workshop was to review the existing site selection process and determine if the process is valid and useful for future site selections.[15]

The final report from the workshop included the following recommendations:

- Follow the 2014 site selection study recommendations but allow up to three adjoining counties to combine and submit a single application;
- Revise weighting of the application, but not the site selection study;
- Outline weighted factors in the application packet;
- Limit counties to a single site proposal to ensure counties put their best product forward and apply resources to that site accordingly;
- Keep the site selection committee intact, but change the point of contact to a non-voting member;
- Redesign the application form;
- Revise the score sheet to add a scoring scale and train site selection committee members accordingly;
- Rank order sites in the next site selection process from one through four and award homes 8,9, and 10 to the top three sites with the fourth site being an alternate if site number three is disqualified by FDVA or the USDVA; and
- Allow runner-up sites in scoring to become alternate sites.[16]

On November 10, 2015, FDVA presented the recommendations to the Governor and Cabinet for approval. The Governor and Cabinet approved all but one of the recommendations. Specifically, the recommendation to rank order sites in the next site selection process from one through four and award homes 8,9, and 10 to the top three sites was not accepted.

Effect of Proposed Changes

The bill creates a single-step site selection process, in new s. 296.42, F.S. The bill requires FDVA to contract for a study to determine the most appropriate county for construction of a new nursing home based on the greatest level of need. The study must be delivered to the Governor, President of the Senate, and the Speaker of the House of Representatives by November 1, 2016, and a new study must be conducted and submitted every 4 years thereafter.

The bill requires the study to use the following criteria to rank each county:

- The distance from the geographic center of the county to the nearest existing state veterans' nursing home;
- The number of veterans aged 65 years and older living in the county;
- The availability of emergency health care in the county, as determined by:
    - The number of general hospitals;
    - The number of emergency room holding beds per hospital; and
    - The number of in-house physicians per hospital on staff in the emergency room 24 hours per day.
- The presence of an existing Veterans' Health Administration Medical Center or Outpatient Clinic in the county;
- The number of existing nursing home beds per 1,000 elderly male residents of the county;
- The presence of accredited education institutions with health care programs in the county; and

[15] FDVA, *State Veterans' Nursing Home Site Selection Process Workshop Results and Recommendations, Final Report*, (March 12, 2015).
[16] Id.

- The county poverty rate.

The county with the highest ranking must be selected as the site for the new home, subject to approval by the Governor and the Cabinet. The bill requires the next highest ranked county to be selected if a higher ranked county cannot participate. The study must be used to determine the site for any veterans' nursing home authorized before July 1, 2020. For any veterans' nursing home authorized before November 1, 2016, the bill requires the FDVA to use the 2014 Site Selection Study.

B. SECTION DIRECTORY:

Section 1: Creates s. 296.42, F.S., relating to the site selection process for state veterans' nursing homes.

Section 2: Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill requires FDVA to contract for a study to rank each county according to greatest need to determine the most appropriate site for a new veterans' nursing home. The Site Selection Study for the determination of the seventh state nursing home location was competitively procured and a contract was awarded to Hoy + Stark Architects, P.A. for a total cost of $38,692.[17] This additional cost can be absorbed with existing appropriations.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

[17] E-mail correspondence, FDVA, March 19, 2015, (on file with Health Innovation Subcommittee staff).

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

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 state veterans' nursing homes; creating s. 296.42, F.S.; directing the Department of Veterans' Affairs to contract for a study to determine the need for additional state veterans' nursing homes and the most appropriate counties in which to locate the homes; directing the department to submit the study to the Governor and Legislature; providing study criteria for ranking each county according to need; requiring the department to use specified studies to select new nursing home sites; directing the department to contract for subsequent studies and submit the studies to the Governor and Legislature; providing an effective date.

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

Section 1. Section 296.42, Florida Statutes, is created to read:

296.42 Site selection process for state veterans' nursing homes.—

(1) The department shall contract for a study to determine the need for new state veterans' nursing homes and the most appropriate counties in which to locate the homes based on the greatest level of need. The department shall submit the study to the Governor, the President of the Senate, and the Speaker of

the House of Representatives by November 1, 2016.

(2) The study shall use the following criteria to rank each county according to need:

(a) The distance from the geographic center of the county to the nearest existing state veterans' nursing home.

(b) The number of veterans age 65 years or older residing in the county.

(c) The presence of an existing federal Veterans' Health Administration medical center or outpatient clinic in the county.

(d) Elements of emergency health care in the county, as determined by:

1. The number of general hospitals.

2. The number of emergency room holding beds per hospital.

3. The number of in-house physicians per hospital on staff in the emergency room 24 hours per day.

(e) The number of existing community nursing home beds per 1,000 males age 65 years or older residing in the county.

(f) The presence of an accredited educational institution offering health care programs in the county.

(g) The county poverty rate.

(3) The department shall use the study ranking to select each new state veterans' nursing home site authorized before July 1, 2020, subject to approval by the Governor and Cabinet. For each new nursing home, the department shall select the highest-ranked county in the study which does not have a

veterans' nursing home. If the highest-ranked county cannot serve as the site, the department shall select the next-highest-ranked county. The department shall use the 2014 Site Selection Study to select a county for any new state veterans' nursing home authorized before November 1, 2016, subject to approval by the Governor and Cabinet.

(4) The department shall contract for and submit a new study in accordance with this section by November 1, 2020, and every 4 years thereafter.

Section 2. This act shall take effect July 1, 2016.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 595 Reimbursement to Health Access Settings for Dental Hygiene Services for Children
SPONSOR(S): Health Innovation Subcommittee; Plasencia
TIED BILLS: **IDEN./SIM. BILLS:** SB 580

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	10 Y, 0 N, As CS	McElroy	Poche
2) Health Care Appropriations Subcommittee	13 Y, 0 N	Clark	Pridgeon
3) Health & Human Services Committee		McElroy	Calamas

SUMMARY ANALYSIS

Section 466.024(2), F.S., authorizes licensed dental hygienists to perform a limited number of unsupervised remediable tasks in health access settings, such as county health departments, Head Start programs, and other facilities, as defined in s. 466.003(14), F.S. Section 409.906(6), F.S., authorizes the Agency for Health Care Administration (AHCA) to pay for dental services provided to a recipient under age 21, by or under the supervision of a licensed dentist. AHCA interprets s. 409.906(6), F.S., as barring reimbursement for unsupervised tasks performed by licensed dental hygienists pursuant to s. 466.024(2).

HB 595 amends s. 409.906(6), F.S., to expressly authorize reimbursement to the health access setting by Medicaid for the remediable tasks that a licensed dental hygienist is authorized to perform under s. 466.024(2), F.S., without supervision by a licensed dentist, when the services are provided to children under the age of 21 in the Medicaid program.

The bill has an indeterminate but likely insignificant fiscal impact on the Agency for Health Care Administration.

The bill provides an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Oral Health

Oral health has a significant impact on an individual's physical and mental health. It can influence how individuals grow, enjoy life, look, speak, chew, taste food and socialize, as well as their feelings of social well-being.[1] It can also affect, be affected or contribute to various diseases and conditions including:[2]

- Endocarditis;
- Cardiovascular disease;
- Diabetes;
- HIV/AIDS;
- Osteoporosis; and
- Alzheimer's disease.

For children, poor oral health can result in pain, discomfort, disfigurement, acute and chronic infections, eating and sleep disruption and an overall reduction of quality of life.[3] Children with poorer oral health are also more likely to miss school, have a lower grade-point average and otherwise perform poorly in school.[4] In fact, one study concluded that visits or dental problems accounted for 117,000 hours of school lost per 100,000 children.[5]

Tooth decay is one of the most common, and easily preventable, chronic conditions of childhood in the United States.[6] About 20% of children aged 5-11 and 13% of adolescents aged 12-19 have at least one untreated tooth decay.[7] The prevalence of tooth decay is more than twice as high, 25% compared to 11%, for children from low-income families.[8]

Dental Workforce

Currently, there is a national workforce shortage of dentists, and it is projected to worsen in the future. In 2012, there were 190,800 dentists with an estimated need of 197,800 dentists, resulting in a shortage of 7,000 dentists.[9] By 2025, projections have 202,600 dentists in practice with a need for

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[1] *Oral Health, General Health and Quality of Life*, World Health Organization, Aubrey Sheiham, Volume 83, Number 9, September 2005, 641-720. http://www.who.int/bulletin/volumes/83/9/editorial30905html/en/ (last visited November 23, 2015).
[2] *What Conditions May be Linked to Oral Health*, Mayo Clinic. http://www.mayoclinic.org/healthy-lifestyle/adult-health/in-depth/dental/art-20047475?pg=2 (last visited on November 23, 2015).
[3] Id.
[4] *Impact of Poor Oral Health on Children's School Attendance and Performance*, Stephanie L. Jackson, DDS, MS, corresponding author William F. Vann, Jr, DMD, PhD, Jonathan B. Kotch, MD, MPH, Bhavna T. Pahel, PhD, MPH, BDS, and Jessica Y. Lee, DDS, PhD, MPH, American Journal of Public Health, Am J Public Health. 2011 October; 101(10): 1900–1906. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3222359/ (last visited on November 23, 2015); *The Impact of Oral Health on the Academic Performance of Disadvantaged Children*, Hazem Seirawan, DDS, MPH, MS, Sharon Faust, DDS, and Roseann Mulligan, DDS, MS, American Journal of Public Health, Am J Public Health. 2012 September; 102(9): 1729–1734. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3482021/ (last visited on November 23, 2015).
[5] *Supra* footnote 1.
[6] *Children's Oral Health*, Centers for Disease Control and Prevention, Division of Oral Health, National Center for Chronic Disease Prevention and Health Promotion. http://www.cdc.gov/oralhealth/children_adults/child.htm (last visited November 23, 2015).
[7] Id.
[8] Id.
[9] U.S. Department of Health and Human Services, Health Resources and Services Administration, National Center for Health Workforce Analysis. National and State-Level Projections of Dentists and Dental Hygienists in the U.S., 2012-2025. Rockville,

211,200 dentists.[10] This projected shortage of 8,600 dentists, combined with the 2012 shortage, results in a shortage of 15,600 dentists by the year 2025. All 50 states and the District of Columbia are projected to have a shortfall of dentists with Florida projected to have the second highest shortfall in the nation (1,152) by 2025.[11]

Dental hygienists are trending in the opposite direction of dentists. There is currently an excess supply of dental hygienists and by 2025 the national excess supply is projected to be 28,100.[12] Florida again follows the national trend and is projected to have the third largest excess supply of dental hygienists (2,768) by 2025.[13] However, not all states are projected to have an excess supply.[14]

Dental Hygienists

Dental Hygienists are regulated by ch. 466, F.S., and by the Board of Dentistry (Board) within the Department of Health. Dental hygienists are focused on preventing dental disease. They are educated and trained to evaluate the patient's oral health; expose, process and interpret dental X-ray films; and remove calculus deposits, stains, and plaque above and below the gumline.[15] They also apply preventive agents such as fluorides and sealants to teeth when allowed by state regulations.[16] Dental hygienists may also perform certain tasks which are delegated by a licensed dentist. These delegable tasks are established either in statute or by rule and include:[17]

- Taking impressions for study casts but not for the purpose of fabricating any intraoral restorations or orthodontic appliance;
- Placing periodontal dressings;
- Removing periodontal or surgical dressings;
- Removing sutures;
- Placing or removing rubber dams;
- Placing or removing matrices;
- Placing or removing temporary restorations;
- Applying cavity liners, varnishes, or bases;
- Polishing amalgam restorations;
- Polishing clinical crowns of the teeth for the purpose of removing stains but not changing the existing contour of the tooth;
- Dental charting[18];
- Obtaining bacteriological cytological specimens not involving cutting of the tissue; and
- Administering local anesthesia pursuant to s. 466.017(5).

The Board establishes by rule whether these tasks are to be performed under direct, indirect, or general supervision of the dentist.[19] A dental hygienist may perform these tasks in multiple settings, including:[20]

Maryland, 2015. http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwjv-aSQyKfJAhUBZiYKHRIGCSMQFggdMAA&url=http%3A%2F%2Fbhpr.hrsa.gov%2Fhealthworkforce%2Fsupplydemand%2Fdentistry%2Fnationalstatelevelprojectionsdentists.pdf&usg=AFQjCNG2CoEtGnpvOZqQmrtmRhCMWC85BA&bvm=bv.108194040,d.eWE (last visited on November 23, 2015).

[10] Id.

[11] Id.

[12] Id.

[13] Id.

[14] Id.

[15] S. 466.023, F.S.

[16] See Rule 64B5-16.006, F.A.C.

[17] S. 466.024 (1), F.S.

[18] "Dental Charting" is a recording of visual observations of clinical conditions of the oral cavity without the use of X rays, laboratory tests, or other diagnostic methods or equipment, except the instruments necessary to record visual restorations, missing teeth, suspicious areas, and periodontal pockets. S. 466.0235.

[19] S. 466.023(1), F.S. "Direct supervision" means supervision whereby a dentist diagnoses the condition to be treated, a dentist authorizes the procedure to be performed, a dentist remains on the premises while the procedures are performed, and a dentist

- In the office of a licensed dentist;
- In public health programs and institutions of the Department of Children and Families, Department of Health, and Department of Juvenile Justice under the general supervision of a licensed dentist; and
- In a health access setting.

Scope of Practice in Health Access Settings

In 2011, the Legislature expanded the scope of practice for dental hygienists providing dental services to children under the age of 21 in health access settings[21] in an effort to maximize the existing dental workforce. The legislation authorized licensed dental hygienists to perform certain remediable tasks in a health access setting without the physical presence, prior examination or authorization of a dentist.[22] These tasks include:

- Perform dental charting as defined in s. 466.0235 and as provided by rule;
- Measure and record a patient's blood pressure rate, pulse rate, respiration rate, and oral temperature;
- Record a patient's case history;
- Apply topical fluorides, including fluoride varnishes, which are approved by the American Dental Association or the Food and Drug Administration;
- Apply dental sealants; and
- Remove calculus deposits, accretions, and stains from exposed surfaces of the teeth and from tooth surfaces within the gingival sulcus.[23]

Numerous safeguards are in place to ensure patient safety when unsupervised services are provided in health access settings. For example, when a dental hygienist performs one of the above procedures, the patient must be notified that the visit with the dental hygienist is not a substitute for a comprehensive dental exam.[24] Additionally, a dentist is required to conduct an oral examination within 13 months of a dental hygienist removing calculus deposits, accretions, and stains from a patient's teeth.[25] Also, a dental hygienist providing such services must maintain professional malpractice insurance coverage that has minimum limits of $100,000 per occurrence and $300,000 in the aggregate through the employing health access setting or through an individual policy.[26]

Reimbursement for Children's Dental Care Services Provided in Health Access Settings

The absence of dentist supervision of the tasks performed by a dental hygienist in a health access setting does not preclude reimbursement for those services. Specifically, s. 466.024(4), F.S., states:

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approves the work performed before dismissal of the patient. "Indirect supervision" means supervision whereby a dentist authorizes the procedure and a dentist is on the premises while the procedures are performed. "General supervision" means supervision whereby a dentist authorizes the procedures which are being carried out but need not be present when the authorized procedures are being performed. The authorized procedures may also be performed at a place other than the dentist's usual place of practice. The issuance of a written work authorization to a commercial dental laboratory by a dentist does not constitute general supervision. S. 466.003 (8), (9) and (10), F.S.

[20] S. 466.023(2), F.S.

[21] "Health access setting" means a program or an institution of the Department of Children and Families, the Department of Health, the Department of Juvenile Justice, a nonprofit community health center, a Head Start center, a federally qualified health center or look-alike as defined by federal law, a school-based prevention program, a clinic operated by an accredited college of dentistry, or an accredited dental hygiene program in this state if such community service program or institution immediately reports to the Board of Dentistry all violations of s. 466.027, s. 466.028, or other practice act or standard of care violations related to the actions or inactions of a dentist, dental hygienist, or dental assistant engaged in the delivery of dental care in such setting. S. 466.003(14), F.S.

[22] S. 466.024 (2), F.S.

[23] Id.

[24] S. 466.024 (3)(a), F.S.

[25] S. 466.024 (2)(f) 2, F.S.

[26] S. 466.024 (5)(c), F.S.

> This section does not prevent a program operated by one of the health access settings as defined in s. 466.003 or a nonprofit organization that is exempt from federal income taxation under s. 501(a) of the Internal Revenue Code and described in s. 501(c)(3) of the Internal Revenue Code from billing and obtaining reimbursement for the services described in this section which are provided by a dental hygienist or from making or maintaining any records pursuant to s. 456.057 necessary to obtain reimbursement.

As such, programs providing dental care in health access settings may seek reimbursement for specified dental services provided by dental hygienists, irrespective of whether those services were supervised by a dentist.

Medicaid

Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of the federal and state governments established to provide coverage for health services for eligible persons. The program is administered by the Agency for Health Care Administration (AHCA) and financed by federal and state funds. AHCA delegates certain functions to other state agencies, including the Department of Children and Families, the Agency for Persons with Disabilities, and the Department of Elderly Affairs.

The structure of each state's Medicaid program varies and what states must pay for is largely determined by the federal government, as a condition of receiving federal funds. Federal law sets the amount, scope, and duration of services offered in the program, among other requirements. These federal requirements create an entitlement that comes with constitutional due process protections. The entitlement means that two parts of the Medicaid cost equation – people and utilization – are largely predetermined for the states: Some populations are entitled to enroll in the program; and enrollees are entitled to certain benefits.

The federal government sets the minimum mandatory benefits to be covered in every state Medicaid program. These benefits include physician services, hospital services, home health services, and family planning.[27] States can add benefits, with federal approval. Florida has added many optional benefits, including prescription drugs, dental services, and dialysis.[28]

Medicaid Reimbursement for Children's Dental Services

Under the Medicaid program, AHCA is statutorily authorized to pay for diagnostic, preventive, or corrective procedures, including orthodontia in severe cases, provided to a recipient under age 21, by or under the supervision of a licensed dentist.[29] AHCA interprets this provision as prohibiting reimbursement under the Medicaid program for any delegable tasks[30] performed by a dental hygienist or dental assistant unless the task was performed under the supervision of a dentist. This provision predates the dental hygienist scope of practice expansion contained within s. 466.024, F.S., and, as applied by AHCA, functions to limit the scope of practice for dental hygienists in the Medicaid program.

Effect of Proposed Changes

HB 595 amends s. 409.906(6), F.S., to expressly authorize reimbursement to the health access setting by Medicaid for the remediable tasks that a licensed dental hygienist is authorized to perform under s. 466.024(2), F.S., without supervision by a licensed dentist, when the services are provided to children under the age of 21 in the Medicaid program. This allows the Medicaid program and Medicaid recipients to benefit from the dental hygienist scope of practice expansion in s. 466.024(2), F.S.

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[27] S. 409.905, F.S.
[28] S. 409.906, F.S.
[29] S. 409.906 (6), F.S.
[30] A dentist may delegate remediable tasks to dental hygienists or dental assistants when such tasks pose no risk to the patient.

B. SECTION DIRECTORY:

Section 1: Amending s. 409.906, F.S., relating to optional Medicaid services.
Section 2: Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

AHCA would be permitted to reimburse health access settings for remediable tasks performed by licensed dental hygienists, as outlined in s. 466.024(2), F.S., on children under age 21 in the Medicaid program. The majority of the expenditures for this reimbursement would be through Medicaid capitation payments to managed care organizations participating in the MMA program. It is unknown how many services would be provided by licensed dental hygienists in lieu of services provided and reimbursed under the supervision of a dentist, or how many additional services will be provided that would not have been provided before, but for this bill.[31] Any additional costs to managed care organizations would not be reflected in the capitation rates for at least one year as capitation rates are set each September. Additionally, the increased costs would likely be minimal and result in an immaterial increase or no increase at all to managed care capitation rates.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health access settings may be reimbursed for remediable tasks performed by licensed dental hygienists, as authorized under s. 466.024(2), F.S., on children under age 21 in the Medicaid program.

D. FISCAL COMMENTS:

In Fiscal Year 2014-15 AHCA reported that approximately $16.2 million was reimbursed to health care access settings under the supervision of a dentist either through the fee-for-service system or through encounters with managed care organizations under contract with AHCA.

[31] Email from Agency from Health Care Administration dated January 6, 2016, on file with Health Care Appropriations Subcommittee Staff.

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:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On December 2, 2015, the Health Innovation Subcommittee adopted one amendment and reported the bill favorably as a committee substitute. The amendment further clarifies that only a health access setting, and not a licensed dental hygienist, is eligible for reimbursement for remediable tasks performed by a licensed dental hygienists, as authorized under s. 466.024(2), F.S., on children under age 21 in the Medicaid program.

The analysis is drafted to the committee substitute as passed by the Health Innovation Subcommittee.

A bill to be entitled

An act relating to reimbursement to health access settings for dental hygiene services for children; amending s. 409.906, F.S.; authorizing reimbursement for children's dental services provided by licensed dental hygienists in certain circumstances; providing an effective date.

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

Section 1. Subsection (6) of section 409.906, Florida Statutes, is amended to read:

409.906 Optional Medicaid services.—Subject to specific appropriations, the agency may make payments for services which are optional to the state under Title XIX of the Social Security Act and are furnished by Medicaid providers to recipients who are determined to be eligible on the dates on which the services were provided. Any optional service that is provided shall be provided only when medically necessary and in accordance with state and federal law. Optional services rendered by providers in mobile units to Medicaid recipients may be restricted or prohibited by the agency. Nothing in this section shall be construed to prevent or limit the agency from adjusting fees, reimbursement rates, lengths of stay, number of visits, or number of services, or making any other adjustments necessary to comply with the availability of moneys and any limitations or

directions provided for in the General Appropriations Act or chapter 216. If necessary to safeguard the state's systems of providing services to elderly and disabled persons and subject to the notice and review provisions of s. 216.177, the Governor may direct the Agency for Health Care Administration to amend the Medicaid state plan to delete the optional Medicaid service known as "Intermediate Care Facilities for the Developmentally Disabled." Optional services may include:

(6) CHILDREN'S DENTAL SERVICES.—The agency may pay for diagnostic, preventive, or corrective procedures, including orthodontia in severe cases, provided to a recipient under age 21, by or under the supervision of a licensed dentist. The agency may also reimburse a health access setting as defined in s. 466.003 for the remediable tasks that a licensed dental hygienist is authorized to perform under s. 466.024(2). Services provided under this program include treatment of the teeth and associated structures of the oral cavity, as well as treatment of disease, injury, or impairment that may affect the oral or general health of the individual. However, Medicaid will not provide reimbursement for dental services provided in a mobile dental unit, except for a mobile dental unit:

(a) Owned by, operated by, or having a contractual agreement with the Department of Health and complying with Medicaid's county health department clinic services program specifications as a county health department clinic services provider.

(b) Owned by, operated by, or having a contractual arrangement with a federally qualified health center and complying with Medicaid's federally qualified health center specifications as a federally qualified health center provider.

(c) Rendering dental services to Medicaid recipients, 21 years of age and older, at nursing facilities.

(d) Owned by, operated by, or having a contractual agreement with a state-approved dental educational institution.

Section 2. This act shall take effect July 1, 2016.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7041 PCB GVOPS 16-03 OGSR/Florida Center for Brain Tumor Research
SPONSOR(S): Government Operations Subcommittee, Trumbull
TIED BILLS: **IDEN./SIM. BILLS:** SB 7024

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Government Operations Subcommittee	12 Y, 0 N	Toliver	Williamson
1) Health & Human Services Committee		Guzzo	Calamas

SUMMARY ANALYSIS

The Open Government Sunset Review Act requires the Legislature to review each public record and each public meeting exemption five years after enactment. If the Legislature does not reenact the exemption, it automatically repeals on October 2nd of the fifth year after enactment.

The Florida Center for Brain Tumor Research (center) is established within the Evelyn F. and William L. McKnight Brain Institute of the University of Florida. The goal of the center is to find cures for brain tumors and its purpose is to:

- Foster collaboration with brain cancer research organizations and institutions;
- Provide a central repository for brain tumor biopsies;
- Improve and monitor brain tumor biomedical research programs;
- Facilitate funding opportunities; and
- Foster improved technology transfer of brain tumor research findings into clinical trials and widespread public use.

Current law provides a public record exemption for the following information held by the center before, on, or after July 1, 2011:

- Personal identifying information of a donor to the central repository for brain tumor biopsies or the brain tumor registry; and
- Any information received from an individual from another state or nation or the Federal Government that is otherwise confidential or exempt pursuant to the laws of that state or nation or pursuant to federal law.

The bill reenacts the public record exemption, which will repeal on October 2, 2016, if this bill does not become law.

The bill does not appear to have a fiscal impact on state or local governments.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Open Government Sunset Review Act

The Open Government Sunset Review Act (Act)[1] sets forth a legislative review process for newly created or substantially amended public record or public meeting exemptions. It requires an automatic repeal of the exemption on October 2nd of the fifth year after creation or substantial amendment, unless the Legislature reenacts the exemption.[2]

The Act provides that a public record or public meeting exemption may be created or maintained only if it serves an identifiable public purpose. In addition, it may be no broader than is necessary to meet one of the following purposes:

- Allows the state or its political subdivisions to effectively and efficiently administer a governmental program, which administration would be significantly impaired without the exemption.
- Protects sensitive personal information that, if released, would be defamatory or would jeopardize an individual's safety; however, only the identity of an individual may be exempted under this provision.
- Protects trade or business secrets.[3]

If, and only if, in reenacting an exemption that will repeal and the exemption is expanded (essentially creating a new exemption), then a public necessity statement and a two-thirds vote for passage are required.[4] If the exemption is reenacted with grammatical or stylistic changes that do not expand the exemption, if the exemption is narrowed, or if an exception to the exemption is created[5] then a public necessity statement and a two-thirds vote for passage are not required.

Florida Center for Brain Tumor Research

The Florida Center for Brain Tumor Research (center) is established within the Evelyn F. and William L. McKnight Brain Institute of the University of Florida.[6] The goal of the center is to find cures for brain tumors[7] and its purpose is to:

- Foster collaboration with brain cancer research organizations and other institutions;
- Provide a central repository for brain tumor biopsies from individuals throughout the state;
- Improve and monitor brain tumor biomedical research programs within the state;
- Facilitate funding opportunities; and
- Foster improved technology transfer of brain tumor research findings into clinical trials and widespread public use.[8]

Current law requires the center to be funded through private, state, and federal sources.[9] According to the center, 100 percent of its funding is provided by the state when funds are appropriated, and an additional 20 percent above its working budget is provided by Accelerate Brain Cancer Cure, which is a

[1] Section 119.15, F.S.
[2] Section 119.15(3), F.S.
[3] Section 119.15(6)(b), F.S.
[4] Section 24(c), Art. I, FLA. CONST.
[5] An example of an exception to a public record exemption would be allowing another agency access to confidential and exempt records.
[6] Section 381.853(3), F.S.
[7] Section 381.853(3)(b), F.S.
[8] Section 381.853(3)(a), F.S.
[9] Section 381.853(3)(g), F.S.

private foundation.[10] However, during years when funding is not provided, the University of Florida Department of Neurosurgery provides funding.[11]

Current law establishes a scientific advisory council (council) within the center.[12] The council, which must meet at least annually,[13] consists of members from the University of Florida, Scripps Research Institute Florida, University of Miami, Mayo Clinic in Jacksonville, Cleveland Clinic Florida, H. Lee Moffitt Cancer Center and Research Institute, University of Florida Health Cancer Center at Orlando Health, and a neurosurgeon in private practice.[14]

Public Record Exemption under Review

In 2006, the Legislature created a public record exemption for the following information held by the center:

- An individual's medical record; and
- Any information received from an individual from another state or nation or the Federal Government that is otherwise confidential or exempt pursuant to the laws of that state or nation or pursuant to federal law.[15]

Pursuant to the Open Government Sunset Review Act, the public record exemption was scheduled to repeal on October 2, 2011; however, the Legislature reenacted the exemption with changes. In 2011, the public record exemption for medical records was replaced with a public record exemption for personal identifying information of a donor to the central repository for brain tumor biopsies or the brain tumor registry.[16] The public record exemption was also made retroactive.[17]

As such, the following information is currently confidential and exempt[18] from public record requirements:

- Personal identifying information of a donor to the central repository for brain tumor biopsies or the brain tumor registry.
- Any information received from an individual from another state or nation or the Federal Government that is otherwise confidential or exempt pursuant to the laws of that state or nation or pursuant to federal law.[19]

The confidential and exempt information may be disclosed to a person engaged in bona fide research if that person agrees to:

- Submit a research plan to the center that has been approved by an institutional review board. The plan must specify the exact nature of the information requested, the intended use of the requested information, and the reason the research could not practicably be conducted without the information;
- Sign a confidentiality agreement with the center;
- Maintain the confidentiality of the information received; and

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[10] Open Government Sunset Review of s. 381.8531, F.S., relating to the Florida Center for Brain Tumor Research, questionnaire by House and Senate staff, August 12, 2015, at question 1. (hereinafter referred to as OGSR Questionnaire)(on file with the Government Operations Subcommittee).

[11] *Id.*

[12] Section 381.853(4), F.S.

[13] *Id.*

[14] OGSR Questionnaire at question 2.

[15] Chapter 2006-259, L.O.F.; codified as s. 381.8531, F.S.

[16] Chapter 2011-203, L.O.F.

[17] In 2001, the Florida Supreme Court ruled that a public record exemption does not apply retroactively unless the legislation clearly expresses such intent. *Memorial Hospital-West Volusia, Inc. v. News-Journal Corporation*, 729 So.2d 373 (Fla. 2001).

[18] There is a difference between records the Legislature designates exempt from public records requirements and those the Legislature deems confidential and exempt. A record classified as exempt from public disclosure may be disclosed under certain circumstances. *See Williams v. City of Minneola*, 575 So. 2d 683, 687 (Fla. 5th DCA 1991) *review denied*, 589 So. 2d 289 (Fla. 1991). If the Legislature designates a record as confidential and exempt from public disclosure, such record may not be released by the custodian of public records to anyone other than the persons or entities specifically designated in statute. *See WFTV, Inc. v. Sch. Bd. of Seminole Cnty*, 874 So. 2d 48, 53 (Fla. 5th DCA 2004), *review denied*, 892 So. 2d 1015 (Fla. 2004); Op. Att'y Gen. Fla. 85-692 (1985).

[19] Section 381.8531(1), F.S.

- Destroy any confidential information to the extent permitted by law and upon conclusion of the research.[20]

The 2011 public necessity statement for the public record exemption provides that:

> Brain tumors are a leading cause of death, and there is a significant need to discover cures and develop treatment modalities for brain tumors, which can be facilitated by a registry and repository of specimens from persons diagnosed with brain tumors. The disclosure of such information could hinder the availability of specimens for research. Matters of personal health are traditionally private and confidential concerns between the patient and the health care provider...For these reasons, the donor's expectation of and right to privacy in all matters regarding his or her personal health necessitates this exemption.[21]

Pursuant to the Open Government Sunset Review Act, the exemption will repeal on October 2, 2016, unless reenacted by the Legislature.[22]

During the 2015 interim, Government Operations Subcommittee staff sent the center a questionnaire as part of the Open Government Sunset Review process. The center recommended reenactment of the public record exemption and provided that "[i]f the information is not exempt, the researchers will have to inform potential donors that their data is a public record, thus risking the loss of those potential donors."[23]

Effect of the Bill

The bill removes the repeal date, thereby reenacting the public record exemption for the following information held by center before, on, or after July 1, 2011:

- Personal identifying information of a donor to the central repository for brain tumor biopsies or the brain tumor registry; and
- Any information received from an individual from another state or nation or the Federal Government that is otherwise confidential or exempt pursuant to the laws of that state or nation or pursuant to federal law.

B. SECTION DIRECTORY:

Section 1: Amends s. 381.8531, F.S., relating to the Florida Center for Brain Tumor Research; public records exemption.

Section 2: Provides an effective date of October 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

[20] Section 381.8531(2), F.S.
[21] Section 2, ch. 2011-203, L.O.F.
[22] Section 381.8531(3), F.S.
[23] OGSR questionnaire at question 9.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to a review under the Open Government Sunset Review Act; amending s. 381.8531, F.S., relating to an exemption from public records requirements for information held by the Florida Center for Brain Tumor Research; removing the scheduled repeal of the exemption; providing an effective date.

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

Section 1. Section 381.8531, Florida Statutes, is amended to read:

381.8531 Florida Center for Brain Tumor Research; public records exemption.—

(1) The following information held by the Florida Center for Brain Tumor Research before, on, or after July 1, 2011, is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution:

(a) Personal identifying information of a donor to the central repository for brain tumor biopsies or the brain tumor registry.

(b) Any information received from an individual from another state or nation or the Federal Government that is otherwise confidential or exempt pursuant to the laws of that state or nation or pursuant to federal law.

(2) Such information may be disclosed to a person engaged in bona fide research if that person agrees to:

(a) Submit to the Florida Center for Brain Tumor Research a research plan that has been approved by an institutional review board and that specifies the exact nature of the information requested, the intended use of the information, and the reason that the research could not practicably be conducted without the information;

(b) Sign a confidentiality agreement with the Florida Center for Brain Tumor Research;

(c) Maintain the confidentiality of the information received; and

(d) To the extent permitted by law and after the research has concluded, destroy any confidential information obtained.

~~(3) This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2016, unless reviewed and saved from repeal through reenactment by the Legislature.~~

Section 2. This act shall take effect October 1, 2016.

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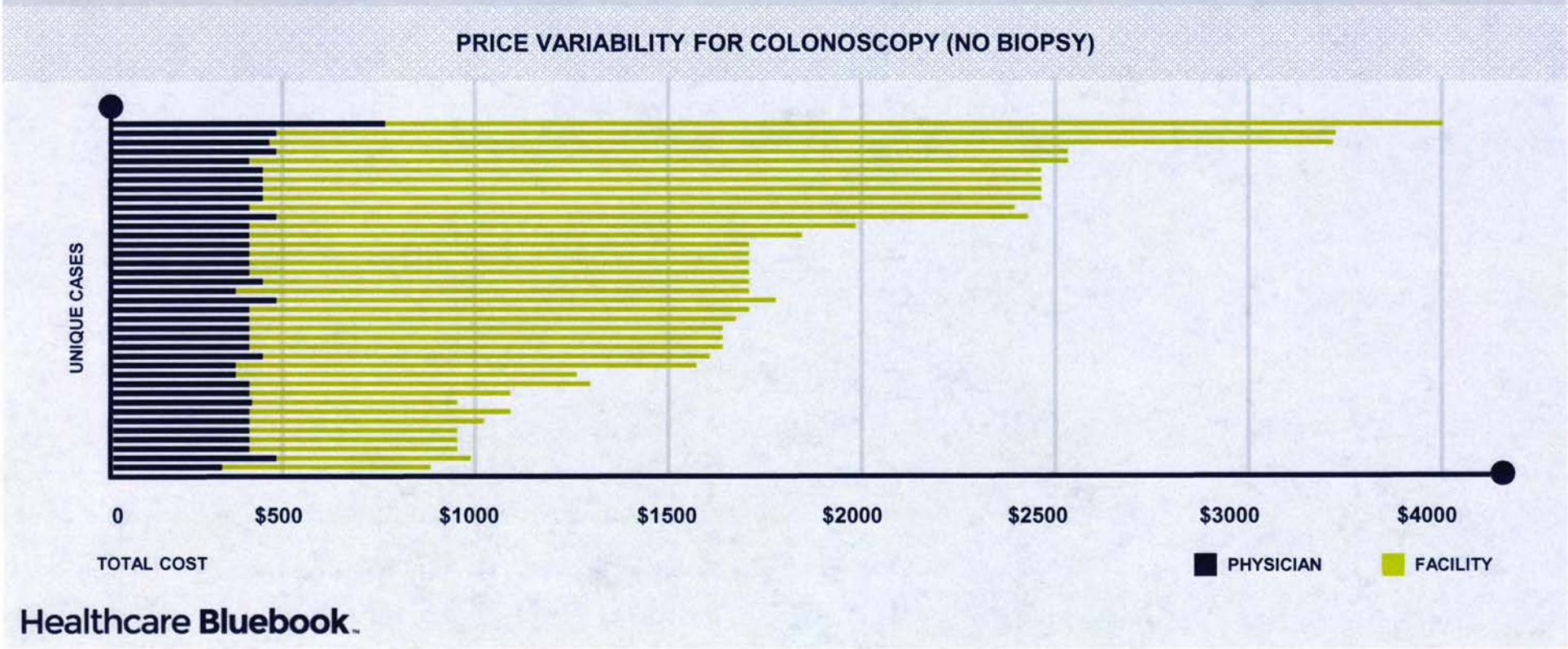

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ALL services are impacted…

HEALTHCARE PRICE VARIANCE REPORT		MARKET | MIAMI	
Market Basket of Common Procedures	**Low Price**	**High Price**	**Variance**
1. Screening Colonoscopy	$749	$5,857	782%
2. Sleep Study	$610	$4,125	676%
3. Shoulder MRI (with contrast)	$399	$3,775	946%
4. Knee Arthroscopy	$2,387	$13,881	582%
5. Cholecystectomy (laparoscopic)	$5,360	$16,750	313%
6. Carpal Tunnel Surgery	$1,908	$9,663	506%
7. Ear Tube Placement (tympanostomy)	$1,131	$8,942	791%
8. Hysteroscopy (with biopsy)	$2,573	$10,285	400%
9. Chest CT (no contrast)	$252	$2,857	1134%
10. Abdominal Ultrasound	$115	$939	817%
	Average Market Variance		**695%**
Equivalent Variance in a Gallon of Gas	$3.00	$20.84	695%

What gas would cost per gallon with the same price variance

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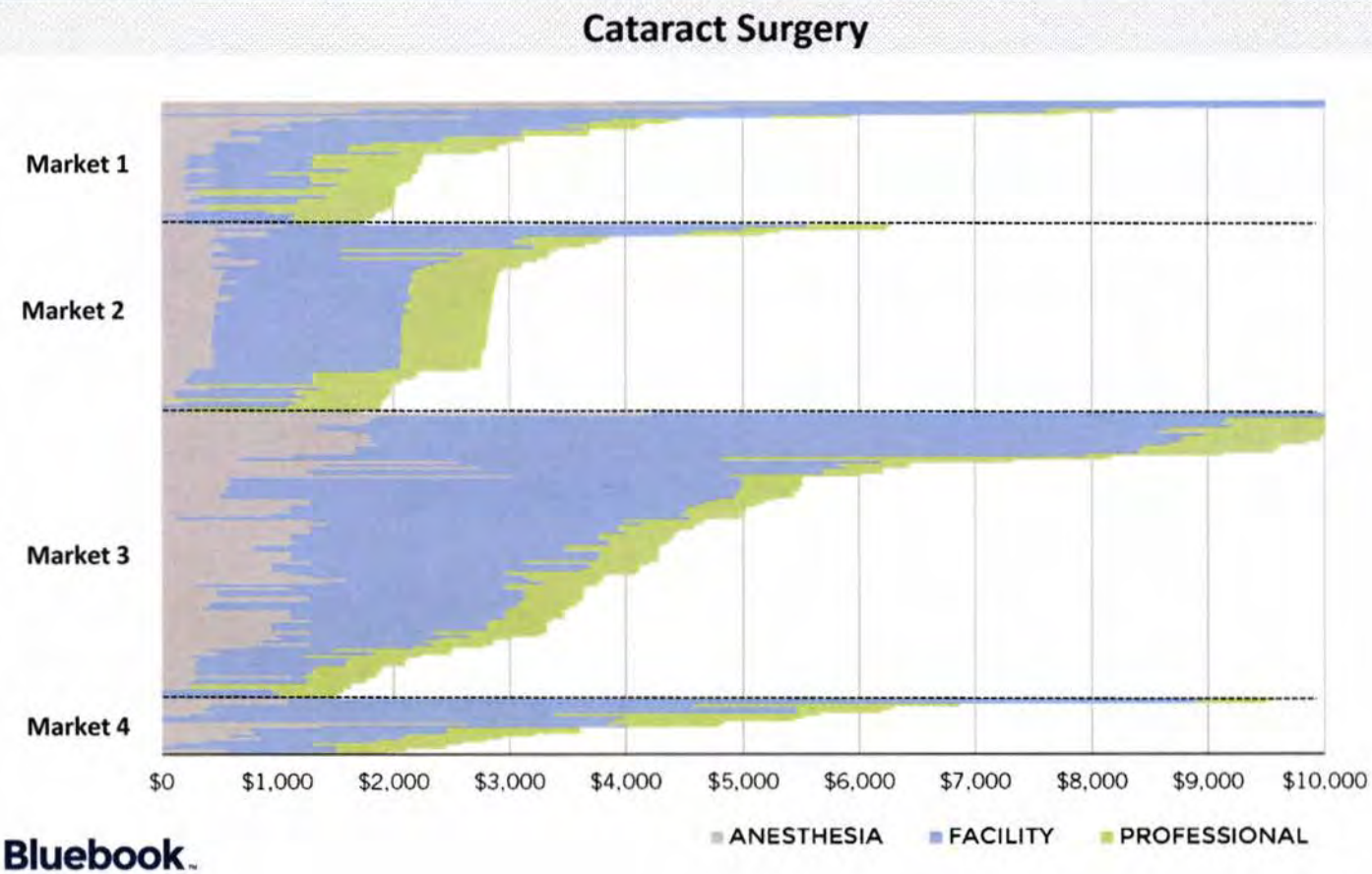
and *ALL* markets and networks



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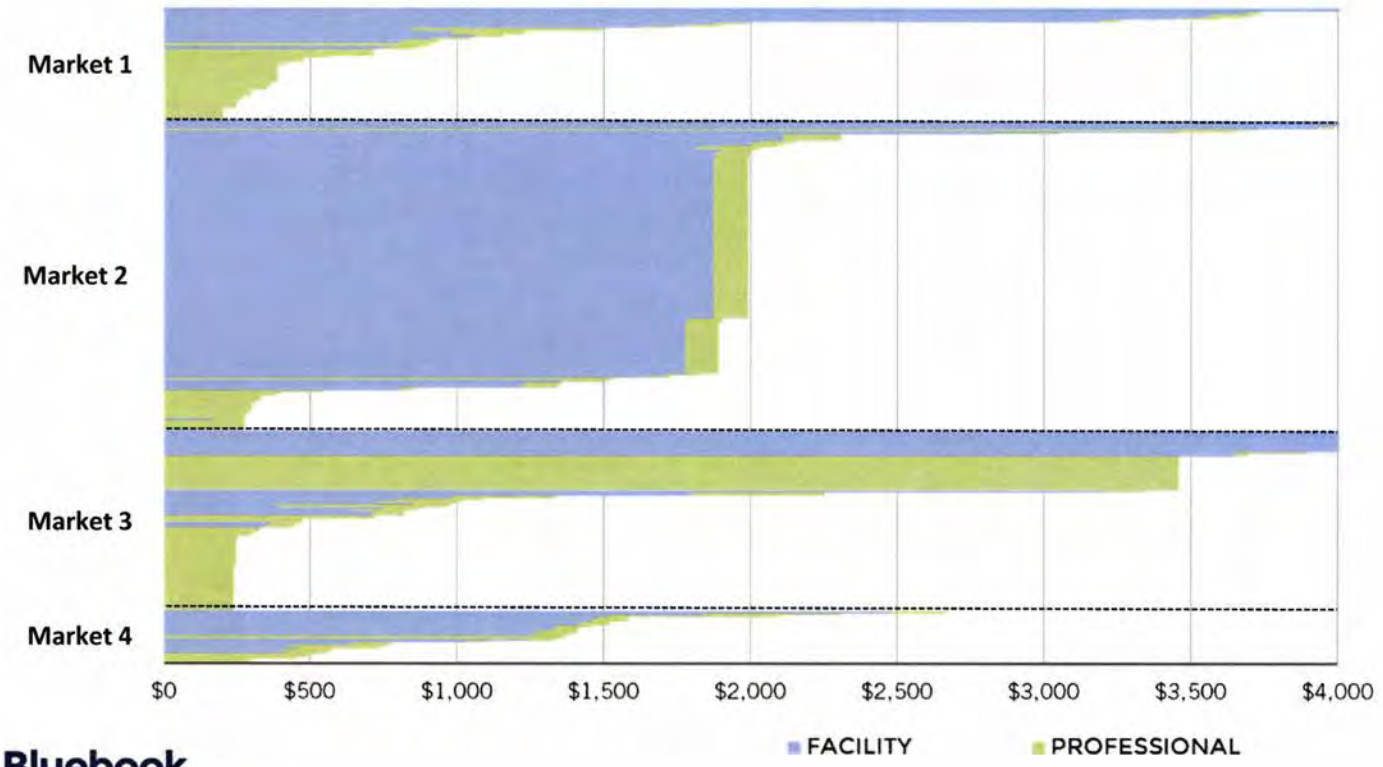
and *ALL* markets and networks

Abdomen and Pelvis CT (with Contrast)



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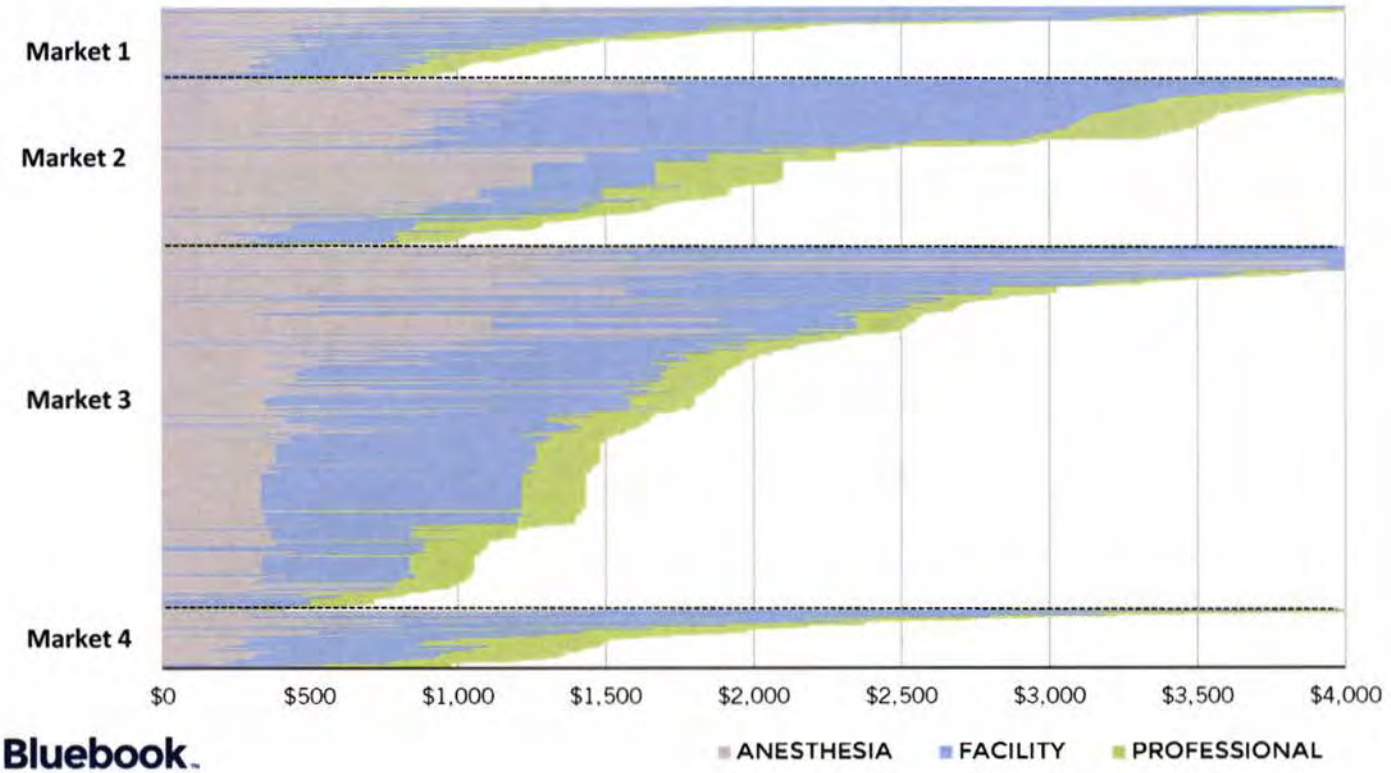
Colonoscopy (no biopsy)



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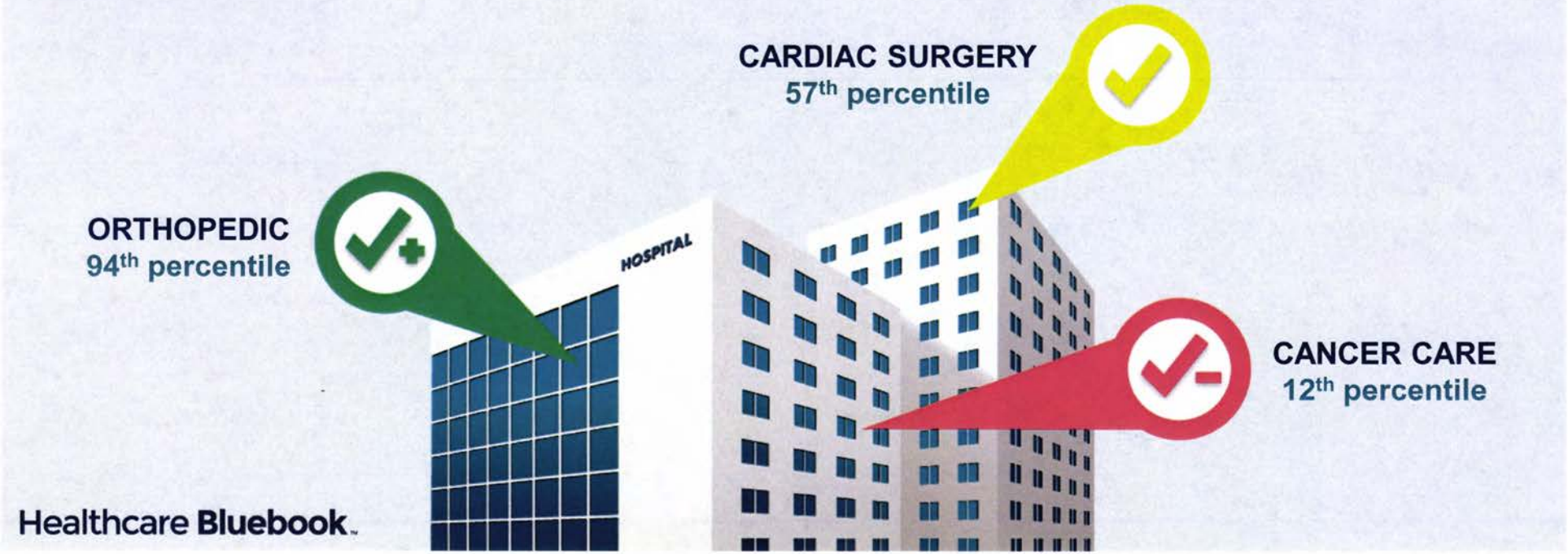
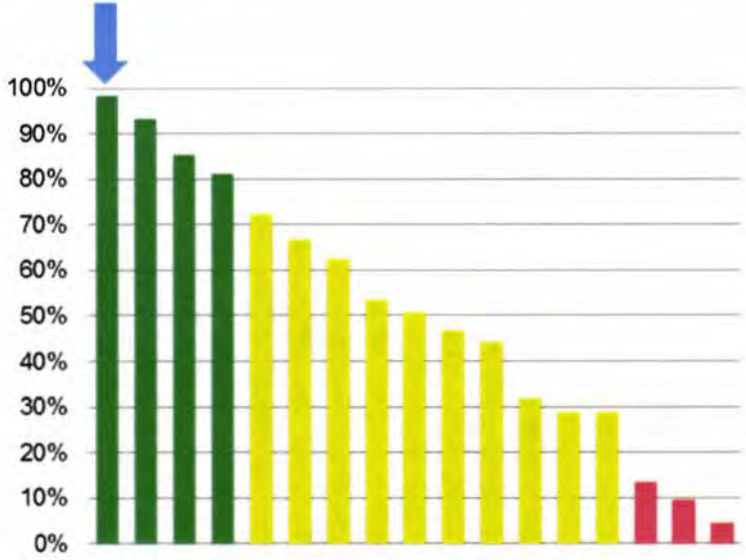
Hospitals may do everything, but they are not *great* at everything…



The Quality Problem

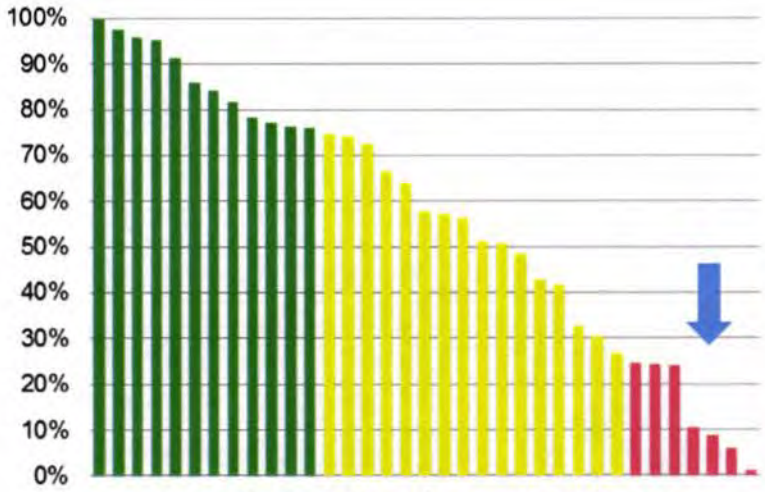


Cardiac Surgery (Major)

99.9th Percentile Nationally

1 out of 16 in Metro Area

1 out of 1,148 nationally



Joint Replacement

8.8th Percentile Nationally

31 out of 33 in Metro Area

3,190 out of 3,491 nationally

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STRATEGY MATTERS

1. Simple
2. Practical
3. Outcomes-Driven

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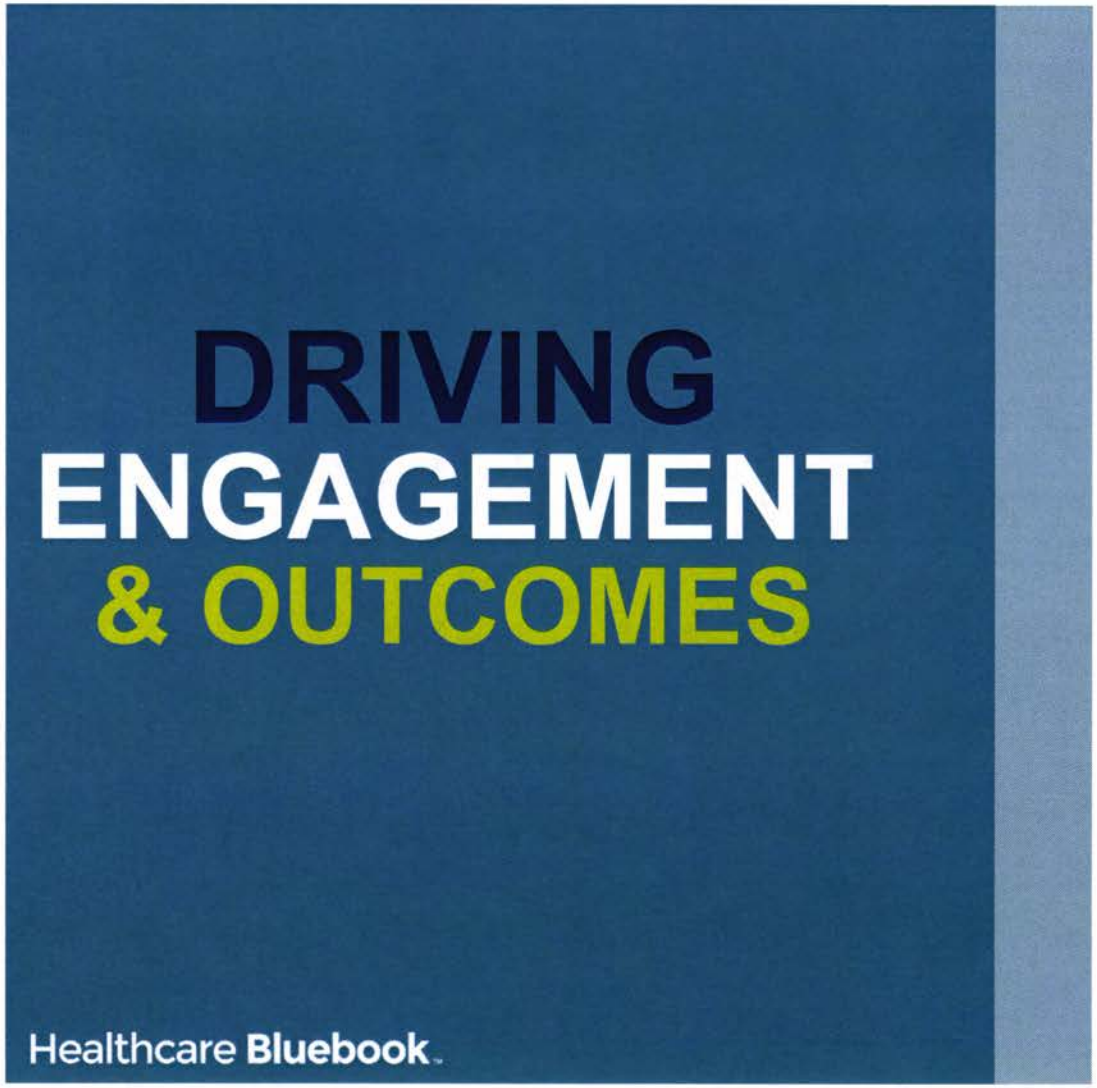


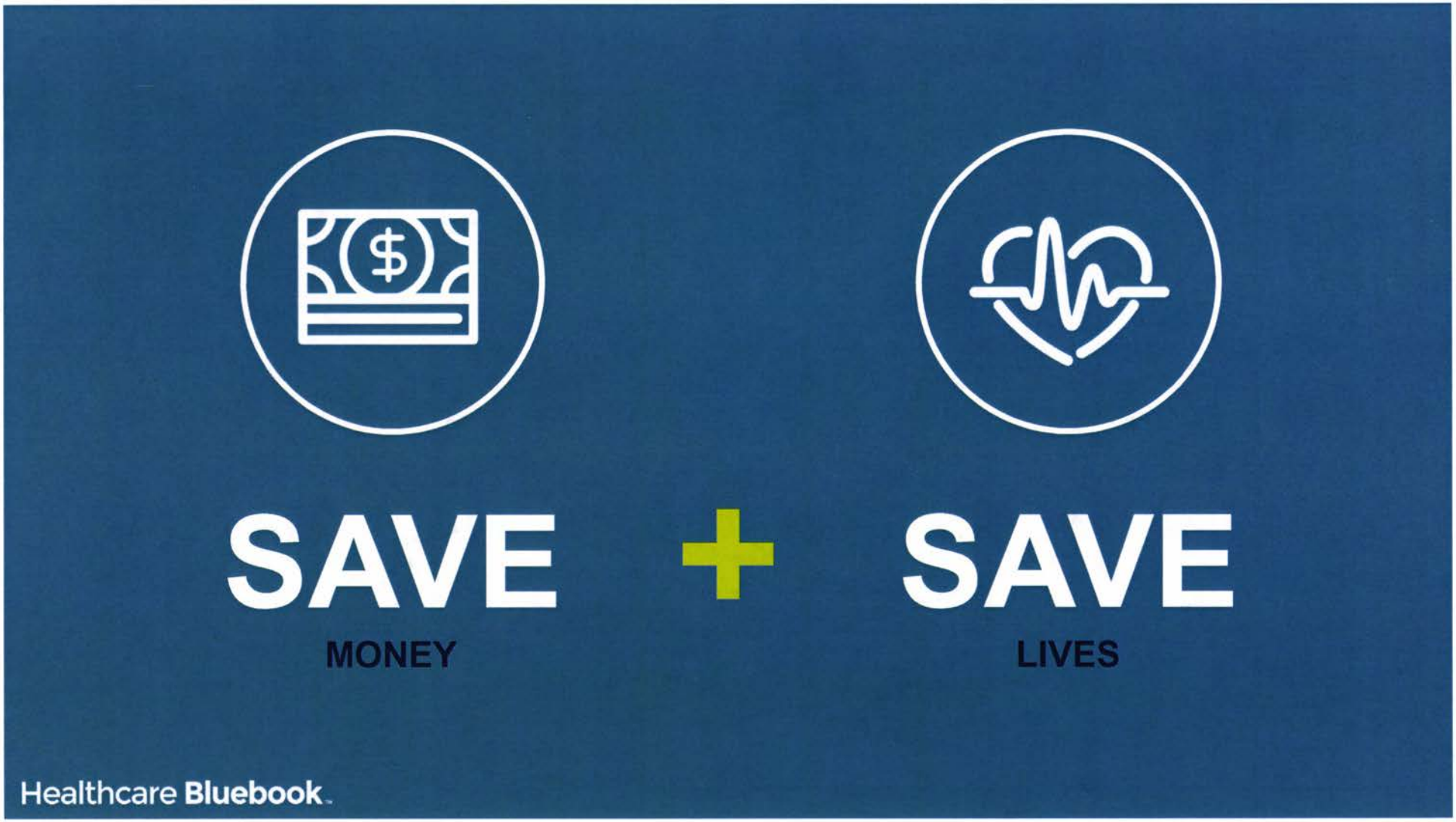
Communication & Education

Rewards

Integration

Mobility

- Bluebook pioneered the outcomes based reward approach and was the first to offer cash rewards.
- Why pay for registration, when you can invest in outcomes?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