

The Florida Senate
COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Young, Chair
Senator Passidomo, Vice Chair

MEETING DATE: Tuesday, February 21, 2017**TIME:** 12:30—3:00 p.m.**PLACE:** Pat Thomas Committee Room, 412 Knott Building**MEMBERS:** Senator Young, Chair; Senator Passidomo, Vice Chair; Senators Book, Hukill, Hutson, Montford, and Powell

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	CS/SB 182 Banking and Insurance / Mayfield (Similar H 95)	Consumer Protection from Nonmedical Changes to Prescription Drug Formularies; Limiting changes to a health insurance policy prescription drug formulary during a policy year; requiring small employer carriers to limit changes to prescription drug formularies under certain circumstances, etc. BI 02/07/2017 Fav/CS HP 02/21/2017 Fav/CS AP RC	Fav/CS Yeas 5 Nays 0
2	CS/SB 240 Banking and Insurance / Lee (Similar CS/H 161)	Direct Primary Care; Specifying that a direct primary care agreement does not constitute insurance and is not subject to ch. 636, F.S., relating to prepaid limited health service organizations and discount medical plan organizations, or any other chapter of the Florida Insurance Code; providing that certain certificates of authority and licenses are not required to market, sell, or offer to sell a direct primary care agreement, etc. BI 02/07/2017 Fav/CS HP 02/21/2017 Fav/CS AHS AP	Fav/CS Yeas 5 Nays 0
3	SB 510 Gainer (Similar H 429)	Grant Program for Rural Hospitals; Requiring the Department of Health to establish and administer the Florida Rural Hospital Capital Improvement Competitive Grant Program for certain rural hospitals; deleting requirements for certain information in grant applications, etc. HP 02/21/2017 Fav/CS AHS AP	Fav/CS Yeas 5 Nays 0

Consideration of proposed bill:

COMMITTEE MEETING EXPANDED AGENDA

Health Policy

Tuesday, February 21, 2017, 12:30—3:00 p.m.

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
4	SPB 7012	Ratification of Department of Health Rules; Ratifying a rule, adopted by the Board of Medicine, relating to the standard of care for office surgery for the sole and exclusive purpose of satisfying any condition on effectiveness pursuant to s. 120.541(3), F.S., which requires ratification of any rule exceeding the specified thresholds for likely adverse impact on or increase in regulatory costs, etc.	Submitted as Committee Bill Yeas 5 Nays 0

Other Related Meeting Documents

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: CS/CS/SB 182

INTRODUCER: Health Policy Committee; Banking and Insurance Committee and Senator Mayfield

SUBJECT: Consumer Protection from Nonmedical Changes to Prescription Drug Formularies

DATE: February 21, 2017

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	Fav/CS
2.	Lloyd	Stovall	HP	Fav/CS
3.			AP	
4.			RC	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 182 amends the Insurance Code to provide additional consumer protections by prohibiting an individual or group insurance policy that is issued in this state and provides medical coverage or a health maintenance organization (HMO) from removing a covered prescription drug from its formulary except during coverage renewal with some limited exceptions. The bill also prohibits an insurer or HMO from reclassifying a drug to a more restrictive tier, increasing the out-of-pocket costs (e.g., copayment, coinsurance, or deductible) of an insured, or reclassifying a drug to higher-cost sharing tier during the policy year. Under current law, only HMOs offering group contracts are prohibited from increasing the copayment for any benefit or removing, amending or limiting any of the contract benefits except at renewal time with some exceptions.

Often, insureds with chronic, disabling conditions select a health insurance policy or contract based on the availability of certain drugs on the formulary at a preferred cost. Typically, health insurers and pharmacy benefit managers (PBMs) may change their prescription drug formularies during the year in response to the availability of new drugs or changes in prices by drug manufacturers. As a result, certain prescription drugs may become more costly or unavailable, thereby restricting the insureds access to these drugs during a plan year. The insured is unable to switch to a different health insurance plan until the next open enrollment.

The Division of State Group Insurance (DSGI) of the Department of Management Services indicates that the bill will have an indeterminate, negative fiscal impact. The DSGI's PBM estimates the annual loss of rebates from drug manufacturers to the state is \$9.2 million and the annual additional costs of drugs to the DSGI is \$50,000.

The bill has no fiscal impact on the Florida Medicaid program, as it does not amend ch. 409, F.S., which governs the Florida Medicaid program, nor does it require Medicaid to amend existing policies or procedures.

II. Present Situation:

Access to affordable health care can be a significant issue for anyone with an illness, but it is particularly critical for individuals who have conditions with the potential to cause death, disability, or serious discomfort unless treated with the most appropriate medical care. In recent years, many innovative treatments for diseases that affect large populations, such as cancer, hepatitis C, diabetes, and multiple sclerosis have been approved. Some of the benefits of these innovative drugs include fewer side effects, convenience (oral solids instead of injectables), and greater efficacy.¹ However, the financial burden from out-of-pocket drug costs can lead patients with chronic illnesses to forgo prescribed drugs, ultimately affecting their health.

Prescription Drug Cost Containment

In 2014, spending on retail prescription drugs in the United States was approximately \$298 billion.² In 2015, total retail prescription drug spending increased by 9 percent, reaching \$325 billion. The significant growth in 2015 was attributed to certain cost drivers, such as, spending on new drugs, price growth for existing brand-name drugs, increased spending on generics, and a decrease in the number of expensive drugs whose patents have expired.³

Due to increasing health care expenditures, public and private employers and insurers continue to look for cost containment methods, including the reduction of prescription drug costs. Many employer-sponsored health plans and insurers contract with pharmacy benefit managers (PBMs). The PBMs negotiate drug prices with pharmacies and drug manufacturers on behalf of health plans and, in addition to other administrative, clinical, and cost containment services, process drug claims for the health plans. The PBM generally manages the list of preferred drug products (formulary) for each of its plan sponsors. Insurers and self-insured employers provide insureds with financial incentives, such as lower copayments, to use formulary drugs.

Non-medical switching or substitution of prescription drugs occurs when there may be multiple options available within a treatment class and a less expensive or patient-preferred medicine is substituted, often for cost containment reasons. Non-medical switching may be as simple as the substitution of a brand name drug for its generic equivalent. Generic drugs are copies of brand-name drugs and are the same in dosage form, safety, strength, route of administration,

¹ See HEALTH AFFAIRS 35, No. 9 (2016): 1595-1603.

² See HEALTH AFFAIRS 36, No. 1 (2017):166-176.

³ *Id.*

performance characteristics, and intended use.⁴ A generic drug must pass the same safety standards as a brand-name drug. The second method of switching or substitution involves dispensing drugs that are therapeutically equivalent to but chemically different from the originally prescribed drug.⁵

Research notes that the biologic therapy medications of some patients are being switched for nonclinical reasons, despite the lack of data to support this practice and an abundance of data demonstrating clinically meaningful differences among biologics.⁶ For example, one study reviewing the reason for adjusting anti-tumor necrosis (TNF) agents involving patients primarily with rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, or ulcerative colitis found that non-medical switching of anti-TNF agents was associated with an increase in side effects and lack of efficacy that also led to an increase in health care utilization.⁷

Federal Patient Protection and Affordable Care Act

Health Insurance Reforms

The federal Patient Protection and Affordable Care Act (PPACA) was signed into law on March 23, 2010.⁸ The PPACA requires health insurers to make coverage available to all individuals and employers, without exclusions for preexisting conditions and without basing premiums on any health-related factors. The PPACA also mandates required essential health benefits,⁹ cost-sharing limits, rating and underwriting standards, and appeals of adverse benefit determinations.

The PPACA requires issuers (insurers and HMOs) of qualified health plans (QHPs) to provide 10 categories of essential health benefits (EHB), which includes prescription drugs.¹⁰ To be certified as a QHP, the insurer must also submit an application, follow established limits on cost sharing, and be certified by the federal Health Insurance Marketplace.¹¹ The federal deadline for

⁴ Federal Food and Drug Administration, *Understanding Generic Drugs* available at <http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/default.htm> (last visited Feb. 13, 2017).

⁵ Rachel Chu, et al, *Patient Safety and Comfort - The Challenges of Switching Medicines* (2010) available at http://www.patients-rights.org/uploadimages/Patient_Safety_and_Comfort_The_Challenges_of_Switching.pdf (last viewed Feb. 13, 2017).

⁶ See Alan Reynolds, et al, *When is switching warranted among biologic therapies in rheumatoid arthritis?* Medscape.com, http://www.medscape.com/viewarticle/768031_5 (last viewed Feb. 13, 2017).

⁷ D.T. Rubin, et al, *Analysis of outcomes after non-medical switching of anti-tumor necrosis factor agents*, European Crohn's and Colitis Organisation (2015) available at https://www.ecco-ibd.eu/index.php/publications/congress-abstract-s/abstracts-2015/item/p354-analysis-of-outcomes-after-non-medical-switching-of-anti-tumor-necrosis-factor-agents.html?category_id=430 (last viewed Feb. 13, 2017).

⁸ The Patient Protection and Affordable Care Act (Pub. Law No. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. Law No. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010.

⁹ 42 U.S.C. s.18022.

¹⁰ See Center for Consumer Information & Insurance Oversight, *Information on Essential Health Benefits (EHB) Benchmark Plans* <https://www.cms.gov/ccio/resources/data-resources/ehb.html> (last visited Feb. 13, 2017) for Florida's benchmark plan.

¹¹ Center for Consumer Information & Insurance Oversight, *Qualified Health Plans*, <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp.html> (last viewed Feb. 13, 2017).

insurers and HMOs to submit 2018 rates and forms to the Centers for Medicare and Medicaid and the Florida Office of Insurance Regulation is May 13, 2017.^{12,13}

Prescription Drug Coverage

For purposes of complying with PPACA's EHBs for prescription drugs, issuers must include in their formulary drug list the greater of one drug for each U.S. Pharmacopeia (USP) category and class; or the same number of drugs in each USP category and class as the state's EHB benchmark plan. Issuers must have a Pharmacy and Therapeutics Committee design formularies using scientific evidence that will include consideration of safety and efficacy, cover a range of drugs in a broad distribution of therapeutic categories and classes, and provide access to drugs that are included in broadly accepted treatment guidelines. Plans providing EHBs must have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not included on the plan's formulary drug list. Such procedures must include a process to request an expedited review.¹⁴

An issuer's plan does not meet the EHB benchmark if its benefit design discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.¹⁵ Issuers of QHPs may not employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in QHPs.¹⁶

Changes in Medicare Part D Formularies

Medicare Part D¹⁷ plans may alter their formularies from year to year, and in limited circumstances, to make changes to their formularies within a plan year.¹⁸ Plans may not change therapeutic categories and classes of drugs within a plan year, except to account for new therapeutic uses or to add newly approved Part D drugs. If Part D plans remove drugs from their formularies during a plan year (or change cost-sharing or access requirements), they must provide timely notice to the Centers for Medicare and Medicaid Services (CMS), affected enrollees, physicians, pharmacies, and pharmacists.

¹² Center for Consumer Information and Insurance Oversight (CCIIO), Centers for Medicare & Medicaid Services (CMS), *2018 Letter to Issuers in the Federally-facilitated Marketplaces* (Dec. 16, 2016), p. 7, available at <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-2018-Letter-to-Issuers-in-the-Federally-facilitated-Marketplaces.pdf>. (last viewed Feb. 13, 2017).

¹³ President Trump, Executive Order 13765, *Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal*, <https://www.whitehouse.gov/the-press-office/2017/01/2/executive-order-minimizing-economic-burden-patient-protection-and> (Jan. 20, 2017). President Trump issued an executive order indicating that it is the intent of his administration to seek the prompt repeal of PPACA. (last viewed: Feb. 13, 2017).

¹⁴ 45 C.F.R. s. 156.122.

¹⁵ 45 C.F.R. s. 156.125.

¹⁶ 45 C.F.R. s. 156.225.

¹⁷ The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173) established a voluntary, outpatient prescription drug benefit under Medicare Part D, effective January 1, 2006. Medicare Part D provides coverage through private prescription drug plans (PDPs) that offer only drug coverage, or through Medicare Advantage (MA) prescription drug plans (MA-PDs) that offer coverage as part of broader, managed care plans.

¹⁸ Centers for Medicare and Medicaid, *Medicare Prescription Drug Benefit Manual*, Chapter 6, (Jan. 15, 2016) available at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>. (last viewed Feb. 13, 2017).

Formulary changes are allowed in limited circumstances. Plans may immediately remove drugs from their formularies that are deemed unsafe by the FDA or are pulled from the market by their manufacturers. Plans may make formulary maintenance changes after March 1, such as replacing a brand-name drug with a new generic drug or modifying formularies because of new information on safety or effectiveness. These changes require CMS approval and 60 days' notice to appropriate parties.

The CMS will generally give positive consideration to formulary maintenance changes such as expanding formularies by adding drugs, moving a drug to a lower tier (thereby reducing copayments or coinsurance), or eliminating utilization management requirements. Plans may only remove drugs from a formulary, move covered drugs to a less-preferred tier status, or add utilization management requirements in accordance with approved procedures and after 60 days' notice to appropriate parties. Plans may make such changes only if enrollees currently taking the affected drugs are exempt from the formulary change for the remainder of the plan year.

Regulation of Insurers and Health Maintenance Organizations in Florida

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, HMOs, and other risk-bearing entities.¹⁹ The Agency for Health Care Administration (AHCA) regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from the AHCA.²⁰

Currently, under the Insurance Code, an HMO may increase the copayment for any benefit, or delete, amend, or limit any of the benefits under a group contract only upon written notice to the contract holder at least 45 days in advance of the time of coverage renewal. The HMO may amend the contract with the contract holder, with such amendment to be effective immediately at the time of coverage renewal. The written notice to the contract holder must specifically identify any deletions, amendments, or limitations to any of the benefits provided in the group contract during the current contract period, which will be included in the group contract upon renewal. This provision does not apply to any increases in benefits. The notice requirements do not apply if benefits are amended, deleted, or limited, pursuant to a request of the contract holder.²¹

Florida's State Group Insurance Program

Under the authority of s. 110.123, F.S., the DMS, through the DGSI, administers the state group health insurance program under a cafeteria plan consistent with section 125, Internal Revenue Code. To administer the state group health insurance program, the DMS contracts with third party administrators for self-insured health plans, insured HMOs, and a pharmacy benefit manager (PBM) for the state employees' self-insured prescription drug program pursuant to s. 110.12315, F.S.

The state employees' self-insured prescription drug program has three cost-share categories for members: generic drugs, preferred brand name drugs (those brand name drugs on the preferred

¹⁹ Section 20.121(3), F.S.

²⁰ Section 641.21(1), F.S.

²¹ Section 641.31(36), F.S.

drug list), and non-preferred brand name drugs (those brand name drugs not on the preferred drug list). Contractually the PBM for the state employees' self-insured prescription drug program updates the preferred drug list quarterly as brand drugs enter the market and as the PBM negotiates pricing, including rebates with manufacturers.

Generic drugs are the least expensive and have the lowest member cost share, preferred brand name drugs have the middle cost share, and non-preferred brand name drugs are the most expensive and have the highest member cost share. Generally, prescriptions written for a brand name drug, preferred or non-preferred, will be substituted with a generic drug when available. If the prescribing provider states on the prescription that the brand name drug is "medically necessary" over the generic equivalent, the member will pay only the brand name (preferred or non-preferred) cost share. If the member requests the brand name drug over the generic equivalent then the member will pay the brand name, (preferred or non-preferred) cost share plus the difference between the cost of the generic drug and the brand name drug.

The program covers all federal legend drugs (open formulary) for covered medical conditions, and employs very limited utilization review and clinical review for traditional or specialty prescription drugs. Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions such as cancer, rheumatoid arthritis and multiple sclerosis. Specialty drugs often require special handling (e.g., refrigeration during shipping) and administration (such as injection or infusion).

The federal out-of-pocket limit applies to members of the state group self-insured health plans and insured HMOs, all of which include prescription drug coverage. Copayments (and coinsurance for high deductible plans) for each drug tier are the same for all members, as follows:

Drug Tier	Retail – Up to 30-Day Supply	Retail and Mail – Up to 90-Day Supply and Specialty Medications
Generic	\$7	\$14
Preferred Brand	\$30	\$60
Non-Preferred Brand	\$50	\$100

The program typically makes benefits changes on a plan year basis, which is January 1 through December 31.²²

Health Insurance Mandate Report

Section 624.215, F.S., requires that a report assessing the social and financial impact of any proposal for legislation that mandates health benefit coverage or mandates offering requirements must be submitted to AHCA and the legislative committee having jurisdictions.

According to a report provided by advocates of the bill, the bill will not increase coverage of drug benefits or the total cost of health care.²³ The bill creates transparency for consumers to

²² Department of Management Services, *Senate Bill 182 Analysis* (Jan. 19, 2017) (on file with the Senate Committee on Banking and Insurance).

²³ *Non-Medical Switching, Health Insurance Mandate Report* (Jan. 2017) (on file with the Senate Committee on Banking and Insurance).

know that the coverage benefit they sign up for is the coverage benefit they will receive for the plan year. The bill addresses the practice of some insurers and HMOs marketing certain pharmacy benefits to consumers at open enrollment, only to change the benefits during the plan year when insureds are generally unable to change plans. According to the report, there is no indication that the bill will have an impact on the cost of coverage. Advocates cite studies that document that some nonclinical drug substitutions may increase overall health care costs and result in adverse outcomes.

Regulation of Prescription Drug Formularies Changes in Other States

Staff conducted a limited survey of some states that had enacted legislation addressing formulary benefit changes or cost-sharing limits. In Louisiana, the formulary change must occur at the time of coverage renewal and prior notice is required to each affected covered employer and enrollee, or individual.²⁴ California prohibits changes in cost sharing designs during the plan or policy year, except when such change is required by state or federal law.²⁵ Nevada generally prohibits a health insurer that offers individual coverage from removing prescription drugs from a formulary or moving a drug to a higher cost-sharing tier during the plan year with some exceptions.²⁶ New Mexico generally limits when health insurance policies may change prescription drug coverage, with exceptions, and requires prior notification of all affected enrollees.²⁷ Virginia requires insurers to establish a process for insureds to obtain continued access to drugs that they have been receiving for at least six months prior to a formulary change at a cost-sharing level that is no higher than the level imposed on formulary drugs.²⁸ Texas prohibits insurers and HMOs from making mid-year formulary benefit and cost-sharing changes.²⁹

III. Effect of Proposed Changes:

Section 1 creates s. 627.42393, F.S., and **Sections 2 and 3** amend s. 627.6699, F.S., and s. 641.31, F.S., respectively.

CS/CS/SB 182 amends the Insurance Code to provide additional consumer protections by prohibiting a health insurer or HMO from removing a covered drug from its formulary during the policy year except during coverage renewal with some limited exceptions. These provisions would apply to individual and group policies and contracts. An insurer or HMO may remove a prescription drug from its list of covered drugs during the policy year if:

- The United States Food and Drug Administration has issued a statement about the drug which calls into question the clinical safety of the drug; or
- The manufacturer of the drug has notified the United States Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by s. 506C of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c.

²⁴ La Admin. Code title 37, pt. XIII, ss. 14111, 14115, and 14117.

²⁵ CAL. INS. Code, §10199.449; Effective Jan. 1, 2017; Approved by the Governor August 25, 2016.

²⁶ Nevada Division of Insurance, *Adopted Regulation R074-14* (uncodified).

²⁷ N.M. Stat. ss. 59A-22-49.4, 59A-23-7.13, 59A-46-50.4, and 59A-47-45.4.

²⁸ See Va. Code Ann. s. 38.2-3407.9.01.

²⁹ Tex. Ins. Code ss. 1369.0541 and 1501.108.

CS/CS/SB 182 also prohibits an insurer or HMO from reclassifying a drug to a more restrictive drug tier; increasing the amount that an insured must pay out-of-pocket for a copayment, coinsurance, or deductible for prescription drugs, or reclassifying a drug to a higher cost-sharing tier during the policy year.

The bill also:

- Does not prohibit the addition of prescription drugs to the list of drugs covered under the policy during the policy year.
- Does not alter or amend s. 465.025, F.S., which provides conditions under which a pharmacist may substitute a generically equivalent drug product for a brand name drug product.
- Does not alter or amend s. 465.0252, F.S., which provides conditions under which a pharmacist may dispense a substitute biological product for the prescribed biological product.

The provisions of the bill do not apply to grandfathered health plans, as defined in s. 627.402, F.S., or to benefits set forth in s. 627.6513(1)-(14), F.S.

Section 4 provides that this act fulfills an important state interest.

Section 5 provides the bill is effective January 1, 2018.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The county/municipality mandates provision of article VII, section 18 of the Florida Constitution may apply if the bill requires local governments to spend funds. If those provisions do apply, in order for the law to be binding upon the cities and counties, the Legislature must find that the law fulfills an important state interest, and one of the following relevant exceptions must apply:

- The expenditure is required to comply with a law that applies to all persons similarly situated; or
- The law must be approved by two-thirds of the membership of each house of the Legislature.

Since this bill requires all public sector health plans to limit drug changes in the formulary and insureds' cost sharing, it appears the bill applies to all persons similarly situated (state, counties, and municipalities).

The bill includes a finding that the act fulfills an important state interest.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. **Fiscal Impact Statement:**

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

By limiting changes to the prescription drug formulary, CS/CS/SB 182 would allow insureds to receive their brand drugs at a preferred cost for the policy year. Currently, the Insurance Code only prohibits HMO group contracts from increasing a member's copayment for any benefit or reducing a benefit during a plan year with some exceptions.

The prohibition on mid-policy year changes to drug formularies may increase the claim costs for health insurers and HMOs providing prescription drug benefits. Any increased costs would likely be passed along to insureds. The provisions of the bill would not apply to ERISA (Employee Retirement Income Security Act of 1974)³⁰ self-insured plans, which represent approximately 50 percent of the insureds in Florida. ERISA preempts the regulation of such plans by state regulation.

C. Government Sector Impact:

Division of State Group Insurance

The bill provides limitations on changes in formularies by allowing insureds to continue to obtain specified brand drugs at a "preferred" cost share throughout a calendar year; as a result, CS/CS/SB 182 prohibits the State Employees' Prescription Drug Plan from obtaining lower costs, even when the PBM negotiates better pricing and rebates for equally clinically effective brand and generic drugs.

The PBM states for the three quarterly formulary updates in 2016, approximately 1,100 of 139,000 drug plan users were impacted.

The DSGI indicates that the bill will have an indeterminate and substantial negative fiscal impact.³¹ The severity of the impact would be contingent on the number of brand drugs that are required to remain on the preferred drug list when other, less expensive, interchangeable and clinically appropriate brand and generic drugs are available. The DSGI notes, that not only would the cost of the medication be higher for the prescription drug program, but also the rebates from manufacturers to the program would be reduced significantly. The PBM provided the following estimates regarding the recurring impact on the DSGI:

³⁰ 29 U.S.C. 1001 et seq. (1974).

³¹ Department of Management Services, *Senate Bill 182 Analysis* (Jan. 19, 2017) (on file with the Senate Committee on Banking and Insurance).

- An additional cost of drugs to the State of Florida of \$50,000.
- Loss of manufacturers' rebates to the State of Florida of \$9.2 million.

Florida Medicaid Program

According to the Agency for Healthcare Administration, the bill has no fiscal impact on the Florida Medicaid program since it does not amend ch. 409, F.S., governing Florida Medicaid, nor does it require Medicaid to amend existing policies or procedures.³²

The Florida Healthy Kids Corporation also confirmed that the bill would have no fiscal impact on its contracts with managed care plans. The Florida Healthy Kids Corporation's benefits, policies, and procedures are separately prescribed in statute under ch. 409, F.S., as part of the Florida KidCare Program and under s. 624.91, F.S.³³

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 627.6699 and 641.31.

This bill creates section 627.42393 of the Florida Statutes.

IX. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS by Health Policy on February 21, 2017:

The CS/CS by Health Policy clarifies which policies are covered, modifies that changes may only be at the time of coverage renewal to be consistent with other state and federal provisions, and adds that the act fulfills an important state interest.

CS by Banking and Insurance on February 7, 2017:

The CS corrects a scrivener's error.

³² E-mail from Tony Guzzo, Agency for Healthcare Administration (Feb. 1, 2017) (on file with the Senate Committee on Banking and Insurance).

³³ E-mail from Steve Malono, Florida Healthy Kids Corporation (Feb. 13, 2017) (on file with the Senate Committee on Health Policy).

B. Amendments:

None.

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



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LEGISLATIVE ACTION

Senate	.	House
Comm: RS	.	
02/22/2017	.	
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The Committee on Health Policy (Mayfield) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause
and insert:

Section 1. Paragraph (k) is added to subsection (3) of
section 110.123, Florida Statutes, to read:

110.123 State group insurance program.—

(3) STATE GROUP INSURANCE PROGRAM.—

(k) Sections 627.42393 and 641.31(36)(a) do not apply to
the state group insurance program.



284826

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

627.42393 Insurance policies; limiting changes to prescription drug formularies.—

(1) Other than at the time of coverage renewal, an individual or group insurance policy that is delivered, issued for delivery, renewed, amended, or continued in this state and that provides medical, major medical, or similar comprehensive coverage may not:

(a) Remove a covered prescription drug from its list of covered drugs during the policy year unless the United States Food and Drug Administration has issued a statement about the drug which calls into question the clinical safety of the drug, or the manufacturer of the drug has notified the United States Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by s. 506C of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c.

(b) Reclassify a drug to a more restrictive drug tier or increase the amount that an insured must pay for a copayment, coinsurance, or deductible for prescription drug benefits, or reclassify a drug to a higher cost-sharing tier during the policy year.

(2) This section does not prohibit the addition of prescription drugs to the list of drugs covered under the policy during the policy year.

(3) This section does not apply to a grandfathered health plan as defined in s. 627.402 or to benefits set forth in s. 627.6513(1)-(14).

(4) This section does not alter or amend s. 465.025, which



284826

provides conditions under which a pharmacist may substitute a generically equivalent drug product for a brand name drug product.

(5) This section does not alter or amend s. 465.0252, which provides conditions under which a pharmacist may dispense a substitute biological product for the prescribed biological product.

Section 3. Paragraph (e) of subsection (5) of section 627.6699, Florida Statutes, is amended to read:

627.6699 Employee Health Care Access Act.—

(5) AVAILABILITY OF COVERAGE.—

(e) All health benefit plans issued under this section must comply with the following conditions:

1. For employers who have fewer than two employees, a late enrollee may be excluded from coverage for no longer than 24 months if he or she was not covered by creditable coverage continually to a date not more than 63 days before the effective date of his or her new coverage.

2. Any requirement used by a small employer carrier in determining whether to provide coverage to a small employer group, including requirements for minimum participation of eligible employees and minimum employer contributions, must be applied uniformly among all small employer groups having the same number of eligible employees applying for coverage or receiving coverage from the small employer carrier, except that a small employer carrier that participates in, administers, or issues health benefits pursuant to s. 381.0406 which do not include a preexisting condition exclusion may require as a condition of offering such benefits that the employer has had no



284826

health insurance coverage for its employees for a period of at least 6 months. A small employer carrier may vary application of minimum participation requirements and minimum employer contribution requirements only by the size of the small employer group.

3. In applying minimum participation requirements with respect to a small employer, a small employer carrier shall not consider as an eligible employee employees or dependents who have qualifying existing coverage in an employer-based group insurance plan or an ERISA qualified self-insurance plan in determining whether the applicable percentage of participation is met. However, a small employer carrier may count eligible employees and dependents who have coverage under another health plan that is sponsored by that employer.

4. A small employer carrier shall not increase any requirement for minimum employee participation or any requirement for minimum employer contribution applicable to a small employer at any time after the small employer has been accepted for coverage, unless the employer size has changed, in which case the small employer carrier may apply the requirements that are applicable to the new group size.

5. If a small employer carrier offers coverage to a small employer, it must offer coverage to all the small employer's eligible employees and their dependents. A small employer carrier may not offer coverage limited to certain persons in a group or to part of a group, except with respect to late enrollees.

6. A small employer carrier may not modify any health benefit plan issued to a small employer with respect to a small



284826

employer or any eligible employee or dependent through riders, endorsements, or otherwise to restrict or exclude coverage for certain diseases or medical conditions otherwise covered by the health benefit plan.

7. An initial enrollment period of at least 30 days must be provided. An annual 30-day open enrollment period must be offered to each small employer's eligible employees and their dependents. A small employer carrier must provide special enrollment periods as required by s. 627.65615.

8. A small employer carrier must limit changes to prescription drug formularies as required by s. 627.42393.

Section 4. Subsection (36) of section 641.31, Florida Statutes, is amended to read:

641.31 Health maintenance contracts.—

(36) A health maintenance organization may increase the copayment for any benefit, or delete, amend, or limit any of the benefits to which a subscriber is entitled under the group contract only, upon written notice to the contract holder at least 45 days in advance of the time of coverage renewal. The health maintenance organization may amend the contract with the contract holder, with such amendment to be effective immediately at the time of coverage renewal. The written notice to the contract holder must ~~shall~~ specifically identify any deletions, amendments, or limitations to any of the benefits provided in the group contract during the current contract period which will be included in the group contract upon renewal. This subsection does not apply to any increases in benefits. The 45-day notice requirement does ~~shall~~ not apply if benefits are amended, deleted, or limited at the request of the contract holder.



284826

(a) Other than at the time of coverage renewal, a health maintenance organization that provides medical, major medical, or similar comprehensive coverage may not:

1. Remove a covered prescription drug from its list of covered drugs during the contract year unless the United States Food and Drug Administration has issued a statement about the drug which calls into question the clinical safety of the drug, or the manufacturer of the drug has notified the United States Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by s. 506C of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c.

2. Reclassify a drug to a more restrictive drug tier or increase the amount that an insured must pay for a copayment, coinsurance, or deductible for prescription drug benefits, or reclassify a drug to a higher cost-sharing tier during the contract year.

(b) This subsection does not:

1. Prohibit the addition of prescription drugs to the list of drugs covered during the contract year.

2. Apply to a grandfathered health plan as defined in s. 627.402 or to benefits set forth in s. 627.6513(1)-(14).

3. Alter or amend s. 465.025, which provides conditions under which a pharmacist may substitute a generically equivalent drug product for a brand name drug product.

4. Alter or amend s. 465.0252, which provides conditions under which a pharmacist may dispense a substitute biological product for the prescribed biological product.

Section 5. The Legislature finds that this act fulfills an important state interest.



284826

Section 6. This act shall take effect January 1, 2018.

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

And the title is amended as follows:

Delete everything before the enacting clause
and insert:

A bill to be entitled

An act relating to consumer protection from nonmedical changes to prescription drug formularies; amending s. 110.123, F.S.; providing that certain provisions prohibiting nonmedical changes to prescription drug formularies do not apply to the state group insurance program; creating s. 627.42393, F.S.; limiting, under specified circumstances, changes to a health insurance policy prescription drug formulary during a policy year; providing construction and applicability; amending s. 627.6699, F.S.; requiring small employer carriers to limit changes to prescription drug formularies under certain circumstances; amending s. 641.31, F.S.; limiting, under specified circumstances, changes to a health maintenance contract prescription drug formulary during a contract year; providing construction and applicability; providing a declaration of important state interest; providing an effective date.



531074

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/22/2017	.	
	.	
	.	
	.	

The Committee on Health Policy (Mayfield) recommended the following:

Senate Substitute for Amendment (284826) (with title amendment)

Delete everything after the enacting clause and insert:

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

627.42393 Insurance policies; limiting changes to prescription drug formularies.—

(1) Other than at the time of coverage renewal, an



531074

individual or group insurance policy that is delivered, issued for delivery, renewed, amended, or continued in this state and that provides medical, major medical, or similar comprehensive coverage may not:

(a) Remove a covered prescription drug from its list of covered drugs during the policy year unless the United States Food and Drug Administration has issued a statement about the drug which calls into question the clinical safety of the drug, or the manufacturer of the drug has notified the United States Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by s. 506C of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c.

(b) Reclassify a drug to a more restrictive drug tier or increase the amount that an insured must pay for a copayment, coinsurance, or deductible for prescription drug benefits, or reclassify a drug to a higher cost-sharing tier during the policy year.

(2) This section does not prohibit the addition of prescription drugs to the list of drugs covered under the policy during the policy year.

(3) This section does not apply to a grandfathered health plan as defined in s. 627.402 or to benefits set forth in s. 627.6513(1)-(14).

(4) This section does not alter or amend s. 465.025, which provides conditions under which a pharmacist may substitute a generically equivalent drug product for a brand name drug product.

(5) This section does not alter or amend s. 465.0252, which provides conditions under which a pharmacist may dispense a



531074

40 substitute biological product for the prescribed biological
41 product.

42 Section 2. Paragraph (e) of subsection (5) of section
43 627.6699, Florida Statutes, is amended to read:

44 627.6699 Employee Health Care Access Act.—

45 (5) AVAILABILITY OF COVERAGE.—

46 (e) All health benefit plans issued under this section must
47 comply with the following conditions:

48 1. For employers who have fewer than two employees, a late
49 enrollee may be excluded from coverage for no longer than 24
50 months if he or she was not covered by creditable coverage
51 continually to a date not more than 63 days before the effective
52 date of his or her new coverage.

53 2. Any requirement used by a small employer carrier in
54 determining whether to provide coverage to a small employer
55 group, including requirements for minimum participation of
56 eligible employees and minimum employer contributions, must be
57 applied uniformly among all small employer groups having the
58 same number of eligible employees applying for coverage or
59 receiving coverage from the small employer carrier, except that
60 a small employer carrier that participates in, administers, or
61 issues health benefits pursuant to s. 381.0406 which do not
62 include a preexisting condition exclusion may require as a
63 condition of offering such benefits that the employer has had no
64 health insurance coverage for its employees for a period of at
65 least 6 months. A small employer carrier may vary application of
66 minimum participation requirements and minimum employer
67 contribution requirements only by the size of the small employer
68 group.



531074

69 3. In applying minimum participation requirements with
70 respect to a small employer, a small employer carrier shall not
71 consider as an eligible employee employees or dependents who
72 have qualifying existing coverage in an employer-based group
73 insurance plan or an ERISA qualified self-insurance plan in
74 determining whether the applicable percentage of participation
75 is met. However, a small employer carrier may count eligible
76 employees and dependents who have coverage under another health
77 plan that is sponsored by that employer.

78 4. A small employer carrier shall not increase any
79 requirement for minimum employee participation or any
80 requirement for minimum employer contribution applicable to a
81 small employer at any time after the small employer has been
82 accepted for coverage, unless the employer size has changed, in
83 which case the small employer carrier may apply the requirements
84 that are applicable to the new group size.

85 5. If a small employer carrier offers coverage to a small
86 employer, it must offer coverage to all the small employer's
87 eligible employees and their dependents. A small employer
88 carrier may not offer coverage limited to certain persons in a
89 group or to part of a group, except with respect to late
90 enrollees.

91 6. A small employer carrier may not modify any health
92 benefit plan issued to a small employer with respect to a small
93 employer or any eligible employee or dependent through riders,
94 endorsements, or otherwise to restrict or exclude coverage for
95 certain diseases or medical conditions otherwise covered by the
96 health benefit plan.

97 7. An initial enrollment period of at least 30 days must be



531074

provided. An annual 30-day open enrollment period must be offered to each small employer's eligible employees and their dependents. A small employer carrier must provide special enrollment periods as required by s. 627.65615.

8. A small employer carrier must limit changes to prescription drug formularies as required by s. 627.42393.

Section 3. Subsection (36) of section 641.31, Florida Statutes, is amended to read:

641.31 Health maintenance contracts.—

(36) A health maintenance organization may increase the copayment for any benefit, or delete, amend, or limit any of the benefits to which a subscriber is entitled under the group contract only, upon written notice to the contract holder at least 45 days in advance of the time of coverage renewal. The health maintenance organization may amend the contract with the contract holder, with such amendment to be effective immediately at the time of coverage renewal. The written notice to the contract holder must ~~shall~~ specifically identify any deletions, amendments, or limitations to any of the benefits provided in the group contract during the current contract period which will be included in the group contract upon renewal. This subsection does not apply to any increases in benefits. The 45-day notice requirement does ~~shall~~ not apply if benefits are amended, deleted, or limited at the request of the contract holder.

(a) Other than at the time of coverage renewal, a health maintenance organization that provides medical, major medical, or similar comprehensive coverage may not:

1. Remove a covered prescription drug from its list of covered drugs during the contract year unless the United States



531074

Food and Drug Administration has issued a statement about the drug which calls into question the clinical safety of the drug, or the manufacturer of the drug has notified the United States Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by s. 506C of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c.

2. Reclassify a drug to a more restrictive drug tier or increase the amount that an insured must pay for a copayment, coinsurance, or deductible for prescription drug benefits, or reclassify a drug to a higher cost-sharing tier during the contract year.

(b) This subsection does not:

1. Prohibit the addition of prescription drugs to the list of drugs covered during the contract year.

2. Apply to a grandfathered health plan as defined in s. 627.402 or to benefits set forth in s. 627.6513(1)-(14).

3. Alter or amend s. 465.025, which provides conditions under which a pharmacist may substitute a generically equivalent drug product for a brand name drug product.

4. Alter or amend s. 465.0252, which provides conditions under which a pharmacist may dispense a substitute biological product for the prescribed biological product.

Section 4. The Legislature finds that this act fulfills an important state interest.

Section 5. This act shall take effect January 1, 2018.

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

And the title is amended as follows:

Delete everything before the enacting clause



531074

and insert:

A bill to be entitled

An act relating to consumer protection from nonmedical changes to prescription drug formularies; creating s. 627.42393, F.S.; limiting, under specified circumstances, changes to a health insurance policy prescription drug formulary during a policy year; providing construction and applicability; amending s. 627.6699, F.S.; requiring small employer carriers to limit changes to prescription drug formularies under certain circumstances; amending s. 641.31, F.S.; limiting, under specified circumstances, changes to a health maintenance contract prescription drug formulary during a contract year; providing construction and applicability; providing a declaration of important state interest; providing an effective date.

By the Committee on Banking and Insurance; and Senator Mayfield

597-01717-17

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A bill to be entitled

An act relating to consumer protection from nonmedical changes to prescription drug formularies; creating s. 627.42393, F.S.; limiting changes to a health insurance policy prescription drug formulary during a policy year; providing applicability and construction; amending s. 627.6699, F.S.; requiring small employer carriers to limit changes to prescription drug formularies under certain circumstances; amending s. 641.31, F.S.; limiting changes to a health maintenance contract prescription drug formulary during a contract year; providing applicability and construction; providing an effective date.

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

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

627.42393 Insurance policies; limiting changes to prescription drug formularies.—

(1) Other than during an open enrollment period, an individual or group insurance policy that is delivered, issued for delivery, renewed, amended, or continued in this state and that provides medical, major medical, or similar comprehensive coverage may not:

(a) Remove a covered prescription drug from its list of covered drugs during the policy year unless the United States Food and Drug Administration has issued a statement about the drug which calls into question the clinical safety of the drug, or the manufacturer of the drug has notified the United States Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by s. 506C

597-01717-17

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of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c.

(b) Reclassify a drug to a more restrictive drug tier or increase the amount that an insured must pay for a copayment, coinsurance, or deductible for prescription drug benefits, or reclassify a drug to a higher cost-sharing tier during the policy year.

(2) This section does not prohibit the addition of prescription drugs to the list of drugs covered under the policy during the policy year.

(3) This section does not apply to a grandfathered health plan as defined in s. 627.402 or to benefits set forth in s. 627.6513(1)-(14).

(4) This section does not alter or amend s. 465.025, which provides conditions under which a pharmacist may substitute a generically equivalent drug product for a brand name drug product.

(5) This section does not alter or amend s. 465.0252, which provides conditions under which a pharmacist may dispense a substitute biological product for the prescribed biological product.

Section 2. Paragraph (e) of subsection (5) of section 627.6699, Florida Statutes, is amended to read:

627.6699 Employee Health Care Access Act.—

(5) AVAILABILITY OF COVERAGE.—

(e) All health benefit plans issued under this section must comply with the following conditions:

1. For employers who have fewer than two employees, a late enrollee may be excluded from coverage for no longer than 24 months if he or she was not covered by creditable coverage

597-01717-17

2017182c1

continually to a date not more than 63 days before the effective date of his or her new coverage.

2. Any requirement used by a small employer carrier in determining whether to provide coverage to a small employer group, including requirements for minimum participation of eligible employees and minimum employer contributions, must be applied uniformly among all small employer groups having the same number of eligible employees applying for coverage or receiving coverage from the small employer carrier, except that a small employer carrier that participates in, administers, or issues health benefits pursuant to s. 381.0406 which do not include a preexisting condition exclusion may require as a condition of offering such benefits that the employer has had no health insurance coverage for its employees for a period of at least 6 months. A small employer carrier may vary application of minimum participation requirements and minimum employer contribution requirements only by the size of the small employer group.

3. In applying minimum participation requirements with respect to a small employer, a small employer carrier shall not consider as an eligible employee employees or dependents who have qualifying existing coverage in an employer-based group insurance plan or an ERISA qualified self-insurance plan in determining whether the applicable percentage of participation is met. However, a small employer carrier may count eligible employees and dependents who have coverage under another health plan that is sponsored by that employer.

4. A small employer carrier shall not increase any requirement for minimum employee participation or any

597-01717-17

2017182c1

requirement for minimum employer contribution applicable to a small employer at any time after the small employer has been accepted for coverage, unless the employer size has changed, in which case the small employer carrier may apply the requirements that are applicable to the new group size.

5. If a small employer carrier offers coverage to a small employer, it must offer coverage to all the small employer's eligible employees and their dependents. A small employer carrier may not offer coverage limited to certain persons in a group or to part of a group, except with respect to late enrollees.

6. A small employer carrier may not modify any health benefit plan issued to a small employer with respect to a small employer or any eligible employee or dependent through riders, endorsements, or otherwise to restrict or exclude coverage for certain diseases or medical conditions otherwise covered by the health benefit plan.

7. An initial enrollment period of at least 30 days must be provided. An annual 30-day open enrollment period must be offered to each small employer's eligible employees and their dependents. A small employer carrier must provide special enrollment periods as required by s. 627.65615.

8. A small employer carrier must limit changes to prescription drug formularies as required by s. 627.42393.

Section 3. Subsection (44) is added to section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(44)(a) Other than during an open enrollment period, a health maintenance contract that is delivered, issued for

597-01717-17 2017182c1

120 delivery, renewed, amended, or continued in this state and that
 121 provides medical, major medical, or similar comprehensive
 122 coverage may not:

123 1. Remove a covered prescription drug from its list of
 124 covered drugs during the contract year unless the United States
 125 Food and Drug Administration has issued a statement about the
 126 drug which calls into question the clinical safety of the drug,
 127 or the manufacturer of the drug has notified the United States
 128 Food and Drug Administration of a manufacturing discontinuance
 129 or potential discontinuance of the drug as required by s. 506C
 130 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c.

131 2. Reclassify a drug to a more restrictive drug tier or
 132 increase the amount that an insured must pay for a copayment,
 133 coinsurance, or deductible for prescription drug benefits, or
 134 reclassify a drug to a higher cost-sharing tier during the
 135 contract year.

136 (b) This subsection does not prohibit the addition of
 137 prescription drugs to the list of drugs covered during the
 138 contract year.

139 (c) This subsection does not apply to a grandfathered
 140 health plan as defined in s. 627.402 or to benefits set forth in
 141 s. 627.6513(1)-(14).

142 (d) This subsection does not alter or amend s. 465.025,
 143 which provides conditions under which a pharmacist may
 144 substitute a generically equivalent drug product for a brand
 145 name drug product.

146 (e) This subsection does not alter or amend s. 465.0252,
 147 which provides conditions under which a pharmacist may dispense
 148 a substitute biological product for the prescribed biological

597-01717-17

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149 product.

150 Section 4. This act shall take effect January 1, 2018.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Education, *Vice Chair*
Appropriations Subcommittee on the Environment
and Natural Resources
Appropriations Subcommittee on General
Government
Banking and Insurance
Judiciary

JOINT COMMITTEE:

Joint Legislative Auditing Committee,
Alternating Chair

SENATOR DEBBIE MAYFIELD
17th District

February 7, 2017

Chairman Young
316 Senate Office Building
404 South Monroe Street
Tallahassee, FL 32399-1100

Re: SB 182

Dear Chairman Young,

I am respectfully requesting Senate Bill 182, a bill relating to Consumer Protection from Nonmedical Changes to Prescription Drug Formularies, be placed on the agenda for your committee on Health Policy.

I appreciate your consideration of this bill and I look forward to working with you and the Health Policy committee. If there are any questions or concerns, please do not hesitate to call my office at 850-487-5017.

Thank you,

A handwritten signature in blue ink, appearing to read "Debbie Mayfield".

Senator Debbie Mayfield
District 17

Cc: Sandra Stovall, Beau Giles, Melonie Hoyt, Brian McManus

REPLY TO:

- ☐ 900 E. Strawbridge Avenue, Melbourne, Florida 32901 (321) 409-2025
- ☐ 1801 27th Street, Vero Beach, Florida 32960 (772) 226-1970
- ☐ 324 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5017

Senate's Website: www.flsenate.gov

JOE NEGRON
President of the Senate

ANITERE FLORES
President Pro Tempore

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-21-17
Meeting Date

SB 182
Bill Number (if applicable)

Topic Consumer Protection From Nonmedical Charges Amendment Barcode (if applicable)

Name Margaret S. Hooper

Job Title Public Policy Coordinator

Address 124 Marriott Drive #203 Phone 850.922.6703
Street

Tallahassee FL 32301 Email Margaret.D@FDDC.org
City State Zip

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Developmental Disabilities Council

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-21-17
Meeting Date

182
Bill Number (if applicable)

Topic Bait & Switch

Amendment Barcode (if applicable)

Name Jennifer Ross

Job Title Ambassador

Address 2378 Geranium Ave
Street

Phone 904-838-3228

Middleburg FL 32068
City State Zip

Email jjross98@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Arthritis Foundation

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17

Meeting Date

182

Bill Number (if applicable)

Topic Consumer Protection from Non-Medical Charges

Amendment Barcode (if applicable)

Name Fely Curva, Ph.D.

Job Title Senior Partner, Curva & Assoc., LLC

Address 1212 Piedmont Dr.

Street

Phone (850) 508-2256

Tallahassee

City

FL

State

32312

Zip

Email fely.curva@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Budd Bell Clearinghouse on Human Services

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

February 21, 2017
Meeting Date

CS/SB 182
Bill Number (if applicable)

Topic Consumer Protection for Nonmedical Changes to Prescription
Name Dorene Barker Drug Formulations

Amendment Barcode (if applicable)

Job Title Associate State Director

Address 200 W. College, St 304
Street
Tallahassee FL 32301
City State Zip

Phone 850-228-6387

Email dbarker@carp.org

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing AARP

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

2-21-17

Meeting Date

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

SB 185

Bill Number (if applicable)

Topic FAIR X

Amendment Barcode (if applicable)

Name JERI FRANCOEUR

Job Title PATIENT ADVOCATE

Address 1 SHARON TERR
Street

Phone 386-295-1554

ORMOND BEACH FL 32174
City State Zip

Email jfrancoeur@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing FLORIDA BREAST CANCER FOUNDATION

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/2017
Meeting Date

SB 1905
Bill Number (if applicable)

Topic FAIR X

Amendment Barcode (if applicable)

Name Valencia Robinson

Job Title Patient Advocate

Address 1620 Piccadilly Dr.
Street
Daytona Beach FL 32117
City State Zip

Phone 306-405-7917

Email robinsonvalencia@gmail.com

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Holida Breast Cancer Foundation

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-21-17

Meeting Date

182

Bill Number (if applicable)

Topic CS/SB 182

Amendment Barcode (if applicable)

Name Audrey Brown

Job Title President and CEO

Address 200 W. College Ave.
Street

Phone 850-386-2904

Tallahassee, FL 32301
City State Zip

Email audrey@fahp.net

Speaking: ☐ For ☒ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Association of Health Plans

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21

Meeting Date

SB 182

Bill Number (if applicable)

Topic Drug Formularies

Amendment Barcode (if applicable)

Name Brewster BevisJob Title Senior Vice PresidentAddress 516 N. Adams StPhone 2247173

Street

TallahasseeFL32301Email bbevis@aif.com

City

State

Zip

Speaking: ☐ For ☒ Against ☐ InformationWaive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)Representing Associated Industries of FloridaAppearing at request of Chair: ☐ Yes ☒ NoLobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

2-21-17

Meeting Date

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

182

Bill Number (if applicable)

Topic Non Med Switching

Amendment Barcode (if applicable)

Name Matt Jordan

Job Title GRD

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Phone 850-514-2801

Street

Tallahassee FL 32303

City

State

Zip

Email matt.jordan@carer.org

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing American Cancer Society Cancer Action Network

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1/21/12
Meeting Date

CS/SB 182
Bill Number (if applicable)

Topic Consumer Protection

Amendment Barcode (if applicable)

Name Aimee Diaz Lyon

Job Title _____

Address 119 South Monroe Street #200

Phone 850-205-9000

Street

Tallahassee

City

FL

State

32301

Zip

Email aimée.diazlyon@mhdfirm.com

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing The AIDS Institute

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

APPEARANCE RECORD

412-K
12:30 PM

2-21-2017
Meeting Date

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

SB 182 ✓
Bill Number (if applicable)

Topic CONSUMER PROTECTION FROM NON-MEDICAL CHARGES

Amendment Barcode (if applicable)

Name STEPHEN R. WINN

Job Title EXECUTIVE DIRECTOR

Address 2544 BLAIRSTONE PINES DR

Phone 878-7364

TALLAHASSEE FL 32301
City State Zip

Email _____

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking. ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing FLORIDA OSTEOPATHIC MEDICAL ASSOCIATION

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17
Meeting Date

182
Bill Number (if applicable)

Topic Non-medical switching of medications

Amendment Barcode (if applicable)

Name Alisa LaPort

Job Title Executive Director

Address PO Box 966

Phone 671-4445

Street

TLH
City

FL
State

32301
Zip

Email alisa@namiFlorida.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing NAMI Florida (National Alliance on Mental Illness)

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17

Meeting Date

182

Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Nuland

Job Title _____

Address 1000 Riverside Ave

Street

Phone 904-233-3051

Jacksonville, FL 32204

City

State

Zip

Email nulandlaw@aol.com

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Gastroenterologic Society

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-21-17

Meeting Date

SB182

Bill Number (if applicable)

Strike-all

Amendment Barcode (if applicable)

Topic NonMedical Change 3

Name Joy Ryan

Job Title

Address 325 W. College Ave.

Street

Tallahassee, FL 32312

City

State

Zip

Phone 425-4000

Email joy@meenanlawfirm.com

Speaking: ☐ For ☒ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing America's Health Insurance Plans

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17

Meeting Date

182

Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Julio Perez-Dawner, MD

Job Title _____

Address 1000 Riverside Ave #220
Street

Phone 355-0800
904-233-30

City

State

Zip

Email FloridaChapter@comcast.net

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Chapter, American College of Physicians

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17
Meeting Date

182
Bill Number (if applicable)

Topic Consumer Protection from Nonmedical
Name Mary Thomas changes

Amendment Barcode (if applicable)

Job Title Assistant Gen. Counsel

Address 1430 Piedmont Dr E
Street

Phone 850 224 6496

Tallahassee FL 32308
City State Zip

Email MThomas@flmedical.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

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S-001 (10/14/14)

THE FLORIDA SENATE

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Meeting Date

Bill Number (if applicable)

Topic Consumer Protection

Amendment Barcode (if applicable)

Name Doug Bell

Job Title _____

Address 101 N. Monroe

Phone 681-4270

Street

TLH

Email douglas.bello@tides.org

City

State

Zip

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against

(The Chair will read this information into the record.)

Representing FL Chapter American Academy of Pediatrics

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17

Meeting Date

182

Bill Number (if applicable)

Topic Consumer Protection

Amendment Barcode (if applicable)

Name Melanie Brown

Job Title Government Affairs Director / Team JB

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Phone 850 224 1900

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32301

Email

City

State

Zip

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing FL Society of Dermatologists

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

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S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/20/21
Meeting Date

182
Bill Number (if applicable)

Topic SB 182

Amendment Barcode (if applicable)

Name Rebecca Roman

Job Title Associate

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Street

Phone 727 916 0608

Tallahassee FL
City State Zip

Email rebecca@adamsst
adams

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Pharm Assoc.

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: CS/CS/SB 240

INTRODUCER: Health Policy Committee; Banking and Insurance Committee and Senator Lee

SUBJECT: Direct Primary Care

DATE: February 22, 2017

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	Fav/CS
2.	Lloyd	Stovall	HP	Fav/CS
3.			AHS	
4.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 240 amends the Florida Insurance Code (code) to provide that a direct primary care agreement is not insurance and is not subject to regulation under the code. Direct primary care (DPC) is a primary care medical practice model that eliminates third party payers from the primary care provider-patient relationship. The bill also defines and establishes DPC agreements in ch. 456, F.S., relating to general provisions for health care practitioners.

Through a contractual agreement, a patient pays a monthly fee, usually between \$50 and \$100 per individual, to the primary care provider for defined primary care services. As of June 2016, 16 states have adopted DPC laws that define DPC as a medical service outside the scope of state insurance regulation. The bill defines terms and specifies certain provisions, including consumer disclosures, which must be included in a DPC agreement.

The Agency for Health Care Administration (AHCA) is required to submit a waiver to the appropriate federal authorities by January 1, 2018, to provide Medicaid recipients in the Statewide Medicaid Managed Care program the opportunity to select DPC agreements as a delivery service option.

II. Present Situation:

Direct Primary Care

Direct primary care is a primary care medical practice model that eliminates third party payers from the provider-patient relationship. Through a contractual agreement, a patient generally pays a monthly retainer fee, on average \$77 per individual,¹ to the primary care provider for defined primary care services, such as office visits, preventive care, annual physical examination, and routine laboratory tests.

After paying the monthly fee, a patient can access all services under the agreement at no extra charge based on the terms of the agreement. Typically, DPC practices provide routine preventive services, screenings, or tests, like lab tests, mammograms, Pap screenings, and vaccinations. A primary care provider DPC model can be designed to address most health care issues, including women's health services, pediatric care, urgent care, wellness education, and chronic disease management.

Some of the potential benefits of the DPC model for providers include reducing patient volume, minimizing administrative and staffing expenses; increasing time with patients; and increasing revenues. In the DPC practice model, the primary care provider eliminates administrative costs associated with filing and resolving insurance claims. Direct primary care practices claim to reduce expenses by more than 40 percent by eliminating administrative staff resources associated with third-party costs.²

In 2014, the American Academy of Private Physicians (AAPP) estimated that approximately 5,500 physicians operate under some type of direct financial relationship with their patients, outside of standard insurance coverage. According to the AAPP, that number has increased around 25 percent per year since 2010.³ The Direct Primary Care Coalition has adopted model state legislation for DPC agreements.⁴ As of June 2016, 16 states have adopted DPC legislation, which defines DPC as a medical service outside the scope of state insurance regulation.⁵

The DPC practice model is often compared to the concierge practice model. However, while both provide access to primary care services for a periodic fee, the concierge model continues to

¹ A study of 141 DPC practices found the average monthly retainer fee to be \$77.38. Of the 141 practices identified, 116 (82 percent) have cost information available online. When these 116 practices were analyzed, the average monthly cost to the patient was \$93.26 (median monthly cost, \$75.00; range, \$26.67 to \$562.50 per month). Of the 116 DPCs noted, 36 charged a one-time enrollment fee and the average enrollment fee was \$78. Twenty-eight of 116 DPCs charged a fee for office visits in addition to the retainer fee, and the average visit fee was \$16. See Phillip M. Eskew and Kathleen Klink, *Direct Primary Care: Practice Distribution and Cost Across the Nation*, Journal of the Amer. Bd. of Family Med. (Nov.-Dec. 2015) Vol. 28, No. 6, p. 797, available at: <http://www.jabfm.org/content/28/6/793.full.pdf> (last viewed Feb. 10, 2017).

² Lisa Zamosky, Direct-Pay Medical Practices Could Diminish Payer Headaches, MEDICAL ECONOMICS, (April 24, 2014), <http://medicaleconomics.modernmedicine.com/medical-economics/content/tags/concierge-service/direct-pay-medical-practices-could-diminish-payer-h>. (last viewed Feb. 10, 2017).

³ David Twiddy, *Practice Transformation: Taking the Direct Primary Care Route*, Family Practice Management, No. 3, (May-June 2014), available at: <http://www.aafp.org/fpm/2014/0500/p10.html> (last viewed Feb. 10, 2017).

⁴ Direct Primary Care Coalition Model State Legislation, available at: <http://www.dpcare.org/dpcc-model-legislation>. (last viewed Feb. 10, 2017).

⁵ See <http://www.dpcare.org/> (last viewed Feb. 10, 2017).

bill third party payors, such as insurers, in addition to the collection of membership and retainer fees.⁶

Federal Health Care Reform and Direct Primary Care

The federal Patient Protection and Affordable Care Act (PPACA)⁷ requires health insurers to make guaranteed issue coverage available to all individuals and employers, without exclusions for preexisting conditions and without basing premiums on any health-related factors. The PPACA also mandates that insurers that offer qualified health plans (QHPs) provide 10 categories of essential health benefits,⁸ which includes preventive⁹ care and other benefits.

The PPACA addresses the DPC practice model as part of health care reform. A QHP may provide coverage through a DPC medical home plan that meets criteria¹⁰ established by the federal Department of Health and Human Services (DHHS), provided the QHP meets all other applicable requirements.¹¹ Insureds who are enrolled in a DPC medical home plan are compliant with the individual mandate if they have coverage for other services, such as a wraparound catastrophic health policy¹² or high deductible, health insurance plans¹³ to provide coverage for severe injuries or chronic conditions.

In Colorado and Washington, qualified health plans offer DPC medical home coverage on the state-based health insurance exchanges.¹⁴ One of those qualified health plans also participates as a managed care plan in Washington and offers access to its DPC medical home provider sites for its Medicaid managed care plan enrollees. The three clinics offer extended office hours and 24/7 access to physicians for the recipients.¹⁵ In Michigan for the 2016-2017 state fiscal year, the Department of Health and Human Services through the annual appropriations bill has been tasked to review and consider implementing a pilot program to allow Medicaid enrollees in managed care to participate in a direct primary care provider plan. Outcomes and performance specified in that bill include:

- The number of enrollees in the pilot program by Medicaid eligibility category;
- Direct primary care cost per enrollee; and
- Other Medicaid managed care cost savings generated from direct primary care.¹⁶

⁶ Eskew and Klink, *supra* note 1, at 793.

⁷ Pub. Law No. 111-148 (Mar. 23, 2010) amended by Pub. Law. No. 111-152 (Mar. 30, 2010).

⁸ 42 U.S.C. s.18022.

⁹ Available at: <https://www.hhs.gov/healthcare/about-the-law/preventive-care/index.html#>. (last viewed Feb. 13, 2017). Many of these preventive services must be covered without any cost sharing by the patient.

¹⁰ The HHS has not adopted criteria to date.

¹¹ See 42 U.S.C. ss. 18021(a)(3) and 18022.

¹² Catastrophic plans are a form of high deductible plans, which meet the minimum essential coverage requirements. See 42 U.S.C s. 18021 for eligibility and coverage requirements.

¹³ A high deductible health plan (HDHP) has a higher deductible than typical plans and a maximum limit on amount of the annual deductible and out-of-pocket medical expenses that an insured must pay for covered expenses. Out-of-pocket expenses include copayments and other amounts, excluding premiums.

¹⁴ See http://www.akleg.gov/basis/get_documents.asp?session=29&docid=7936 (last visited Feb. 13, 2017).

¹⁵ Qliance, *New Primary Care Model Delivers 20 Percent Lower Overall Healthcare Costs, Increases Patient Satisfaction*, State of Reform (Jan. 15, 2015) <http://stateofreform.com/news/industry/healthcare-providers/2015/01/qliance-study-shows-monthly-fee-primary-care-model-saves-20-percent-claims/> (last viewed Feb. 21, 2017).

¹⁶ 2016 Mich. Pub. Acts No. 268; section 1701; (See: <http://www.legislature.mi.gov/documents/2015-2016/publicact/pdf/2016-PA-0268.pdf>).

While the DHHS regulations do not consider DPC medical homes as insurance,¹⁷ the Internal Revenue Service (IRS) regulations will not permit tax deductions for those individuals with both health savings accounts (HSAs) and DPCs as the tax code considers the DPC a second health plan.¹⁸ The IRS Code additionally does not permit the periodic payments made to primary care physicians under a DPC model to qualify as a medical expense under Section 213(d) of the IRS Code.

State Regulation of Insurance

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, HMOs, and other risk-bearing entities. These specified entities must meet certain requirements for licensure. The Agency for Health Care Administration (agency) issues regulations regarding the quality of care provided by HMOs and prepaid health clinics under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, a HMO and a prepaid health clinic must receive a Health Care Provider Certificate¹⁹ from the agency pursuant to part III of ch. 641, F.S.²⁰

Currently, Florida law does not address DPC agreements. However, a medical provider offering DPC agreements may be considered to be operating a prepaid health clinic if the medical provider is offering to provide services in exchange for a prepaid fixed fee.²¹

Prepaid Health Clinics

Prepaid health clinics²² are required to obtain a certificate of authority from the OIR pursuant to part II of chapter 641, F.S. The entity must meet minimum surplus requirements²³ and comply with solvency protections for the benefit of subscribers by securing insurance or filing a surety bond with the OIR.²⁴ Part II also provides that the procedures for offering basic services and offering and terminating contracts to subscribers may not unfairly discriminate based on age, health, or economic status.²⁵

¹⁷ 45 C.F.R. s. 156.245 (10-1-2016).

¹⁸ 26 U.S. Code s. 223

¹⁹ Section 641.49, F.S.

²⁰ Section 641.48, F.S., provides that the purpose of part III of ch. 641, F.S., is to ensure that HMOs and prepaid health clinics deliver high-quality care to their subscribers.

²¹ Part II of ch. 641, F.S.

²² Section 641.402, F.S., defines the term, “prepaid health clinic,” to mean any organization authorized under part II that provides, either directly or through arrangements with other persons, basic services to persons enrolled with such organization, on a prepaid per capita or prepaid aggregate fixed-sum basis, including those basic services which subscribers might reasonably require to maintain good health. However, no clinic that provides or contracts for, either directly or indirectly, inpatient hospital services, hospital inpatient physician services, or indemnity against the cost of such services shall be a prepaid health clinic.

²³ Section 641.406, F.S. Each prepaid health clinic must maintain minimum surplus in the amount of \$150,000 or 10 percent of total liabilities, whichever is greater.

²⁴ Section 641.409, F.S.

²⁵ Section 641.406, F.S.

Prepaid Limited Health Service Organizations

Prepaid limited health service organizations provide limited health services to enrollees through an exclusive panel of providers in exchange for a prepayment authorized under ch. 636, F.S. Limited health services include ambulance, dental, vision, mental health, substance abuse, chiropractic, podiatric, and pharmaceutical. Provider arrangements for prepaid limited health service organizations are authorized in s. 636.035, F.S., and must comply with the requirements in that section.

State Regulation of Health Care Practitioners

The Department of Health (DOH) is responsible for the licensure and regulation of most health care practitioners in the state. In addition to the regulatory authority in specific practice acts for each profession or occupation, ch. 456, F.S., provides the general regulatory provisions for health care professions within the DOH, Medical Quality Assurance Division.

Section 456.001, F.S., defines “health care practitioner” as any person licensed under chs. 457, (acupuncture); 458 (medicine); 459 (osteopathic medicine); 460 (chiropractic medicine); 461 (podiatric medicine); 462 (naturopathic medicine); 463 (optometry); 464 (nursing); 465 (pharmacy); 466 (dentistry and dental hygiene); 467 (midwifery); 478 (electrology or electrolysis); 480 (massage therapy); 484 (opticianry and hearing aid specialists); 486 (physical therapy); 490 (psychology); 491 (psychotherapy), F.S., or parts III or IV of ch. 483 (clinical laboratory personnel or medical physics), F.S.

Additionally, the miscellaneous professions and occupations regulated in parts I, II, III, V, X, XIII, or XIV (speech-language pathology and audiology; nursing home administration; occupational therapy; respiratory therapy; dietetics and nutrition practice; athletic trainers; and orthotics, prosthetics, and pedorthics) of ch. 468, F.S., are considered health care practitioners under s. 456.001, F.S.

Statewide Medicaid Managed Care**Florida Medicaid**

The Medicaid program is a partnership between the federal and state governments to provide medical care to low income children and disabled persons. Each state operates its own Medicaid program under a state plan that must be approved by the federal Centers for Medicare & Medicaid Services (CMS). The state plan outlines Medicaid eligibility standards, policies, and reimbursement methodologies.

Florida Medicaid is administered by the Agency for Health Care Administration (AHCA) and is financed with federal and state funds. The Department of Children and Families (DCF) determines Medicaid eligibility and transmits that information to the AHCA. The AHCA is designated as the single state Medicaid agency and has the lead responsibility for the overall program.²⁶

²⁶ See s. 409.963, F.S.

Over 4 million Floridians are currently enrolled in Medicaid.²⁷ The Medicaid program's estimated expenditures for the 2016-2017 fiscal year are \$25.8 billion.²⁸ The current traditional federal share is 60.67 percent with the state paying 39.33 percent for Medicaid enrollees.²⁹ Florida has the fourth largest Medicaid population in the country and fifth largest in expenditures.³⁰

Medicaid currently covers:

- 47 percent of Florida's children;
- 63 percent of Florida's births; and
- 61 percent of Florida's nursing homes days.³¹

The structures of state Medicaid programs vary from state to state, and each state's share of expenditures also varies and is largely determined by the federal government. Approximately 85 percent of Florida's Medicaid program is enrolled in managed care. Federal law and regulations set the minimum amount, scope, and duration of services offered in the program, among other requirements. State Medicaid benefits are provided in statute under s. 409.903, F.S. (Mandatory Payments for Eligible Persons) and s. 409.904, F.S. (Optional Payments for Eligible Persons).

Applicants for Medicaid must be United States citizens or qualified noncitizens, must be Florida residents, and must provide social security numbers for data matching. While self-attestation is permitted for a number of data elements on the application, most components are matched through the Federal Data Services Hub.³² Applicants must also agree to cooperate with Child Support Enforcement during the application process and eligibility process.³³

Minimum eligibility coverage thresholds are established in federal law for certain population groups, such as children, as well as minimum benefits and maximum cost sharing. The minimum benefits include items such as physician services, hospital services, home health services, and family planning.³⁴ States can add benefits, pending federal approval. Florida has added benefits, including prescription drugs, adult dental services, and dialysis.³⁵ For children under age 21, the benefits must include the Early and Periodic Screening, Diagnostic and Treatment services,

²⁷ Agency for Health Care Administration, *Report of Medicaid Eligibles* (Dec. 31, 2016) (on file with the Senate Committee on Health Policy).

²⁸ Social Services Estimating Conference, *Medicaid Services Expenditures* (Dec. 7, 2016) available at: www.edr.state.fl.us/Content/conferences/medicaid/medexp_summary.pdf

²⁹ Office of Economic and Demographic Research, *Social Services Estimating Conference - Official FMAP Estimate* (November 2016) available at: <http://edr.state.fl.us/Content/conferences/medicaid/fmap.pdf> (last viewed Feb. 20, 2017). The SSEC has also created a "real time" FMAP blend" for the Statewide Medicaid Managed Care Program which is 60.99 percent for SFY 2016-17.

³⁰ Agency for Health Care Administration, Senate Health and Human Services Appropriations Committee Presentation, *Agency for Health Care Administration - Florida Medicaid* (January 11, 2017), at slide 2, available at: http://www.flsenate.gov/PublishedContent/Committees/2016-2018/AHS/MeetingRecords/MeetingPacket_3554.pdf (last viewed Feb. 20, 2017).

³¹ *Id.* at 10.

³² Florida Dep't of Children and Families, *Family-Related Medicaid Programs Fact Sheet*, p. 4 (April 2016) available at: <http://www.dcf.state.fl.us/programs/access/docs/Family-RelatedMedicaidFactSheet.pdf> (last viewed Feb. 21, 2017).

³³ *Id.*

³⁴ Section 409.905, F.S.

³⁵ Section 409.906, F.S.

which are those health care and diagnostic services and treatment and measures that may be needed to correct or ameliorate defects or physical and mental illnesses and conditions discovered by screening services, consistent with federal law.³⁶

Statewide Medicaid Managed Care

Part IV of ch. 409, F.S., was created in 2011 by ch. 2011-134, L.O.F., and governs the Statewide Medicaid Managed Care program (SMMC). The program, authorized under federal Medicaid waivers, is designed for the AHCA to issue invitations to negotiate³⁷ and competitively procure contracts with managed care plans in 11 regions of the state to provide comprehensive Medicaid coverage for most of the state's enrollees in the Medicaid program. SMMC has two components: managed medical assistance (MMA) and long-term care managed care (LTCMC).

The LTCMC component began enrolling Medicaid recipients in August 2013 and completed its statewide roll-out in March 2014. The MMA component began enrolling Medicaid recipients in May 2014 and finished its roll-out in August 2014. As of December 2016, there were over 3.2 million Medicaid recipients enrolled in an MMA plan and 94,320 recipients enrolled in an LTC plan.³⁸

III. Effect of Proposed Changes:

Direct Primary Care Agreements (Sections 2 and 3)

The CS/CS 240 creates s. 456.0625, F.S., establishing direct primary care agreements within ch. 456, F.S., relating to the general provisions for health care practitioners.

The bill defines the following terms within ch. 456, F.S.:

- “Direct primary care agreement” is a contract between a primary care provider and a patient, the patient’s legal representative, or an employer which must satisfy certain requirements within the bill and does not indemnify for services provided by a third party.
- “Primary care provider” is a licensed health care practitioner under ch. 458, F.S., (medical doctor or physician assistant), ch. 459, F.S., (osteopathic doctor or physician assistant), ch. 460, F.S., (chiropractic physician), or ch. 464, F.S., (nurses and advanced registered nurse practitioners), or a primary care group practice that provides medical services which are commonly provided without referral from another health care provider.
- “Primary care service” is the screening, assessment, diagnosis, and treatment of a patient for the purpose of promoting health or detecting and managing disease or injury within the competency and training of the primary care provider.

The bill authorizes a primary care provider or an agent of the primary care provider to execute a DPC agreement. DPC agreements are subject to the provisions of s. 624.27, F.S., which specify

³⁶ See Section 1905 9(r) of the Social Security Act.

³⁷ An “invitation to negotiate” is a written or electronically posted solicitation for vendors to submit competitive, sealed replies for the purpose of selecting one or more vendors with which to commence negotiations for the procurement of commodities or contractual services. See s. 287.012(17), F.S.

³⁸ Agency for Health Care Administration, *Supra* note 30, at slide 12.

that such agreements are not insurance, and therefore are not subject to any chapter of the Florida Insurance Code. Additionally, the act of entering into a DPC agreement does not constitute the business of insurance and would not be subject to any chapter of the Florida Insurance Code.

To market, sell, or offer to sell a DPC agreement, a primary care provider or agent of a primary care provider is not required to obtain a certification of authority or license under any chapter of the Florida Insurance Code, pursuant to s. 456.0625, F.S.

The bill specifies the following minimum requirements and disclosures for DPC agreements:

- Be in writing and signed by the provider or the provider's agent and the patient, the patient's legal representative, or their employer;
- Allow a party to terminate the agreement with 30 days' advance written notice and provide for the immediate termination of the agreement if the physician-patient relationship is violated or a party breaches the terms of the agreement;
- Describe the scope of primary care services covered by the monthly fee.
- Specify the monthly fee and any fees for primary care services not covered by the monthly fee.
- Specify the duration of the agreement and any automatic renewal provisions.
- Offer a refund of monthly fees paid in advance if the provider ceases to offer primary care services for any reason.
- Contain the following statements in contrasting color and 12-point or larger type, on the same page as the applicant's signature:
 - "This agreement is not insurance, and the primary care provider will not file any claims against the patient's health insurance policy or plan for reimbursement of any primary care services covered by this agreement."
 - "This agreement does not qualify as minimum essential coverage to satisfy the individual shared responsibility provision of the federal Patient Protection and Affordable Care Act, Pub. L. No. 111-148."
 - "This agreement is not workers' compensation insurance and may not replace the employer's obligations under ch. 440, F.S."

Medicaid Managed Care Waiver for Direct Primary Care Agreements (Section 1)

The bill directs the Agency for Health Care Administration to seek a waiver from the appropriate federal authorities to allow Medicaid recipients in the Statewide Medicaid Managed Medical Assistance Program (program) the opportunity to participate in direct primary care agreements within the program. Section 409.977, F.S., is amended to clarify the amount of financial assistance that may be given to recipients who participate and to provide a waiver submission deadline of January 1, 2018.

Effective Date

The bill is effective July 1, 2017.

IV. Constitutional Issues:**A. Municipality/County Mandates Restrictions:**

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

CS/CS/SB 240 removes regulatory uncertainty for health care providers by stating that the direct primary care agreement is not insurance, and as a result, the OIR does not regulate the agreements. This statutory change eliminates a long-standing concern with part II of ch. 641, F.S., which requires licensure and regulation of prepaid health clinics. Currently, that section of the code is unclear about the treatment of these types of arrangements with providers. To date, the OIR has not licensed any direct primary care providers under part II to provide such services.³⁹

Additional primary care providers may elect to pursue a direct primary care model and establish direct primary care practices, which may increase patients' access to affordable primary care services.

Many individuals have high deductible policies and must meet a significant out of pocket cost to access many types of medical care. The DPC agreements may provide a less expensive option for accessing certain services. For many patients, the greater use of direct primary care agreements may decrease reliance on emergency rooms as a source of routine care.

C. Government Sector Impact:

The establishment of the DPC agreements under ch. 456, F.S., the chapter relating to general provisions for health care practitioners, means that oversight responsibility for the actions of health care practitioners will fall under the Department of Health and the appropriate healthcare professional boards. To the extent that issues arise between

³⁹ Office of Insurance Regulation, *Senate Bill 240 Analysis* (Jan. 17, 2017) (on file with the Senate Committee on Banking and Insurance).

practitioners and patients with DPC agreements, the department could see an increase in complaint activity.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill does not include a provision relating to non-discrimination based on health status. The model bill provides the following:

Direct primary care practices may not decline to accept new direct primary care patients or discontinue care to existing patients solely because of the patient's health status. A direct practice may decline to accept a patient if the practice has reached its maximum capacity, or if the patient's medical condition is such that the provider is unable to provide the appropriate level and type of primary care services the patient requires.⁴⁰

VIII. Statutes Affected:

This bill substantially amends section 409.977 of the Florida Statutes.

This bill creates the following new sections of the Florida Statutes: 456.0625 and 624.27.

IX. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS by Health Policy on February 21, 2017:

The CS/CS retains the exemption of the DPC agreements from the Florida Insurance Code in ch. 624, F.S., and defines and establishes DPC agreements in ch. 456, F.S. The CS/CS also directs the AHCA to submit a Medicaid waiver to the appropriate federal authorities to provide Medicaid enrollees the opportunity to choose DPC agreements within the Statewide Medicaid Managed Care program.

CS by Banking and Insurance on February 7, 2017:

The CS provides an additional mandatory disclosure to the direct primary care agreement that states that the agreement is not workers' compensation insurance and may not replace the employer's obligation under ch. 440, F.S.

- B. **Amendments:**

None.

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

⁴⁰ See <http://www.dpcare.org/dpcc-model-legislation> (last viewed Feb. 13, 2017.)



292958

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/21/2017	.	
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	.	
	.	

The Committee on Health Policy (Lee) recommended the following:

Senate Amendment (with title amendment)

Before line 20
insert:

Section 1. Subsection (4) of section 409.977, Florida Statutes, is amended, present subsection (5) of that section is redesignated as subsection (6), and a new subsection (5) is added to that section, to read:

409.977 Enrollment.—

(4) The agency shall:

(a) Develop a process to enable a recipient with access to



292958

12 employer-sponsored health care coverage to opt out of all
13 managed care plans and to use Medicaid financial assistance to
14 pay for the recipient's share of the cost in such employer-
15 sponsored coverage.

16 (b) ~~Contingent upon federal approval, the agency shall also~~
17 enable recipients with access to other insurance or related
18 products providing access to health care services created
19 pursuant to state law, including any product available under the
20 Florida Health Choices Program, or any health exchange, to opt
21 out.

22 (c) Provide ~~The amount of~~ financial assistance ~~provided~~ for
23 each recipient in an amount may not to exceed the amount of the
24 Medicaid premium that would have been paid to a managed care
25 plan for that recipient opting to receive services under this
26 subsection.

27 (d) ~~The agency shall~~ Seek federal approval to require
28 Medicaid recipients with access to employer-sponsored health
29 care coverage to enroll in that coverage and use Medicaid
30 financial assistance to pay for the recipient's share of the
31 cost for such coverage. The amount of financial assistance
32 provided for each recipient may not exceed the amount of the
33 Medicaid premium that would have been paid to a managed care
34 plan for that recipient.

35 (5) For the 2017-2018 statewide Medicaid managed medical
36 assistance program procurement process, the agency must consider
37 respondents' proposals in response to requests for information
38 on the feasibility, structure, and possible cost savings of
39 direct primary care agreements in coordination with the managed
40 care plans as a service delivery option.



292958

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

And the title is amended as follows:

Delete line 2

and insert:

An act relating to direct primary care; amending s.
409.977, F.S.; requiring the Agency for Health Care
Administration to provide specified financial
assistance to certain Medicaid recipients; requiring
the agency to include certain proposals in response to
requests for information relating to direct primary
care agreements during a certain timeframe of the
statewide Medicaid managed medical assistance program
procurement process; creating s.



903220

LEGISLATIVE ACTION

Senate	.	House
Comm: WD	.	
02/21/2017	.	
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The Committee on Health Policy (Lee) recommended the following:

Senate Amendment to Amendment (292958)

Delete line 39
and insert:
direct primary care agreements, as defined in s. 456.0625, in
coordination with the managed



168396

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/21/2017	.	
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	.	
	.	

The Committee on Health Policy (Lee) recommended the following:

Senate Amendment (with title amendment)

Before line 20
insert:

Section 1. Subsection (4) of section 409.977, Florida
Statutes, is amended to read:

409.977 Enrollment.—

(4) The agency shall:

(a) Develop a process to enable a recipient with access to
employer-sponsored health care coverage to opt out of all
managed care plans and to use Medicaid financial assistance to



168396

12 pay for the recipient's share of the cost in such employer-
13 sponsored coverage.

14 (b) ~~Contingent upon federal approval, the agency shall also~~
15 enable recipients with access to other insurance or related
16 products providing access to health care services created
17 pursuant to state law, including any product available under the
18 Florida Health Choices Program, or any health exchange, to opt
19 out.

20 (c) ~~Provide The amount of~~ financial assistance ~~provided~~ for
21 each recipient in an amount ~~may~~ not to exceed the amount of the
22 Medicaid premium which ~~that~~ would have been paid to a managed
23 care plan for that recipient opting to receive services under
24 this subsection.

25 (d) ~~The agency shall~~ Seek federal approval to require
26 Medicaid recipients with access to employer-sponsored health
27 care coverage to enroll in that coverage and use Medicaid
28 financial assistance to pay for the recipient's share of the
29 cost for such coverage. The amount of financial assistance
30 provided for each recipient may not exceed the amount of the
31 Medicaid premium that would have been paid to a managed care
32 plan for that recipient.

33 (e) By January 1, 2018, resubmit an appropriate federal
34 waiver or waiver amendment to the Centers for Medicare and
35 Medicaid Services, the United States Department of Health and
36 Human Services, or any other designated federal entity to
37 incorporate the election by a recipient for a direct primary
38 care agreement within the Statewide Medicaid Managed Care
39 program.



168396

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

42 And the title is amended as follows:

43 Delete line 2

44 and insert:

45 An act relating to direct primary care; amending s.
46 409.977, F.S.; requiring the Agency for Health Care
47 Administration to provide specified financial
48 assistance to certain Medicaid recipients; requiring
49 the agency to resubmit, by a specified date, certain
50 federal waivers or waiver amendments to specified
51 federal entities to incorporate recipient elections of
52 certain direct primary care agreements; creating s.



439140

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/21/2017	.	
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	.	
	.	

The Committee on Health Policy (Lee) recommended the following:

Senate Amendment to Amendment (168396)

Delete line 38
and insert:
care agreement, as defined in s. 456.0625, within the Statewide
Medicaid Managed Care



935168

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/21/2017	.	
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	.	

The Committee on Health Policy (Lee) recommended the following:

Senate Amendment (with title amendment)

Delete lines 20 - 83
and insert:

Section 1. Section 456.0625, Florida Statutes, is created
to read:

456.0625 Direct primary care agreements.—

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

(a) "Direct primary care agreement" means a contract
between a primary care provider and a patient, the patient's
legal representative, or an employer which meets the



935168

requirements specified under subsection (3) and which does not indemnify for services provided by a third party.

(b) "Primary care provider" means a health care practitioner licensed under chapter 458, chapter 459, chapter 460, or chapter 464 or a primary care group practice that provides medical services to patients which are commonly provided without referral from another health care provider.

(c) "Primary care service" means the screening, assessment, diagnosis, and treatment of a patient for the purpose of promoting health or detecting and managing disease or injury within the competency and training of the primary care provider.

(2) A primary care provider or an agent of the primary care provider may enter into a direct primary care agreement for providing primary care services. Section 624.27 applies to a direct primary care agreement.

(3) A direct primary care agreement must:

(a) Be in writing.

(b) Be signed by the primary care provider or an agent of the primary care provider and the patient, the patient's legal representative, or an employer.

(c) Allow a party to terminate the agreement by giving the other party at least 30 days' advance written notice. The agreement may provide for immediate termination due to a violation of the physician-patient relationship or a breach of the terms of the agreement.

(d) Describe the scope of primary care services that are covered by the monthly fee.

(e) Specify the monthly fee and any fees for primary care services not covered by the monthly fee.



935168

41 (f) Specify the duration of the agreement and any automatic
42 renewal provisions.

43 (g) Offer a refund to the patient of monthly fees paid in
44 advance if the primary care provider ceases to offer primary
45 care services for any reason.

46 (h) Contain, in contrasting color and in not less than 12-
47 point type, the following statements on the same page as the
48 applicant's signature:

49 1. This agreement is not health insurance, and the primary
50 care provider will not file any claims against the patient's
51 health insurance policy or plan for reimbursement of any primary
52 care services covered by this agreement.

53 2. This agreement does not qualify as minimum essential
54 coverage to satisfy the individual shared responsibility
55 provision of the federal Patient Protection and Affordable Care
56 Act, Pub. L. No. 111-148.

57 3. This agreement is not workers' compensation insurance
58 and may not replace the employer's obligations under chapter
59 440, Florida Statutes.

60 Section 2. Section 624.27, Florida Statutes, is created to
61 read:

62 624.27 Application of code as to direct primary care
63 agreements.—

64 (1) A direct primary care agreement, as defined in s.
65 456.0625, does not constitute insurance and is not subject to
66 any chapter of the Florida Insurance Code. The act of entering
67 into a direct primary care agreement does not constitute the
68 business of insurance and is not subject to any chapter of the
69 Florida Insurance Code.



935168

(2) A primary care provider or an agent of a primary care provider is not required to obtain a certificate of authority or license under any chapter of the Florida Insurance Code to market, sell, or offer to sell a direct primary care agreement pursuant to s. 456.0625.

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

And the title is amended as follows:

Delete lines 3 - 16
and insert:

456.0625, F.S.; defining terms; authorizing primary care providers or their agents to enter into direct primary care agreements for providing primary care services; providing applicability; specifying requirements for direct primary care agreements; creating s. 624.27, F.S.; providing construction and applicability of the Florida Insurance Code as to direct primary care agreements; providing an exception for primary care providers or their agents from certain requirements under the code under certain circumstances; providing an effective date.

By the Committee on Banking and Insurance; and Senator Lee

597-01716-17

2017240c1

A bill to be entitled

An act relating to direct primary care; creating s. 624.27, F.S.; defining terms; specifying that a direct primary care agreement does not constitute insurance and is not subject to ch. 636, F.S., relating to prepaid limited health service organizations and discount medical plan organizations, or any other chapter of the Florida Insurance Code; specifying that entering into a direct primary care agreement does not constitute the business of insurance and is not subject to ch. 636, F.S., or any other chapter of the code; providing that certain certificates of authority and licenses are not required to market, sell, or offer to sell a direct primary care agreement; specifying requirements for direct primary care agreements; providing an effective date.

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

Section 1. Section 624.27, Florida Statutes, is created to read:

624.27 Application of code as to direct primary care agreements.—

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

(a) "Direct primary care agreement" means a contract between a primary care provider and a patient, the patient's legal representative, or an employer which meets the requirements specified under subsection (4) and does not indemnify for services provided by a third party.

(b) "Primary care provider" means a health care practitioner licensed under chapter 458, chapter 459, chapter 460, or chapter 464, or a primary care group practice that

597-01716-17

2017240c1

provides medical services to patients which are commonly provided without referral from another health care provider.

(c) "Primary care service" means the screening, assessment, diagnosis, and treatment of a patient for the purpose of promoting health or detecting and managing disease or injury within the competency and training of the primary care provider.

(2) A direct primary care agreement does not constitute insurance and is not subject to chapter 636 or any other chapter of the Florida Insurance Code. The act of entering into a direct primary care agreement does not constitute the business of insurance and is not subject to chapter 636 or any other chapter of the Florida Insurance Code.

(3) A primary care provider or an agent of a primary care provider is not required to obtain a certificate of authority or license under chapter 636 or any other chapter of the Florida Insurance Code to market, sell, or offer to sell a direct primary care agreement.

(4) For purposes of this section, a direct primary care agreement must:

(a) Be in writing.

(b) Be signed by the primary care provider or an agent of the primary care provider and the patient, the patient's legal representative, or an employer.

(c) Allow a party to terminate the agreement by giving the other party at least 30 days' advance written notice. The agreement may provide for immediate termination due to a violation of the physician-patient relationship or a breach of the terms of the agreement.

(d) Describe the scope of primary care services that are

597-01716-17

2017240c1

covered by the monthly fee.

(e) Specify the monthly fee and any fees for primary care services not covered by the monthly fee.

(f) Specify the duration of the agreement and any automatic renewal provisions.

(g) Offer a refund to the patient of monthly fees paid in advance if the primary care provider ceases to offer primary care services for any reason.

(h) Contain, in contrasting color and in not less than 12-point type, the following statements on the same page as the applicant's signature:

1. This agreement is not health insurance, and the primary care provider will not file any claims against the patient's health insurance policy or plan for reimbursement of any primary care services covered by this agreement.

2. This agreement does not qualify as minimum essential coverage to satisfy the individual shared responsibility provision of the federal Patient Protection and Affordable Care Act, Pub. L. No. 111-148.

3. This agreement is not workers' compensation insurance and may not replace the employer's obligations under chapter 440, Florida Statutes.

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



The Florida Senate

Committee Agenda Request

To: Senator Dana Young, Chair
Senate Committee on Health Policy

Subject: Committee Agenda Request

Date: February 7th, 2017

I respectfully request that **Senate Bill #240**, relating to Direct Primary Care, be placed on the:

- ☐ committee agenda at your earliest possible convenience.
- ☒ next committee agenda.

A handwritten signature in blue ink that reads "Tom Lee".

Senator Tom Lee
Florida Senate, District 20

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

1/21/17
Meeting Date

CS/SB 240
Bill Number (if applicable)

Topic Direct Primary Care

Amendment Barcode (if applicable)

Name Aimee Diaz Lyon

Job Title _____

Address 119 South Monroe Street #200
Street
Tallahassee FL 32301
City State Zip

Phone 850-205-9000

Email aimée.diazlyon@mhdfirm.com

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Academy of Family Physicians

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

Feb 21, 2017

Meeting Date

SB 240

Bill Number (if applicable)

Topic SB 240 Direct Primary Care

Amendment Barcode (if applicable)

Name JACK HEBERT

Job Title _____

Address 2861 Executive Dr #100

Street

Phone 727-560-3323

Clearwater FL 33762

City

State

Zip

Email jade@themallardgroup.com

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Chiropractic Assn.

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

412-K
12:30 PM

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-21-2017

Meeting Date

SB 240 ✓
Bill Number (if applicable)

Topic DIRECT PRIMARY CARE

Amendment Barcode (if applicable)

Name STEPHEN R. WINN

Job Title EXECUTIVE DIRECTOR

Address 2544 BLAIRSTONE PINES DR

Phone 8178-7364

Street

TALLAHASSEE

FL

32301

City

State

Zip

Email _____

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing FLORIDA OSTEOPATHIC MEDICAL ASSOCIATION

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17

Meeting Date

SB240

Bill Number (if applicable)

Topic Direct Primary Care

Amendment Barcode (if applicable)

Name Logan Pike

Job Title Director of Public Affairs

Address 100 N. Duval St

Phone (850) 386-3131

Street

TLH

City

FL

State

32301

Zip

Email lpike@jamesmadison.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing James Madison Institute

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☐ Yes ☒ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17
Meeting Date

240
Bill Number (if applicable)

Topic Direct Primary Care

Amendment Barcode (if applicable)

Name Mary Thomas

Job Title Assistant Gen. Counsel

Address 1430 Redmont Dr E
Street

Phone 850 224 6496

Tallahassee FL 32308
City State Zip

Email MThomas@flmedical.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17

Meeting Date

240

Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Noland

Job Title _____

Address 1000 Riverside Ave

Phone 904-233-3051

Street

Jacksonville, FL 32204

Email nolandlaw@aol.com

City

State

Zip

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Chapter, American College of Physicians

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17
Meeting Date

240
Bill Number (if applicable)

Topic Direct Primary Care

Amendment Barcode (if applicable)

Name Tim Nungesser

Job Title Legislative Director

Address 110 E. Jefferson St.
Street
Tallahassee FL 32301
City State Zip

Phone 850-445-5361

Email tim.nungesser@fla.gov

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing National Federation of Independent Business

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2-21-17

Meeting Date

SB 240

Bill Number (if applicable)

Topic Direct Primary Care

Amendment Barcode (if applicable)

Name Skylar Zander

Job Title Deputy State Director

Address 200 W College Ave Suite 109

Phone 850-728-4522

Street

Tallahassee

FL

32301

City

State

Zip

Email szander@atphg.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Americans for Prosperity

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: CS/SB 510

INTRODUCER: Health Policy Committee; and Senators Gainer and Montford

SUBJECT: Grant Program for Rural Hospitals

DATE: February 22, 2017

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	Fav/CS
2.			AHS	
3.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 510 establishes the Florida Rural Hospital Capital Improvement Competitive Grant Program to award funds of up to \$750,000, subject to appropriation, to eligible rural hospitals through a competitive grant application process. The competitive grant program replaces the Rural Hospital Capital Improvement Grant Program that has not been funded since 2008.

The competitive grant program will be administered by the Department of Health (DOH). The funds may only be used for the purchase of hospital and medical equipment or infrastructure improvements. To be eligible for grant funds a rural hospital must demonstrate that:

- Grant funds are necessary to maintain or improve the quality of its health care services;
- Grant funds will result in a return on investment to the taxpayers of this state; and
- A satisfactory record-keeping system exists for grant expenditures.

The bill requires DOH to develop criteria for scoring and ranking grant applicants, including:

- The social and economic benefit to the surrounding community;
- The promotion of economic development in the surrounding community;
- The expansion of available services to the underserved populations in the community; and
- The availability of private or public matching funds, or in-kind contributions, for the requested grant funds.

The DOH is required to submit an annual report to the Governor and the Legislature pertaining to grants awarded under the program.

The bill takes effect upon becoming law.

II. Present Situation:

In 1999, the Legislature enacted s. 395.6061, F.S., to establish a rural hospital capital improvement grant program, in furtherance of its finding that rural hospitals were the nucleus or “backbone” of rural health care systems.¹ The program is a mechanism for rural hospitals to apply for grant funds from the DOH, if funds are appropriated for this purpose. Each rural hospital must receive a minimum of \$100,000 annually, if funds are available, upon application to the DOH, for projects to acquire, repair, improve, or upgrade systems, facilities, or equipment.

Section 395.602, F.S., defines a “rural hospital” as a licensed, acute care hospital having 100 or fewer licensed beds, and an emergency room, which is:

- The sole provider in a county with a population density no greater than 100 persons per square mile;
- In a county with a population density no greater than 100 persons per square mile, and at least 30 minutes travel time, from another acute care hospital in the same county;
- Supported by a tax district or sub-district whose boundaries encompass a population no greater than 100 persons per square mile;
- Classified by the Centers for Medicare and Medicaid Services (CMS) as a sole community hospital;²
- A hospital with a service area³ that has a population no greater than 100 persons per square mile; or
- A critical access hospital.⁴

¹ See s. 395.602(1), F.S.

² A *sole community hospital* is defined by 42 C.F.R. s. 412.92, as a hospital located more than 35 miles from other like hospitals, or it is located in a rural area (as defined in § 412.64) and meets one of the following conditions:

(1) The hospital is located between 25 and 35 miles from other like hospitals and meets one of the following criteria:

- No more than 25 percent of residents who become hospital inpatients or no more than 25 percent of the Medicare beneficiaries who become hospital inpatients in the hospital's service area are admitted to other like hospitals located within a 35-mile radius of the hospital, or, if larger, within its service area;
- The hospital has fewer than 50 beds and the intermediary certifies that the hospital would have met the criteria in paragraph (a)(1)(i) of this section were it not for the fact that some beneficiaries or residents were forced to seek care outside the service area due to the unavailability of necessary specialty services at the community hospital; or
- Because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years.

(2) The hospital is located between 15 and 25 miles from other like hospitals but because of local topography or periods of prolonged severe weather conditions, the other like hospitals are inaccessible for at least 30 days in each 2 out of 3 years.

(3) Because of distance, posted speed limits, and predictable weather conditions, the travel time between the hospital and the nearest like hospital is at least 45 minutes.

³ *Service area* means the fewest number of zip codes that account for 75 percent of the hospital's discharges for the most recent 5-year period, based on information available from the hospital inpatient discharge database in the Florida Center for Health Information and Transparency at the Agency for Health Care Administration. See s. 408.07 (43)(d), F.S.

⁴ A *Critical Access Hospital* is a small rural hospital of 25 beds or less that is reimbursed for 101 percent of the cost of providing services to Medicare patients as a means to stabilize and improve access to hospital care in rural areas. A critical access hospital must provide 24 hour emergency, outpatient, and limited inpatient services, and must meet other requirements

As of January 30, 2017, Florida has 29 rural hospitals.⁵

The rural hospital grant program application must include the following:

- A description of the problem to be solved with the grant funds;
- The strategy proposed to resolve the problem;
- The organizational structure, financial system, and facilities that are essential to the proposed solution;
- The projected longevity of the proposed solution after the grant funds are expended;
- Evidence of participation in a rural health network;⁶
- Evidence that the rural hospital has difficulty in obtaining funding or that funds available for the proposed solution are inadequate;
- Evidence that the grant funds will assist in maintaining or returning the hospital to an economically stable condition or will involve innovative alternatives for discontinued services;
- Evidence of a satisfactory record-keeping system to account for grant fund expenditures within the rural county; and
- A rural health network plan that includes a description of how the plan was developed, the goals of the plan, the links with existing health care providers under the plan, indicators quantifying the hospital's financial well-being, measurable outcome targets, and the current physical and operational condition of the hospital.

Under s. 395.6061, F.S., any rural hospital that completes an application to DOH that contains the above criteria, shall receive a minimum of \$100,000. The DOH must consider any information submitted in a grant application to determine eligibility and the amount of the award. None of the individual items in the application by itself may be used to deny grant eligibility.

In administering this grant program, the DOH is required to establish, by rule, criteria for awarding grants for any remaining funds, after each eligible applicant is allowed \$100,000. This additional award must be used exclusively for the support and assistance of rural hospitals. Criteria shall include:

- The level of uncompensated care rendered by the hospital;
- Participation in a rural health network; and
- The proposed use of the grant by the rural hospital to resolve a specific problem.

to support the services provided. The Centers for Medicare and Medicaid Services designates which hospitals are critical access hospitals. See s. 408.07(15), F.S. and Agency for Health Care Administration, *Special Designations*, available at: <http://www.floridahealthfinder.gov/about-ahca/facility-locator-glossary.aspx#topic9> (last viewed Feb. 15, 2017).

⁵ Florida Department of Health, Programs and Services, Rural Health, *Florida Rural Hospital Directory*, available at: <http://www.floridahealth.gov/programs-and-services/community-health/rural-health/index.html>, (last viewed Feb. 15, 2017).

⁶ A rural health network is a non-profit legal entity, consisting of rural and urban health care providers, organized to plan and deliver health care services on a competitive basis in a rural area. See s. 381.0406, F.S.

The Rural Hospital Capital Improvement Fund was last funded in the 2008-2009 General Appropriations Act in the amount of \$3 million.⁷ The DOH currently has no staff dedicated to this program.⁸

III. Effect of Proposed Changes:

CS/SB 510 amends s. 395.6061, F.S.; declaring that rural hospitals have a limited ability to increase operating revenues, or access other sources of public or private funding, that are needed to replace or maintain high-cost medical equipment, or improve infrastructure. This inability to access alternative funding sources, places rural patients' access to quality health care at risk.

The bill requires the DOH to establish and administer the Florida Rural Hospital Capital Improvement Competitive Grant Program; and repeals the Rural Hospital Capital Improvement Grant Program. Eligible rural hospitals may apply for grants up to \$750,000, subject to annual legislative appropriation. In order to be eligible for a grant, a rural hospital must demonstrate that:

- Grant funds are necessary to maintain or improve the quality of its health care services;
- There is a return on investment to the taxpayers of this state; and
- A satisfactory record-keeping system exists for grant expenditures.

The DOH is required to establish, by rule, a competitive grant application process and determine criteria to score and rank applications. The criteria must include, at a minimum:

- The social and economic benefit to the surrounding community;
- The promotion of economic development in the surrounding community;
- The expansion of available services to the underserved populations in the community; and
- The availability of private or public matching funds, or in-kind contributions, for the requested grant funds.

Grant funds are restricted to equipment purchases or facility infrastructure improvements in the rural hospital's service area.

The DOH must provide an annual report to the Governor, President of the Senate, and the Speaker of the House of Representatives, for each grantee, which includes:

- The amount awarded;
- A brief description detailing what the funds will be used for;
- The anticipated outcomes to be achieved; and
- The return on investment to the taxpayers of this state

The bill takes effect upon becoming law.

⁷ E-mail from Thomas Joos, Florida Department of Health, Division of Health Statistics, Office of Rural Health (Feb. 15, 2017) (on file with the Senate Committee on Health Policy).

⁸ E-mail from Paul Runk, Legislative Planning Director, Florida Department of Health (Feb. 14, 2017) (on file with the Senate Committee on Health Policy).

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Currently there are 29 rural hospitals that could compete for these funds, if appropriated. A rural hospital could receive a grant award up to \$750,000.

C. Government Sector Impact:

This program is subject to legislative appropriation. The DOH would incur costs to implement and administer the program, if it is funded.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill does not specify a due date for submitting the annual report.

VIII. Statutes Affected:

This bill substantially amends section 395.6061 of the Florida Statutes.

IX. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on February 21, 2017:

The CS adds the requirement for the applicant to demonstrate that a record-keeping system exists for grant expenditures in order to be eligible to compete for a grant award. The CS also removes preferences for grant award decision making, and specifies minimum criteria the DOH is to use in scoring and ranking applicants.

- B. **Amendments:**

None.



608818

LEGISLATIVE ACTION

Senate	.	House
Comm: RCS	.	
02/21/2017	.	
	.	
	.	
	.	

The Committee on Health Policy (Gainer) recommended the following:

Senate Amendment (with title amendment)

Delete lines 42 - 59
and insert:
and on criteria established by the department.

(3) GRANT ELIGIBILITY.—In order to be eligible for a grant award, a hospital must be a rural hospital, as defined in s. 395.602, and must demonstrate that:

(a) Grant funds are necessary to maintain or improve the quality of its health care services;



608818

(b) There is a return on investment to the taxpayers of this state; and

(c) A satisfactory recordkeeping system will be in place to account for the expenditures of grant funds within the rural county.

(4) AWARD OF GRANTS.—The department shall establish by rule a grant application process and criteria for the evaluation of applications. The department shall score and rank grant applications based on criteria that must include, at a minimum, the following:

(a) The social and economic benefit to the surrounding community.

(b) The promotion of economic development in the surrounding community.

(c) The expansion of available services to the underserved populations in the community.

(d) The availability of private or public matching funds, or in-kind contributions, for the requested grant funds.

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

And the title is amended as follows:

Delete lines 9 - 10

and insert:

eligibility; providing criteria for grant application
ranking; establishing allowable use of funds;
requiring the department to submit an

By Senator Gainer

2-00435A-17

2017510__

A bill to be entitled

An act relating to a grant program for rural hospitals; amending s. 395.6061, F.S.; providing legislative findings and intent; requiring the Department of Health to establish and administer the Florida Rural Hospital Capital Improvement Competitive Grant Program for certain rural hospitals; revising the amount of a grant award; revising grant eligibility and preferences; establishing allowable uses of funds; requiring the department to submit an annual report to the Governor and the Legislature; deleting requirements for certain information in grant applications; deleting provisions relating to the disbursement of funds; providing an effective date.

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

Section 1. Section 395.6061, Florida Statutes, is amended to read:

395.6061 Rural hospital capital improvement.—

(1) LEGISLATIVE FINDINGS AND INTENT.—The Legislature finds that rural hospitals have limited ability to increase operating revenues or to access other public or private funding sources that are needed to maintain critical infrastructure, including, but not limited to, the replacement of high-cost medical care equipment or improvements to facility infrastructure. Rural hospitals that do not have reasonable access to alternative sources of revenue to pay for critical infrastructure needs are at risk, and patient access, care, and quality are threatened. Therefore, the Legislature finds that it is necessary to establish the Florida Rural Hospital Capital Improvement Competitive Grant Program for eligible rural hospitals to ensure

2-00435A-17

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their sustainability.

(2) FLORIDA RURAL HOSPITAL CAPITAL IMPROVEMENT COMPETITIVE GRANT PROGRAM.—The Department of Health shall establish and administer the Florida Rural Hospital Capital Improvement Competitive Grant Program for rural hospitals. Subject to annual appropriation, the department shall establish grant awards up to \$750,000 for each hospital that meets the eligibility requirements in subsection (3). Grants must be made available to eligible rural hospitals based on the competitive grant program and on criteria established by the agency.

(3) GRANT ELIGIBILITY.—In order to be eligible for a grant award, a hospital must be a rural hospital, as defined in s. 395.602, and must demonstrate that:

(a) Grant funds are necessary to maintain or improve the quality of its health care services; and

(b) There is a return on investment to the taxpayers of this state.

(4) AWARD OF GRANTS.—The department shall establish by rule a grant application process and criteria for the evaluation of applications. It shall score and rank grant applications based on these criteria. Preference in grant award decisions shall be given to any applicant that leverages additional private or public matching funds or in-kind contributions. Preference in grant award decisions shall also be given to any applicant that demonstrates hospital practices targeted to reducing unnecessary emergency room visits and preventable hospitalizations through increased access to primary care services.

(5) ALLOWABLE USES OF FUNDS.—Grant awards may be used only for hospital medical equipment purchases or facility

2-00435A-17

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62 infrastructure improvements in the rural area serviced by the
 63 grantee.

64 (6) REPORT.—The department shall provide an annual report
 65 to the Governor, the President of the Senate, and the Speaker of
 66 the House of Representatives which includes the list of grantees
 67 and, for each grantee, the amount awarded, a brief description
 68 detailing what the funds will be used for, the anticipated
 69 outcomes to be achieved, and the return on investment to the
 70 taxpayers of this state. There is established a rural hospital
 71 capital improvement grant program.

72 (1) A rural hospital as defined in s. 395.602 may apply to
 73 the department for a grant. The grant application must provide
 74 information that includes:

75 (a) A statement indicating the problem the rural hospital
 76 proposes to solve with the grant funds;

77 (b) The strategy proposed to resolve the problem;

78 (c) The organizational structure, financial system, and
 79 facilities that are essential to the proposed solution;

80 (d) The projected longevity of the proposed solution after
 81 the grant funds are expended;

82 (e) Evidence of participation in a rural health network as
 83 defined in s. 381.0406;

84 (f) Evidence that the rural hospital has difficulty in
 85 obtaining funding or that funds available for the proposed
 86 solution are inadequate;

87 (g) Evidence that the grant funds will assist in
 88 maintaining or returning the hospital to an economically stable
 89 condition or that any plan for closure or realignment of
 90 services will involve development of innovative alternatives for

2-00435A-17

2017510

91 ~~the discontinued services;~~

92 ~~(h) Evidence of a satisfactory record-keeping system to~~
 93 ~~account for grant fund expenditures within the rural county;~~

94 ~~(i) A rural health network plan that includes a description~~
 95 ~~of how the plan was developed, the goals of the plan, the links~~
 96 ~~with existing health care providers under the plan, indicators~~
 97 ~~quantifying the hospital's financial well-being, measurable~~
 98 ~~outcome targets, and the current physical and operational~~
 99 ~~condition of the hospital.~~

100 ~~(2) Each rural hospital as defined in s. 395.602 shall~~
 101 ~~receive a minimum of \$100,000 annually, subject to legislative~~
 102 ~~appropriation, upon application to the Department of Health, for~~
 103 ~~projects to acquire, repair, improve, or upgrade systems,~~
 104 ~~facilities, or equipment.~~

105 ~~(3) Any remaining funds shall annually be disbursed to~~
 106 ~~rural hospitals in accordance with this section. The Department~~
 107 ~~of Health shall establish, by rule, criteria for awarding grants~~
 108 ~~for any remaining funds, which must be used exclusively for the~~
 109 ~~support and assistance of rural hospitals as defined in s.~~
 110 ~~395.602, including criteria relating to the level of~~
 111 ~~uncompensated care rendered by the hospital, the participation~~
 112 ~~in a rural health network as defined in s. 381.0406, and the~~
 113 ~~proposed use of the grant by the rural hospital to resolve a~~
 114 ~~specific problem. The department must consider any information~~
 115 ~~submitted in an application for the grants in accordance with~~
 116 ~~subsection (1) in determining eligibility for and the amount of~~
 117 ~~the grant, and none of the individual items of information by~~
 118 ~~itself may be used to deny grant eligibility.~~

119 ~~(4) The department shall ensure that the funds are used~~

2-00435A-17

2017510

120 solely for the purposes specified in this section. The total
121 grants awarded pursuant to this section shall not exceed the
122 amount appropriated for this program.

123 Section 2. This act shall take effect upon becoming a law.



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Transportation, *Chair*
Commerce and Tourism, *Vice Chair*
Appropriations
Appropriations Subcommittee on Transportation,
Tourism, and Economic Development
Banking and Insurance

JOINT COMMITTEE:

Joint Administrative Procedures Committee

SENATOR GEORGE B. GAINER

2nd District

February 9, 2017

Re: SB 510

Dear Chair Young,

I am respectfully requesting Senate Bill 510, a bill relating to Grant Program for Rural Hospitals, be placed on the agenda for your committee on Health Policy.

I appreciate your consideration of this bill and I look forward to working with you and the Health Policy committee. If there are any questions or concerns, please do not hesitate to call my office at (850) 487-5002.

Thank you,

A handwritten signature in blue ink, reading "George B. Gainer".

Senator George Gainer
District 2

Cc. Sandra Stovall, Brian McManus, Beau Giles, Melanie Hoyt

REPLY TO:

□ 302 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5002

Senate's Website: www.flsenate.gov

JOE NEGRON
President of the Senate

ANITERE FLORES
President Pro Tempore

THE FLORIDA SENATE
APPEARANCE RECORD

2-21-17

Meeting Date

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

510

Bill Number (if applicable)

608818

Amendment Barcode (if applicable)

Topic Rural Hospital Grant

Name Bryan Cherry

Job Title Associate

Address 205 S. Adams St.

Street

Tallahassee FL. 32301

City

State

Zip

Phone (850) 205-0885

Email bryan@adamistadvocates.com

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Doctors Memorial Hospital - Bonifay

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17

Meeting Date

SB 510

Bill Number (if applicable)

Topic

Grant Program for Rural Hospitals

Amendment Barcode (if applicable)

Name

Lisa Hurlbey

Job Title

Address

311 E. Park Ave.

Street

Lallahassee, FL

City

State

32307

Zip

Phone

850.224.5081

Email

lhurlbey@smithbryantandmeyer.com

Speaking:

☐

For

☐

Against

☐

Information

~~Waive Speaking~~

Waive Speaking:

☒

In Support

☐

Against

(The Chair will read this information into the record.)

Representing

Florida Association of Counties

Appearing at request of Chair:

☐

Yes

☒

No

Lobbyist registered with Legislature:

☒

Yes

☐

No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17
Meeting Date

570
Bill Number (if applicable)

Topic Rural Grant Program

Amendment Barcode (if applicable)

Name Crystal Stickle

Job Title VP Gov Affairs

Address 306 E College
Street

Phone 445 4344

TLH FL
City State Zip

Email _____

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing FL Hospital Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Health Policy

BILL: SPB 7012

INTRODUCER: Health Policy Committee

SUBJECT: Ratification of Department of Health Rules

DATE: February 22, 2017

REVISED: _____

ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1. Stovall	Stovall		HP Submitted as Committee Bill

I. Summary:

SPB 7012 ratifies Rule 64B8-9.009, F.A.C., adopted by the Department of Health (department) and the Board of Medicine (board) for the Standard of Care for Office Surgery. This adopted rule requires two additional drugs be maintained in the office when performing Level I office surgery. Level I office surgery includes minor procedures with minimal sedation or topical or local anesthesia where the chances of complication requiring hospitalization are remote.

The Statement of Estimated Regulatory Costs (SERC) developed by the board determined that the proposed rule will likely increase regulatory costs in excess of \$1 million in the aggregate within 5 years after implementation of the rule. Accordingly, the rule must be ratified by the Legislature before it may go into effect.

This act takes effect upon becoming a law.

II. Present Situation:

Rulemaking Authority and Legislative Ratification

A rule is an agency statement of general applicability that interprets, implements, or prescribes law or policy.¹ Rulemaking authority is delegated by the Legislature to an agency in law, and authorizes an agency to adopt, develop, establish, or otherwise create a rule.² An agency may not engage in rulemaking unless it has a legislative grant of authority to do so.³ The statutory authority for rulemaking must be specific enough to guide an agency's rulemaking and an agency rule must not exceed the bounds of authority granted by the Legislature.⁴

¹ Section 120.52(16), F.S.

² Section 120.52(17), F.S.

³ See ss. 120.52(8) and 120.536(1), F.S.

⁴ See *Sloban v. Florida Board of Pharmacy*, 982 So. 2d 26 (Fla. 1st DCA 2008) and *Southwest Florida Water Management District v. Save the Manatee Club, Inc.*, 773 So. 2d 594 (Fla. 1st DCA 2000).

Prior to the adoption, amendment, or repeal of any rule an agency must file a notice of the proposed rule in the Florida Administrative Register (F.A.R.).⁵ The notice of the proposed rule must include:

- An explanation of the purpose and effect;
- The specific legal authority for the rule;
- The full text of the rule;
- A summary of the agency's SERC, if one is prepared; and
- Whether legislative ratification is required.⁶

SERC Requirements

Agencies must prepare a SERC for a rule that has an adverse impact on small businesses or that increases regulatory costs more than \$200,000 in the aggregate within 1 year after implementation of the rule.⁷

A SERC must include estimates of:

- The number of people and entities effected by the proposed rule;
- The cost to the agency and other governmental entities to implement and enforce the proposed rule;
- Transactional costs likely to be incurred by people, entities, and governmental agencies for compliance; and
- An analysis of the proposed rule's impact on small businesses, counties, and cities.⁸

The SERC must also include an economic analysis on the likelihood that the proposed rule will have an adverse impact in excess of \$1 million within the first 5 years of implementation on:

- Economic growth, private-sector job creation or employment, or private-sector investment;
- Business competitiveness,⁹ productivity, or innovation; or
- Regulatory costs, including any transactional costs.^{10,11}

If the economic analysis results in an adverse impact or regulatory costs in excess of \$1 million within 5 years after implementation of the rule, then the rule must be ratified by the Legislature in order to take effect.¹²

⁵ Section 120.54(3)(a)2., F.S.

⁶ Section 120.54(3)(a)1., F.S.

⁷ Sections 120.54(3)(b) and 120.541(1)(b), F.S.

⁸ Section 120.541(2)(b)-(e), F.S. A small city has an unincarcerated population of 10,000 or less. A small county has an unincarcerated population of 75,000 or less. A small business employs less than 200 people, and has a net worth of \$5 million or less. *See* ss. 120.52(18), (19), and 288.703(6), respectively.

⁹ Business competitiveness includes the ability of those doing business in Florida to compete with those doing business in other states or domestic markets.

¹⁰ Transactional costs are direct costs that are readily ascertainable based upon standard business practices. They include filing fees, the cost of obtaining a license, the cost of equipment required to be installed or used, procedures required to be employed to comply with the rule, additional operating costs, the cost of monitoring and reporting, and any other costs necessary to comply with the rules.

¹¹ Section 120.541(2)(a), F.S.

¹² Section 120.541(3), F.S. Legislative ratification is not required for adoption of federal standards, amendments to the Florida Building Code, or amendments to the Florida Fire Prevention Code. *See* s. 120.541(4), F.S.

Level I Office Surgery Rule

The Board of Medicine is created within the department to ensure that every physician practicing in the state meets minimum requirements for safe practice.¹³ The practice of medicine is regulated under ch. 458, F.S., and the board has authority to adopt rules to implement the provisions of that chapter.¹⁴

More specifically, the board may establish by rule standards of practice and standards of care for particular practice settings, including but not limited to:

- Education and training,
- Equipment and supplies,
- Medications including anesthetics,
- Assistance of and delegation to other personnel,
- Transfer agreements,
- Sterilization,
- Records,
- Performance of complex or multiple procedures,
- Informed consent, and
- Policy and procedure manuals.¹⁵

The rule relating to the standard of care for office surgery was initially adopted in February 1994, and has been amended numerous times.¹⁶ Under this rule there are general standards relating to all office surgery¹⁷ as well as specific standards for each of three levels of office surgery.¹⁸ The levels of office surgery are differentiated primarily according to the level of sedation and anesthesia required for the procedure and patient risk.

The general standards require the surgeon to examine the patient prior to the surgery to evaluate the patient for any risks from anesthesia and the surgical procedure to be performed. The surgeon must also maintain records of the surgical procedure, including a written informed consent from the patient if required for the particular procedure. Additional general standards regulate liposuction procedures, limit the duration of certain procedures, set the standards for anesthetic monitoring, require a current policy and procedure manual, and require a risk management

¹³ Sections 458.307(1) and 458.301, F.S.

¹⁴ Section 458.309(1), F.S.

¹⁵ Section 458.331(1)(v), F.S.

¹⁶ See the Florida Administrative Code history note for Rule 64B8-9.009, *available at*: <https://www.flrules.org/gateway/ruleNo.asp?id=64B8-9.009> (last visited Feb. 14, 2017).

¹⁷ Office surgery is defined in the rule as surgery which is performed outside of any facility licensed under ch. 390, F.S., (an abortion clinic) or ch. 395, F.S., (a hospital or ambulatory surgical center). See Rule 64B8-9.009(1)(d), F.A.C.

¹⁸ Level I includes minor procedures with minimal sedation or topical or local anesthesia where the chances of complication requiring hospitalization are remote. Level II involves moderate sedation and analgesia or conscious sedation. The physician, or the facility where the procedure is being performed, must have a transfer agreement with a nearby hospital unless the physician has staff privileges at a nearby hospital to perform the same procedure on an out-patient basis. Level III involves surgery in which the patient's level of sedation is that of deep sedation and analgesia or general anesthesia and requires a more rigorous evaluation of the patient as a suitable candidate for Level III office surgery. The surgeon must have staff privileges at a hospital to perform the same procedure or meet other comparable background, training, and experience criteria in order to perform these procedures in an office setting.

program. All physicians must be qualified by education, training, and experience to perform any procedure in the office surgery setting.¹⁹

Specific standards for the levels of office surgery pertain to sedation and anesthesia; transfer agreements to, or staff privileges at, nearby hospitals; the physician's training; required equipment and supplies, including medications; assistance of other personnel; and emergency policies and procedures.

Level I office surgery includes the following:

- Minor procedures such as excision of skin lesions, moles, warts, cysts, lipomas and repair of lacerations or surgery limited to the skin and subcutaneous tissue performed under topical or local anesthesia not involving drug-induced alteration of consciousness other than minimal pre-operative tranquilization of the patient.
- Liposuction involving the removal of less than 4000cc supernatant fat.
- Incision and drainage of superficial abscesses, limited endoscopies, skin biopsies, arthrocentesis, thoracentesis, paracentesis, dilation of urethra, cysto-scopic procedures, and closed reduction of simple fractures or small joint dislocations.
- Anesthesia is limited to minimal sedation. The patient's level of sedation is that of minimal sedation and anxiolysis and the chances of complications requiring hospitalization are remote. Minimal sedation and anxiolysis is a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes, and ventilator and cardiovascular functions are unaffected. Controlled substances²⁰ are limited to oral administration in doses appropriate for the unsupervised treatment of insomnia, anxiety, or pain.²¹
- Chances of complication requiring hospitalization are remote.

Under Level I, the surgeon's continuing medical education must include subjects relating to regional anesthetic drugs and the surgeon must hold current certification in Advanced Cardiac Life Support. At least one assistant must hold current certification in Basic Life Support. The physician's office must have available intravenous access supplies, oxygen, oral airways, and a positive pressure ventilation device. The current rule further requires the following medications in the office: atropine, diphenhydramine, epinephrine, and hydrocortisone.

Amendment to Rule 64B8-9.009, F.A.C.

The board filed an amendment to Rule 648-9.009, F.A.C., for adoption with the Department of State on June 15, 2016. This amendment clarifies language pertaining to Level I office surgery and added two drugs to the list of medications that must be available for Level I office surgery. A physician's office that performs Level I office surgery is required to have Flumazenil if a benzodiazepine is administered and Naloxone if an opiate is administered. Flumazenil is used for

¹⁹ Rule 64B8-9.009(2), F.A.C.

²⁰ Refers to controlled substances as defined in ss. 893.02 and 893.03, F.S.

²¹ This bullet is text from the adopted rule under consideration for ratification. This text is intended to clarify the rule currently in effect.

reversing drowsiness, sedation, and other effects caused by benzodiazepines.²² Naloxone blocks or reverses the effects of opioid²³ medication, including extreme drowsiness, slowed breathing, or loss of consciousness. These newly listed medications may be administered, if needed, to reverse the effects of other medications administered for the surgical procedure.

The department prepared a SERC in accordance with state rulemaking requirements.²⁴ The estimated cost to each physician's office performing Level I office surgeries is \$29.98 for the required quantity of Flumazenil and \$55.96 for the required quantity of Naloxone for a total of \$85.96.²⁵ According to the board, the actual number of physician offices is unknown but the board assumes that approximately 20,468 physicians' offices in private practice would perform a minor procedure defined in the rule as Level I office surgery. The aggregate regulatory costs for initial compliance with the proposed rule is \$1,759,429.²⁶ As a result, the proposed rule amendment requires ratification by the Legislature prior to taking effect.

III. Effect of Proposed Changes:

The proposed bill ratifies Rule 64B8-9.09, F.A.C., Standard of Care for Office Surgery solely to meet the condition for effectiveness of the rule imposed by s. 120.541(3), F.S.

The proposed bill also:

- Directs that the act shall not be codified in the F.S.;
- Requires that after the act becomes law, its enactment and effective date shall be noted in the Florida Administrative Code, the F.A.R., or both, as appropriate;
- Provides that the act does not alter rulemaking authority or constitute a legislative preemption of, or exception to, any other provision of law regarding adoption or enforcement of the rule and is intended to preserve the status of the rule; and
- Does not cure any rulemaking defect or preempt any challenge based on a lack of authority or a violation of requirements governing adoption of the rule.

The act is effective upon becoming a law. At that time, the rule becomes effective.²⁷

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

²² Benzodiazepines include drugs such as Valium, Versed, and Xanax. Among other uses, they may be used before surgery to induce relaxation and amnesia (memory loss). See <https://www.drugs.com/drug-class/benzodiazepines.html> (last visited Feb. 15, 2017).

²³ Opioids reduce the sending of pain messages to the brain and reduce feelings of pain. See <http://www.webmd.com/pain-management/guide/narcotic-pain-medications#1> (last visited Feb. 15, 2017).

²⁴ *Supra* note 7. A copy of the SERC is available in the Senate Health Policy Committee.

²⁵ The SERC states that the shelf life of these drugs is at or exceed 5 years, therefore no replacement costs are included in the fiscal analysis.

²⁶ The SERC indicates that the rule increases regulatory costs by \$1,937,500.88 over the first 5 years of implementation. However, the cost of a medication that is currently required by rule, was inadvertently included in that calculation.

²⁷ Section 120.54(3)(e)6., F.S.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:**A. Tax/Fee Issues:**

None.

B. Private Sector Impact:

The proposed bill enables a rule to go into effect that will impose a requirement on physicians who perform Level I office surgery to maintain specified drugs in the office. The estimated cost per physician's office is \$85.96 over a 5-year period.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates an undesignated section of Florida law.

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

FOR CONSIDERATION By the Committee on Health Policy

588-01654-17

20177012pb

A bill to be entitled

An act relating to ratification of Department of Health rules; ratifying a rule, adopted by the Board of Medicine, relating to the standard of care for office surgery for the sole and exclusive purpose of satisfying any condition on effectiveness pursuant to s. 120.541(3), F.S., which requires ratification of any rule exceeding the specified thresholds for likely adverse impact on or increase in regulatory costs; providing applicability; providing an effective date.

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

Section 1. (1) The following rule is ratified for the sole and exclusive purpose of satisfying any condition on effectiveness imposed under s. 120.541(3), Florida Statutes: Rule 64B8-9.009, Florida Administrative Code, titled "Standard of Care for Office Surgery" as filed for adoption with the Department of State pursuant to the certification package dated June 15, 2016.

(2) This act serves no other purpose and may not be codified in the Florida Statutes. After this act becomes law, its enactment and effective date shall be noted in the Florida Administrative Code, the Florida Administrative Register, or both, as appropriate. This act does not alter rulemaking authority delegated by prior law, does not constitute legislative preemption of or an exception to any provision of law governing adoption or enforcement of the cited rule, and is intended to preserve the status of the cited rule as a rule

Page 1 of 2

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

588-01654-17

20177012pb

under chapter 120, Florida Statutes. This act does not cure any rulemaking defect or preempt any challenge based on a lack of authority or a violation of the legal requirements governing the adoption of the cited rule.

Section 2. This act shall take effect upon becoming a law.

Page 2 of 2

CODING: Words ~~stricken~~ are deletions; words underlined are additions.

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17
Meeting Date

7012
Bill Number (if applicable)

Topic Ratification of DOH Rules

Amendment Barcode (if applicable)

Name Mary Thomas

Job Title Assistant Gen. Counsel

Address 1430 Piedmont Dr E
Street
Tallahassee FL 32308
City State Zip

Phone 850 224 6496

Email MThomas@flmedical.org

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Medical Association

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE
APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17

Meeting Date

7012

Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Noland

Job Title _____

Address 1000 Riverside Ave #240

Phone 904-233-3051

Street

Jacksonville FL 32204

Email nolandlaw@aol.com

City

State

Zip

Speaking: ☒ For ☐ Against ☐ Information

Waive Speaking: ☐ In Support ☐ Against
(The Chair will read this information into the record.)

Representing Florida Chapter, American College of Surgeons

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

(Deliver BOTH copies of this form to the Senator or Senate Professional Staff conducting the meeting)

2/21/17

Meeting Date

7012

Bill Number (if applicable)

Topic Board of Medicine

Amendment Barcode (if applicable)

Name Melanie Brown

Job Title Gov't Affairs Dir / Team HB

Address PO BOX 10805

Phone 850 224 1900

Street

Tall, FL

32302

Zip

Email

Speaking: ☐ For ☐ Against ☐ Information

Waive Speaking: ☒ In Support ☐ Against
(The Chair will read this information into the record.)

Representing FL Society of Dermatologists

Appearing at request of Chair: ☐ Yes ☒ No

Lobbyist registered with Legislature: ☒ Yes ☐ No

While it is a Senate tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this meeting. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard.

This form is part of the public record for this meeting.

S-001 (10/14/14)



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Education, *Chair*
Regulated Industries, *Vice Chair*
Appropriations Subcommittee on the Environment
and Natural Resources
Health Policy
Transportation

JOINT COMMITTEE:

Joint Committee on Public Counsel Oversight

SENATOR DOROTHY L. HUKILL

14th District

February 17, 2017

The Honorable Dana D. Young
Health Policy Committee, Chair
530 Knott Building
404 S. Monroe Street
Tallahassee, FL 32399-1100

Re: Request for Excusal from Committee Meeting

Dear Chairwoman Young:

Please excuse me from the Health Policy Committee on February 21, 2017 at 12:30 p.m. as I will not be able to attend due to illness.

If you have any questions, please do not hesitate to contact me.

Sincerely,

A handwritten signature in cursive script that reads "Dorothy L. Hukill".

Dorothy L. Hukill
State Senator, District 14

cc: Sandra Stovall, Staff Director of the Health Policy Committee
Celia Georgiades, Committee Administrative Assistant of the Health Policy Committee

REPLY TO:

□ 209 Dunlawton Avenue, Unit 17, Port Orange, Florida 32127 (386) 304-7630 FAX: (888) 263-3818

Senate's Website: www.flsenate.gov

JOE NEGRON
President of the Senate

ANITERE FLORES
President Pro Tempore



THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Environmental Preservation and
Conservation, *Chair*
Appropriations Subcommittee on the Environment
and Natural Resources, *Vice Chair*
Appropriations
Appropriations Subcommittee on Health and
Human Services
Health Policy
Rules

SENATOR LAUREN FRANCES BOOK

Democratic Leader Pro Tempore
32nd District

January 12, 2017

The Honorable Dana D. Young
Chair, Health Policy Committee

Via Email

Dear Chair Young:

As you are aware, I am pregnant and carrying twins. As a result of my high-risk pregnancy, my doctors have advised that with barely five weeks before delivery, it is not advisable to travel at the end of January, nor during the month of February. I will be present for Committee meetings this week but respectfully request that I be excused from any scheduled meetings held during the weeks of January 23rd, February 6th, February 13th, and February 20th.

I plan to closely monitor meetings from my home. It is my intention to relocate to Tallahassee for Session on Saturday, March 4th, 2017 and be present throughout the Session.

Thank you for your understanding and consideration of this request for excused absences.

Sincerely,

Lauren F. Book
Senator, 32nd District

Cc: President Negron
Ms. Sandra Stovall, Staff Director;
Ms. Celia Georgiades, Committee Administrative Assistant

REPLY TO:

□ 202 Senate Office Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5032

Senate's Website: www.flsenate.gov

JOE NEGRON
President of the Senate

ANITERE FLORES
President Pro Tempore

CourtSmart Tag Report

Room: KN 412

Caption: Senate Health Policy Committee

Case No.:

Judge:

Type:

Started: 2/21/2017 12:35:08 PM

Ends: 2/21/2017 1:31:11 PM

Length: 00:56:04

12:35:09 PM Meeting called to order
12:35:25 PM Opening Remarks
12:36:25 PM Tab 1 SB 182
12:36:45 PM Senator Mayfield presents SB 182
12:39:00 PM Sub Amd 531774 Question
12:39:33 PM Sen Mayfield response
12:39:45 PM Sen Montford question
12:39:56 PM Senator Mayfield to respond
12:40:12 PM Margaret Hooper, Florida Developmental Disabilities Council- waives in support
12:41:06 PM Jennifer Ross, Ambassador, Arthritis Foundation, speaks in support
12:43:33 PM Fely Curva, PhD, Budd Bell Clearinghouse on Human Services- waives in support
12:43:39 PM Dorene Barker, Associate State Director, AARP, waives in support
12:43:45 PM FI foundation waives in support
12:43:52 PM Rebecca Ramon, Tallahassee Pharm. Association - waive in support
12:44:04 PM Audrey Brown, Florida Association of Health Plans, speaks in opposition
12:45:08 PM Jeri Francoeur, Florida Breast Cancer Foundation- waive in support
12:46:08 PM Valencia Robinson, Florida Breast Cancer Foundation
12:48:22 PM Senator Passidomo w/question
12:48:40 PM Speaker Audrey Brown
12:50:38 PM Senator Passidomo w/follow-up
12:52:03 PM Audrey Brown
12:53:04 PM Sen Hutson question
12:53:31 PM Audrey Brown
12:54:05 PM Sen Hutson follow up
12:54:27 PM Speaker
12:54:44 PM Chair Young w/question
12:55:51 PM Audrey Brown to answer
12:56:11 PM Brewster Bevis, Associated Industries of Florida, speaks in opposition
12:57:12 PM Matt Jordan, American Cancer Society waives in support
12:57:25 PM Aimee Diaz Lyon, waives in support
12:57:34 PM Stephen Winn, FL Osteopathic Medical Association- waives in support
12:57:47 PM Alisa LaPolt, National Alliance on Mental Illness- waives in support
12:58:08 PM Chris Nuland, Florida Gastroenterologic Society -waives in support
12:58:48 PM Joy Ryan, AHIP, speaks in opposition
1:00:15 PM Julio Perez Downes, MD, speaks in support
1:02:06 PM Mary Thomas, FMA, waives in support
1:02:23 PM Doug Bell, waives in support
1:02:27 PM Melanie Brown, waives in support
1:02:37 PM Florida Pharmacy Association, waives in support
1:02:55 PM debate
1:03:07 PM Call for vote
1:03:13 PM Sub Amen adopted
1:03:23 PM questions on bill
1:03:33 PM Sen Passidomo comments
1:04:31 PM Sen Hutson comments
1:05:10 PM Chair Young comments
1:06:11 PM Sen Mayfield closes on the bill
1:08:45 PM roll call CS/SB 182
1:09:09 PM SB passes favorably
1:09:38 PM Tab 3 SB 510
1:09:45 PM Sen Montford explains
1:10:26 PM Barcode 608818

1:11:52 PM Bryan Cherry, Doctor's Memorial Hospital-Bonifay -waives in support
1:12:06 PM Sen Montford waives to close on amend
1:12:22 PM Lisa Hurley, Florida Association of Counties -waive in support
1:12:40 PM Crystal Stickle, Florida Hospital Association -waives in support
1:12:51 PM roll call SB 510
1:13:02 PM SB 510 passes favorably
1:13:22 PM Tab 2 CS/SB 240
1:13:43 PM Sen Lee explains
1:15:01 PM Call for questions for Sen. Lee
1:15:19 PM Amend BC 935168 Sen Lee explains
1:15:52 PM Chair calls for questions and debate
1:16:02 PM Sen Lee waive to close
1:16:12 PM Amend adopted 935168
1:16:26 PM Amend 168396 Sen Lee explains
1:17:54 PM Call for questions on A 168396
1:18:15 PM Sen Hutson question
1:18:18 PM Sen. Lee responds
1:19:13 PM Sen Hutson follow up question
1:19:23 PM Vice Chair Passidomo
1:19:43 PM Sen Lee response
1:21:03 PM A 168396 BC 439140
1:21:54 PM A to Amend adopted
1:22:14 PM Sen Lee waives close
1:22:23 PM Amend adopted
1:23:34 PM Sen Montford questions
1:25:57 PM Sen Lee explains
1:26:06 PM waives in support
1:26:09 PM FI Chiropractic waive in support
1:26:19 PM Chris Nuland, waives in support
1:26:45 PM Tim NFIB, waives in support
1:26:51 PM Sklyar, waives in support
1:27:09 PM Chair Young speaks
1:27:20 PM Sen Lee closes on the bill
1:27:34 PM Roll Call CS/CS 240
1:27:46 PM CS/CS SB 240 passes favorably
1:28:04 PM Tab 4 SPB 7012
1:28:19 PM Chair Young explains
1:29:14 PM Vice Chair Passidomo
1:29:51 PM Mary Thomas, FMA -waives in support
1:29:59 PM Chris Nuland, waive in support
1:30:09 PM Melanie Brown waives in support
1:30:29 PM Roll Call SPB 7012
1:30:42 PM SPB 7012 passes favorably
1:30:56 PM Meeting adjourned