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.)

Prepare	d By: The Profe	essional Staff of the Approp	oriations Subcommi	ttee on Health and Human Services
BILL:	CS/CS/SB 240			
INTRODUCER:	Health Policy Committee; Banking and Insurance Committee; and Senator Lee and others			
SUBJECT: Direct Primary Care				
DATE:	March 20, 2	2017 REVISED:		
ANAL	YST	STAFF DIRECTOR	REFERENCE	ACTION
. Johnson		Knudson	BI	Fav/CS
. Lloyd		Stovall	HP	Fav/CS
Loe		Williams	AHS	Recommend: Favorable
			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 chapter 456, Florida Statutes, 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 (SMMC) program the opportunity to select DPC agreements as a delivery service option.

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

The effective date of the bill is July 1, 2017.

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, 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

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).

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 bill third party payers, 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 preventive 9 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 DHHS 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

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).

• Other Medicaid managed care cost savings generated from direct primary care. 16

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 AHCA 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, an HMO and a prepaid health clinic must receive a Health Care Provider Certificate¹⁹ from the AHCA 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

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

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 government and state governments to provide medical care to low income children, pregnant women, individuals with disabilities, and individuals 65 years of age and older. 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 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 60.99 percent with the state paying 39.01 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 and pregnant women, 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. States can add benefits, pending federal approval. Florida has added benefits, including prescription drugs, adult dental services, and dialysis. For children under age 21, the benefits must include the Early and Periodic Screening, Diagnostic

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.

and Treatment services, which are those health care, diagnostic services, 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 (SMMC) program. 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)

Section 2 creates s. 456.0625, F.S., to recognize direct primary care agreements within ch. 456, F.S., relating to the general provisions for health care practitioners.

Section 2 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.

Section 2 authorizes a primary care provider or an agent of the primary care provider to execute a DPC agreement. Section 3 expressly exempts DPC agreements from the Florida Insurance

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.

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.

Section 2 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; and
- Contain the following statements in contrasting color and 12-point or larger type on the same page as the applicant's signature:
 - o "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."
 - o "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)

Section 1 amends s. 409.977, F.S., to direct the AHCA to seek a waiver from the appropriate federal authorities to allow Medicaid recipients in the SMMC program the opportunity to participate in direct primary care agreements within the program. Section 1 also clarifies the amount of financial assistance that may be given to recipients who participate and provides 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. The department could see an increase in complaint activity to the extent that issues arise between practitioners and patients with DPC agreements.

The AHCA will incur costs related to the submission of the federal waiver or waiver amendment for the SMMC program required under this bill; however, these costs should be absorbed within existing resources.

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

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 or waiver amendment 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.)