The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Young, Chair
Senator Passidomo, Vice Chair

MEETING DATE: Tuesday, October 24, 2017
TIME: 9:00—10:30 a.m.
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Young, Chair; Senator Passidomo, Vice Chair; Senators Benacquisto, Book, Hukill, Hutson, Montford, and Powell

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**CS/SB 80** Banking and Insurance / Lee (Similar H 37)	Direct Primary Care Agreements; Specifying that a direct primary care agreement does not constitute insurance and is not subject to 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 the code, etc. BI 09/13/2017 BI 10/10/2017 Fav/CS HP 10/24/2017 Favorable AP	Favorable Yeas 8 Nays 0
2	Update on the Implementation of SB 8-A (2017A), Medical Use of Marijuana by Christian Bax, Department of Health		Discussed
	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/SB 80
INTRODUCER:	Banking and Insurance Committee and Senator Lee
SUBJECT:	Direct Primary Care Agreements
DATE:	October 19, 2017 REVISED:

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

Please see Section IX. for Additional Information:

PLEASE MAKE SELECTION

I. Summary:

CS/SB 80 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. 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. The bill also defines DPC agreements and requires them to meet statutory requirements, including consumer disclosures. A contract that does not meet these requirements is not a DPC agreement, and thus will not be exempt from the code.

As of September 2017, 23 states have adopted DPC laws that define DPC as a medical service outside the scope of state insurance regulation.

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.[1] Through a contractual agreement, a patient generally

[1] 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 generally continues to bill third party payers, such as insurers on a fee for service basis, in addition to the collection of membership and retainer fees. *See* Phillip M. Eskew and Kathleen Klink,

pays a monthly retainer fee, on average $77 per individual,[2] 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.[3]

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.[4] The Direct Primary Care Coalition has adopted model state legislation for DPC agreements.[5] As of September 2017, 23 states have adopted DPC legislation, which defines DPC as a medical service outside the scope of state insurance regulation.[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. The PPACA also mandates that insurers that offer qualified health

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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 Oct. 19, 2017).

[2] *Id.* 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. The average monthly cost to the patient was $93.26 (median monthly cost, $75.00; range, $26.67 to $562.50 per month) for these 116 practices. 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.

[3] Lisa Zamosky, Direct-Pay Medical Practices Could Diminish Payer Headaches, MEDICAL ECONOMICS, (Apr. 24, 2014).

[4] 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 Oct. 19, 2017).

[5] Direct Primary Care Coalition Model State Legislation, *available at* http://www.dpcare.org/dpcc-model-legislation. (last viewed Oct. 19, 2017).

[6] See https://www.dpcare.org/state-level-progress-and-issues (last viewed Oct. 19, 2017).

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

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.[10] Federal regulations provide that a QHP may provide coverage through a DPC medical home plan that meets criteria[11] established by the federal Department of Health and Human Services (HHS), if the plan meets all other applicable requirements.[12] For example, an individual could enroll in a DPC plan and obtain coverage through a high deductible health plan (HDHP),[13] which would provide coverage for severe injuries or chronic conditions. Such an individual may benefit from enrolling in a DPC medical home plan since it may provide greater degree of access to health care for a monthly fee that is substantially less than the annual deductible of the HDHP.

Federal Tax Treatment of Direct Primary Care

Currently the federal tax treatment of direct primary care medical home plans may discourage the use of such plans. For an individual to be eligible to make tax-deductible contributions to a Health Savings Account (HSA), the individual must be covered by an HDHP and no other plan that is not an HDHP, unless the other plan qualifies as disregarded coverage.[14] A DPC medical home plan is not delineated as one of the disregarded coverages under the Internal Revenue Service (IRS) Code. According to the IRS, an individual would not be eligible to make tax-deductible contributions to an HSA while covered by both an HDHP and a DPC medical home plan, unless the DPC plan provided preventive care only.[15] Further, the IRS Code does not permit the periodic payments made to primary care physicians under a DPC model to qualify as a medical expense.[16] Federal legislation is pending to address these issues.[17]

State Regulation of Insurance

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, health maintenance organizations (HMOs), and other risk-bearing entities. These specified entities must meet certain requirements for licensure. The Agency for Health Care Administration (AHCA)

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[8] 42 U.S.C. s. 18022.
[9] Available at: https://www.hhs.gov/healthcare/about-the-law/preventive-care/index.html# (last viewed Oct. 19, 2017).
[10] *See* 42 U.S.C. ss. 18021. The Secretary of Health and Human Services shall permit a qualified health plan to provide coverage through a qualified direct primary care medical home plan that meets criteria established by the Secretary, so long as the qualified health plan meets all requirements that are otherwise applicable and the services covered by the medical home plan are coordinated with the entity offering the qualified health plan.
[11] The HHS has not adopted criteria to date.
[12] *See* 45 C.F.R. 156.245.
[13] A high deductible health plan (HDHP) has a higher deductible than typical plans and a maximum limit on the amount of the annual deductible and out-of-pocket medical expenses an insured must pay for covered services. In 2017, for self-only coverage, the annual minimum deductible is $1,300 and the maximum is $6,550. An HDHP may provide preventive care benefits without a deductible or with a deductible less than the minimum annual deductible. See https://www.irs.gov/publications/p969#en_US_2016_publink1000204030 (last viewed Oct. 19, 2017).
[14] 26 U.S.C. s. 223(c).
[15] *See* U.S. Department of Treasury letter from John A. Koskinen, Commissioner of the Internal Revenue Service, to U.S. Senator Patty Murray (Jun. 30, 2014) (on filed with Senate Committee on Banking and Insurance).
[16] *See* 26 U.S.C. s. 213(d).
[17] The Primary Care Enhancement Act of 2017 available at https://www.congress.gov/bill/115th-congress/house-bill/365/text (last viewed Oct. 19, 2017).

establishes quality of care standards for 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 Certificate[18] from the AHCA pursuant to part III of ch. 641, F.S.[19]

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.[20]

Prepaid Health Clinics

Prepaid health clinics[21] are required to obtain a certificate of authority from the OIR pursuant to part II of ch. 641, F.S. The entity must meet minimum surplus requirements,[22] and comply with solvency protections for the benefit of subscribers by securing insurance or filing a surety bond with the OIR.[23] 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.[24]

Prepaid Limited Health Services Organizations

Prepaid limited health services 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 includes 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. These organizations must comply with the requirements of s. 636.035, F.S., obtain a certificate of authority from the OIR,[25] and meet the minimum solvency requirements. The statute allows organizations to meet the solvency component through evidence of a fidelity bond of at least $50,000 or the deposit of an equal amount in cash or securities with the OIR.[26]

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[18] Section 641.49, F.S.

[19] 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.

[20] Part II of ch. 641, F.S.

[21] 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.

[22] Section 641.406, F.S.

[23] Section 641.409, F.S.

[24] Section 641.406, F.S.

[25] Section 636.007, F.S.

[26] Section 636.046, F.S., provides the statutory requirements for insolvency protection for prepaid limited health service organizations, including the minimum market value of the deposit with the OIR for insolvency protection of $50,000. The options to provide the $50,000 through a blanket fidelity bond, cash, securities or other investments can be found on the *Office of Insurance Regulation Company Admissions, Application for Certificate of Authority, Prepaid Limited Health Service Organization Application, Section III-4 Insurance,* which is at, https://www.floir.com/siteDocuments/plhso_all_forms.pdf (last visited Oct. 19, 2017).

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.

III. Effect of Proposed Changes:

Section 1 creates s. 624.27, F.S., which expressly exempts DPC agreements from the Florida Insurance Code. The section provides that the act of entering into a DPC agreement does not constitute the business of insurance and is not subject to the Florida Insurance Code. The section also provides that a primary care provider or an 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, in order to market, sell, or offer to sell a DPC agreement.

To qualify for the exemption, a direct primary care agreement must meet the following minimum requirements and disclosures:

- 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:

- "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."
- "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, 26 U.S.C. s. 5000A."
- "This agreement is not workers' compensation insurance and does not replace an employer's obligations under ch. 440, F.S."

Further, the section defines the following terms:

- "Direct primary care agreement" means a contract between a primary care provider and a patient, the patient's legal representative, or an employer which must satisfy the requirements regarding contract terms and disclosures within subsection (4) of the bill and does not indemnify for services provided by a third party.
- "Primary care provider" means 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, who provides primary care services to patients.
- "Primary care services" means the screening, assessment, diagnosis, and treatment conducted within the competency and training of the primary care provider for the purpose of promoting health or detecting and managing disease or injury.

Section 2 provides that the bill takes effect July 1, 2018.

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:

This bill 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 regarding 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.

Additional primary care providers may elect to pursue a direct primary care model and establish direct primary care practices that 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:

According to the Department of Management Services, the bill would not have a direct impact on the department, which includes the Division of State Group Insurance.[27]

The Agency for Health Care Administration and the DOH report no direct impact to their respective agencies.[28, 29]

VI. Technical Deficiencies:

None.

VII. Related Issues:

The OIR notes that the direct primary care contract is required to offer a refund if the primary care provider ceases to provide primary care services for any reason. However, the legislation does not require any collateral be posted for the refund payments such as a surety bond. Therefore, there is some risk to consumers potentially that they may not receive their refunds if a provider ceases to provide services in the future.[30]

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[27] Florida Department of Management Services, *Analysis of SB 80* (Oct. 4, 2017) (on file with the Senate Committee on Banking and Insurance).
[28] Agency for Health Care Administration, *2018 No Agency Impact Statement* (Oct. 17, 2017) (on file with the Senate Committee on Health Policy).
[29] Florida Department of Health, *E-Mail Communication from Paul Runk – No Fiscal Impact* (Oct. 17, 2017) (on file with the Senate Committee on Health Policy).
[30] The Florida Office of Insurance Regulation, *2018 Agency Bill Analysis – CS/SB 80* (Oct. 17, 2017) (on file with the Senate Committee on Health Policy).

VIII. Statutes Affected:

This bill creates section 624.27 of the Florida Statutes.

IX. Additional Information:

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

CS by Banking and Insurance on October 10, 2017:
The CS places the direct primary care contracting requirements within the Florida Insurance Code, rather than ch. 456, F.S.

B. Amendments:

None.

By the Committee on Banking and Insurance; and Senator Lee

597-00751-18 201880c1

A bill to be entitled

An act relating to direct primary care agreements; creating s. 624.27, F.S.; providing definitions; specifying that a direct primary care agreement does not constitute insurance and is not subject to 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 the code; providing that a certificate of authority or a license under the code is not required to market, sell, or offer to sell a direct primary care agreement; specifying requirements for a direct primary care agreement; 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 Direct primary care agreements; exemption from code.—

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

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

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

597-00751-18 201880c1

services to patients.

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

(2) A direct primary care agreement does not constitute insurance and is not subject to 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 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 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 the patient's 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.

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

(g) Offer a refund to the patient, the patient's legal representative, or the patient's employer 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 at least 12-point type, the following statement on the signature page: "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 the agreement. This agreement does not qualify as minimum essential coverage to satisfy the individual shared responsibility provision of the Patient Protection and Affordable Care Act, 26 U.S.C. s. 5000A. This agreement is not workers' compensation insurance and does not replace an employer's obligations under chapter 440, Florida Statutes."

Section 2. This act shall take effect July 1, 2018.

The Florida Senate

Committee Agenda Request

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

Subject: Committee Agenda Request

Date: October 10th, 2017

I respectfully request that **Senate Bill #80**, relating to **Direct Primary Care**, be placed on the:

☐ committee agenda at your earliest possible convenience.

☒ next committee agenda.

Tom Lee

Senator Tom Lee
Florida Senate, District 20

File signed original with committee office

S-020 (03/2004)

THE FLORIDA SENATE

APPEARANCE RECORD

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

10-24-17
Meeting Date

80
Bill Number (if applicable)

Topic DIRECT PRIM. CARE

Amendment Barcode (if applicable)

Name SAL NUZZO

Job Title VP POLICY

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing THE JAMES MADISON INST.

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)

Duplicate

THE FLORIDA SENATE

APPEARANCE RECORD

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

10/24/17
Meeting Date

SB 0
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Tim Nungesser

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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

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S-001 (10/14/14)

THE FLORIDA SENATE

APPEARANCE RECORD

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10/24/17
Meeting Date

SB 80
Bill Number (if applicable)

Topic Direct Primary Care

Amendment Barcode (if applicable)

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Speaking: ☐ For ☐ Against ☐ Information

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

Representing Florida Chiropractic Physician 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

APPEARANCE RECORD

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10-24-2017
Meeting Date

80
Bill Number (if applicable)

Topic DIRECT PRIMARY CARE

Amendment Barcode (if applicable)

Name STEPHEN R. WINN

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Email

Speaking: [X] For [ ] Against [ ] Information

Waive Speaking: [X] 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: [X] 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

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10-24-17
Meeting Date

SB 80
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Skylar Zander

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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

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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)

10/24/17
Meeting Date

80
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Chris Nuland

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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

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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)

10-24-17
Meeting Date

SB 80
Bill Number (if applicable)

Topic Direct Primary Care

Amendment Barcode (if applicable)

Name Mary Thomas

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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

APPEARANCE RECORD

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

10/24/17
Meeting Date

SB 80
Bill Number (if applicable)

Topic Direct Primary Care

Amendment Barcode (if applicable)

Name Jay Millson

Job Title EVP

Address 13941 Bartram Park Blvd
Street

Jacksonville FL 32258
City *State* *Zip*

Phone 904-400-6189

Email jmillson@fafp.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing FL Academy of Family Physicians

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

10/24/17
Meeting Date

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

SB 80
Bill Number (if applicable)

Topic Direct Primary Care

Amendment Barcode (if applicable)

Name Alexandra Abboud

Job Title Gov. Affairs Liaison

Address 118 E Jefferson street
Street

Tallahassee FL 32301
City *State* *Zip*

Phone 850-224-1089

Email aabboud@floridadental.org

Speaking: ☐ For ☐ Against ☐ Information

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

Representing The Florida Dental 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

APPEARANCE RECORD

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10/24/17
Meeting Date

CS/SB 80
Bill Number (if applicable)

Topic DIRECT PRIMARY CARE

Amendment Barcode (if applicable)

Name PAUL LAMBERT

Job Title ATTORNEY

Address 263 Rosehill Dr. N.
Street

Phone 850-597-2696

TALLAHASSEE 32312
City *State* *Zip*

Email plambert@paullambertlaw.com

Speaking: ☑ For ☐ Against ☐ Information

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

Representing FLORIDA CHIROPRACTIC 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.

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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)

10-28-2017
Meeting Date

80
Bill Number (if applicable)

Topic _____

Amendment Barcode (if applicable)

Name Brian Pitts

Job Title Trustee

Address 1119 Newton Ave S
Street

Phone 727/897-9291

St. Petersburg FL 33705
City *State* *Zip*

Email justice2jesus@yahoo.com

Speaking: ☐ For ☐ Against ☑ Information

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

Representing Justice-2-Jesus

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)

FLORIDA DEPARTMENT OF HEALTH

Office Of Medical Marijuana Use

Low-THC Cannabis & Medical Marijuana

MedicalMarijuanaUse@FLHealth.gov

Florida HEALTH

Medical Marijuana in Florida

- Medical marijuana was first legalized in Florida under the Compassionate Medical Cannabis Act of 2014. The act authorized a low tetrahydrocannabinol (low-THC) and high cannabidiol (CBD) form of marijuana for medical use by patients suffering from cancer or seizures.
- The 2016 Right to Try Act allowed patients with terminal illnesses access to “full potency” medical marijuana.
- In November, 2016, 71 percent of Florida voters voted for Amendment 2, which created Article X, section 29 of the Florida Constitution. Amendment 2 expanded access to both low-THC and full-potency medical marijuana for a larger list of medical conditions.
- SB 8-A (2017) implemented Amendment 2.

Timeline

Jun 6, 2014	SB 1030 “Compassionate Medical Cannabis Act of 2014” signed into law
Mar 25, 2016	HB 307 “The Right to Try Act” signed into law
Nov 8, 2016	Amendment 2 passed
Jan 3, 2017	Amendment 2 became effective
June 9, 2017	Senate Bill 8-A passed in special session
June 23, 2017	Senate Bill 8A signed into law
July 1, 2017	Rule 1-1.01, Medical Marijuana for Debilitating Medical Conditions, became effective

What is *Medical* Marijuana in Florida

Authorized Use

- Full potency medical marijuana, *and* low-THC cannabis under 381.986. F.S., for all qualifying conditions.
- Medical use is the acquisition, possession, use, delivery, transfer, or administration of marijuana authorized by a qualified ordering physician.
- Medical marijuana is only provided through an approved Medical Marijuana Treatment Center (MMTC).

Unauthorized Use

- Marijuana that was not purchased or acquired from a MMTC.
- Marijuana in forms for smoking, commercially produced food items other than edibles, and marijuana seeds or flower, except for flower in a sealed, tamper-proof receptacle for vaping.
- Use in a manner inconsistent with the qualified physician's directions or certification.
- Transfer of marijuana to a person other than an authorized qualified patient or the qualified patient's caregiver on their behalf.

Medical Marijuana Treatment Center (MMTC) Qualifications

All Medical Marijuana Treatment Centers (MMTCs) must:

- Be vertically integrated
- Have been registered to do business in the state for at least 5 consecutive years before submitting an application
- Possess a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131 F.S.
- Upon approval, post a $5 million performance bond issued by an authorized surety insurance company

MMTC Licensure Phases

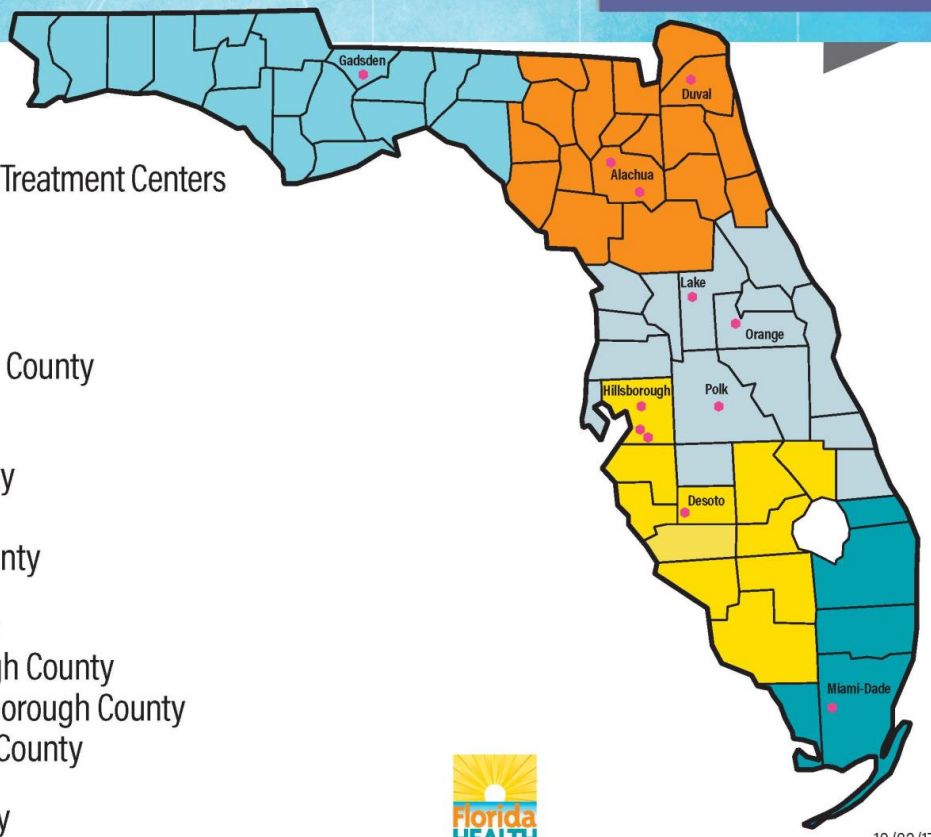
- Phase 1: By July 3, 2017, DOH must license any entity that holds an active, license under former Compassionate Use Act.
- Phase 2: By August 1, 2017, DOH must license any applicant whose application was scored but denied a license by DOH under the Compassionate Use Act, and which had an ongoing administrative or judicial challenge as of January 1, 2017, or had a final ranking within one point of the highest final ranking in its region.
- Phase 3: By October 3, 2017, DOH must issue additional licenses for MMTCs, one of which is a recognized class member of Pigford v. Glickman and is a member of the Black Farmers and Agriculturalists Association (Florida Chapter).
- Phase 4: Upon reaching 100,000 patients in the registry, and for each additional 100,000 patients thereafter, DOH must license 4 more MMTCs within 6 months.

FLORIDA DEPARTMENT OF HEALTH

Office of Medical Marijuana Use

Low-THC Cannabis & Medical Marijuana

Medical Marijuana Treatment Centers



Approved Medical Marijuana Treatment Centers

Trulieve—Gadsden County

Aphria—Alachua County
The Green Solution—Alachua County
Loop's—Duval County

Knox Medical—Orange County
GrowHealthy—Polk County
Treadwell Nursery—Lake County

3 Boys—Hillsborough County
Plants of Ruskin—Hillsborough County
Surterra Therapeutics—Hillsborough County
Sun Bulb Company—DeSoto County

Curaleaf—Miami-Dade County

Florida HEALTH

10/23/17

Florida HEALTH

Phase 1 and 2 Approved MMTCs by Region

Dispensary Distribution Method and Current Dispensing Locations

Dispensary Distribution	MMTC*	Retail Dispensary Locations
• **Statewide Maximum** - Each MMTC may have up to 25 dispensaries statewide, before the patient population reaches 100,000. Each MMTC gets an additional 5 dispensaries for each additional 100,000 patients. • **Regional Maximum** - The statewide maximum is distributed in the 5 regions (Northwest, Northeast, Central, Southwest and Southeast) based on regional population. • MMTCs may purchase dispensary slots from other MMTCs. • These limits sunset on April 1, 2020.	Surterra Therapeutics	Tallahassee, Tampa
	Trulieve	Bradenton, Clearwater, Edgewater, Jacksonville, Miami, Lady Lake, Pensacola, St. Petersburg, Tallahassee, Tampa
	Knox Medical	Gainesville, Jacksonville, Lake Worth, Orlando, Tallahassee
	Curaleaf	Kendall, Miami

*** These are the only MMTCs currently operating retail dispensaries.**

Phase 3 MMTC Licensure and Procurements

- DOH adopted rules and noticed proposed regulations that establish the MMTC application procedure pursuant to s. 381.986, F.S. and Art. X, S. 29 Fla. Const. (Notice of Proposed Regulation 1-1.02 & 2-1.01 Emergency Rule 64ER17-1 & 64ER17-2).
- DOH is procuring outside specialists to evaluate new applications.
  - Request for Quotes issued to state term contracts; currently reviewing quotes received.
- DOH is currently negotiating with vendors to outsource the patient and caregiver identification card program.
- DOH has developed an Request for Proposals for the statewide seed-to-sale tracking system.

MMTC Rules and Regulations

The department is in the process of developing rules for:

- Pesticide use
- Fine and fee collection
- Labeling and packaging standards
- Edible standards
- Dosing guidelines
- Testing laboratory Certification

Qualified Physician Requirements

- Only a qualified physician may issue a certification for low-THC cannabis and medical marijuana for patients. 1,047 qualified physicians are currently registered with DOH.
- To be a qualified physician, a doctor must:
  - Have a clear/active license as a medical or osteopathic physician (ch. 458 or 459, F.S.)
  - Complete a course and examination provided by the Florida Medical Association or the Florida Osteopathic Medical Association.
- To issue a certification, a qualified physician must:
  - Conduct a physical examination while physically present in the same room as the patient and assess the patient's medical history.
  - Diagnose the patient with a qualifying medical condition
  - Determine that the benefits of medical marijuana would likely outweigh the potential health risks for the patient, and record this determination. If a patient is under age18, a second physician must agree and record the agreement.

Qualified Physician Requirements, cont'd

- To issue a certification, a qualified physician must (continued):
  - Determine if the patient is pregnant and record it. A physician may not issue a physician certification, except for low-THC cannabis, to a patient who is pregnant.
  - Review the patient's controlled drug prescription history in the Prescription Drug Monitoring Program database.
  - Review the Medical Marijuana Use Registry and confirm that the patient does not have an active physician certification from another qualified physician.
  - Have registered for this patient in the Medical Marijuana Use Registry and entered the physician certification information into the registry, including the qualifying condition, dosage, amount and forms of marijuana authorized, and any types of marijuana delivery devices needed.
  - Evaluate the patient at least every 30 weeks.

Requirements for Patients

Only a qualified patient may use low-THC cannabis and medical marijuana. There are currently 41,300 qualified patients in Florida.

To be a qualified patient, a person must:

- Be a Florida resident
- Not fraudulently represent qualification
- Have debilitating medical condition
- Be placed in the registry by physician and linked to only one physician
- Have Office of Medical Marijuana Use Identification Card
- Not transfer product to anyone else
- Use only in permitted places

Requirements for Caregivers

Only registered caregivers may obtain and administer Low-THC cannabis and medical marijuana for qualified patients.

To qualify as a caregiver, a person must:

- Be 21 years old (with certain exceptions)
- Pass a background check (with certain exceptions)
- Complete a course and examination provided by DOH, when available

To obtain and assist qualified patients, a caregiver must:

- Only transfer product to qualified patients
- Not use a patient's medical marijuana
- Not administer medical marijuana in prohibited places
- Assist only one qualified patient (with certain exceptions)
- Not receive compensation
- Have the caregiver ID card in immediate possession at all times when possessing, delivering, administering

Identification Cards

Identification card statutory requirements:

- Must be renewed annually
- Must be resistant to counterfeiting and tampering
- Must include:
  - The name, address, and date of birth of the qualified patient or caregiver.
  - A full-face, passport-type, color photograph of the qualified patient or caregiver taken within the 90 days immediately preceding registration or the Florida driver license or Florida identification card photograph of the qualified patient or caregiver obtained directly from the Department of Highway Safety and Motor Vehicles.
  - The expiration date of the identification card.
- DOH has released an ITN, and is currently in negotiations to outsource the production of cards, as directed by SB 8-A.
- Each qualified patient must have an approved application prior to filling an order at an MMTC
- The current processing time for identification cards is approximately 30 days
- The OMMU has issued over 20,000 identification cards
- Common application deficiencies: Photo submitted is not a passport style photo, payment not signed, application not signed

Public Education

Education Campaign Requirements:

- Promote legal requirements for use and possession
- Promote information regarding safe use of marijuana, including prevention of unintended ingestion, particularly in children
- Publicize the short-term and long-term health effects of marijuana use, particularly on minors and young adults
- Educate on use of medical marijuana for individuals diagnosed with terminal conditions and those who provide palliative or hospice services
- **Conduct research to establish baseline knowledge**

Current Status:

- Established partnership with the Florida Survey Research Center (FSRC), based at UF and lead by Dr. Michael Scicchitano
- Survey in draft to be disseminated to five regions of the state to establish baseline knowledge and perception of medical marijuana in Florida
  - Data will be analyzed by FSRC and a report provided to DOH that will guide message development moving forward
- Completed review of public education campaigns in other states that have already implemented medical marijuana

Note: FAMU, Florida Highway Safety and Motor Vehicles and Florida Department of Law Enforcement also received funding for education campaigns.

Statutory Deadlines

July 3, 2017	Grant MMTC licenses to licensed dispensing organizations
Aug 1, 2017	Grant MMTC licenses (5) to any denied DO with a pending legal challenge as of January 1, 2017, or a final ranking within one point the regional winner that proves it has the infrastructure and ability to begin cultivating within 30 days
Oct 3, 2017	Grant MMTC license to a member of the Black Farmers, give preference to two applicants that own citrus processing facilities and two more to reach the requirement
Oct 3, 2017	Must begin issuing patient and caregiver ID cards
Jan 1, 2018	Physician certification pattern review panel shall submit an annual report to Governor, President and Speaker. Department and applicable boards shall initiate nonemergency rulemaking pursuant to Ch. 120
Jan 15, 2018	DOH must submit to the research board and quarterly thereafter data sets for each patient registered in the registry, including condition and daily dose amounts
Jan 31, 2018	Submit to Governor, President and Speaker the annual evaluation of the marijuana use and prevention campaign as assessed by an independent entity
May 1, 2018	Establish supplemental fees to cover costs of marijuana education and use prevention campaign, as well as Medical Marijuana Research and Education at H. Lee Moffitt Cancer Center

Implementation Update

- Granted seven MMTC licenses to existing Dispensing Organizations
- Approved five new MMTCs and have commenced cultivation authorization inspections
- Issued MMTC application grading RFQ
- Established OMMU organizational structure for 28 initial FTEs as well as the 27 FTEs held in reserve by SB-8A
- Developed position descriptions, class codes and pay bands for each new position
- Assembled screening and interview teams that have begun establishing these positions and hiring candidates
- Developed RFP for Statewide Seed-to-Sale Tracking
- Developed ITN for Medical Marijuana Identification Card outsourcing and have commenced negotiations with vendors
- Engaged Moffitt in order to fulfill their requirements of SB 8-A and are finalizing an agreement with the organization
- Established a relationship with the University of Florida to fulfill the research and educational requirements of SB 8-A

Legal Challenges

- Home Grow:
  - Redner v. DOH, et. al., 13th Judicial Circuit Case No. 17-CA-5677

- Smoking Ban:
  - People United for Medical Marijuana v. DOH, et. al.,
    2d Judicial Circuit Case No. 2017-CA-1394

- Constitutionality of Black Farmers Provision 381.986(8)(a)2 F.S.
  - Smith v. DOH, 2d Judicial Circuit Case No. 2017–CA-001972

- MMTC Licensure:
  - Tropiflora, LLC v. DOH, 2d Judicial Circuit Case No. 2016-CA-1330
  - Keith St. Germain v. DOH Case No. 17-5011

Questions?

Duplicate

THE FLORIDA SENATE

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10/24/17
Meeting Date

Bill Number (if applicable)

Topic Implementation of SB 8A

Amendment Barcode (if applicable)

Name Christian Bax

Job Title Director - Office of Medical Marijuana Use

Address 4052 Bald Cypress Way
Street

Phone 850-245-4444

Tallahassee FL 32399
City *State* *Zip*

Email

Speaking: ☐ For ☐ Against ☑ Information

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

Representing Florida Department of Health

Appearing at request of Chair: ☑ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☑ No

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Meeting Date

Bill Number (if applicable)

Amendment Barcode (if applicable)

Topic OMMU

Name Nichole Geary

Job Title General Counsel DOH

Address _____ Phone _____

Street

_____ Email _____

City *State* *Zip*

Speaking: ☐ For ☐ Against ☒ Information

Waive Speaking: ☐ In Support ☐ Against

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

Representing _____

Appearing at request of Chair: ☐ Yes ☐ No

Lobbyist registered with Legislature: ☐ Yes ☐ No

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S-001 (10/14/14)

CourtSmart Tag Report

Room: KN 412 **Case No.:** **Type:**
Caption: Senate Committee on Health Policy **Judge:**

Started: 10/24/2017 9:04:52 AM
Ends: 10/24/2017 10:27:10 AM Length: 01:22:19

9:04:58 AM Meeting called to order by Chair Young
9:06:44 AM Christian Bax, Department of Health
9:07:20 AM Short Recess
9:07:40 AM Recording Paused
9:09:52 AM Recording Resumed
9:09:52 AM Senator Lee to explain his bill
9:13:09 AM Questions on the bill by Chair
9:13:21 AM Senator Lee explains
9:15:06 AM Appearance cards read and waiving in support
9:16:24 AM Brian Pitts, Justice for Jeasus speaks
9:23:08 AM Senator Lee closes on bill
9:24:24 AM Vote on bill
9:24:57 AM Christian Bax, Department of Health, Office of medical Marijuana Use
9:42:44 AM Chair asks question to Christian Bax
9:43:16 AM Christian answers question regarding licensing
9:44:50 AM chair follows up on licensure question
9:45:03 AM Christian responds
9:45:20 AM Chair follows up with more questions
9:45:41 AM Christian responds
9:46:49 AM Chairs continues with licensure questions
9:48:21 AM Senator Book asks question to Christian Bax
9:49:06 AM Christian responds
9:49:26 AM Senator Book continues with question
9:50:30 AM Christian responds
9:52:49 AM Senator Book continues with questions
9:53:53 AM Christian responds
9:57:17 AM Senator Book continues with more questions
9:59:36 AM Vice Char Passidomo has questions for Christian Bax
10:01:05 AM Legal Counsel for DOH responds
10:03:30 AM Senator Passidomo continues with question to Legal Counsel for DOH
10:04:01 AM Nicole Geary, Legal Counsel responds
10:07:11 AM Senator Montford asks questions to Nicole Leary Legal Counsel at DOH
10:07:57 AM Senator Montford asks question to Christian Bax
10:10:17 AM Christian responds to Senator Montford
10:15:41 AM Chair makes statement regarding litigation
10:15:54 AM Senator Powell asks questions to Christian Bax
10:16:25 AM Christian Bax responds to Senator Powell
10:17:11 AM Senator Powell with follow up question regarding ID cards
10:17:40 AM Christian Bax responds
10:21:00 AM Senator Benaquisto asks questions to Christian Bax
10:21:19 AM Christian Bax responds to Senator Benaquisto
10:22:37 AM Senator Benaquisto follows up with more questions regarding dosage

10:23:20 AM Chair follows up with questions to Christian Bax
10:24:04 AM Christian Bax responds to Chair Young
10:26:39 AM Chair Young closing remarks
10:26:57 AM Senator Passidomo moves we rise