The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY Senator Burton, Chair Senator Brodeur, Vice Chair

MEETING DATE: Wednesday, October 18, 2023

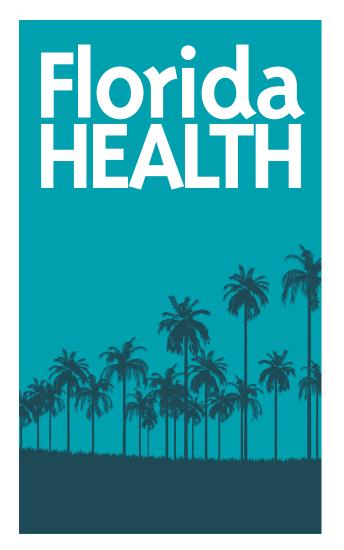
TIME: 2:00—3:30 p.m.

PLACE: Pat Thomas Committee Room, 412 Knott Building

MEMBERS: Senator Burton, Chair; Senator Brodeur, Vice Chair; Senators Albritton, Avila, Book, Calatayud,

Davis, Garcia, Harrell, and Osgood

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION	
1	Presentation on Collaborative Pharmac CS/HB 389 (2020) – Department of Hea	Presented		
2	Update on Florida's Medical Marijuana	Presented		
	Other Related Meeting Documents			



IMPLEMENTATION OF COLLABORATIVE PHARMACY PRACTICE FOR CHRONIC HEALTH CONDITIONS

Jessica Sapp, Chief

Bureau of Health Care Practitioner Regulation Division of Medical Quality Assurance Florida Department of Health

OBJECTIVES

- Comparison of collaborative pharmacy practice arrangements.
- Summary of CS/HB 389 (2020), Chapter 2020-7, Laws of Florida.
- Description of certification requirements for pharmacists to collaboratively manage chronic health conditions.
- Timeline of implementation and collaboration efforts with the Boards of Medicine and Osteopathic Medicine.
- Analysis of collaborative pharmacy practice data.



How We Work

The Division of Medical Quality Assurance (MQA) regulates health care practitioners and facilities through professional licensure, facility permitting, and administrative enforcement in order to preserve the health, safety, and welfare of the public.



COLLABORATIVE PHARMACY PRACTICE ARRANGEMENTS

CONSULTANT PHARMACISTS

A consultant pharmacist licensed pursuant to Section 465.0125, Florida Statutes, may provide medication management services in a health care facility through a written collaborative practice agreement with a physician, a podiatric physician, or a dentist.



CERTIFIED PHARMACISTS

A pharmacist certified pursuant to Section 465.1865, Florida Statutes, may collaboratively manage specific chronic health conditions through a collaborative practice agreement with a physician.



LEGISLATIVE SUMMARY

CS/HB 389, Chapter 2020-7, Laws of Florida Practice of Pharmacy



Expands the scope of practice for eligible pharmacists to:

- Collaboratively manage specified chronic health conditions through a written collaborative practice agreement (CPA) with a physician.
- Test for and treat minor, nonchronic health conditions through a written protocol with a physician.

Requires consultation with the Boards of Medicine and Osteopathic Medicine.



COLLABORATIVE PHARMACIST CERTIFICATION



Licensed pharmacists are eligible to collaboratively practice under section 465.1865, Florida Statutes, if certain criteria are met.

Qualifications



Hold an active, unencumbered Florida pharmacist license.

Have a doctor of pharmacy degree or five years of experience.

Complete a 20-hour initial certification course.

Maintain at least \$250,000 of professional liability coverage.

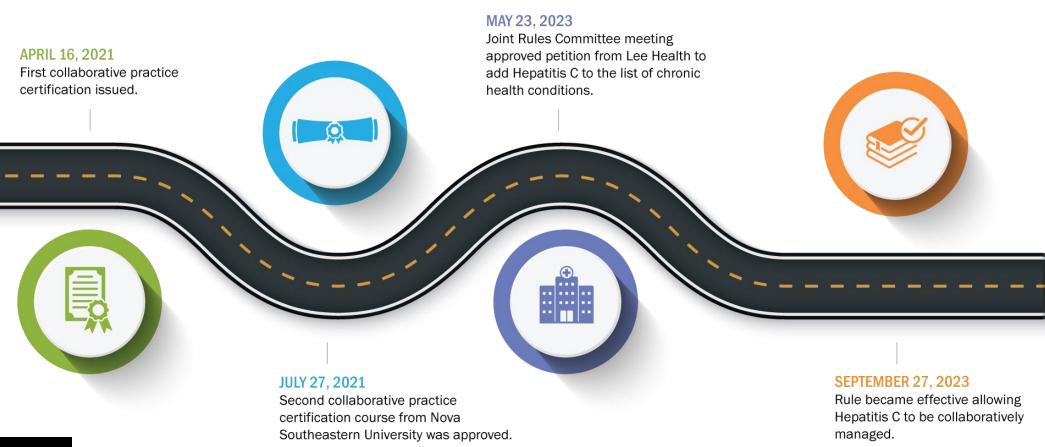
Have a system to maintain records of patients receiving services.



IMPLEMENTATION TIMELINE



IMPLEMENTATION TIMELINE



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COLLABORATIVE PHARMACY PRACTICE STATISTICS

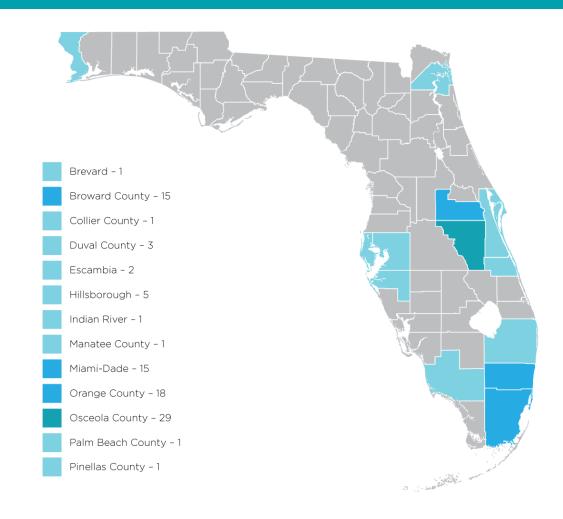




COLLABORATIVE PHARMACY PRACTICE LOCATIONS

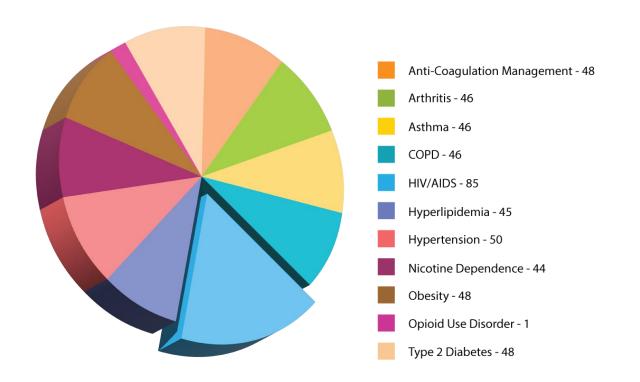


This represents the location of the 97 active CPAs between physicians and pharmacists where specific chronic health conditions are managed.





COLLABORATIVELY MANAGED CHRONIC HEALTH CONDITIONS





CPAs allow pharmacists to collaboratively manage the illustrated chronic health conditions as outlined in section 465.1865(1), Florida Statutes, and rule 64B16-31.007, Florida Administrative Code.



QUESTIONS?

Jessica Sapp, Chief

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An act relating to the practice of pharmacy; amending s. 381.0031, F.S.; requiring specified licensed pharmacists to report certain information relating to public health to the Department of Health; amending s. 465.003, F.S.; revising the definition of the term "practice of the profession of pharmacy"; creating s. 465.1865, F.S.; providing definitions; providing requirements for pharmacists to provide services under a collaborative pharmacy practice agreement; requiring the terms and conditions of such agreement to be appropriate to the training of the pharmacist and the scope of practice of the physician; requiring notification to the board upon practicing under a collaborative pharmacy practice agreement; requiring pharmacists to submit a copy of the signed collaborative pharmacy practice agreement to the Board of Pharmacy; providing for the maintenance of patient records for a certain period of time; providing for renewal of such agreement; requiring a pharmacist and the collaborating physician to maintain on file and make available the collaborative pharmacy practice agreement; prohibiting certain actions relating to such agreement; requiring specified continuing education for a pharmacist who practices under a

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collaborative pharmacy practice agreement; requiring the Board of Pharmacy to adopt rules in consultation with the Board of Medicine and the Board of Osteopathic Medicine; creating s. 465.1895, F.S.; requiring the Board of Pharmacy to identify minor, nonchronic health conditions that a pharmacist may test or screen for and treat; providing requirements for a pharmacist to test or screen for and treat minor, nonchronic health conditions; requiring the board to develop a formulary of medicinal drugs that a pharmacist may prescribe; providing requirements for the written protocol between a pharmacist and a supervising physician; prohibiting a pharmacist from providing certain services under certain circumstances; requiring a pharmacist to complete a specified amount of continuing education; providing additional requirements for pharmacists and pharmacies providing testing and screening services; providing for applicability; providing an effective date. Be It Enacted by the Legislature of the State of Florida: Section 1. Subsection (2) of section 381.0031, Florida Statutes, is amended to read: Epidemiological research; report of diseases of 381.0031

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public health significance to department.-

(2) Any practitioner licensed in this state to practice medicine, osteopathic medicine, chiropractic medicine, naturopathy, or veterinary medicine; any licensed pharmacist authorized under a protocol with a supervising physician under s. 465.1895, or a collaborative pharmacy practice agreement, as defined in s. 465.1865, to perform or order and evaluate laboratory and clinical tests; any hospital licensed under part I of chapter 395; or any laboratory appropriately certified by the Centers for Medicare and Medicaid Services under the federal Clinical Laboratory Improvement Amendments and the federal rules adopted thereunder which diagnoses or suspects the existence of a disease of public health significance shall immediately report the fact to the Department of Health.

Section 2. Subsection (13) of section 465.003, Florida Statutes, is amended to read:

465.003 Definitions.—As used in this chapter, the term:

(13) "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and conducting other pharmaceutical services. For purposes of this subsection, "other pharmaceutical services"

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means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy; and initiating, modifying, or discontinuing drug therapy for a chronic health condition under a collaborative pharmacy practice agreement. However, Nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law or specifically authorized by s. 465.1865 or s. 465.1895. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s.

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TOT	465.189, the testing or screening for and treatment of minor,
102	nonchronic health conditions pursuant to s. 465.1895, and the
103	preparation of prepackaged drug products in facilities holding
104	Class III institutional pharmacy permits.
105	Section 3. Section 465.1865, Florida Statutes, is created
106	to read:
107	465.1865 Collaborative pharmacy practice for chronic
108	health conditions.—
109	(1) For purposes of this section, the term:
110	(a) "Collaborative pharmacy practice agreement" means a
111	written agreement between a pharmacist who meets the
112	qualifications of this section and a physician licensed under
113	chapter 458 or chapter 459 in which a collaborating physician
114	authorizes a pharmacist to provide specified patient care
115	services to the collaborating physician's patients.
116	(b) "Chronic health condition" means:
117	1. Arthritis;
118	2. Asthma;
119	3. Chronic obstructive pulmonary diseases;
120	4. Type 2 diabetes;
121	5. Human immunodeficiency virus or acquired immune
122	<pre>deficiency syndrome;</pre>
123	6. Obesity; or
124	7. Any other chronic condition adopted in rule by the
125	board, in consultation with the Board of Medicine and Board of

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Osteopathic Medicine.

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127	(2) To provide services under a collaborative pharmacy
128	practice agreement, a pharmacist must be certified by the board,
129	according to the rules adopted by the board in consultation with
130	the Board of Medicine and the Board of Osteopathic Medicine. To
131	be certified, a pharmacist must, at a minimum:
132	(a) Hold an active and unencumbered license to practice
133	pharmacy in this state.
134	(b) Have earned a degree of doctor of pharmacy or have
135	completed 5 years of experience as a licensed pharmacist.
136	(c) Have completed an initial 20-hour course approved by
137	the board, in consultation with the Board of Medicine and Board
138	of Osteopathic Medicine, that includes, at a minimum,
139	instruction on the following:
140	1. Performance of patient assessments.
141	2. Ordering, performing, and interpreting clinical and
142	laboratory tests related to collaborative pharmacy practice.

- laboratory tests related to collaborative pharmacy practice.
- Evaluating and managing diseases and health conditions in collaboration with other health care practitioners.
 - 4. Any other area required by board.
- (d) Maintain at least \$250,000 of professional liability insurance coverage. However, a pharmacist who maintains professional liability insurance coverage pursuant to s. 465.1895 satisfies this requirement.
 - Have established a system to maintain records of all (e)

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151	patients receiving services under a collaborative pharmacy
152	practice agreement for a period of 5 years from each patient's
153	most recent provision of service.

- calcing and the services delegated to the pharmacist's training and the services delegated to the pharmacist must be within the collaborating physician's scope of practice. A copy of the certification issued under subsection (2) must be included as an attachment to the collaborative pharmacy practice agreement.
- (a) A collaborative pharmacy practice agreement must include the following:
- 1. Name of the collaborating physician's patient or patients for whom a pharmacist may provide services.
- 2. Each chronic health condition to be collaboratively managed.
- 3. Specific medicinal drug or drugs to be managed by the pharmacist for each patient.
- 4. Circumstances under which the pharmacist may order or perform and evaluate laboratory or clinical tests.
- 5. Conditions and events upon which the pharmacist must notify the collaborating physician and the manner and timeframe in which such notification must occur.
- 6. Beginning and ending dates for the collaborative pharmacy practice agreement and termination procedures,

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176	includin	g procedures	for	patient	notification	and	medical
177	records	transfers.					

- 7. A statement that the collaborative pharmacy practice agreement may be terminated, in writing, by either party at any time.
- (b) A collaborative pharmacy practice agreement shall automatically terminate 2 years after execution if not renewed.
- (c) The pharmacist, along with the collaborating physician, must maintain on file the collaborative pharmacy practice agreement at his or her practice location, and must make such agreements available to the department or board upon request or inspection.
- (d) A pharmacist who enters into a collaborative pharmacy practice agreement must submit a copy of the signed agreement to the board before the agreement may be implemented.
 - (4) A pharmacist may not:
- (a) Modify or discontinue medicinal drugs prescribed by a health care practitioner with whom he or she does not have a collaborative pharmacy practice agreement.
- (b) Enter into a collaborative pharmacy practice agreement while acting as an employee without the written approval of the owner of the pharmacy.
- (5) A physician may not delegate the authority to initiate or prescribe a controlled substance as described in s. 893.03 or 21 U.S.C. s. 812 to a pharmacist.

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(6) A pharmacist who practices under a collaborative
pharmacy practice agreement must complete an 8-hour continuing
education course approved by the board that addresses issues
related to collaborative pharmacy practice each biennial
licensure renewal in addition to the continuing education
requirements under s. 465.009. A pharmacist must submit
confirmation of having completed such course when applying for
licensure renewal. A pharmacist who fails to comply with this
subsection shall be prohibited from practicing under a
collaborative pharmacy practice agreement under this section.
(7) The board, in consultation with the Board of Medicine
and the Board of Osteopathic Medicine, shall adopt rules
pursuant to ss. 120.536(1) and 120.54 to implement this section.
Section 4. Section 465.1895, Florida Statutes, is created
to read:
465.1895 Testing or screening for and treatment of minor,
nonchronic health conditions
(1) A pharmacist may test or screen for and treat minor,
nonchronic health conditions within the framework of an
established written protocol with a supervising physician
licensed under chapter 458 or chapter 459. For purposes of this
section, a minor, nonchronic health condition is typically a
short-term condition that is generally managed with minimal
treatment or self-care, and includes:
(a) Influenza

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(b)

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226	(b) Streptococcus.
227	(c) Lice.
228	(d) Skin conditions, such as ringworm and athlete's foot.
229	(e) Minor, uncomplicated infections.
230	(2) A pharmacist who tests or screens for and treats
231	minor, nonchronic health conditions under this section must:
232	(a) Hold an active and unencumbered license to practice
233	pharmacy in the state.
234	(b) Hold a certification issued by the board to test and
235	screen for and treat minor, nonchronic health conditions, in
236	accordance with requirements established by the board in rule in
237	consultation with the Board of Medicine and Board of Osteopathic
238	Medicine. The certification must require a pharmacist to
239	complete, on a one-time basis, a 20-hour education course
240	approved by the board in consultation with the Board of Medicine
241	and the Board of Osteopathic Medicine. The course, at a minimum,
242	must address patient assessments; point-of-care testing
243	procedures; safe and effective treatment of minor, nonchronic
244	health conditions; and identification of contraindications.
245	(c) Maintain at least \$250,000 of liability coverage. A
246	pharmacist who maintains liability coverage pursuant to s.
247	465.1865 satisfies this requirement.
248	(d) Report a diagnosis or suspected existence of a disease
249	of public health significance to the department pursuant to s.
250	<u>381.0031.</u>

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- (e) Upon request of a patient, furnish patient records to a health care practitioner designated by the patient.
- (f) Maintain records of all patients receiving services under this section for a period of 5 years from each patient's most recent provision of service.
- (3) The board shall adopt, by rule, a formulary of medicinal drugs that a pharmacist may prescribe for the minor, nonchronic health conditions approved under subsection (1). The formulary must include medicinal drugs approved by the United States Food and Drug Administration which are indicated for treatment of the minor, nonchronic health condition. The formulary may not include any controlled substance as described in s. 893.03 or 21 U.S.C. s. 812.
- (4) A pharmacist who tests or screens for and treats minor, nonchronic health conditions under this section may use any tests that may guide diagnosis or clinical decisionmaking which the Centers for Medicare and Medicaid Services has determined qualifies for a waiver under the federal Clinical Laboratory Improvement Amendments of 1988, or the federal rules adopted thereunder, or any established screening procedures that can safely be performed by a pharmacist.
- (5) The written protocol between a pharmacist and supervising physician under this subsection must include particular terms and conditions imposed by the supervising physician relating to the testing and screening for and

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treatment	of minor	r, nonchi	conic hea	alth cond	litions ι	ınder t	<u>this</u>
section. T	he terms	and cor	nditions	must be	appropri	iate to	o the
pharmacist	's trair	ning. A p	oharmaci:	st who er	nters int	to sucl	<u>1 a</u>
protocol w	rith a su	apervisir	ng physic	cian must	submit	the pi	rotocol
to the boa	rd.						

- (a) At a minimum, the protocol shall include:
- 1. Specific categories of patients who the pharmacist is authorized to test or screen for and treat minor, nonchronic health conditions.
- 2. The physician's instructions for obtaining relevant patient medical history for the purpose of identifying disqualifying health conditions, adverse reactions, and contraindications to the approved course of treatment.
- 3. The physician's instructions for the treatment of minor, nonchronic health conditions based on the patient's age, symptoms, and test results, including negative results.
- 4. A process and schedule for the physician to review the pharmacist's actions under the protocol.
- 5. A process and schedule for the pharmacist to notify the physician of the patient's condition, tests administered, test results, and course of treatment.
- 6. Any other requirements as established by the board in consultation with the Board of Medicine and the Board of Osteopathic Medicine.
 - (b) A pharmacist authorized to test and screen for and

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treat minor, nonchronic conditions under a protocol shall provide evidence of current certification by the board to the supervising physician. A supervising physician shall review the pharmacist's actions in accordance with the protocol.

- (6) A pharmacist providing services under this section may not perform such services while acting as an employee without the written approval of the owner of the pharmacy.
- (7) A pharmacist providing services under this section must complete a 3-hour continuing education course approved by the board addressing issues related to minor, nonchronic health conditions each biennial licensure renewal in addition to the continuing education requirements under s. 465.009. Each pharmacist must submit confirmation of having completed the course when applying for licensure renewal. A pharmacist who fails to comply with this subsection may not provide testing, screening, or treatment services.
- (8) A pharmacist providing services under this section must provide a patient with written information to advise the patient to seek followup care from his or her primary care physician. The board, by rule, shall adopt guidelines for the circumstances under which the information required under this subsection shall be provided.
- (9) The pharmacy in which a pharmacist tests and screens for and treats minor, nonchronic health conditions must prominently display signage indicating that any patient

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326	receiving testing, screening, or treatment services under this
327	section is advised to seek followup care from his or her primary
328	care physician.
329	(10) A pharmacist providing services under this section
330	must comply with applicable state and federal laws and
331	regulations.
332	(11) The requirements of the section do not apply with
333	respect to minor, nonchronic health conditions when treated with
334	over-the-counter products.
335	Section 5. This act shall take effect July 1, 2020.
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THE FLORIDA SENATE 2020 SUMMARY OF LEGISLATION PASSED

Committee on Health Policy

CS/HB 389 — Practice of Pharmacy

by Health and Human Services Committee and Rep. Sirois and others (CS/SB 714 by Health Policy Committee and Senator Hutson)

The bill (Chapter 2020-7, L.O.F.) expands the scope of practice for pharmacists in two ways, by creating specified parameters under which pharmacists may:

- Enter into a collaborative pharmacy practice agreement with a physician to treat that physician's patients for chronic health conditions; and
- Test or screen for and treat minor, nonchronic health conditions for any patient who qualifies for such testing and treatment under the provisions and requirements of a written protocol with a supervising physician.

Collaborative Pharmacy Practice for Chronic Health Conditions

Under the bill, a "collaborative pharmacy practice agreement" (collaborative agreement) means a written agreement between a pharmacist who meets qualifications specified in the bill and a Florida-licensed allopathic or osteopathic physician in which the collaborating physician authorizes the pharmacist to provide specified patient care to the physician's patients named in the agreement.

The bill defines "chronic health condition" to mean arthritis, asthma, chronic obstructive pulmonary diseases, type 2 diabetes, HIV/AIDS, obesity, or any other chronic condition adopted in rule by the Board of Pharmacy (BOP) in consultation with the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM).

Before providing services under a collaborative agreement, a pharmacist must be certified by the BOP according to rules adopted by the BOP in consultation with the BOM and BOOM. Requirements for certification include minimum standards for experience and education, including completion of an initial 20-hour course providing instruction on topics such as performing patient assessments, ordering and interpreting laboratory tests, evaluating and managing diseases and health conditions, and other subjects required by the BOP. Certification also requires a pharmacist to maintain at least \$250,000 in professional liability insurance coverage and to establish a system to maintain patient records for five years.

The terms and conditions of a collaborative agreement must be appropriate to the pharmacist's training, and services delegated to the pharmacist must be within the collaborating physician's scope of practice. A copy of the pharmacist's certification issued BOP must be included as an attachment to the collaborative agreement. A collaborative agreement must, among other requirements, include:

- The names of the physician's patient(s) who may be treated by the pharmacist;
- Each chronic health condition to be collaboratively managed;
- Specific drugs to be managed by the pharmacist for each patient;

- Circumstances under which the pharmacist may order, perform, or evaluate lab or clinical tests; and
- Conditions that require the pharmacist to notify the collaborating physician.

A pharmacist who enters into a collaborative agreement must submit a copy of the signed agreement to the BOP before the agreement may be implemented. A collaborative agreement will automatically terminate two years after execution if not renewed.

The bill prohibits a pharmacist from:

- Modifying or discontinuing drugs prescribed by a health care practitioner with whom he
 or she does not have a collaborative agreement; or
- Entering into a collaborative agreement while acting as an employee of a pharmacy without the written approval of the pharmacy owner.

The bill prohibits a physician from delegating the authority to initiate or prescribe controlled substances to a pharmacist.

A pharmacist who practices under a collaborative agreement must complete an eight-hour continuing education course approved by the BOP that addresses issues related to collaborative pharmacy practice with each biennial renewal of the pharmacist's license, in addition to continuing education requirements he or she must meet under preexisting law.

The bill requires the BOP, in consultation with the BOM and BOOM, to adopt rules to implement the bill's provisions for collaborative pharmacy practice.

Testing and Screening for and Treatment of Minor, Nonchronic Health Conditions by Pharmacists

The bill authorizes pharmacists who meet qualifications specified in the bill to test or screen for and treat minor, nonchronic health conditions within the framework of a written protocol with a supervising allopathic or osteopathic physician licensed in Florida. Under the bill, a minor, nonchronic health condition is typically a short-term condition that is generally managed with minimal treatment or self-care and includes:

- Influenza:
- Streptococcus;
- Lice;
- Skin conditions, such as ringworm and athlete's foot; and
- Minor, uncomplicated infections.

To qualify under the bill, a pharmacist must be certified by the BOP to have met certain educational requirements, including completion of a 20-hour education program approved by the BOP in consultation with the BOM and BOOM which must address patient assessments, point-of-care testing procedures, safe and effective treatments, and identification of contraindications.

This summary is provided for information only and does not represent the opinion of any Senator, Senate Officer, or Senate Office.

A pharmacist so certified by the BOP must provide evidence of the certification to the supervising physician.

A pharmacist who tests and treats under the bill must also maintain at least \$250,000 in liability coverage; furnish a patient's records, upon the patient's request, to a health care practitioner designated by a patient; and maintain patient records for five years from each patient's most recent provision of service.

The BOP is required to adopt by rule a formulary of drugs that a pharmacist may prescribe under a test-and-treat protocol for minor, nonchronic health conditions covered under the protocol. Such drugs must be approved by the federal Food and Drug Administration which are indicated for the treatment of such conditions. The formulary may not include controlled substances.

The bill provides that a pharmacist who tests and treats may use any tests that guide the diagnosis or clinical decision-making which the federal Centers for Medicare & Medicaid Services has determined qualify for a waiver under the federal Clinical Laboratory Improvement Amendments of 1988, or federal rules adopted thereunder, or any established screening procedures that can safely be performed by a pharmacist.

A written protocol between a pharmacist and supervising physician must include particular terms and conditions imposed by the supervising physician relating to the testing and screening for and treatment of minor, nonchronic health conditions. The terms and conditions must be appropriate to the pharmacist's training. A pharmacist who enters into such a protocol with a supervising physician must submit the protocol to the BOP. The protocol must include:

- Specific categories of patients who the pharmacist is authorized to test or screen for and treat minor, nonchronic health conditions;
- The physician's instructions for obtaining relevant patient medical history for the purpose of identifying disqualifying health conditions, adverse reactions, and contraindications to the approved course of treatment;
- The physician's instructions for the treatment of minor, nonchronic health conditions based on the patient's age, symptoms, and test results, including negative results;
- A process and schedule for the physician to review the pharmacist's actions under the protocol;
- A process and schedule for the pharmacist to notify the physician of the patient's condition, tests administered, test results, and course of treatment; and
- Any other requirements as established by the BOP in consultation with the BOM and BOOM.

A pharmacist certified by the BOP to test and treat under the bill must complete a three-hour continuing education course approved by the BOP that addresses issue related to minor, nonchronic health conditions with each biennial renewal of the pharmacist's license, in addition to continuing education requirements he or she must meet under preexisting law.

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A pharmacist providing test-and-treat services under the bill may not perform such services while acting as an employee of a pharmacy without the written approval of the pharmacy owner.

A pharmacist who tests and treats under the bill must provide a patient with written information to advise the patient to seek follow-up care from his or her primary care physician. The BOP must adopt rules for the circumstances under which such information must be provided.

A pharmacy in which a pharmacist tests and treats under the bill must prominently display signage indicating that any patient receiving testing, screening, or treatment services as authorized under the bill is advised to seek follow-up care from his or her primary care physician.

The bill provides that its test-and-treat provisions do not apply with respect to minor, nonchronic health conditions when treated with over-the-counter products.

Other Provisions

The bill:

- Provides that its two requirements for \$250,000 in professional liability coverage (the first for collaborative pharmacy practice and the second for testing for and treating minor, nonchronic health conditions) are not duplicative and that coverage for either satisfies both requirements;
- Adds pharmacists who are authorized to perform or order and evaluate laboratory or clinical tests under a collaborative pharmacy practice or test-and-treat protocol, to the list of health care practitioners and facilities that, upon the diagnosis or suspicion of the existence of a disease of public health significance, must immediately report that fact to the Department of Health; and
- Amends the statutory definition of "practice of the profession of pharmacy" to conform to the bill's provisions.

These provisions became law upon approval by the Governor on March 11, 2020, and take effect July 1, 2020.

Vote: Senate 28-12; House 98-17

CS/HB 389 Page: 4

64B16-31.007 Collaborative Practice Certification; Chronic Health Conditions.

Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to Section 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement:

- (1) Hyperlipidemia:
- (2) Hypertension;
- (3) Anti-coagulation management;
- (4) Nicotine Dependence;
- (5) Opioid use disorder;
- (6) Hepatitis C
- (7) Those chronic health conditions enumerated in Section 465.1865(1)(b), F.S.

Rulemaking Authority 465.1865 FS. Law Implemented 465.1865 FS. History—New 10-28-20, Amended 4-29-21, 9-27-23.

The Florida Senate

10 18 23	APPEARANCE RECORD	Collaborative Pharmacy Position
Meeting Date	Deliver both copies of this form to Senate professional staff conducting the meeting	Bill Number or Topic
- Health Policy Committee		Amendment Barcode (if applicable)
Name Jessica Sapp	Phone	550-245-4463
Address 4052 Bald Cypy	ess way Email je	ssica. Sappefinealth.gov
Tall PL	32301 State Zip	
Speaking: For Agai	nst Information OR Waive Speaking	g:
	PLEASE CHECK ONE OF THE FOLLOWING:	
Lam appearing without compensation or sponsorship.	I am a registered lobbyist, representing:	I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022 Joint Rules.pdf (flsenate.gov)

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

S-001 (08/10/2021)

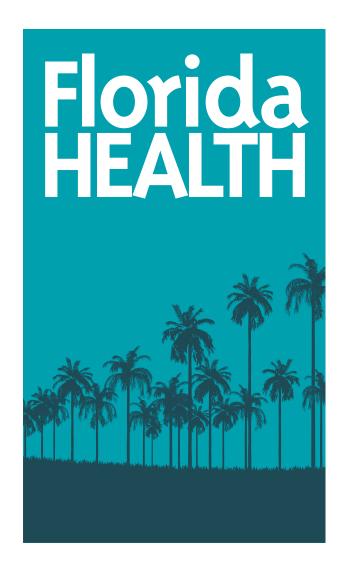
The Florida Senate

10	0 18 0		APPEAK	ANCE	KECOKD	1017	phurmay pr	netuc
4	Meeting Date	Clan		ooth copies of t onal staff condu	his form to acting the meeting	Bill No	imber or Topic	
	Committee	/~	í			Amendment	Barcode (if applicable)	
Name	Clayd	IA DAV	Ant		Phone	80567	1979	
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	Street							· (
	City	State		Zip				
	Speaking: Fo	or Against	Information	OR	Waive Speaking:	In Support	Against	
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S-001 (08/10/2021)





FLORIDA'S MEDICAL MARIJUANA PROGRAM UPDATE

Senate Health Policy Committee October 18, 2023

Christopher Kimball, Director Office of Medical Marijuana Use

PRESENTATION ROADMAP

- Program Background
 - Office of Medical Marijuana Use's (OMMU) Purpose
 - Education and Research Stakeholders
 - Program Timeline and Key Terms
- Patient Access By the Numbers
- Compliance Update
- Licensing Update
- Statutory Implementation & Rulemaking
- Procurements
- Questions and Answers



KEY TERMS

- Qualified patient
- Qualifying medical conditions
- Qualified physician
- Physician certification
- Caregiver
- Route of administration
- Medical marijuana treatment centers (MMTCs)
- Certified marijuana testing laboratories (CMTLs)
- Medical Marijuana Use Registry (MMUR)
- Seed-to-Sale Tracking System



OMMU's Purpose

- To promote the health and safety of qualified patients and the public as it relates to medical marijuana through:
 - Developing and implementing the Department of Health's rules for medical marijuana.
 - Overseeing the statewide Medical Marijuana Use Registry (MMUR).
 - Licensing Florida businesses (medical marijuana treatment centers or MMTCs) to cultivate, process and dispense medical marijuana to qualified patients and their caregivers.
 - Certifying marijuana testing laboratories (CMTLs) which test samples
 of all retail batches to be dispensed by MMTCs to qualified patients.



RESEARCH AND EDUCATION

- Consortium for Medical Marijuana Clinical Outcomes
 Research (s. 1004.4351, F.S.) led by the University of Florida.
- Medical Marijuana Education and Research Initiative (s. 381.986(7)(d), F.S.), Florida Agricultural and Mechanical University, Division of Research.
- Physician Certification Pattern Review Panel (s. 381.986(4)(j), F.S.), Board of Medicine and Board of Osteopathic Medicine.
- Florida Physician Medical Marijuana Course (s. 381.986(3)(a) and (c), F.S.), Florida Medical Association and Florida Osteopathic Medical Association.



PROGRAM TIMELINE

2016

Amendment 2, creates Article X, Section 29 of the Florida Constitution. 2018

The OMMU replaces the Office of Compassionate Use.

2019

Marijuana in a form for smoking becomes an approved route of administration.



PROGRAM TIMELINE

2020

Edible products become an approved route of administration.

2021

The Florida Supreme Court upholds the vertically integrated structure of MMTCs.

2023

Telehealth is permitted for renewal physician certifications.

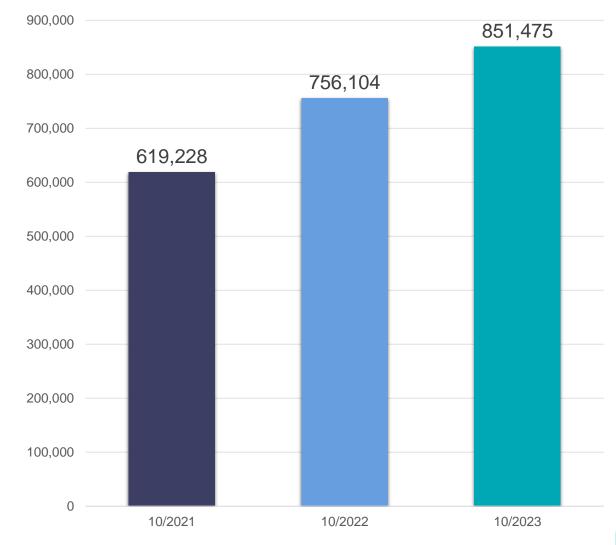


PATIENT ACCESS NUMBERS

- Qualified patients (851,475) and caregivers (9,284)
- Qualified physicians (2,688)
- Medical Marijuana Treatment Centers (MMTCs) (24)
 - Cultivation facilities (39)
 - Processing facilities (32)
 - Dispensing facilities (591)
 - Fulfillment and storage facilities (14)
- Certified Marijuana Testing Laboratories (CMTLs) (9)

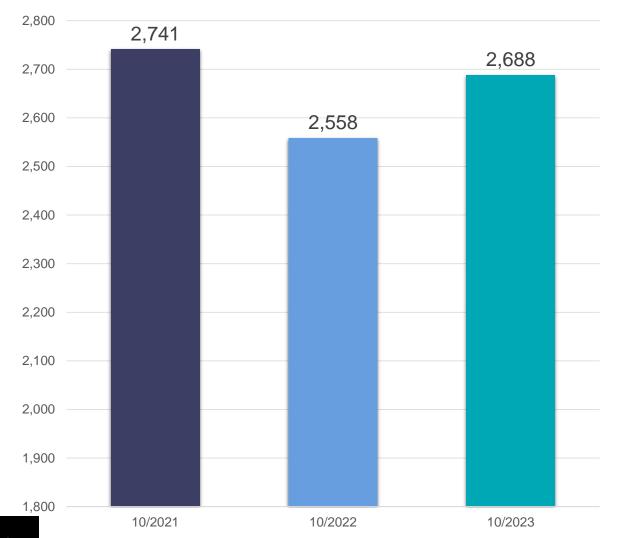


Active Qualified Patients





Data source: OMMU Weekly Updates, https://knowthefactsmmj.com/about/weekly-updates/

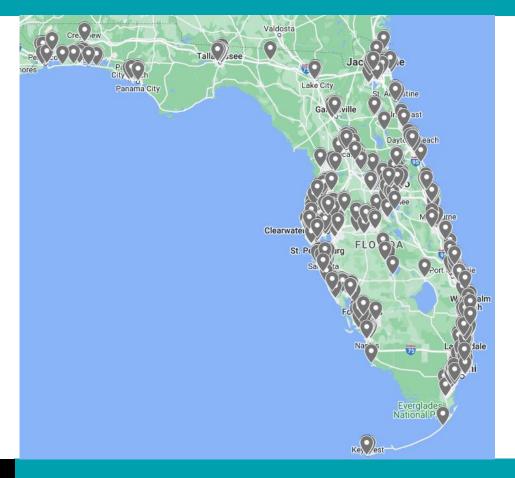


Active Qualified Physicians



Data source: OMMU Weekly Updates, https://knowthefactsmmj.com/about/weekly-updates/

PATIENT ACCESS



MMTC Facility Type	Number of Facilities
Dispensing Facility	591
Cultivation Facility	39
Processing Facility	32
Fulfillment and Storage Facility	14
TOTAL FACILITIES	676

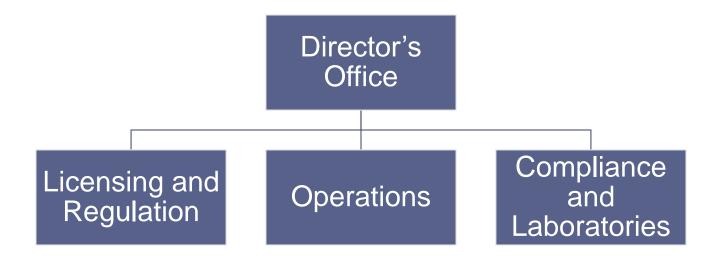


COMPLIANCE UPDATE

- FY2022-23 Employee Background Screenings (12,743)
 - Individuals deemed ineligible for employment (549).
- FY2022-23 MMTC and CMTL Inspections (2,176: 48% increase from previous year)
 - Facility and process approval inspections (928).
 - Compliance inspections (1,229).
 - Complaint inspections (19).
- FY2022-23 MMTC and CMTL Notices of Violation (502)
 - Subset with fines (168).
- Department's Laboratory Cannabis Expansion
 - November 2023: Fully operational target.
 - April 2024: Accreditation target.



OMMU STRUCTURE





PIGFORD/BLACK FARMER LITIGATION (BFL) MMTC LICENSING UPDATE

- On September 20, 2022, the Department issued notices of intent to approve and deny *Pigford/BFL* applications for MMTC licensure. Unsuccessful applicants filed petitions challenging the Department's notices. Litigation ensued and is pending.
- On June 26, 2023, HB 387 became law.
- On July 11, 2023, the Department awarded two (2) *Pigford/BFL* licenses pursuant to the new law.
- On the same day, the Department issued letters to Pigford/BFL applicants providing 90 days to cure deficiencies identified in the notices of intent to deny pursuant to HB 387.
- The Department is currently reviewing responsive materials.



APRIL 2023 MMTC APPLICATION LICENSING UPDATE

- From April 24-28, 2023, the Department received 74 applications for up to 22 available MMTC licenses.
- The Errors and Omissions process for the batching cycle has concluded.
- 73 applications (1 withdrew) are currently under review pursuant to a competitive process for award of the 22 licenses.

STATUTORY IMPLEMENTATION AND RULEMAKING

HB 387 (2023)

- Telehealth: Implementing the provision allowing physician recertifications via telehealth.
- Pigford/BFL MMTC License: Reviewing submitted applicant responses to the 90-day cure letters.

HB 1387 (2023)

- Product names, advertising, trade names and logos: The OMMU has notified licensees of the law change and is in the process of implementation.
 - Reviewing submitted products, advertisements, tradenames, and logos for compliance with the new statutory requirements.
- Background Screening Updates: Began implementing of the CMTL employee screening provision on July 1, 2023.



STATUTORY IMPLEMENTATION AND RULEMAKING

Seed-to-Sale Tracking System Implementation

- Seed-to-Sale tracking system delivered in June 2023.
- Currently in User Acceptance Testing.
- Rule development underway to direct MMTC and CMTL integration into the Department's Seed-to-Sale tracking system.
- Next steps: Adopt Seed-to-Sale rules and initiate industry user testing and integration.

Florida HEALTH

OMMU PROCUREMENTS

System	Vendor Name	Current Contract Term	Contract/ Purchase Order Amount
Seed-to-Sale Tracking System	BioTech Medical Software, Inc	July 1, 2022 – June 30, 2027 (Five-year agreement with renewal clause)	\$768,000
Medical Marijuana Use Registry (MMUR)	Five Points Technology Group, Inc.	July 1, 2021 – June 30, 2024 (Three-year agreement with yearly renewal clause)	\$3,049,147
Compliance, Licensure, Enforcement and Regulatory System (CLEAR)	Kyra Solutions, Inc	January 1, 2020 – December 31, 2023 (Three-year agreement with yearly renewal clause)	\$42,000



THANK YOU



CONTACT

Mailing Address:

Office of Medical Marijuana Use 4052 Bald Cypress Way, Bin M-01 Tallahassee, FL 32399 **Phone**: 850-245-4657

FAX: 850-487-7046

Email:

MedicalMarijuanaUse@flhealth.gov

Website: www.knowthefactsmmj.com



DET 18, 2023	APPEARANCE RECORD	Offer of Medical Marisuma USE
Meeting Date HETLTH POLICY	Deliver both copies of this form to Senate professional staff conducting the meeting	Bill Number or Topic
Committee		Amendment Barcode (if applicable)
Name CHRISTOPHER K	IMBALL Phone	
Address 4052 BMLD CYPR	ESS WAY BIN M-01 Email	
City Sto	1 32399 ate Zip	
Speaking: For Agains	st Maive Speakin	g:
)	PLEASE CHECK ONE OF THE FOLLOWING	:
I am appearing without compensation or sponsorship.	I am a registered lobbyist, representing:	I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022 Joint Rules.pdf (flsenate.gov)

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

The Florida Senate **APPEARANCE RECORD** Medical Connessis Deliver both copies of this form to Bill Number or Topic Senate professional staff conducting the meeting

Amendment Barcode (if applicable)

Address

Waive Speaking: In Support

Against

PLEASE CHECK ONE OF THE FOLLOWING:

I am appearing without compensation or sponsorship.

I am a registered lobbyist, representing:

I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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

12/12/2022	The Florida S	enate	11/11/2000
10/18/2020	APPEARANCE	RECORD	Maryuara
Meeting Date Houch	Deliver both copies of Senate professional staff condu		● III Number or Topic
Committee	. /		Amendment Barcode (if applicable)
Name Lena Iru	idad	Phone <u>856</u>	4172638
Address 911 42ndSt Un	HB	Email trin	idad consult egmail
Street	1		U.com
West Palm Beac City State	hFL 334	07	
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APPEARANCE RECORD

Deliver both copies of this form to

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Bil	ll Number 🛭	Topic	7.0

Senate professional staff conducting the meeting	Bill Number of Topic
)—————————————————————————————————————	Amendment Barcode (if applicable)
	Othegreenlokr.com
- 34953 Zip	
Information OR Waive Speaking:	In Support
PLEASE CHECK ONE OF THE FOLLOWING:	
I am a registered lobbyist, representing:	I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:
	Phone

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APPEARANCE RECORD

Medical Campabis

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Meeting Date	D	eliver both copies of thi	is form to	Bill Number or Topic
alth Policy				
Committee				Amendment Barcode (if applicable)
Randy Ren	bert		Phone	7-851-7422
	ya Way		Email <u>kev</u>	nbertfanilytams@gmas
Street	0			COM
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City	State	ZIP		
Speaking: For [Against Inform	ation OR	Waive Speaking:	☐ In Support ☐ Against
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While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022 Joint Rules.pdf (flsenate.gov)

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Howth Policy	Deliver both copies of this for Senate professional staff conduction	
Committee		Amendment Barcode (if applicable)
Name BASIMHA Jame	5	Phone 551-214-6708
Address 16175 Ramblin	g VINE Dr. E	Email Jamesbe Carnewbis. Com
Tampa F City St	2 336 24 ate Zip	_
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* ,	PLEASE CHECK ONE OF THE	FOLLOWING:
I am appearing without compensation or sponsorship.	I am a registered lobbyist, representing:	I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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

11/18/22

10,	1/8/23 Meeting Date 1// 1/2/2019	 Deliver both	NCE RECORD copies of this form to staff conducting the meeting	HB Medical Cannobis Bill Number or Topic
Name	Raymond D	nkrthen	Phone	Amendment Barcode (if applicable)
Address	Street OXBOW	Rel	Email	
	Minneola City	F/a 347 State Zip	,5	
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10 10-22	The Florida Senate	
10-18-23	APPEARANCE REG	CORD Medical Marigueta
Health Policy	Deliver both copies of this form Senate professional staff conducting the	
Name Committee	Robin 52n	Amendment Barcode (if applicable) Phone 386-341-6346
Address 424 E	Central Ave	Email Genesi's Coqual-ground.
Orlando	PL	
City Speaking: For	State Zip Against Information OR Waive	re Speaking:
I am appearing without	PLEASE CHECK ONE OF THE FOI	LLOWING:
compensation or sponsorship.	representing:	something of value for my appearance

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S-001 (08/10/2021)

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sponsored by:

APPEARANCE RECORD

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	Committee			Amendment Barcode (if applicable)
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	Tallahassee	F1 323 61 State Zip		
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THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

COMMITTEES:

Appropriations
Appropriations Committee on Health and
Human Services
Children, Families, and Elder Affairs
Education Postsecondary
Health Policy
Judiciary
Rules

JOINT COMMITTEE:
Joint Legislative Budget Commission

SENATOR LAUREN BOOK

Democratic Leader 35th District

October 18, 2023

The Honorable Colleen Burton, Chair Committee on Health Policy 530 Knott Building 404 South Monroe Street Tallahassee, FL 32399-1100

Dear Chair Burton:

I respectfully request to be excused from your Committee on Health Policy scheduled October 18, 2023 at 2:00 PM. I regret that I had an unavoidable conflict and sincerely apologize for any inconvenience this may cause.

Thank you for your consideration. Please feel free to contact me at (850) 487-5035 if you have any questions.

Kindest Regards,

Senator Lauren Book Minority Leader

Florida Senate, District 35

cc: Allen Brown, Staff Director

Anhar Al-Asadi, Committee Administrative Assistant

CourtSmart Tag Report

Room: KB 412 Case No.: - Type:

Caption: Health Policy Committee Judge:

Started: 10/18/2023 2:01:05 PM

Ends: 10/18/2023 3:30:34 PM Length: 01:29:30

2:01:15 PM Chair Burton calls meeting to order

2:01:21 PM Roll call by CAA 2:01:36 PM Quorum present

2:01:42 PM Opening remarks by Chair Burton

2:02:47 PM Tab 1, Jessica Sapp, Bureau Chief of Health Care Practitioner Regulation DOH

2:03:03 PM Ms. Sapp presents
2:11:25 PM Presentation concludes

2:11:30 PM Questions:
2:11:33 PM Senator Harrell
2:12:05 PM Ms. Sapp responds
2:12:29 PM Senator Harrell
2:12:45 PM Ms. Sapp responds

2:13:04 PM Back and forth in questions

2:15:28 PM Senator Calatayud
2:16:13 PM Ms. Sapp responds
Chair Burton
Ms. Sapp responds

2:19:03 PM Ms. Sapp 2:19:15 PM Senator Harrell 2:19:33 PM Ms. Sapp

 2:19:44 PM
 Senator Davis

 2:20:14 PM
 Ms. Sapp

 2:20:38 PM
 Chair Burton

 2:20:48 PM
 Ms. Sapp

 2:21:22 PM
 Chair Burton

 2:22:03 PM
 Ms. Sapp

 2:22:57 PM
 Chair Burton

 2:23:13 PM
 Ms. Sapp

2:23:33 PM Senator Harrell

2:25:40 PM Ms. Sapp

2:25:56 PM Back and forth in questions **2:28:47 PM** Appearance cards:

2.20.47 FWI Appearance cards.

2:29:00 PM Claudia Davant, Florida Pharmacy Assoc., waives speaking

2:29:14 PM Tab 2, Christopher Kimball, Director of DOH Office of Medical Marijuana Use

2:29:45 PM Mr. Kimball presents
2:50:16 PM Presentation concludes

2:50:21 PM Questions:
2:50:25 PM Senator Osgood
2:50:39 PM Senator Osgood
2:51:09 PM Senator Osgood
2:51:22 PM Mr. Kimball responds
2:51:44 PM Senator Davis

2:52:52 PM Mr. Kimball responds
2:53:51 PM Senator Harrell
2:54:36 PM Mr. Kimball responds
2:54:55 PM Senator Harrell

2:55:15 PM Mr. Kimball

2:55:59 PM	Senator Harrell
2:56:16 PM	Mr. Kimball
2:57:31 PM	Chair Burton
2:57:56 PM	Mr. Kimball
2:57:58 PM	Senator Brodeur with comments
2:59:12 PM	Senator Davis
3:00:09 PM	Mr. Kimball
3:01:38 PM	Senator Davis
3:03:46 PM	Mr. Kimball
3:05:43 PM	Senator Harrell
3:06:50 PM	Mr. Kimball
3:08:34 PM	Senator Harrell
3:08:54 PM	Mr. Kimball
3:10:21 PM	Senator Davis
3:11:01 PM	Mr. Kimball
3:11:57 PM	Senator Davis
3:12:53 PM	Mr. Kimball
3:14:29 PM	Senator Davis
3:15:56 PM	Mr. Kimball
3:16:54 PM	Senator Harrell
3:17:57 PM	Mr. Kimball
3:18:33 PM	Senator Harrell
3:19:20 PM	Mr. Kimball
3:20:38 PM 3:20:55 PM	Senator Harrell Mr. Kimball
3:20:55 PM 3:21:40 PM	Senator Harrell
3:22:28 PM	Mr. Kimball
3:23:03 PM	Appearance forms:
3:23:22 PM	Ishmael Qawly, speaking for information
3:24:57 PM	Leena Trinidad, speaking for information
3:26:27 PM	Senator Brodeur comment
3:26:46 PM	Angie Willoughby, Equal Ground, speaking for information
3:28:25 PM	Names read into record for remaining: Basimha James, Raymond Warthen, Genesis Robinson, Deandre
Smith	Than 100 rough from the result of the result
3:29:05 PM	Randy Rembert, speaking for information
3:29:57 PM	Senator Brodeur moves to adjourn
3:30:22 PM	Meeting adjourned
	· ,