

Health Quality Subcommittee

Monday, January 11, 2016 4:00 PM - 6:00 PM 306 HOB

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

(AMENDED 1/7/2016 4:35:02PM)

Amended(1)

Health Quality Subcommittee

Start Date and Time:

Monday, January 11, 2016 04:00 pm

End Date and Time:

Monday, January 11, 2016 06:00 pm

Location:

306 HOB

Duration:

2.00 hrs

Consideration of the following bill(s):

HB 139 Dental Care by Cummings

HB 261 Cosmetic Product Registration by Latvala

HB 391 Pub. Rec./Emergency Medical Technicians or Paramedics by Passidomo

HB 571 Music Therapy by Campbell

Pursuant to rule 7.12, the deadline for amendments to bills on the agenda by non-appointed members is 6:00 p.m., Friday, January 8, 2016.

By request of the chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Friday, January 8, 2016.

NOTICE FINALIZED on 01/07/2016 4:35PM by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

HB 139 Dental Care

SPONSOR(S): Cummings and others

TIED BILLS:

IDEN./SIM. BILLS: SB 234

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF	
1) Health Quality Subcommittee		Guzzo 16	O'Callaghan M	
2) Appropriations Committee			• • • • • • • • • • • • • • • • • • • •	
3) Health & Human Services Committee				

SUMMARY ANALYSIS

The bill requires the Department of Health (DOH) to develop and implement a dental care access account initiative (Initiative) to benefit dentists employed by a public health program or committed to opening a private practice capable of serving at least 1,200 patients in a dental health professional shortage area or medically underserved area.

The bill requires DOH to implement an electronic benefits transfer system enabling selected dentists to spend awarded funds on:

- Repayment of dental school student loans;
- Investment in property, facilities, or equipment required to establish and operate a dental office; and
- Transitional expenses associated with relocation or opening a dental practice.

The bill requires DOH to establish application procedures and selection criteria for the Initiative. An applicant may submit proof to DOH of having spent the capital to have made substantial progress in opening a dental practice to serve at least 1,200 patients. The bill authorizes DOH to limit the number of applicants selected and give priority to dentists in areas with a higher need, as ranked by the Department of Economic Opportunity.

The bill states the funds needed to implement the Initiative are subject to a legislative appropriation. Each award may not be less than \$10,000 or exceed \$100,000. The bill authorizes local sources to contribute to a dental care access account, but no state award may exceed three times the amount contributed to an account in the same year from local sources. The bill specifies that a dentist's salary and employer expenditures from a public health program not funded by state dollars may constitute as local matching funds.

The bill directs DOH to close an account no later than five years after the first deposit or immediately if the dentist does not follow the requirements of, or no longer participates in, the Initiative and includes provisions for the return or reallocation of unspent funds. The bill requires DOH to create a process to verify if funds withdrawn from an account have been used for authorized purposes.

The bill requires DOH to develop a marketing plan for the Initiative in cooperation with Florida dental schools and the Florida Dental Association.

The bill requires DOH to develop and submit an annual report on the Initiative to the Governor and the Legislature.

The bill has a significant negative fiscal impact on DOH and no fiscal impact on local governments.

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0139.HQS.DOCX

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Health Professional Shortage Areas

Health Professional Shortage Areas (HPSAs) are designated by the U.S. Department of Health and Human Services' Health Resources and Services Administration according to criteria developed in accordance with section 332 of the Public Health Services Act.¹ HPSA designations are used to identify areas and population groups within the U.S. that are experiencing a shortage of health care professionals.²

There are three categories of HPSA designation: primary care, dental, and mental health. A HPSA designation may be based on a geographic area, population group, or facility experiencing a shortage of health care providers or a lack of access to health care services. A geographic HPSA indicates that the entire area may experience barriers in accessing care, while a population HPSA indicates that a particular subpopulation of an area, such as homeless or low-income persons, may be underserved. A facility HPSA designation is granted to a unique facility that primarily cares for an underserved population. The primary factor used to determine a HPSA designation is the number of health care professionals relative to the population in a defined area.³

In the U.S., there are approximately 4,900 dental HPSAs. The threshold for a dental HPSA is a population-to-provider ratio of at least 5,000 to 1.4

Medically Underserved Area

Medically Underserved Areas (MUA) are also designated by the U.S. Department of Health and Human Services. These areas are designated using one of the three following methods and can be a whole county or group of contiguous counties, or census tracts:

- MUA Designation, which applies the Index of Medical Underservice (IMU) and calculates a score based on the:
 - o Ratio of primary care physicians per 1,000 population;
 - Percentage of the population with incomes below the poverty level;
 - o Infant mortality rate; and
 - Percentage of population age 65 and older.
- Medically Underserved Populations (MUP) Designation, which builds off data collected under the MUA designation process and reviews the ratio of primary care physicians serving the population seeking the designation. A MUP is a group of people who encounter economic or cultural barriers to primary health care services.
- Exceptional MUP Designation, which includes those population groups that do not meet the criteria of an IMU, but may be considered for designation because of unusual conditions.

STORAGE NAME: h0139.HQS.DOCX

¹Pub L. No. 107-251 codified at 42 U.S.C. s. 256(f).

² 42 C.F.R. §5.1; see also Health Resources and Services Administration, Guidelines for Primary Medical Care/Dental HPSA Designation, available at http://bhpr.hrsa.gov/shortaqe/hpsas/designationcriteria/medicaldentalhpsaguidelines.html (last visited December 14, 2015).

³ Health Resources and Services Administration , Shortage Designation: Health Professional Shortage Areas & Medically Underserved Areas/Populations , available at http://www.hrsa.gov/shortage/ (last visited December 14, 2015).

⁴ Id.

Requests for this designation must be requested by the Governor or another senior executive level official and local state health official.⁵

Cost of Dental Education

In the U.S., combined undergraduate and dental school debt jumped from \$106,000 in 2000 to more than \$220,000 in 2012, an increase of 109 percent in 12 years. Approximately two-thirds of all undergraduates and 90 percent of dental students rely on student loans to finance their degrees. Among all U.S. dental schools, the total cost of attendance over the past 10 years for four years of dental school rose dramatically—by 93 percent for in-state residents (from about \$89,000 to \$171,000) and by 82 percent for out-of-state residents (from \$128,000 to \$234,000).

Unlike Florida, 30 states have a state dental student loan repayment program.⁷ Those states may have an advantage in recruiting dentists to serve low-income populations or rural areas.

Access to Dental Care and Dental Workforce in Florida

Florida has a high population of residents who lack access to dental services; there are currently 218 designated dental HPSAs in Florida.⁸ There is a noticeable shortage of dentists in certain parts of the state, especially in the central Panhandle counties and interior counties of south Florida. Most dentists are disproportionately concentrated in the more populous areas of the state. The ratio of dentists to Florida residents is approximately 1 to every 2,200 people.⁹

Lower patient densities, rural income disparities, and lower dental care reimbursement levels make it difficult to recruit and retain dentists in rural communities of the state. According to the most recent population data, 16.3 percent of Florida residents¹⁰ were living below the poverty level.¹¹ The majority of these residents utilize dental public health programs¹² for their dental care, but only 1.4 percent of Florida dentists practice in public health programs and only 14 percent of Florida dentists accept Medicaid.¹³ Only 27.4 percent of low-income Floridians have access to dental care.¹⁴

DOH provides dental care in some county health departments. According to DOH, there are currently 16 vacant dentist positions out of the 82 total positions within DOH. 15

¹³ Supra, FN 9 at pg. 6.

¹⁵ Florida, Dep't of Health, *Legislative Bill Analysis HB 139* (September 23, 2015) (on file with Health Quality Subcommittee staff). **STORAGE NAME**: h0139.HQS.DOCX

⁵ Health Resources and Services Administration, Medically Underserved Areas/Populations, available at http://www.hrsa.gov/shortage/mua/index.html (last visited December 14, 2015).

⁶ American Dental Education Association, A Report of the ADEA Presidential Task Force on the Cost of Higher Education and Student Borrowing,17 (March 2013), available at:

http://www.adea.org/uploadedFiles/ADEA/Content_Conversion_Final/publications/Documents/ADEACostandBorrowingReportMarch20 13.pdf (last visited December 14, 2015).

⁷ National Health Services Corps, State Loan Repayment Program, *State Loan Repayment Program Fact Sheet,* available at https://nhsc.hrsa.gov/loanrepayment/stateloanrepaymentprogram/index.html (last visited December 14, 2015).

⁸ National Health Services Corps, *State-by-State Guide*, available at http://nhsc.hrsa.gov/ambassadors/states/FL.html (last visited December 14, 2015).

⁹ Florida Dep't of Health, *Report on the 2011-2012 Workforce Survey of Dentists*, April 2014, available at http://www.floridahealth.gov/programs-and-services/community-health/dental-health/workforce-reports/florida-workforce-survey-of-dental-hygienists-2011-2012.pdf. (last visited December 14, 2015).

The Florida Dep't of Health, Florida CHARTS, Programment (1977) (1977).

¹⁰ Florida Dep't of Health, Florida CHARTS, *Percentage of Individuals Living Below Poverty Level*, available at http://www.floridacharts.com/charts/OtherIndicators/NonVitalIndRateOnlyDataViewer.aspx?cid=0294 (last visited December 14, 2015).

¹¹ This figure is \$11,670 for an individual as defined by the US Department of Health and Human Services.

¹² "Public health program" includes a county health department, a children's medical services program, a federally funded community health center, a federally funded migrant health center, or other publicly funded or nonprofit health care program designated by the DOH. Section 381.0302(2)(e), F.S.

¹⁴ Florida Dep't of Health, Florida Charts, Access to Dental Care by Low Income Persons 2012, available at http://www.floridacharts.com/charts/OtherIndicators/NonVitalIndNoGrpDataViewer.aspx?cid=0266 (December 14, 2015).

Effect of Proposed Changes

Florida Dental Care Access Account Initiative

HB 139 creates the dental care access account initiative (Initiative) to be implemented by the Department of Health (DOH). The Initiative is conditioned on the availability of funds to be appropriated by the Legislature and is intended to increase the number of dentists practicing in dental HPSAs or MUAs.

Eligible Dentists

The Initiative may benefit Florida licensed dentists who are:

- Actively employed by a public health program in a dental HPSA or a MUA; or
- Committed to opening a private practice in a dental HPSA or MUA by residing in the area, maintaining a Medicaid provider agreement, enrolling with one or more Medicaid managed care plans, expending capital to open an office to serve at least 1,200 patients, and obtaining community financial support.

Applications

The bill requires DOH to establish application procedures for dentists who wish to apply for a dental care access account (account). The bill allows an applicant to demonstrate in the application that he or she has spent sufficient capital to make progress in opening a dental practice that is capable of serving at least 1,200 patients by providing proof of:

- Contracts for the purchase or lease of a practice location; and
- Acquisition of at least 30 percent of the value of equipment and supplies necessary to operate a dental practice.

The bill authorizes DOH to limit the number of applicants selected and give priority to practitioners in areas with a higher need, ranked by the Department of Economic Opportunity. The bill also authorizes DOH to establish additional priority selection criteria.

Required Use of the Account

The bill requires DOH to establish individual dental care access accounts for selected dentists. The accounts will be managed through an electronic benefits transfer system that enables each participating dentist to spend funds for the following purposes:

- Repayment of dental school student loans;
- Investment in property, facilities, or equipment necessary to establish and operate a dental office consisting of at least two operatories; and
- Payment of transitional expenses related to the relocation or opening of a dental practice that are specifically approved by DOH.

The bill authorizes DOH to create a verification process to confirm that funds withdrawn from an account have been used for authorized purposes.

Account Monetary Limits

Subject to available state appropriations, the bill requires DOH to distribute funds in amounts of at least \$10,000 but not to exceed \$100,000 per account. The bill authorizes DOH to accept funds for deposit into a designated account from local sources. No state award may exceed three times the amount contributed to an account in the same year from a local source.

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The bill specifies that a dentist's salary and employer expenditures from a public health program not funded by state dollars may constitute local matching funds. State funds may not be included in a determination of the amount contributed from a local source.

Account Closure

HB 139 directs DOH to close an account no later than five years after the first deposit, or immediately if the dentist:

- No longer works for a public health program, unless the dentist opens a private practice in a dental HPSA or MUA within 30 days of no longer working for a public health program;
- No longer practices in a HPSA or MUA;
- Has been terminated from Medicaid; or
- Has participated in any fraudulent activity.

The bill authorizes DOH to award remaining state funds, after 5 years or from terminated accounts, to another account. A dentist is required to repay any funds withdrawn from the account after the occurrence of an event which requires account closure. The bill authorizes DOH to recover inappropriately spent funds through disciplinary enforcement actions and other methods authorized by law.

The bill also requires DOH to proportionately return unspent funds from donated sources that remain in a closed account to the appropriate donor source.

Reporting Requirements

The bill establishes a reporting process for the evaluation and accountability of the Initiative. Starting January 1, 2018, DOH must submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives, which must include the:

- Number of patients served by Initiative participating dentists;
- Number of Medicaid recipients served by Initiative participating dentists;
- Average number of hours worked and patients served per week by Initiative participating dentists;
- Number of Initiative participating dentists in each dental health professional shortage area or medically underserved area;
- Amount and source of local matching funds received by DOH;
- · Amount of state funds awarded to Initiative participating dentists; and
- Complete categorical accounting of the use of funds which may include:
 - o Loans:
 - Supplies and equipment;
 - o Rental property:
 - o Real property purchases; and
 - o Salary and wages.

The bill requires DOH to develop a marketing plan for the Initiative in cooperation with the:

- University of Florida College of Dentistry;
- Nova Southeastern University College of Dental Medicine;
- Lake Erie College of Osteopathic Medicine School of Dental Medicine; and the
- Florida Dental Association.

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

B. SECTION DIRECTORY:

Section 1: Creates s. 381.4019, F.S., relating to dental care access accounts.

Section 2: Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

According to DOH, the bill has a significant negative fiscal impact on DOH of \$306,064 for fiscal year 2016-17 with recurring annual costs of \$277,296. The cost estimates include 2 FTEs to administer the Initiative and the contracted services of an electronic benefits transfer system vendor. Estimated expenditures for DOH are as follows: 17

Estimated Expenditures (General Revenue)		
	SALARIES	
1 FTE	\$41,460	\$55,280
Health Care Program	,	
Analyst		
@ \$40,948 - pay grade 24		
1 FTE	\$47,114	\$62,818
Senior Management Analyst		
II		
@ \$46,381 - pay grade 26		
	EXPENSES	
2 FTEs	\$31,484	\$23,486
Calculated with standard DOH	,	
professional package (limited		_
travel) @ \$15,742	\$294	\$0-
2 docking stations (@ \$142		
each		
The second secon	N RESOURCES SERVICE	
2 FTEs	\$712	\$712
Calculated with standard DOH		
Central Office package @		
\$356	Military	, Salidania.
	perating Capital Outlay	
Operating Capital Outlay	\$0.00	\$0.00
	Contractual Services	
Estimate for the development,	\$100,000	\$50,000
implementation and		
maintenance of an electronic		
benefit transfer (EBT) system	40= 500	A
Marketing Campaign*	\$85,000	\$85,000
TOTAL ESTIMATED EXPENDITURES	\$306,064	\$277,296

¹⁶ Florida Dep't of Health, *Legislative Bill Analysis HB 139* (September 23, 2015) (on file with Health Quality Subcommittee staff).

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B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Selected dentists that will receive loan repayment assistance will realize cost reductions in their student loan debt. Such dentists will also be able to spend awarded funds on their business startup costs putting them in a more stable financial situation upon opening their practice.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

Applicability of Municipality/County Mandates Provision:
 Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking authority to DOH to implement the Initiative.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

STORAGE NAME: h0139.HQS.DOCX DATE: 1/4/2016

A bill to be entitled 1 2 An act relating to dental care; creating s. 381.4019, 3 F.S.; establishing a joint local and state dental care access account initiative, subject to the availability 4 5 of funding; authorizing the creation of dental care 6 access accounts; specifying the purpose of the 7 initiative; providing definitions; providing criteria 8 for the selection of dentists for participation in the 9 initiative; providing for the establishment of 10 accounts; requiring the Department of Health to 11 implement an electronic benefit transfer system; 12 providing for the use of funds deposited in the 13 accounts; authorizing the department to distribute state funds to accounts, subject to legislative 14 15 appropriation; authorizing the department to accept contributions from local sources for deposit in 16 17 designated accounts; limiting the number of years that an account may remain open; providing for the 18 immediate closure of accounts under certain 19 20 circumstances; authorizing the department to transfer 21 state funds remaining in a closed account at a 22 specified time; requiring the department to return 23 unspent funds from local sources; requiring a dentist to repay funds in certain circumstances; authorizing 24 25 the department to pursue disciplinary enforcement 26 actions and to use other legal means to recover funds;

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requiring the department to establish by rule application procedures and a process to verify the use of funds withdrawn from a dental care access account; requiring the department to give priority to applications from dentists practicing in certain areas; requiring the Department of Economic Opportunity to rank shortage areas and medically underserved areas; requiring the Department of Health to develop a marketing plan in cooperation with certain dental colleges and the Florida Dental Association; requiring the Department of Health to annually submit a report with certain information to the Governor and the Legislature; requiring rulemaking for the submission of information for such reporting; providing an effective date.

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

Section 1. Section 381.4019, Florida Statutes, is created to read:

381.4019 Dental care access accounts. - Subject to the

availability of funds, the Legislature establishes a joint local and state dental care access account initiative and authorizes the creation of dental care access accounts to promote economic development by supporting qualified dentists who practice in dental health professional shortage areas or medically

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underserved areas or who treat a medically underserved population. The Legislature recognizes that maintaining good oral health is integral to overall health status and that the good health of residents of this state is an important contributing factor in economic development. Better health, including better oral health, enables workers to be more productive, reduces the burden of health care costs, and improves the cognitive development of children.

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

- (a) "Dental health professional shortage area" means a geographic area so designated by the Health Resources and Services Administration of the United States Department of Health and Human Services.
 - (b) "Department" means the Department of Health.
- (c) "Medically underserved area" means a geographic area so designated by the Health Resources and Services

 Administration of the United States Department of Health and Human Services.
- (d) "Public health program" means a county health department, the Children's Medical Services program, a federally qualified community health center, a federally funded migrant health center, or other publicly funded or nonprofit health care program as designated by the department.
- (2) The department shall develop and implement a dental care access account initiative to benefit dentists licensed to practice in this state who demonstrate, as required by the

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department by rule:

(a) Active employment by a public health program located in a dental health professional shortage area or a medically underserved area; or

- (b) A commitment to opening a private practice in a dental health professional shortage area or a medically underserved area evidenced by residing in the designated area, maintaining an active Medicaid provider agreement, enrolling in one or more Medicaid managed care plans, expending sufficient capital to make substantial progress in opening a dental practice that is capable of serving at least 1,200 patients, and obtaining financial support from the local community in which the dentist is practicing or intending to open a practice.
- (3) The department shall establish dental care access accounts as individual benefit accounts for each dentist who satisfies the requirements of subsection (2) and is selected by the department for participation. The department shall implement an electronic benefits transfer system that enables each dentist to spend funds from his or her account for the purposes described in subsection (4).
- (4) Funds contributed from state and local sources to a dental care access account may be used for one or more of the following purposes:
 - (a) Repayment of dental school student loans.
- (b) Investment in property, facilities, or equipment necessary to establish and operate a dental office consisting of

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105 at least two operatories.

- (c) Payment of transitional expenses related to the relocation or opening of a dental practice which are specifically approved by the department.
- shall distribute state funds as an award to each dental care access account. Such awards must be in an amount not more than \$100,000 and at least \$10,000, except that a state award may not exceed 3 times the amount contributed to an account in the same year from local sources. If a dentist qualifies for a dental care access account under paragraph (2)(a), the dentist's salary and associated employer expenditures constitute a local match and qualify the account for a state award if the salary and associated expenditures do not come from state funds. State funds may not be included in a determination of the amount contributed to an account from local sources.
- (6) The department may accept contributions of funds from local sources for deposit in the account of a dentist designated by the donor.
- (7) The department shall close an account no later than 5 years after the first deposit of state or local funds into that account or immediately upon the occurrence of any of the following:
- (a) Termination of the dentist's employment with a public health program unless, within 30 days after such termination, the dentist opens a private practice in a dental health

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131 professional shortage area or medically underserved area.

- (b) Termination of the dentist's practice in a designated dental health professional shortage area or medically underserved area.
- (c) Termination of the dentist's participation in the Florida Medicaid program.
- (d) Participation by the dentist in any fraudulent activity.
- (8) Any state funds remaining in a closed account may be awarded and transferred to another account concurrent with the distribution of funds under the next legislative appropriation for the initiative. The department shall return to the donor on a pro rata basis unspent funds from local sources which remain in a closed account.
- withdrawn account funds after the occurrence of an event specified in subsection (7), has used funds for purposes not authorized in subsection (4), or has not remained eligible for a dental care access account for a minimum of 2 years, the dentist shall repay the funds to his or her account. The department may recover the withdrawn funds through disciplinary enforcement actions and other methods authorized by law.
 - (10) The department shall establish by rule:
- (a) Application procedures for dentists who wish to apply for a dental care access account. An applicant may demonstrate that he or she has expended sufficient capital to make

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substantial progress in opening a dental practice that is capable of serving at least 1,200 patients by documenting contracts for the purchase or lease of a practice location and providing executed obligations for the purchase or other acquisition of at least 30 percent of the value of equipment or supplies necessary to operate a dental practice. The department may limit the number of applicants selected and shall give priority to those applicants practicing in the areas receiving higher rankings pursuant to subsection (11). The department may establish additional criteria for selection which recognize an applicant's active engagement with and commitment to the community providing a local match.

- (b) A process to verify that funds withdrawn from a dental care access account have been used solely for the purposes described in subsection (4).
- (11) The Department of Economic Opportunity shall rank the dental health professional shortage areas and medically underserved areas of the state based on the extent to which limited access to dental care is impeding the area's economic development, with a higher ranking indicating a greater impediment to development.
- (12) The department shall develop a marketing plan for the dental care access account initiative in cooperation with the University of Florida College of Dentistry, the Nova Southeastern University College of Dental Medicine, the Lake Erie College of Osteopathic Medicine School of Dental Medicine,

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183 and the Florida Dental Association.

- (13) (a) By January 1 of each year, beginning in 2018, the department shall issue a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives, which must include:
- 1. The number of patients served by dentists receiving funding under this section.
- 2. The number of Medicaid recipients served by dentists receiving funding under this section.
- 3. The average number of hours worked and patients served in a week by dentists receiving funding under this section.
- 4. The number of dentists in each dental health professional shortage area or medically underserved area receiving funding under this section.
- 5. The amount and source of local matching funds received by the department.
- 6. The amount of state funds awarded to dentists under this section.
- 7. A complete accounting of the use of funds, by categories identified by the department, including, but not limited to, loans, supplies, equipment, rental property payments, real property purchases, and salary and wages.
- (b) The department shall adopt rules to require dentists to report information to the department which is necessary for the department to fulfill its reporting requirement under this subsection.

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

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COMMITTEE/SUBCOMMITTEE AMENDMENT Bill No. HB 139 (2016)

Amendment No. 1

	COMMITTEE/SUBCOMMIT	TTEE ACTION
	ADOPTED	(Y/N)
	ADOPTED AS AMENDED	(Y/N)
	ADOPTED W/O OBJECTION	(Y/N)
	FAILED TO ADOPT	(Y/N)
	WITHDRAWN	(Y/N)
	OTHER	
1	Committee/Subcommittee h	nearing bill: Health Quality
2	Subcommittee	
3	Representative Cummings	offered the following:
4		
5	Amendment (with tit	tle amendment)
5 6	•	·
	Remove line 95 and	·
6	Remove line 95 and the department for parti	insert:
6 7	Remove line 95 and the department for parties establish more than 10 r	insert: cipation. The department may not new dental care access accounts per
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Published On: 1/8/2016 3:02:34 PM



COMMITTEE/SUBCOMMITTEE AMENDMENT Bill No. HB 139 (2016)

Amendment No. 2

	COMMITTEE/SUBCOMMITTEE ACTION		
	ADOPTED (Y/N)		
	ADOPTED AS AMENDED (Y/N)		
	ADOPTED W/O OBJECTION (Y/N)		
	FAILED TO ADOPT (Y/N)		
	WITHDRAWN (Y/N)		
	OTHER		
1	Committee/Subcommittee hearing bill: Health Quality		
2	Subcommittee		
3	Representative Cummings offered the following:		
4			
5	Amendment (with title amendment)		
6	Remove lines 178-183		
7			
8			
9			
10	TITLE AMENDMENT		
11	Remove lines 34-37 and insert:		
12	underserved areas; requiring the Department of Health to		

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Published On: 1/8/2016 3:03:44 PM

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

HB 261

Cosmetic Product Registration

SPONSOR(S): Latvala

TIED BILLS:

IDEN./SIM. BILLS: SB 176

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Langston	O'Callaghan Mo
Government Operations Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The federal Food and Drug Administration (FDA) is responsible for regulating cosmetic products in the United States. The FDA prohibits adulterated or misbranded cosmetic products from being sold to consumers and enforces cosmetic product labeling requirements. Unlike drugs, cosmetic products are not subject to safety inspections and premarket approval. However, the FDA encourages cosmetic manufacturers to voluntarily submit information on facilities, products, and ingredients, which provides the FDA with post-market product information and assists in the assessment of product safety.

The Florida Department of Business and Professional Regulation's Division of Drugs, Devices, and Cosmetics (Division) regulates cosmetics that are manufactured and repackaged in Florida. Cosmetic manufacturers physically located in Florida are required to hold an active cosmetic manufacturer permit issued by the Division. In addition, each product produced or repackaged by such manufacturers is required to be registered with the Division.

HB 261 amends ch. 499, F.S., to remove the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. The bill eliminates the fee for registration of cosmetics. The bill makes conforming changes by removing registration and renewal requirements for cosmetic products, including the requirements to submit registration applications, product labels, and registration and renewal fees. This allows cosmetic manufacturers in Florida to sell cosmetics without registering such products.

The bill removes the Division's authority to issue certificates of free sale for registered cosmetic products in s. 499.003(6), F.S.

Throughout the bill the term "Federal Drug Administration" is revised to correctly reference the federal Food and Drug Administration.

The bill has a significant negative fiscal impact on the Department of Business and Professional Regulation and no fiscal impact on local governments.

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0261.HQS.docx

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Federal Regulation of Cosmetics

In the United States more than 8 billion cosmetics are sold annually which results in over \$60 billion in annual sales.¹ The federal Food and Drug Administration's (FDA) definition of cosmetics covers a broad range of products. For regulatory purposes, the term includes products for the eyes, face, nails, hair, skin, and mouth, which may be in the form of products such as makeup, polish, hair dyes, fragrances, deodorants, shave gel, oral care, lotions, bath products, and products for infants and children.²

The FDA regulates cosmetics under the authority of the federal Food Drug and Cosmetic Act (FDCA) and the Fair Packaging and Labeling Act (FPLA). The FDCA prohibits the adulteration and misbranding of cosmetics and the introduction, receipt, and delivery of adulterated or misbranded cosmetics into interstate commerce.³ A cosmetic is considered to be adulterated if it contains a substance that may cause injury to users under the conditions of use prescribed on the product's labeling or if it contains a soiled or decomposed substance.⁴ A cosmetic is considered to be misbranded if its labeling is false or misleading, if it does not bear the required labeling information, if the container is made or filled in a deceptive manner, or if it does not comply with child resistant packaging requirements.⁵ The FDA is authorized to take action against a cosmetic on the market if a product is found to be adulterated or misbranded, as well as companies and individuals who market such products.⁶ However, the FDA does not have the authority to require a manufacturer to recall a cosmetic product from the marketplace, although the agency has general regulations on voluntary recalls.⁷

Voluntary Regulations

The FDA's legal authority over cosmetics is less comprehensive than other products it regulates, such as drugs and medical devices, with respect to mandatory product approval, regulation, and registration. The FDA does not impose registration requirements on cosmetic manufacturers, but it allows cosmetic manufactures to follow voluntary registration regulations. These voluntary regulations include facility registration, reporting of product's ingredients, and reporting of adverse reactions to products.

Voluntary cosmetic regulation compliance is managed electronically through the FDA's Voluntary Cosmetic Registration Program (VCRP). The VCRP is an electronic reporting system for manufacturers, packers, and distributors of cosmetic products that are distributed commercially in the

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¹ Landa, Michael. "Examining the Current State of Cosmetics," testimony on March 27, 2012, before the Subcommittee on Health Committee on Energy and Commerce, U.S. House of Representatives, accessible at http://www.fda.gov/NewsEvents/Testimony/ucm297215.htm (last visited December 10, 2015).

² 21 C.F.R. §720.4(c)(12) (1992).

³ Amalia Corby-Edwards, FDA Regulation of Cosmetics and Personal Care Products, Congressional Research Service, July 9, 2012, available at

http://asbcouncil.org/sites/default/files/library/docs/crs_report_fda_regulation_of_cosmetics_and_personal_care_products.pdf (last visited December 10, 2015).

⁴ ld.

^{ຼັ} ld.

⁶ U.S. FOOD AND DRUG ADMINISTRATION, *FDA Authority over Cosmetics*, March 20, 2014, http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074162.htm (last visited December 10, 2015).
⁷ *Supra*, note 3.

United States.⁸ Voluntary submission to the VCRP provides the FDA with information on cosmetic businesses and products, which helps support product safety review processes.⁹ As of December 2015, there are 2,970 active online accounts, 1,473 registered establishments, and 45,103 product formulations on file with the VCRP.¹⁰

The FDA does not require good manufacturing practices (GMP) for cosmetic products as it does with drugs and medical devices, unless the product is considered both a cosmetic and a drug.¹¹ GMPs provide standards for product development, monitoring, and control of processes and facilities, providing assurance that products meet FDA quality and safety standards. With the exception of color additives, the FDA does not require safety testing or premarket approval of the ingredients and chemicals used in cosmetic products.¹²

Labeling

The FPLA requires that packages and their labels provide consumers with accurate information about the quantity of contents to prevent consumer deception.¹³ FPLA regulations require cosmetic product labels to disclose:¹⁴

- Identification of the product;
- · Net quantity of contents in terms of weight, measure, or numerical count;
- Material facts about product and its use, such as directions for safe use;
- Name and place of business of the product's manufacturer, packer, or distributor;
- Warning and caution statements for products that are required to bear such statements by the FDCA and FDA regulations; and
- A list of ingredients in descending order of predominance.

Product Ingredients

The FDA is not statutorily authorized to approve a premarket cosmetic product. Therefore, manufactures are responsible for verifying the safety of their products before they are sold to consumers. FDA regulations prohibit or restrict the use of 10 types of ingredients in cosmetic products including chloroform, bithioniol, methylene chloride, and mercury-containing compounds¹⁵ and require warning statements on the labels of certain types of cosmetics. Manufacturers must remove dangerous products from the market once a safety concern emerges. The FDA can pursue enforcement actions against such products or against firms or individuals who violate the law.¹⁶ In general, except for color additives and those ingredients that are prohibited or restricted by regulation, a manufacturer may use any ingredient in the formulation of a cosmetic, provided that the:¹⁷

Ingredient and the finished cosmetic are safe under labeled or customary conditions of use;

http://www.fda.gov/Cosmetics/RegistrationProgram/default.htm (last visited December 10, 2015).

¹⁷ Supra, note 6. STORAGE NAME: h0261.HQS.docx

⁸ U.S. FOOD AND DRUG ADMINISTRATION, Voluntary Cosmetic Registration Program,

Information from the VCRP is used by the Cosmetic Ingredient Review, an industry funded organization, to assess ingredient safety and determine priorities for ingredient safety review. *Id.*

¹⁰ U.S. FOOD AND DRUG ADMINISTRATION, Registration Reports,

http://www.fda.gov/Cosmetics/RegistrationProgram/RegistrationReports/default.htm (last visited December 9, 2015).

In some cases products that are used for two purposes are considered both a cosmetic and a drug. For example, a shampoo is a cosmetic because its intended use is to cleanse the hair; however, an antidandruff treatment is a drug because its intended use is to treat dandruff. Consequently, an antidandruff shampoo is both a cosmetic and a drug and must comply with the requirements for both cosmetics and drugs. U.S. FOOD AND DRUG ADMINISTRATION, *Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)*, http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm (last visited December 10, 2015).

¹² Supra, note 3.

^{13 15} U.S.C. § 1451-1460 (2009).

¹⁴ Supra, note 1.

¹⁵ U.S. FOOD AND DRUG ADMINISTRATION, Prohibited and Restricted Ingredients,

http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm127406.htm (last visited December 10, 2015).

¹⁶ Supra, note 1.

- · Product is properly labeled; and
- Use of the ingredient does not otherwise cause the cosmetic to be adulterated or misbranded under the laws that FDA enforces.

State Cosmetic Laws

All 50 states have laws and regulations in place that conform to the FDCA, the FPLA, and FDA regulations for cosmetics.¹⁸ Further cosmetic related laws and regulation vary state by state. Very few states, including Louisiana,¹⁹ Nevada,²⁰ and Florida, have mandatory registration requirements for both cosmetic products and manufacturers. New Jersey²¹ and Pennsylvania²² require only cosmetic facilities, not products, to be registered with their respective state agencies. Other states, such as Texas²³ and Illinois,²⁴ authorize their respective state agencies to issue certificates of free sale for the export of in-state produced products.

California and Washington require post-market product reporting. The California Safe Cosmetics Act requires cosmetic manufacturers to notify the state of any product ingredients that are on state or federal lists of chemicals that cause cancer or birth defects.²⁵ Washington only requires this notification for children's cosmetic products.²⁶

Florida Cosmetic Regulation

The Department of Business and Professional Regulation's Division of Drugs, Devices, and Cosmetics (Division) serves to protect the health, safety, and welfare of Florida citizens from injury due to the use of adulterated, contaminated, and misbranded drugs, drug ingredients, and cosmetics²⁷ by administering the provisions of ch. 499, F.S., the Florida Drug and Cosmetic Act (Act).²⁸

The Act conforms to FDA cosmetic laws and regulations and authorizes the Division to issue permits to Florida cosmetic manufacturers and register cosmetic products manufactured or repackaged in Florida.

Manufacturer Permit

Cosmetic manufacturers physically located in Florida must obtain a cosmetic manufacturer permit through the Division.²⁹ Manufacture in this context means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any cosmetic.³⁰ Cosmetic manufacturers also repackage products by changing the container, wrapper, or label of a product, which may include

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¹⁸ U.S. FOOD AND DRUG ADMINISTRATION, Subchapter 3.3- State Operational Authority, http://www.fda.gov/ICECI/Inspections/IOM/ucm122520.htm (last visited December 10, 2015).

⁹ LOUISIANA DEP'T OF HEALTH AND HOSPITALS, Cosmetics, http://dhh.louisiana.gov/index.cfm/page/727 (last visited December 10, 2015).

²⁰ Nev. Rev. Stat. § 585.245; Nev. Admin. Code 585.805.

²¹ New Jersey Dep't of Health, *Wholesale Food and Cosmetic Project*, http://www.nj.gov/health/foodanddrugsafety/wfcp.shtml (last visited December 10, 2015).

²² Pennsylvania Dep't of Health, *Drug, Device, and Cosmetic Program*,

https://www.portal.state.pa.us/portal/server.pt/community/drugs, devices cosmetics/14159 (last visited December 10, 2015).

²³ 25 Tex. Admin. Code §§ 229.301-229.306 (2010).

III. Admin. Code Food Drug and Cosmetic 77 § 720 (2014).
 CALIFORNIA DEP'T OF PUBLIC HEALTH, California Safe Cosmetic Program,

http://www.cdph.ca.gov/programs/cosmetics/Pages/default.aspx (last visited December 11, 2015).

DEP'T OF ECOLOGY, STATE OF WASHINGTON, Children's Safe Product Act, http://www.ecy.wa.gov/programs/hwtr/RTT/cspa/index.html (last visited December 11, 2015).

²⁷ Florida law defines a cosmetic as an article, with the exception of soap, that is: (a) intended to be rubbed, poured, sprinkled, or sprayed on; introduced into; or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance; or (b) intended for use as a component of any such article. S. 499.003(12), F.S.

²⁸ FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, *Division of Drugs, Devices, and Cosmetics*, http://www.myfloridalicense.com/DBPR/ddc/index.html (last visited December 11, 2015).

²⁹ S. 499.01(2)(o), F.S.

³⁰ FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, Cosmetic Manufacturer, http://www.myfloridalicense.com/dbpr/ddc/CosmeticManufacturer.html (last visited December 11, 2015).

altering the quantity of a product into different containers.³¹ A person that only labels or changes the label of a cosmetic, but does not open the container sealed by the manufacturer of the product, is exempt from obtaining a permit.32

Applicants for a cosmetic manufacturer permit must complete and submit an application, pass an onsite inspection, 33 and pay a fee. Applicants must pay a fee of \$800 for a biennial permit and a one-time prepermit inspection fee of \$150.34 As of November 2014, there were 125 establishments with Division issued cosmetic manufacturer permits.³⁵

Division regulations provide guidelines for cosmetic manufacturers to ensure cosmetic product safety and quality and compliance with FDA laws and regulations. The regulations provide that: ³⁶

- Manufacturers must assure that personnel do not contribute to contamination or adulteration of the product:
- Any facility used for the manufacture, processing, packaging, or labeling of a cosmetic shall be of suitable size and construction to produce a product that is not adulterated or misbranded;
- Any facility and equipment used in the manufacture, processing, packaging, or labeling of a cosmetic shall be maintained in a clean and sanitary condition;
- Components, containers, and closures shall not be reactive, additive, or absorptive so as to alter the safety or purity of the cosmetic:
- Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the cosmetic product; and
- An appropriate identification or tracking system should be in place to facilitate a rapid and effective recall or market withdrawal.

Registration of Products

Cosmetics manufactured, packaged, repackaged, labeled or relabeled in Florida must be registered with the Division.³⁷ Products that are both a cosmetic and a drug must be registered as a drug.³⁸ Registration of cosmetic products requires a manufacturer to submit a detailed Division application, a copy of the product labels, and a fee for each product.³⁹ The application includes the following information:

- Manufacturer's contact and address information, type of ownership, and operating hours;
- Name of product as shown on label:
- Identification of the product, if it is for professional use only:
- Manufacturer of the product, including its name, city, and state:
- Identical cosmetic products information; and
- Signed affidavit section.⁴⁰

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³² Supra, note 29.

³³ If the applicant also holds an Over-the-Counter Drug Manufacturer or Prescription Drug Manufacturer permit at the same time an inspection is not required. Supra, note 30 Supra, note 30.

³⁵ Letter from the Director of the Division of Drugs, Devices, and Cosmetics to a representative of the Florida Cosmetic Manufacturers Coalition on November 26, 2014. (on file with Health Quality Subcommittee staff).

Rule 61N-1.010, F.A.C.

³⁷ S. 499.015(1)(a), F.S.

³⁸ Rule 61N-1.016(1)(a), F.A.C.

⁴⁰ FLORIDA DEP'T OF BUSINESS AND PROFESSIONAL REGULATION, Application for Product Registration-Cosmetics Form No.: DBPR-DDC-228, available at http://www.myfloridalicense.com/DBPR/ddc/documents/Product_Registration_Cosmetic_App-228.pdf (last visited December 14, 2015).

New cosmetic products must be registered prior to sale. If a manufacturer has existing registered products, its registered product list must be updated through the formal application process to include any new products.⁴¹ The registration and biennial renewal fee for each cosmetic product is \$30.

Manufacturers often produce similar products or slightly alter products from an outside manufacturer; for example, they may use a different brand name, container, or scent for an almost identical product. In these instances, for registration purposes, the product is not considered separate and distinct. The process for "identical products" requires submission of an application and a \$15 fee and biennial renewal fee for each additional size, quantity, color, flavor, and scent of a registered cosmetic product.42

The Division reviews applicants' product labels to determine compliance with the requirements of the FDCA.⁴³ The Division reviews the ingredients of the cosmetic to determine if the ingredients are approved for use in cosmetics or otherwise safe for cosmetic products. 44 Division pharmacists or drug inspectors review products that may contain ingredients that are prohibited or may change the classification of the product to a drug. 45 Currently, there are 13,024 active cosmetic product registrations with the Division.46

Inspection and Investigation of Cosmetic Manufacturers

Passing an onsite inspection is a prerequisite to issuance of a Cosmetic Manufacturer permit, unless the applicant also holds an Over-the-Counter Drug Manufacturer or Prescription Drug Manufacturer permit at the same address.⁴⁷ Additionally, once a permit has been issued to a cosmetic manufacturer, it is subject to inspection and investigation, whether announced or unannounced, by the Division and the Department of Law Enforcement. 48 Inspections and investigations may include:

- Review and copying of all records pertaining to the manufacture, advertisement, storage, holding, and distribution of any cosmetic.
- Entry to any establishment, vehicle or space therein in which cosmetics are manufactured, processed, repackaged, sold, brokered, held or transported;
- Entry to any establishment, vehicle, or space therein in which records related to cosmetics are held:
- Surveillance of procedures related to cosmetics;
- Collection of facts and information related to cosmetics;
- Questioning of persons who may have information relating to the inspection or investigation and taking sworn statements from these persons, all related to cosmetics;
- Sampling any cosmetic, including any related product (whether or not in finished form), material, component, document, literature, label, labeling or other evidence;
- Photographing any cosmetic including any related component, materials, physical plant, storage condition, article or product;
- Observations and identification of:
 - o Any cosmetic consisting wholly or in part of filthy, putrid or decomposed substances;
 - o Any undesirable conditions or practices bearing on filth, contamination, or decomposition which may result in a cosmetic becoming adulterated or misbranded;
 - Any unsanitary conditions or practices which may render a cosmetic injurious to health;

Rule 61N-1.016(4)(b), F.A.C.

⁴² Rule 61N-1.016(1)(b), F.A.C.

⁴³ Rule 61N-1.009, F.A.C.

⁴⁴ Florida Department of Business and Professional Regulation, 2016 Legislative Bill Analysis SB 176, September 29, 2015. (SB 176 is identical to HB 261, analysis is on file with Health Quality Subcommittee staff).

Supra, note 35.

⁴⁶ Supra, note 44.

⁴⁷ Supra, note 30.

⁴⁸ S. 499.051(1), F.S., Rule 61N-1.019(1)-(3), F.A.C.

- Any faulty manufacturing, processing, packaging, or holding of cosmetics as related to current GMP including recordkeeping;
- Any deviation from recommended processing, storage or temperature requirements for any cosmetic as specified by federal or state law;
- o Any deviation from FDA requirements for the label and labeling of any cosmetic;
- Any other action to determine compliance with chapters 499 and 893, F.S., and chapter 61N-1, F.A.C.
- Taking of evidence related to a cosmetic that is or may be in violation of Chapter 499 or 893,
 F.S., or any rules adopted thereunder; and
- Securing the removal of any potentially misbranded or adulterated cosmetic from commerce or public access.

Certificates of Free Sale

Manufacturers exporting products from the United States are often asked by foreign customers or foreign governments to supply a certificate of free sale (COFS) to ensure that products are in compliance with FDA laws and regulations. A COFS is a document issued by a regulatory agency containing information about a product's regulatory or marketing status. A COFS verifies that products being exported are freely marketed without restriction and are approved for sale in the United States and Florida. So

A COFS can be issued by a federal, state, city office or a non-governmental association such as a Chamber of Commerce. The Division, when requested by a cosmetic manufacturer, issues a COFS for a registered cosmetic product that is to be exported to another country.⁵¹ Enterprise Florida will prepare a COFS for firms involved in the exporting of products manufactured in, or distributed from Florida for a fee of \$20.00.⁵²

Effect of Proposed Changes

HB 261 amends ch. 499, F.S., to remove the requirement that Florida cosmetic manufacturers register cosmetic products with the Division. As such, cosmetic manufacturers located in Florida will no longer be required register cosmetic products with the Division. Florida cosmetic manufacturers' products would be treated the same as cosmetic products manufactured outside of Florida but distributed and sold into Florida. The bill makes conforming changes by removing registration and renewal requirements for cosmetic products, including the requirements to submit registration applications, product labels, and registration and renewal fees.

Florida cosmetic manufacturers would continue to be regulated. They would still be required to have their facilities permitted and be subject to inspection and investigation of their cosmetic products.

The bill also removes the Division's authority to issue COFSs for registered cosmetic products in s. 499.003(6), F.S. While COFSs would not be available from the Division for exported cosmetic products, they would continue to be available from other entities for exported cosmetic products, including Enterprise Florida.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 499.015, F.S., relating to registration of drugs, devices, and cosmetics; issuance of certificates of free sale.

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⁴⁹ U.S. FOOD AND DRUG ADMINISTRATION, *FDA Export Certificate*, December 18, 2014, http://www.fda.gov/RegulatoryInformation/Guidances/ucm125789.htm, (last visited December 15, 2015).

Enterprise Florida, Certificate of Free Sale, available at https://www.enterpriseflorida.com/wp-content/uploads/certificate-of-free-sale-flyer.pdf (last visited December 14, 2015).

⁵¹ Rule 61N-1.017, F.A.C.

⁵² Supra, note 50.

Section 2: Amends s. 499.003, F.S., relating to definitions.

Section 3: Amends s. 499.041, F.S., relating to schedule of fees for drug, device, and cosmetic applications and permits, product registration, and free-sale certificates.

Section 4: Amends s. 499.051, F.S., relating to inspections and investigations.

Section 5: Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

The Division will experience a decrease in revenues associated with no longer receiving payment of fees for cosmetic product registration, product registration renewal, and COFS.

There are 13,024 current, active registered cosmetic products. Product registrations are renewed biennially. The Division's biennial renewal fees from the 13,024 products are approximately \$330,465 (or \$165,232.50 annually). The bill would reduce the Division's revenue from these fees and the revenue reductions would increase the Division fund's anticipated deficit. There would also be a General Revenue service charge loss of \$17,805.10 in Fiscal Year (FY) 2016-2016; \$18,013.16 in FY 2017-2018; and \$18,234.47 in FY 2018-2019. The reduction in the Division's revenue is estimated as follows:⁵³

	Fiscal Year 2016 - 17	Fiscal Year 2017 - 18	Fiscal Year 2018 - 19
Revenue reduction from annual renewals:	(\$165,232.50)	(\$165,232.50)	(\$165,232.50)
Revenue reduction from initial product registrations:	(\$45,225)	(\$46,545)	(\$47,895)
Revenue reduction from COFS:	(\$12,106.20)	(\$13,387.04)	(\$14,803.39)
Total revenue reduction:	(\$222,563.70)	(\$225,164.54)	(\$227,930.89)

2. Expenditures:

It is unclear whether the Division will have a reduction in expenditures if resources used to implement the product registration program are no longer needed or are allocated for other Division responsibilities.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1		Revenues:
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None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill has a positive fiscal impact for cosmetic manufacturers associated with no further payment of \$30 per product registration, \$15 per identical product registration, and biennial renewal fee for both to the Division.

D. FISCAL COMMENTS:

None.

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⁵³ Supra, note 44; Email from David Mica, Legislative Affairs Director, Department of Business and Professional Regulation, RE: HB 261 DBPR Analysis (December 16, 2015.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

- 1. Applicability of Municipality/County Mandates Provision: Not applicable. This bill does not appear to affect county or municipal governments.
- 2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

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A bill to be entitled

An act relating to cosmetic product registration; amending s. 499.015, F.S.; removing the requirement that a person who manufactures, packages, repackages, labels, or relabels a cosmetic in this state must register such cosmetic biennially with the Department of Business and Professional Regulation; amending ss. 499.003, 499.041, and 499.051, F.S.; conforming provisions to changes made by this act; providing an effective date.

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

Section 1. Section 499.015, Florida Statutes, is amended to read:

499.015 Registration of drugs and, devices, and cosmetics; issuance of certificates of free sale.—

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or, device, or cosmetic in this state must register such drug or, device, or cosmetic biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or, device, or cosmetic at the time of registration.

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(b) The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

- and specimens of labels at the time of application for registration of drugs or, devices, and cosmetics packaged and prepared in compliance with the federal act, which submission constitutes a satisfactory compliance for registration of the products. With respect to all other drugs and, devices, and cosmetics, the department may require the submission of a catalog and specimens of labels at the time of application for registration, but the registration will not become effective until the department has examined and approved the label of the drug or, device, or cosmetic product. This approval or denial must include written notification to the manufacturer.
- (3) Except for those persons exempted from the definition of manufacturer in s. 499.003, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug or_{τ} device or_{τ} device
 - (4) Unless a registration is renewed, it expires 2 years

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after the last day of the month in which it was issued. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs $\underline{\text{or}}_{7}$ devices $\underline{\text{or}}$ cosmetics covered by this part until he or she complies with the requirements of this section.

- (5) A product regulated under this section which is not included in the biennial registration may not be sold until it is registered and complies with this section.
- (6) The department may issue a certificate of free sale for any product that is required to be registered under this part.
- (7) A product registration is valid only for the company named on the registration and located at the address on the registration. A person whose product is registered by the department under this section must notify the department before any change in the name or address of the establishment to which the product is registered. If a person whose product is registered ceases conducting business, the person must notify the department before closing the business.
- (8) Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

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(a) The manufacturer's medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

- (b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.
- (9) However, the manufacturer must submit evidence of such registration, listing, or approval with its initial application for a permit to do business in this state, as required in s. 499.01 and any changes to such information previously submitted at the time of renewal of the permit. Evidence of approval, listing, and registration by the federal Food and Drug Administration must include:
- (a) For Class II devices, a copy of the premarket notification letter (510K);
- (b) For Class III devices, a <u>federal Food and Federal</u> Drug Administration premarket approval number;
- (c) For a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, a <u>federal Food and Federal Drug Administration</u> registration number; or
- (d) For a manufacturer of medical devices whose devices are exempt from premarket approval by the <u>federal Food and</u>

 Federal Drug Administration, a <u>federal Food and Federal</u> Drug Administration registration number.
 - Section 2. Subsection (6) of section 499.003, Florida

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105 Statutes, is amended to read:

499.003 Definitions of terms used in this part.—As used in this part, the term:

- (6) "Certificate of free sale" means a document prepared by the department which certifies a drug or_{τ} device, or $cosmetic_{\tau}$ that is registered with the department, as one that can be legally sold in the state.
- Section 3. Subsection (6) of section 499.041, Florida Statutes, is amended to read:
- 499.041 Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.—
- (6) A person that is required to register drugs or, devices, or cosmetic products under s. 499.015 shall pay an annual product registration fee of not less than \$5 or more than \$15 for each separate and distinct product in package form. The registration fee is in addition to the fee charged for a free-sale certificate.
- Section 4. Subsection (2) of section 499.051, Florida Statutes, is amended to read:
 - 499.051 Inspections and investigations.-
- (2) In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with this chapter and rules adopted under this chapter regarding any drug, device, or

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131 cosmetic product.

Section 5. This act shall take effect July 1, 2016.

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

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 391 Pub. Rec./Emergency Medical Technicians or Paramedics

SPONSOR(S): Passidomo

TIED BILLS: IDEN./SIM. BILLS: SB 320

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Guzzo 16	O'Callaghan My
2) Government Operations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

HB 391 creates a public records exemption for certain identification and location information of current or former emergency medical technicians (EMTs) or paramedics certified under ch. 401, F.S., and the spouses and children of the EMTs or paramedics. The exemption is subject to the Open Government Sunset Review Act and will stand repealed on October 2, 2021, unless reviewed and saved from repeal by the Legislature.

The bill also provides a statement of public necessity as required by the Florida Constitution.

The bill may have an insignificant negative fiscal impact on state and local governments.

The bill provides that the act will take effect upon becoming a law.

Article I, s. 24(c) of the Florida Constitution requires a two-thirds vote of the members present and voting for final passage of a newly created or expanded public records or public meetings exemption. The bill creates a public records exemption; thus, it requires a two-thirds vote for final passage.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0391.HQS.DOCX

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Public Records Laws

The Florida Constitution provides that the public has the right to access government records. It guarantees every person a right to inspect or copy any public record of the legislative, executive, and judicial branches of government.

In addition to the Florida Constitution, the Florida Statutes specify conditions under which public access must be provided to government records. The Public Records Act² guarantees every person's right to inspect and copy any state or local government public record.³

Only the Legislature may create an exemption from public records requirements.⁴ An exemption must specifically state the public necessity justifying the exemption and must be tailored to accomplish the stated purpose of the law.⁵ A bill enacting an exemption may not contain other substantive provisions⁶ and must pass by a two-thirds vote of the members present and voting in each house of the Legislature.7

Open Government Sunset Review Act

The Open Government Sunset Review Act (Act) prescribes a legislative review process for newly created or substantially amended public records exemptions.⁸ The Act provides that an exemption automatically repeals on October 2nd of the fifth year after creation or substantial amendment. unless the Legislature reenacts the exemption.9

The Act provides that a public records exemption may be created or maintained only if it serves an identifiable public purpose and is no broader than is necessary. 10 An exemption serves an identifiable purpose if it meets one of the following criteria:

It allows the state or its political subdivision to effectively and efficiently administer a program, and administration would be significantly impaired without the exemption;¹¹

¹ FLA. CONST., art. I, s. 24(a).

² Chapter 119, F.S.

³ Section 119.011(12), F.S., defines "public record" to mean "all documents, papers, letters, maps, books, tapes, photographs, films, sound recordings, data processing software, or other material, regardless of the physical form, characteristics, or means of transmission, made or received pursuant to law or ordinance or in connection with the transaction of official business by any agency." The Public Records Act does not apply to legislative or judicial records. Locke v. Hawkes, 595 So.2d 32 (Fla. 1992). The Legislature's records are public pursuant to s. 11.0431, F.S.

FLA. CONST., art. I, s. 24(c). There is a difference between records the Legislature designates as exempt from public records requirements and those the Legislature designates confidential and exempt. A record classified as exempt from public disclosure may be disclosed under certain circumstances. Williams v. City of Minneola, 575 So.2d 687 (Fla. 5th DCA 1991). If the Legislature designates a record as confidential, such record may not be released, to anyone other than the persons or entities specifically designated in statute. WFTV, Inc. v. The School Board of Seminole, 874 So.2d 48 (Fla. 5th DCA 2004). ⁵ FLA. CONST., art. I, s. 24(c).

⁶ The bill, however, may contain multiple exemptions that relate to one subject.

⁷ FLA. CONST., art. I, s. 24(c).

⁸ Section 119.15, F.S. Section 119.15(4)(b), F.S. provides that an exemption is considered to be substantially amended if it is expanded to include more information or to include meetings. The act does not apply to an exemption that is required by federal law or that applies solely to the legislature or the state court system pursuant to section 119.15(2), F.S.

Section 119.15(3), F.S.

¹⁰ Section 119.15(6)(b), F.S.

¹¹ Section 119.15(6)(b)1., F.S. STORAGE NAME: h0391.HQS.DOCX

- Releasing sensitive personal information would be defamatory or would jeopardize an individual's safety. If this public purpose is cited as the basis of an exemption, only personal identifying information may be made exempt; 12 or
- It protects trade or business secrets. 13

In addition, the Legislature must find that the identifiable public purpose is compelling enough to override Florida's open government public policy and that the purpose of the exemption cannot be accomplished without the exemption.¹⁴

Public Records Exemptions

Current law provides public records exemptions for identification and location information of certain current or former public employees and their spouses and children. ¹⁵ Examples of public employees covered by these exemptions include: law enforcement personnel, firefighters, local government personnel who are responsible for revenue collection and enforcement or child support enforcement, justices and judges, and local and statewide prosecuting attorneys.

Although the types of exempt information vary, the following information is exempt from public records requirements for all of the above-listed public employees:

- Home addresses and telephone numbers of the public employees;
- Home addresses, telephone numbers, and places of employment of the spouses and children of such employees; and
- Names and locations of schools and day care facilities attended by the children of such employees.

If exempt information is held by an agency that is not the employer of the public employee, the public employee must submit a written request to that agency to maintain the public records exemption.¹⁶

Emergency Medical Technicians (EMTs) and Paramedics

EMTs and paramedics take care of sick or injured patients in an emergency medical setting and often work closely with police and firefighters during an emergency situation. The typical duties of an EMT or paramedic include:

- Responding to 911 calls for emergency medical assistance;
- Assessing a patient's condition and determining a course of treatment;
- Following guidelines learned in training or received from physicians who oversee their work;
- Using backboards and restraints to keep patients still and safe in an ambulance during transport;
- Helping transfer patients to the emergency department of a healthcare facility and report their observations and treatment to the staff;
- Creating a patient care report, documenting the medical care given to the patient; and
- Replacing used supplies and checking or cleaning equipment after use.¹⁸

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¹² Section 119.15(6)(b)2., F.S.

¹³ Section 119.15(6)(b)3., F.S.

Section 119.15(6)(b), F.S.

¹⁵ Section 119.071(4)(d), F.S. ¹⁶ Section 119.071(4)(d)3., F.S.

U.S. Bureau of Labor Statistics, EMTs and Paramedics, http://www.bls.gov/ooh/Healthcare/EMTs-and-paramedics.htm#tab-2 (last visited December 17, 2015).

EMTs and paramedics are regulated by the Department of Health (DOH), under ch. 401, Part III, F.S. Currently, there are 31,898 certified EMTs and 29,221 certified paramedics in Florida. "Emergency Medical Technician" is defined under s. 401.23(11), F.S., to mean a person who is certified by DOH to perform basic life support. Section 401.23(17), F.S., defines "Paramedic" as a person who is certified by DOH to perform basic and advanced life support. ²¹

Complaint Investigations

The Investigation Unit of the Emergency Medical Services Section of DOH is responsible for investigating complaints against EMTs and paramedics. Section 401.414, F.S., requires DOH to investigate any complaint that is, in writing, signed by the complainant, and legally sufficient.²² Upon beginning an investigation, DOH must notify the person being investigated and inform them of the substance of the complaint. However, DOH may conduct an investigation without notifying the person being investigated if the act under investigation is a crime. Upon completion of an investigation, DOH must prepare an investigative report containing the investigative findings and the recommendations of DOH concerning the existence of probable cause.²³

The complaint and all information obtained in the investigation are considered confidential and exempt from the public records requirements of s. 119.07(1), F.S., until 10 days after DOH has found the existence of probable cause or until the person who is the subject of the investigation waives confidentiality, whichever occurs first.²⁴

Effect of Proposed Changes

The bill creates a public records exemption for identification and location information of current or former EMTs or paramedics certified under ch. 401, F.S.

The bill makes the following information exempt from public records requirements:

- The home addresses, telephone numbers, dates of birth, and photographs of current or former EMTs or paramedics certified under ch. 401, F.S.;
- The names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such EMTs or paramedics; and
- The names and locations of schools and day care facilities attended by the children of such EMTs or paramedics.

The exemption is subject to an existing requirement under s. 119.071(4)(d)3.,F.S., which provides that if exempt information is held by an agency that is not the employer of the protected public employee, then the protected public employee must submit to that agency a written request to maintain the public records exemption.

The bill provides for repeal of the exemption on October 2, 2021, unless reviewed and saved from repeal by the Legislature.

¹⁹Florida Department of Health, *Emergency Medical Services Section Highlights-July 2015*, available at http://www.floridahealth.gov/licensing-and-regulation/ems-system/ (last visited December 15, 2015).

²⁰ Section 401.23(7), F.S., defines "basic life support" as, the assessment or treatment through the use of techniques described in the Emergency Medical Technician Basic National Standard Curriculum or the National EMS Education Standards of the U.S. Department of Transportation.

²¹ Section 404.23(4), F.S., defines "advanced to the control of the U.S. Department".

²¹ Section 401.23(1), F.S., defines "advanced life support" as, the assessment or treatment by a qualified person through the use of techniques such as endotracheal intubation, the administration of drugs or intravenous fluids, telemetry, cardiac monitoring, cardiac defibrillation, and other techniques described in the EMT-Paramedic National Standard Curriculum or the National EMS Education Standards.

²² Section 401.414(1), F.S., "a complaint is legally sufficient if it contains ultimate facts that show that a violation of ch. 401, part III, F.S., or of any rule adopted by DOH, has occurred.

²³ Section 401.414(2), F.S.

²⁴ Section 401.414(3), F.S.

The bill provides a public necessity statement, which is required by the Florida Constitution. Specifically, the bill states that the exemption is needed to protect EMTs or paramedics, and the spouses and children of both, from the risk of physical and emotional harm by disgruntled individuals who have contentious reactions to actions carried out by the EMTs or paramedics.

The bill takes effect upon becoming a law.

B. SECTION DIRECTORY:

- **Section 1:** Amends s. 119.071, F.S., relating to general exemptions form inspection or copying of public records.
- **Section 2:** Provides a public necessity statement.
- Section 3: Provides an effective date of upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See FISCAL COMMENTS.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

See FISCAL COMMENTS

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

The bill could create a minimal fiscal impact on agencies because staff responsible for complying with public record requests could require training related to creation of the public record exemption. In addition, agencies could incur costs associated with redacting the exempt identification and location information prior to releasing a record. These costs, however, would be absorbed, as they are part of the day-to-day responsibilities of agencies.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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The bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

Vote Requirement

Article I, s. 24(c) of the Florida Constitution requires a two-thirds vote of the members present and voting in each house of the Legislature for passage of a newly-created or expanded public records or public meetings exemption. Because the bill creates a new public records exemption, it requires a two-thirds vote for passage.

Public Necessity Statement

Article I, s. 24(c) of the Florida Constitution requires a public necessity statement for a newly-created or expanded public records or public meetings exemption. The bill creates a new public records exemption and includes a public necessity statement.

Breadth of Exemption

Article I, s. 24(c) of the Florida Constitution requires a newly created public records or public meetings exemption to be no broader than necessary to accomplish the stated purpose of the law. The bill creates a public records exemption for identification and location information emergency medical technicians or paramedics, and the spouses and children of both. The exemption does not appear to be in conflict with the constitutional requirement that the exemption must be no broader than necessary to accomplish its purpose.

B. RULE-MAKING AUTHORITY:

No additional rulemaking is necessary to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

STORAGE NAME: h0391.HQS.DOCX

HB 391 2016

A bill to be entitled 1 2 An act relating to public records; amending s. 3 119.071, F.S.; providing an exemption from public 4 records requirements for certain identifying 5 information of current or former emergency medical 6 technicians or paramedics certified under chapter 401, 7 F.S., and the spouses and children of such medical 8 technicians or paramedics; providing for future 9 legislative review and repeal of the exemption; 10 providing a statement of public necessity; providing 11 an effective date.

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

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Paragraph (d) of subsection (4) of section Section 1. 119.071, Florida Statutes, is amended to read:

119.071 General exemptions from inspection or copying of public records.-

- AGENCY PERSONNEL INFORMATION. -
- (d)1. For purposes of this paragraph, the term "telephone numbers" includes home telephone numbers, personal cellular telephone numbers, personal pager telephone numbers, and telephone numbers associated with personal communications devices.
- The home addresses, telephone numbers, social 2.a.(I) security numbers, dates of birth, and photographs of active or

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former sworn or civilian law enforcement personnel, including correctional and correctional probation officers, personnel of the Department of Children and Families whose duties include the investigation of abuse, neglect, exploitation, fraud, theft, or other criminal activities, personnel of the Department of Health whose duties are to support the investigation of child abuse or neglect, and personnel of the Department of Revenue or local governments whose responsibilities include revenue collection and enforcement or child support enforcement; the home addresses, telephone numbers, social security numbers, photographs, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1).

- (II) The names of the spouses and children of active or former sworn or civilian law enforcement personnel and the other specified agency personnel identified in sub-sub-subparagraph (I) are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- (III) Sub-sub-subparagraph (II) is subject to the Open Government Sunset Review Act in accordance with s. 119.15, and shall stand repealed on October 2, 2018, unless reviewed and saved from repeal through reenactment by the Legislature.
- b. The home addresses, telephone numbers, dates of birth, and photographs of firefighters certified in compliance with s. 633.408; the home addresses, telephone numbers, photographs,

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dates of birth, and places of employment of the spouses and children of such firefighters; and the names and locations of schools and day care facilities attended by the children of such firefighters are exempt from s. 119.07(1).

- c. The home addresses, dates of birth, and telephone numbers of current or former justices of the Supreme Court, district court of appeal judges, circuit court judges, and county court judges; the home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of current or former justices and judges; and the names and locations of schools and day care facilities attended by the children of current or former justices and judges are exempt from s. 119.07(1).
- d.(I) The home addresses, telephone numbers, social security numbers, dates of birth, and photographs of current or former state attorneys, assistant state attorneys, statewide prosecutors, or assistant statewide prosecutors; the home addresses, telephone numbers, social security numbers, photographs, dates of birth, and places of employment of the spouses and children of current or former state attorneys, assistant state attorneys, statewide prosecutors, or assistant statewide prosecutors; and the names and locations of schools and day care facilities attended by the children of current or former state attorneys, assistant state attorneys, statewide prosecutors, or assistant statewide prosecutors are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

(II) The names of the spouses and children of current or former state attorneys, assistant state attorneys, statewide prosecutors, or assistant statewide prosecutors are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

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- (III) Sub-sub-subparagraph (II) is subject to the Open Government Sunset Review Act in accordance with s. 119.15, and shall stand repealed on October 2, 2018, unless reviewed and saved from repeal through reenactment by the Legislature.
- The home addresses, dates of birth, and telephone numbers of general magistrates, special magistrates, judges of compensation claims, administrative law judges of the Division of Administrative Hearings, and child support enforcement hearing officers; the home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of general magistrates, special magistrates, judges of compensation claims, administrative law judges of the Division of Administrative Hearings, and child support enforcement hearing officers; and the names and locations of schools and day care facilities attended by the children of general magistrates, special magistrates, judges of compensation claims, administrative law judges of the Division of Administrative Hearings, and child support enforcement hearing officers are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution if the general magistrate, special magistrate, judge of compensation claims, administrative law judge of the Division of Administrative Hearings, or child support hearing

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officer provides a written statement that the general magistrate, special magistrate, judge of compensation claims, administrative law judge of the Division of Administrative Hearings, or child support hearing officer has made reasonable efforts to protect such information from being accessible through other means available to the public.

- f. The home addresses, telephone numbers, dates of birth, and photographs of current or former human resource, labor relations, or employee relations directors, assistant directors, managers, or assistant managers of any local government agency or water management district whose duties include hiring and firing employees, labor contract negotiation, administration, or other personnel-related duties; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- g. The home addresses, telephone numbers, dates of birth, and photographs of current or former code enforcement officers; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

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h. The home addresses, telephone numbers, places of employment, dates of birth, and photographs of current or former guardians ad litem, as defined in s. 39.820; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such persons; and the names and locations of schools and day care facilities attended by the children of such persons are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution, if the guardian ad litem provides a written statement that the guardian ad litem has made reasonable efforts to protect such information from being accessible through other means available to the public.

i. The home addresses, telephone numbers, dates of birth, and photographs of current or former juvenile probation officers, juvenile probation supervisors, detention superintendents, assistant detention superintendents, juvenile justice detention officers I and II, juvenile justice detention officer supervisors, juvenile justice residential officers, juvenile justice residential officer supervisors I and II, juvenile justice counselor supervisors, human services counselor administrators, senior human services counselor administrators, rehabilitation therapists, and social services counselors of the Department of Juvenile Justice; the names, home addresses, telephone numbers, dates of birth, and places of employment of spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel

are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.

- j.(I) The home addresses, telephone numbers, dates of birth, and photographs of current or former public defenders, assistant public defenders, criminal conflict and civil regional counsel, and assistant criminal conflict and civil regional counsel; the home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such defenders or counsel; and the names and locations of schools and day care facilities attended by the children of such defenders or counsel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution.
- (II) The names of the spouses and children of the specified agency personnel identified in sub-sub-subparagraph (I) are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution. This sub-sub-subparagraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2019, unless reviewed and saved from repeal through reenactment by the Legislature.
- k. The home addresses, telephone numbers, and photographs of current or former investigators or inspectors of the Department of Business and Professional Regulation; the names, home addresses, telephone numbers, and places of employment of the spouses and children of such current or former investigators and inspectors; and the names and locations of schools and day care facilities attended by the children of such current or

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former investigators and inspectors are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution if the investigator or inspector has made reasonable efforts to protect such information from being accessible through other means available to the public. This sub-subparagraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2017, unless reviewed and saved from repeal through reenactment by the Legislature.

- 1. The home addresses and telephone numbers of county tax collectors; the names, home addresses, telephone numbers, and places of employment of the spouses and children of such tax collectors; and the names and locations of schools and day care facilities attended by the children of such tax collectors are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution if the county tax collector has made reasonable efforts to protect such information from being accessible through other means available to the public. This subsubparagraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2017, unless reviewed and saved from repeal through reenactment by the Legislature.
- m. The home addresses, telephone numbers, dates of birth, and photographs of current or former personnel of the Department of Health whose duties include, or result in, the determination or adjudication of eligibility for social security disability benefits, the investigation or prosecution of complaints filed

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against health care practitioners, or the inspection of health care practitioners or health care facilities licensed by the Department of Health; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such personnel; and the names and locations of schools and day care facilities attended by the children of such personnel are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution if the personnel have made reasonable efforts to protect such information from being accessible through other means available to the public. This subsubparagraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2019, unless reviewed and saved from repeal through reenactment by the Legislature.

n. The home addresses, telephone numbers, dates of birth, and photographs of current or former impaired practitioner consultants who are retained by an agency or current or former employees of an impaired practitioner consultant whose duties result in a determination of a person's skill and safety to practice a licensed profession; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such consultants or their employees; and the names and locations of schools and day care facilities attended by the children of such consultants or employees are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution if a consultant or employee has made reasonable

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efforts to protect such information from being accessible through other means available to the public. This subsubparagraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2020, unless reviewed and saved from repeal through reenactment by the Legislature.

- o. The home addresses, telephone numbers, dates of birth, and photographs of current or former emergency medical technicians or paramedics certified under chapter 401; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such emergency medical technicians or paramedics; and the names and locations of schools and day care facilities attended by the children of such emergency medical technicians or paramedics are exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution. This sub-subparagraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2021, unless reviewed and saved from repeal through reenactment by the Legislature.
- 3. An agency that is the custodian of the information specified in subparagraph 2. and that is not the employer of the officer, employee, justice, judge, or other person specified in subparagraph 2. shall maintain the exempt status of that information only if the officer, employee, justice, judge, other person, or employing agency of the designated employee submits a written request for maintenance of the exemption to the

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261 custodial agency.

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- 4. The exemptions in this paragraph apply to information held by an agency before, on, or after the effective date of the exemption.
- 5. Except as otherwise expressly provided in this paragraph, this paragraph is subject to the Open Government Sunset Review Act in accordance with s. 119.15, and shall stand repealed on October 2, 2017, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 2. The Legislature finds that it is a public necessity that the home addresses, telephone numbers, dates of birth, and photographs of current or former emergency medical technicians or paramedics certified under chapter 401, Florida Statutes; the names, home addresses, telephone numbers, dates of birth, and places of employment of the spouses and children of such emergency medical technicians or paramedics; and the names and locations of schools and day care facilities attended by the children of such emergency medical technicians or paramedics be made confidential and exempt from public records requirements. The Legislature finds that the release of such identifying and location information may place such emergency medical technicians or paramedics and their family members in danger of physical and emotional harm from disgruntled individuals who have contentious reactions to actions carried out by the emergency medical technicians or paramedics. The Legislature further finds that the harm that may result from the release of

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287	such identifying and location information outweighs any public
288	benefit derived from disclosure of such information.
89	Section 3. This act shall take effect upon becoming a law

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HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #:

HB 571 Music Therapy

SPONSOR(S): Campbell

TIED BILLS:

IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee		Langston(W)	O'Callaghan
2) Health Care Appropriations Subcommittee		_	,
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Music therapy is clinical, evidence-based use of music interventions to accomplish individualized goals in a therapeutic relationship. Music therapists work in a variety of settings, including but not limited to, hospitals, outpatient clinics, rehabilitation facilities, day care treatment centers, drug and alcohol programs, senior centers, nursing homes, correctional facilities, schools and private practice.

The American Music Therapy Association (AMTA) and the Certification Board for Music Therapists (CBMT), working in tandem, have established the national board certification requirements for the practice of music therapy. AMTA requires music therapists to have a bachelor's degree or higher from one of AMTA's approved colleges and universities and 1,200 hours of clinical training. Initial certification requires passage of the board certification examination. CBMT indicates that over 6,549 music therapists in the U.S. currently maintain a Music Therapist-Board Certified (MT-BC) credential. It is estimated that 253 music therapists in Florida currently maintain an MT-BC credential.

Music therapists are regulated in Georgia, Nevada, North Dakota, Oregon, Rhode Island, and Utah. Currently, music therapists are not regulated in Florida.

HB 571 creates s. 490.0146, F.S., to require the registration of music therapists. It defines "music therapy" as the clinical and evidenced-based use of music intervention by a registered music therapist to accomplish individualized goals for persons of all ages and abilities within a therapeutic relationship and specifies that music therapy does not include the diagnosis or assessment of any physical, mental, or communication disorder.

The bill specifies that any person wishing to work as a music therapist in Florida must register by filing an application with the Florida Board of Psychology (the Board). The Board is required to register each applicant who submits a registration fee, a completed application, and a nonrefundable application fee; is at least 17 years old; and has completed an approved music therapist training program.

The bill provides that registration renewal be conditioned upon completion of 20 hours of continuing education courses each biennium that are approved by the AMTA, or its successor.

The bill requires the Board to adopt rules that establish an application form; establish a registration fee; establish an application fee; establish approved music therapy training programs; and require the display of the registration in a manner that is available to the public and facilitates inspection by the Department of Health.

The bill also provides authority to the Board to develop other rules as necessary to administer the registration of music therapists.

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

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0571.HQS

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

The Sunrise Act and Sunrise Questionnaire

The Sunrise Act (the act), codified in s. 11.62, F.S., requires the Legislature to consider specific factors in determining whether to regulate a new profession or occupation. The Legislative intent in the act provides that:

- No profession or occupation be subject to regulation unless the regulation is necessary to
 protect the public health, safety, or welfare from significant and discernible harm or damage and
 that the state's police power be exercised only to the extent necessary for that purpose; and
- No profession or occupation be regulated in a manner that unnecessarily restricts entry into the practice of the profession or occupation or adversely affects the availability of the services to the public.¹

The Legislature must review all legislation proposing regulation of a previously unregulated profession or occupation and make a determination for regulation based on consideration of the following:

- Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote;
- Whether the practice of the profession or occupation requires specialized skill or training, and
 whether that skill or training is readily measurable or quantifiable so that examination or training
 requirements would reasonably assure initial and continuing professional or occupational ability;
- Whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment;
- Whether the public is or can be effectively protected by other means; and
- Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.²

The act requires the proponents of legislation for the regulation of a profession or occupation to provide specific information in writing to the state agency that is proposed to have jurisdiction over the regulation and to the legislative committees of reference.³ This required information is traditionally compiled in a "Sunrise Questionnaire."

Music Therapy

Music therapy is the specialized use of music by a credentialed professional who develops individualized treatment and supportive interventions for people of all ages and ability levels to address their social, communication, emotional, physical, cognitive, sensory and spiritual needs.⁴ After assessing the strengths and needs of each client, the qualified music therapist provides the indicated treatment including creating, singing, moving to, and/or listening to music.⁵ Through this treatment the

¹ S. 11.62(2), F.S.

² S. 11.62(3), F.S.

³ S. 11.62(4), F.S.

⁴ THE CERTIFIED BOARD FOR MUSIC THERAPISTS, http://www.cbmt.org/ (last visited December 15, 2015).

⁵ AMERICAN MUSIC THERAPY ASSOCIATION, What is Music Therapy, http://www.musictherapy.org/about/musictherapy/ (last visited December 15, 2015).

clients' abilities are strengthened and transferred to other areas of their lives. 6 Music therapy also provides avenues for communication that can be helpful to those who find it difficult to express themselves in words. Research in music therapy supports its effectiveness in many areas such as: overall physical rehabilitation and facilitating movement, increasing people's motivation to become engaged in their treatment, providing emotional support for clients and their families, and providing an outlet for expression of feelings.8

Clinical populations served by music therapy range in age from neonates in the NICU to older adults in hospice care. Music therapy services are provided in a variety of clinical settings, including psychiatric hospitals, rehabilitative facilities, medical hospitals, outpatient clinics, day care treatment centers. agencies serving persons with developmental disabilities, community mental health centers, drug and alcohol programs, senior centers, nursing homes, hospice programs, correctional facilities, halfway houses, schools, and private practice. 10

Music Therapists

Music therapists typically work with individuals who have special needs, which may include medical. learning and academic, mental health, rehabilitation, developmental, communication, or wellness needs. The use of live music interventions demands that the therapist not only possess the knowledge and skills of a trained therapist, but also the unique skill set of a trained musician in order to manipulate the music therapy intervention to fit clients' needs. ¹² Given the diversity of diagnoses with which music therapists work and the practice settings in which they work independently, clinical training and experience are necessary. 13

A music therapist's clinical practice is guided by the integration of the best available research evidence. the client's needs, values, and preferences, and the expertise of the clinician. 4 Music therapists are trained to independently analyze client non-verbal, verbal, psychological, and physiological responses to music and non-music stimuli in order to be clinically effective and refrain from contra-indicated practices. 15 Music therapists use their knowledge, skills, training and experience to facilitate therapeutic, goal oriented music-based interactions that are meaningful and supportive to the function and health of their clients. 16

Accredited Music Therapy Degree Programs

In order to become a credentialed music therapist, a student must earn a bachelor's degree or higher in music therapy from an American Music Therapy Association's (AMTA's) approved college or university. These programs require academic coursework and 1,200 hours of clinical training, including an approved supervised internship.¹⁷ Qualified supervision of clinical training is required and coordinated or verified by the academic institution.¹⁸

⁶ AMERICAN MUSIC THERAPY ASSOCIATION, What is Music Therapy: Definitions and Quotes About Music Therapy, http://www.musictherapy.org/about/quotes/ (last visited December 15, 2015).

⁸ ld.

⁹ FLORIDA SENATE SUNRISE QUESTIONNAIRE, Submitted by the Florida Music Therapy State Task Force, December 16, 2015 (on file with Health Quality Subcommittee Staff).

¹¹ ld.

¹² American Music Therapy Association, Scope of Music Therapy Practice (2015), available at http://www.cbmt.org/upload/CBMT-12 AMTA SoMTP V6.pdf (last visited December 15, 2015).

¹⁴ ld

¹⁵ ld.

An internship may be approved by the academic institution, the AMTA, or by both.

¹⁸ Internship supervisors must meet minimum requirements outlined by the AMTA Education and Clinical Training Standards. A music therapy internship supervisor must have a clinical practice in music therapy (either private or institutional) and demonstrate the following: all professional level competencies; effectiveness as a music therapy clinician in at least one area of practice; general STORAGE NAME: h0571.HQS

Currently in Florida, Florida State University (FSU)¹⁹ and the University of Miami (UM)²⁰ have the only accredited music therapy programs. FSU and UM both offer Bachelor's, Master's, and Doctoral degrees in Music Therapy. 21 FSU graduates approximately 35 - 40 students annually and UM graduates 10 - 12 students annually

National Certification of Music Therapists

There are two national organizations that recognize the music therapy profession: the AMTA and the Certification Board for Music Therapists (CBMT). The CBMT is the only organization that credentials music therapists nationally.²² The professional credential, MT-BC, is granted to individuals who have successfully completed an AMTA-approved academic and clinical training program and have passed a written objective national examination.²³ Currently, a majority of music therapists hold the MT-BC credential.24

The National Music Therapy Registry previously qualified music therapy professionals with the following designations: Registered Music Therapist (RMT), Certified Music Therapist (CMT), or Advanced Certified Music Therapist (ACMT). 25 While new RMT, CMT, and ACMT designations are no longer awarded, individuals who have received and continue to maintain these designations have met certain educational and clinical training standards.²⁶

The Florida Music Therapy State Task Force estimates that there are 253 MT-BC, four RMT, and four CMT in Florida.27

Regulation of Music Therapists

Music therapists are bound by the AMTA Code of Ethics, AMTA Standards of Clinical Practice, CBMT Code of Professional Practice, CBMT Board Certification Domains, and other applicable state and federal laws.²⁸ Both AMTA and CBMT have mechanisms by which music therapists who are in violation of safe and ethical practice are investigated.²⁹

Regulation of music therapists is a recent development at the state level. Wisconsin was the first state, in 1998, to regulate music therapists under its State Registry for Music Therapists through the Wisconsin Department of Regulation and Licensing. Wisconsin does not license state music therapists, and registration is voluntary.³⁰ Music Therapists were first licensed in the states of North Dakota³¹ and Nevada³² in 2011 and Georgia³³ in 2012. In 2014 Rhode Island created a music therapy

understanding of the supervisory needs of internship students, and established skills in supervision. See AMERICAN MUSIC THERAPY ASSOCIATION, AMTA Standards for Education and Clinical Training, http://www.musictherapy.org/members/edctstan/ (last visited December 15, 2015).

FLORIDA STATE UNIVERSITY COLLEGE OF Music, Music Therapy, http://www.music.fsu.edu/Areas-of-Study/Music-Therapy (last visited

²⁰ FROST SCHOOL OF MUSIC UNIVERSITY OF MIAMI, Music Therapy Program, http://www.miami.edu/frost/index.php/music_therapy/ (last visited December 16, 2015).

²¹ Supra, notes 19, 20. ²² Supra, note 4.

THE CERTIFIED BOARD FOR Music Therapists, About Certification, http://www.cbmt.org/about-certification/ (last visited December 15,

Supra, note 4. Over 6,638 music therapists currently maintain the MT-BC credential.

²⁵ American Music Therapy Association, *How to Find a Music Therapist*, http://www.musictherapy.org/about/find/ (last visited December 15, 2015).

ld. These designations were granted prior to 1998 and will expire in 2020. Supra, note 9.

Supra, note 9.

²⁸ Supra, note 12.

³⁰ WISCONSIN CHAPTER FOR MUSIC THERAPY, Wisconsin Music Therapy Registry (2015), http://musictherapywisconsin.org/about-us/wmtr/ (last visited December 14, 2015).

Supra, note 9 at 11. Music therapists are licensed through a newly created Board of Integrative Health.

³² Id. Music therapists are licensed through the Nevada State Board of Health.

³³ Id. The music therapy license is overseen by the Secretary of State and utilizes an ad hoc volunteer Advisory Council. STORAGE NAME: h0571.HQS

registry that is administered by the Rhode Island Department of Health and Utah established state certification for board certified music therapists that is granted by Utah's Division of Occupational and Professional Licensing. 34 Oregon initiated licensure in 2015. 35

Music therapists are not presently regulated in Florida by the Department of Health (DOH) or the Division of Medical Quality Assurance (MQA) within DOH.

Need for Regulation of Music Therapists in Florida

Based on the information in a Sunrise Questionnaire, completed by the Florida Music Therapy State Task Force, ³⁶ Florida music therapists are seeking regulation to protect the public, including certain vulnerable populations treated by music therapists, and to increase consumer access to music therapy services. 37 The Florida Music Therapy State Task Force claims that regulating music therapy would provide the public with assurance that they are protected from the misuse of terms and techniques by unqualified individuals and to ensure competent practice. Also, regulation would prevent unqualified individuals from having access to clients' confidential information and potentially compromising clients' health and wellness issues.38

According to the Florida Music Therapy State Task Force, access to medically, behaviorally, or educationally necessary music therapy services would be improved by regulation, as residents would be able to locate qualified providers recognized by the state. There are some settings where the Florida Music Therapy State Task Force believes regulation is necessary, as with school districts; where lack or regulation prevents individuals from accessing services. Furthermore, the Florida Music Therapy State Task Force claims that access to qualified music therapists would also be made easier for employers and that facilities interested in providing music therapy services would be able to utilize the state system to locate qualified professionals.39

Additionally, according to the Florida Music Therapy State Task Force, there are a growing number of unqualified individuals in the state claiming to be music therapists who do not hold a music therapy degree from an accredited institution or carry the national credential of MT-BC. This potential harm to the public includes misrepresentation of the music therapy profession, as these individuals hold themselves out to the public as being able to produce outcomes that are not based upon evidencebased practice. Their lack of formalized training and credentials may pose unnecessary and unintended risks to clients. 40 For example, the Florida Music Therapy State Task Force states that:

- If the music stimulus is too complex for one's neurological system, it may cause increased agitation and dysregulation.
- Noncompliance with safety protocols and guidelines in the clinical environment, including those related to appropriate sound environment, can result in injury.
- Music has the potential to elicit or evoke intense emotions. The lack of, or ineffective therapeutic responses to, or processing of, these emotions may lead to short term and/or long term social and psychological damage.4

Regulation of Florida Health Care Practitioners

The MQA within DOH and the boards under MQA are responsible for the licensure of health care practitioners in the state. In addition to the regulatory authority in specific practice acts for each

³⁵ Oregon HB 2796A, Chapter 632 (2015 Laws), was signed by the Governor and took effect on July 1, 2015.

³⁶ Supra, note 9 at 4. The Task Force was voluntarily created by approval from the AMTA and CBMT.

³⁷ Id. at 6.

³⁸ ld.

³⁹ ld.

⁴⁰ Id. at 7.

profession or occupation, ch. 456, F.S., provides the general regulatory provisions for health care practitioners. Section 456.001, F.S., defines "health care practitioner" as any person licensed under chapters 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 physicists), 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.

Effect of Proposed Changes

HB 571 creates s. 490.0146, F.S., to require the registration of music therapists. This creates a new regulated industry.

The bill defines "music therapy" as the clinical and evidenced-based use of music intervention by a registered music therapist to accomplish individualized goals for persons of all ages and abilities within a therapeutic relationship and specifies that music therapy does not include the diagnosis or assessment of any physical, mental, or communication disorder.

The bill specifies that any person wishing to work as a music therapist in Florida must register by filing an application with the Florida Board of Psychology (the Board). The Board is required to register each applicant who:

- Remits a registration fee, set by the Board, not to exceed \$50.00 biennially;
- Has completed the application;
- Submits a nonrefundable application fee, set by the Board, not to exceed \$50.00;
- Is at least 17 years old; and
- Has completed a board-approved music therapist training program.

The bill provides that registration renewal be conditioned upon completion of 20 hours of continuing education courses each biennium. The continuing education courses must be approved by the AMTA, or its successor.

The bill requires the Board to adopt rules to:

- Create an application form;
- Establish a registration fee, not to exceed \$50.00 biennially;
- Establish an application fee, not to exceed \$50.00;
- Approve music therapy training programs; and
- Require the display of a registration in a manner that is available to the public and facilitates inspection by DOH.

The bill also provides authority to the Board to develop other rules as necessary to administer the registration of music therapists.

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

B. SECTION DIRECTORY:

Section 1: Creates s. 490.0146, relating to registered music therapists.

Section 2: Provides an effective date of July 1, 2016.

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II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

DOH/MQA will experience an increase in revenues associated with music therapy registration and renewal fees. CBMT indicates that there are over 6,549 music therapists with MT-BC credentials nationwide, yet it is unknown by DOH how many are in Florida; therefore the fiscal impact is indeterminate at this time.

2. Expenditures:

DOH/MQA will incur a recurring increase in workload and costs associated with the regulation of music therapists. CBMT indicates that there are over 6,549 music therapists with MT-BC credentials nationwide, yet it is unknown by DOH how many are in Florida; therefore the fiscal impact is indeterminate at this time.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Music therapists currently maintaining MT-BC credentials, will be required to pay registration and renewal fees to become registered and maintain their registration in Florida.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides rulemaking authority to the Board to develop new rules related to the application, fees, training programs, display of the registration and any other rules needed to administer the section.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Several provisions in s. 490.009, F.S., relating to administrative discipline, reference "license" but not "registration." Language that specifies music therapists will be subject to disciplinary action may be

STORAGE NAME: h0571.HQS DATE: 1/4/2016 needed to clarify that their registrations are also subject to discipline. Additionally, subsection 490.0146(4), F.S., specifies that registration is issued by the "board." However, DOH, not the board, issues "licenses" or "registrations."

DOH believes that additional time will be required to establish the parameters for this profession; rule development, staff training, database development, website creation, application and rule development are unlikely to be in place by July 1, 2016.⁴²

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

⁴² Department of Health, Agency Bill Analysis of 2016 House Bill 571, (November 5, 2015) (on file with Health Quality Subcommittee Staff)

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HB 571 2016

1	A bill to be entitled
2	An act relating to music therapy; creating s.
3	490.0146, F.S.; providing definitions; providing
4	requirements for the registration of music therapists;
5	providing for an application fee; requiring the Board
6	of Psychology to adopt rules; providing an effective
7	date.
8	
9	Be It Enacted by the Legislature of the State of Florida:
10	
11	Section 1. Section 490.0146, Florida Statutes, is created
12	to read:
13	490.0146 Registered music therapists.—
14	(1) As used in this section, the term:
15	(a) "Board" means the Board of Psychology.
16	(a) "Music therapist" means a person registered to
17	practice music therapy pursuant to this section.
18	(b) "Music therapy" means the clinical and evidence-based
19	use of music intervention by a registered music therapist to
20	accomplish individualized goals for people of all ages and
21	ability levels within a therapeutic relationship. The term does
22	not include the diagnosis or assessment of any physical, mental,
23	or communication disorder.
24	(2) Any person who wishes to work as a music therapist in
25	this state must register by filing an application with the board
26	on a form adopted by rule of the board. The board shall register

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

HB 571 2016

each applicant who has remitted a registration fee set by the board, not to exceed \$50 biennially; has completed the application form and remitted a nonrefundable application fee set by the board, not to exceed \$50; is at least 17 years of age; and has completed a music therapist training program approved by the board.

- (3) As a condition of registration renewal, a registered music therapist shall complete 20 hours biennially of continuing education courses approved by the board or the American Music Therapy Association or its successor.
- registration issued by the board under this section to be displayed in such a manner as to make it available to the public and to facilitate inspection by the department. The board may adopt other rules as necessary to administer this section.
 - Section 2. This act shall take effect July 1, 2016.

COMMITTEE/SUBCOMMITTEE AMENDMENT Bill No. HB 571 (2016)

Amendment No.

	COMMITTEE/SUBCOMMITTEE ACTION	
,	ADOPTED (Y/N)	
	ADOPTED AS AMENDED (Y/N)	
	ADOPTED W/O OBJECTION (Y/N)	
	FAILED TO ADOPT (Y/N)	
	WITHDRAWN (Y/N)	
	OTHER	
1	Committee/Subcommittee hearing bill: Health Quality	Money
2	Subcommittee	
3	Representative Campbell offered the following:	
4		
5	Amendment (with title amendment)	
6	Remove everything after the enacting clause and insert:	
7	Section 1. Section 491.017, Florida Statutes, is created	
8	to read:	
9	491.017 Registration of Music Therapists	
10	(1) LEGISLATIVE INTENT The intent of this section is to	2
11	recognize that music therapy affects public health, safety, and	
12	welfare, and that the practice of music therapy should be	
13	subject to regulation to protect the public from the practice of	
14	music therapy by unregistered individuals.	
15	(2) DEFINITIONS	
16	(a) "Board certified music therapist" means an individual	
17	who has completed the education and clinical training	

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requirements established by the American Music Therapy

Association, and who holds current board certification from the

national Certification Board for Music Therapists.

- (b) "Music therapist" means a person registered to practice music therapy pursuant to this section.
- (c) "Music therapy" means the clinical and evidence based use of music interventions to accomplish individualized goals for people of all ages and ability levels within a therapeutic relationship by a board certified music therapist. The music therapy interventions may include, music improvisation, receptive music listening, song writing, lyric discussion, music and imagery, singing, music performance, learning through music, music combined with other arts, music-assisted relaxation, music-based patient education, electronic music technology, adapted music intervention and movement to music. The practice of music therapy does not include the diagnosis or assessment of any physical, mental, or communication disorder. This term includes:
- 1. Accepting referrals for music therapy services from medical, developmental, mental health, or education professionals; family members; clients; caregivers or others involved and authorized with provision of client services;
- 2. Collaborating with primary care providers to review the client's diagnosis, treatment needs, and treatment plan before providing services to a client with an identified clinical or developmental need, or collaborating with the client's treatment

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 team while providing music therapy services to the client;

- 3. Conducting a music therapy assessment of a client to determine if treatment is indicated, and if so, collecting systematic, comprehensive, and accurate information to determine the appropriateness and type of music therapy services to provide for the client;
- 4. Developing an individualized music therapy treatment plan, including individualized goals, objectives, and specific music therapy approaches or interventions, for the client that is based upon the results of the music therapy assessment;
- 5. Developing and implementing an individualized music therapy treatment plan that is consistent with any other developmental, rehabilitative, habilitative, medical, mental health, preventive, wellness care, or educational services being provided to the client;
- 6. Evaluating the client's response to music therapy and the music therapy treatment plan, documenting change and progress and suggesting modifications, as appropriate;
- 7. Developing a plan for determining when the provision of music therapy services is no longer needed in collaboration with the client, physician, or other provider of health care or education of the client, family members of the client, and any other appropriate person upon whom the client relies for support;
- 8. Minimizing any barriers to ensure that the client receives music therapy services in the least restrictive

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environment;

- 9. Collaborating with and educating the client and the family or caregiver of the client, or any other appropriate person regarding the needs of the client that are being addressed in music therapy and the manner in which the music therapy treatment addresses those needs; and
- 10. Utilizing appropriate knowledge and skills to maintain informed practice including use of research, reasoning, and problem solving skills to determine appropriate actions in the context of each specific clinical setting.
 - (3) REGISTRATION. -
- (a) The department shall register an applicant as a music therapist when the applicant submits to the department:
 - 1. A completed application form issued by the department;
 - 2. Application and registration fees; and
- 3. Proof of passing the examination for board certification offered by the national Certification Board for Music Therapists, or any successor organization, or submits proof of being transitioned into board certification, and submits proof that the applicant is currently a board certified music therapist.
- (b) A music therapist registered under this section shall renew such registration biennially by submitting to the department a renewal fee and proof that the applicant holds an active certificate as a board certified music therapist.
 - (c) A registrant shall inform the department within 10

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Bill No. HB 571 (2016)

Amendment No.

days of a change of the registrant's address or change in status as a board certified music therapist.

- (4) PROHIBITED ACTS; EXEMPTIONS.— A person shall not practice music therapy or represent himself or herself as being able to practice music therapy in this state unless the person is registered pursuant to this section. Nothing in this section may be construed to prohibit or restrict the practice, services, or activities of the following:
- (a) Any person licensed, certified, or regulated under the laws of this state in another profession or occupation or personnel supervised by a licensed professional in this state performing work, including the use of music, incidental to the practice of his or her licensed, certified, or regulated profession or occupation, if that person does not represent himself or herself as a music therapist;
- (b) Any person whose training and national certification attests to the individual's preparation and ability to practice his or her certified profession or occupation, if that person does not represent himself or herself as a music therapist;
- (c) Any practice of music therapy as an integral part of a program of study for students enrolled in an accredited music therapy program, if the student does not represent himself or herself as a music therapist; or
- (d) Any person who practices music therapy under the supervision of a registered music therapist, if the person does not represent himself or herself as a music therapist.

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(′.5.	DEPARTMENT	AUTHORITY
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- (a) The department is authorized to establish application, registration, and renewal fees estimated necessary to implement the provisions of this section, but each fee shall not exceed \$50.
- (b) The department is authorized to adopt rules to implement this section.
- (c) The department may deny or revoke registration or renewal of registration for failing to meet the requirements in this section.

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

TITLE AMENDMENT

Remove everything before the enacting clause and insert:
An act relating to music therapists; amending s. 491.017, F.S.;
providing definitions; requiring registration to provide music
therapy services; providing registration criteria; requiring
biennial renewal of registration; prohibiting the practice of
music therapy unless registered; providing exemptions to
registration; providing the Department of Health with rulemaking
and disciplinary authority; providing an effective date.

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