

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Appropriations

BILL: CS/SB 7078

INTRODUCER: Appropriations Committee (Recommended by Appropriations Subcommittee on Health and Human Services); and Health Policy Committee

SUBJECT: Health Care

DATE: April 22, 2019 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
	Williams, et al	Brown		HP Submitted as Committee Bill
1.	Loe	Kidd	AHS	Recommend: Fav/CS
2.	Loe	Kynoch	AP	Fav/CS

Please see Section IX. for Additional Information:
 COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 7078 addresses a variety of health care and health insurance issues, including:

- Access to dental services;
- Transparency of hospital quality information;
- Access to primary and specialist care in a hospital setting;
- Ambulatory surgical center services;
- Pediatric cardiac standards of care;
- Patient notification of hospital observation status;
- Health care contracts in restraint of trade or commerce;
- Expansion of direct health care agreements;
- Consumer cost-containment in health insurance; and
- Portability of health care occupational licensure in the United States.

The bill has an indeterminate fiscal impact on state revenues and state expenditures. The increase in state expenditures related to the expanded duties of the Pediatric Cardiac Technical Advisory Panel is addressed in SB 2500, First Engrossed, the Senate’s proposed General Appropriations Bill for the 2019-2020 fiscal year.

The bill has an effective date of July 1, 2019, except as otherwise provided in the bill.

II. Present Situation:

Access to Dental Services

Federal Responsibilities

Health Resources and Services Administration

The Health Resources and Services Administration (HRSA) within the United States Department of Health and Human Services (HHS), is charged with, among other responsibilities, improving health care for individuals who are geographically isolated, or economically or medically vulnerable.¹ Four of the five HRSA goals focus on access to care through either building a healthy workforce or improvements in accessing quality care and services.²

The HRSA’s workforce programs are designed to strengthen and improve the health care workforce and to connect skilled professionals to communities in need. The HRSA’s Bureau of Health Workforce (BHW) supports workforce training and seeks to expand the availability of clinicians, including dental practitioners, in high-need areas, including in urban, rural, and frontier locations.³ To determine the state’s need, the chart below illustrates Florida’s dental practitioner status, including the percentage of current need that is being met for Florida’s dental HPSA compared to data nationwide.

Florida’s Dental HPSA Snapshot Compared to National Data ^{4,5}							
Number of Sites in Designations <i>(geographic area, population group, or facility)</i>		Population Covered by Designation <i>Low income population 200 percent FPL</i>		Number of Practitioners Needed Projected - 2025 ⁶		Percent of Projected Need Met – 2025	
<i>Nat’l</i>	<i>FL</i>	<i>Nat’l</i> ⁷	<i>FL</i>	<i>Nat’l</i>	<i>FL</i>	<i>Nat’l</i>	<i>FL</i>
5,732	235	20,501,816	1,420,551	28,100	1,152	35.28%	13.28%

According to a February 2015 HRSA study of the dental workforce, all 50 states and the District of Columbia will face a shortage of dentists by 2025. At the national level, the demand for

¹ U.S. Dep’t of Health and Human Services, HRSA, *About HRSA*, <https://www.hrsa.gov/about/index.html> (last visited Feb. 26, 2019).

² *Id.*

³ U.S. Dep’t of Health and Human Services, HRSA, *HRSA Fact Sheet – FY 2018 – Florida*, <https://data.hrsa.gov/data/fact-sheets> (last visited Feb. 26, 2019).

⁴ *Id.*

⁵ U.S. Dep’t of Health and Human Services, HRSA, *HRSA Fact Sheet – FY 2018 – Nation*, <https://data.hrsa.gov/data/fact-sheets> (last visited Feb. 26, 2019).

⁶ U.S. Dep’t of Health and Human Services, HRSA, *National and State-Level Projections of Dentists and Dental Hygienists in the U.S., 2012-2025 (February 2015)*, <https://bhw.hrsa.gov/sites/default/files/bhw/nchwa/projections/nationalstatelevelprojectionsdentists.pdf> (last visited Feb. 27, 2019).

⁷ U.S. Dep’t of Health and Human Services, HRSA, *Shortage Areas*, <https://data.hrsa.gov/data/fact-sheets> (last visited Feb. 26, 2019).

dentists shows a ten percent increase over the need from 2012, from 197,800 to 218,200.⁸ Florida has the second highest level of projected demand, behind only California, with 1,152 dentists needed by 2025.⁹

Multiple national surveys of dentists since the 1950s through today have found significant shifts in the demographics of dentists. For example:¹⁰

- In the 1980s, less than 3 percent of the dental workforce were women. Today, women represent 27 percent of the dental workforce.
- In 1975, less than 10 percent of all working dentists worked part-time. Today, an estimated 14 percent of all working dentists in private practice and 12 percent of all dentists work part-time.
- In 1950, only 0.5 percent of all dentists were employed by another dentist; however, from 2007-2009 almost 17 percent of all active dentists were employees. Among private practitioners, 44 percent of dentists were employees.
- In 1970, less than 10 percent of all active dentists were specialists. Today, approximately 22 percent of dentists are specialists.

In 1975, the profile of a dentist indicated someone who was generally younger than age 45 and male (98 percent). Today, 42 percent of dentists are at least 55 years of age with only 31 percent younger than 45 years of age.

Health Professional Shortage Areas

Health Professional Shortage Areas (HPSAs) are designated by the HRSA according to criteria developed in accordance with section 332 of the Public Health Services Act. HPSA designations are used to identify areas within the United States that are experiencing a shortage of health care professionals or have population groups who face specific barriers to health care. An HPSA can be a geographic area, a population group, or a health care facility. These areas have a shortage of health care professionals or have population groups who face specific barriers to health care.

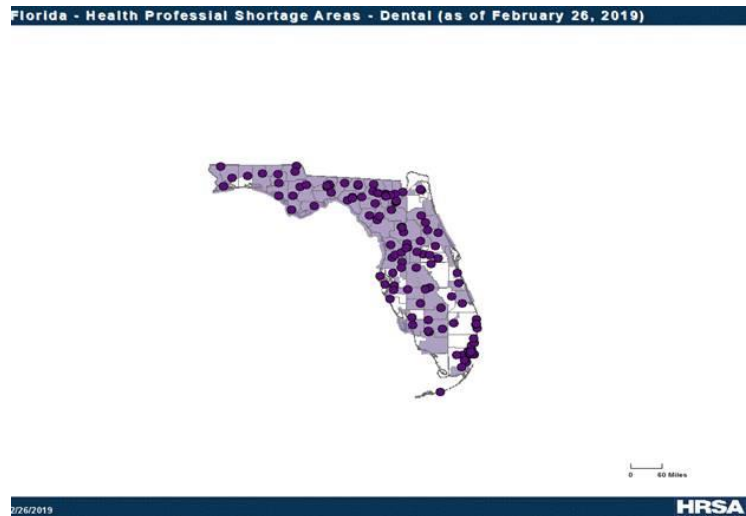
There are three categories for a HPSA designation: (1) primary medical care; (2) dental; and (3) mental health. The map below shows the locations of the current dental HPSAs in Florida.¹¹

⁸ U.S. Dep't of Health and Human Services, *supra* note 6.

⁹ *Id.*

¹⁰ Eric Soloman, DDS, MA, *Dental workforce trends and the future of dental practices*, DENTAL ECONOMICS <https://www.dentaleconomics.com/articles/print/volume-105/issue-2/macroeconomics/dental-workforce-trends-and-the-future-of-dental-practices.html> (last visited Feb. 27, 2018).

¹¹ Map generated based on information held in the U.S. Dep't of Health and Human Services, HRSA Data Warehouse, *Dental Health Professional Shortage Areas (HPSAs) Primary Dataset*, <https://datawarehouse.hrsa.gov/Tools/DataPortalResults.aspx> (results last generated on Feb. 26, 2019).



The primary factor used to determine a HPSA designation is the number of health professionals relative to the population, with consideration of high need. State Primary Care Offices, usually located within a state's main health agency, apply to HRSA for most designations of HPSAs in their states. HRSA will review provider-level data, whether providers are actively engaged in clinical practice, if a provider has any additional practice locations, the number of hours served at each location, the populations served, and the amount of time that a provider spends with specific populations.¹² Primary care and mental health HPSAs can receive a score up to 25 points and dental health can receive a score up to 26 points.¹³

Three scoring criteria are common across all disciplines HPSA (primary care medical, dental, and mental health):

- The population to provider ratio;
- The percentage of the population below 100 percent of the federal poverty level;¹⁴ and
- The travel time to the nearest source of care outside of the HPSA designation.¹⁵

The dental scoring system also reviews the water fluoridation status of the areas. The components of the dental scoring system are then calculated using the points system shown below to arrive at a total score of up to 26 points.¹⁶

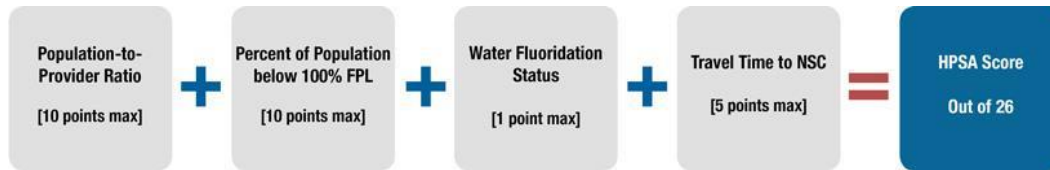
¹² U.S. Dep't of Health and Human Services, HRSA Health Workforce, *Health Professional Shortage Area (HPSA) Shortage Application and Scoring Process*, Shortage Designation Management System, <https://bhw.hrsa.gov/shortage-designation/application-scoring-process> (last visited Feb. 26, 2019).

¹³ U.S. Dep't of Health and Human Services, HRSA Health Workforce, *Health Professional Shortage Area (HPSA) Shortage Application and Scoring Process*, <https://bhw.hrsa.gov/shortage-designation/hpsa-process> (last visited Feb. 26, 2019)

¹⁴ For a family of 4, the maximum income at 100 percent of the federal poverty level is approximately \$25,750 annually. The 2019 federal Health and Human Services income guidelines can be found at <https://aspe.hhs.gov/poverty-guidelines>.

¹⁵ U.S. Dep't of Health and Human Services, *supra*, note 12.

¹⁶ *Id.*



Certain facilities are automatically designated as HPSAs based either on statute or regulations which govern shortages or the type of facility. For example, federally qualified health centers (FQHCs) have a different scoring structure. These facilities may often have multiple sites under one organization. In those instances, the scores of all the related organizations are averaged together to attain a single score for the overall organization.¹⁷

Rural Health Clinics (RHCs) submit a Certificate of Eligibility form.¹⁸ The form requires the RHC to include its RHC Certification letter from the federal Centers for Medicare and Medicaid Services, a copy of its sliding fee scale, agreement to accept Medicare beneficiaries, Medicaid, and CHIP patients, and to make every effort to collect patient fees.¹⁹

Medically Underserved Area

Medically Underserved Areas (MUAs) are also designated by the HRSA. These areas are designated using one of three methods and can consist of a whole county, a group of contiguous counties, or census tracts having too few health care providers, high infant mortality or poverty rates, or a high elderly population.²⁰ Nationally, there are 3,581 such designated areas, with 128 designated in Florida.²¹

The first method, the Index of Medical Underservice (IMU), calculates a score based on the ratio of primary medical care physicians per 1,000 in population, percentage of the population with incomes below the federal poverty level, infant mortality rate, and percentage of population aged 65 or older.²²

The second method, Medically Underserved Populations (MUP), is based on data collected under the MUA 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.²³

The third process, Exceptional MUP Designations, includes those population groups that do not meet the criteria of an IMU but may be considered for designation because of unusual conditions

¹⁷ *Id.*

¹⁸ U.S. Dep't of Health and Human Services, HRSA Health Workforce, *Certificate of Eligibility as an Automatic HPSA*, <https://bhw.hrsa.gov/sites/default/files/bhw/shortagedesignation/BHW%20Certificate%20of%20Eligibility%20Form%20%2810.20.16%29%20v%200.1.3.pdf> (last visited Feb. 26, 2019).

¹⁹ *Id.*

²⁰ U.S. Dep't of Health and Human Services, HRSA Health Workforce, *Medically Underserved Areas and Populations (MUA/Ps)*, <https://bhw.hrsa.gov/shortage-designation/muap> (last visited Feb. 28, 2019).

²¹ U.S. Dep't of Health and Human Services, HRSA, *Shortage Areas*, <https://data.hrsa.gov/topics/health-workforce/shortage-areas> (last visited Feb. 27, 2019).

²² U.S. Dep't of Health and Human Services, HRSA, *Shortage Designation*, <https://bhw.hrsa.gov/shortage-designation/muap-process> (last visited Feb. 27, 2019).

²³ *Supra* note 20.

with a request by the governor or another senior executive level official and a local state health official.²⁴

Medicaid

In 2011, the Legislature passed HB 7107²⁵ creating the Statewide Medicaid Managed Care (SMMC) program as part IV of ch. 409, F.S. The program has two primary components: Managed Medical Assistance (MMA) and Long-Term Care Managed Care (LTCMC). To implement MMA, the law required the AHCA to create an integrated managed care program for the delivery of Medicaid primary and acute care services, including dental. Medicaid recipients who are enrolled in MMA initially received their dental services and other medical services through the same managed care plan. With the recent re-procurement of the SMMC contracts, the dental benefits were carved out of the MMA contracts and separately procured. Three statewide SMMC dental plans were selected as a result of that procurement: Managed Care of North America (MCNA), DentaQuest of Florida, and Liberty Dental Plan.

Medicaid dental benefits are currently being delivered to recipients in MMA, fee-for-service reimbursement systems, iBudget waiver participants, and Medically Needy enrollees under the separately procured dental contracts.²⁶ Preexisting enrollees were required to select a dental plan as their regions were implemented, starting in December 2018. Most dental services are designated as a required benefit only for Medicaid recipients under age the age of 21; however, the dental plans are also providing adult benefits at no extra cost to the state.²⁷

The Dental Workforce

Workforce Studies

The Health Policy Institute (HPI) for the American Dental Association (ADA) recently updated its estimates on the future supply of dentists and concluded Florida's per capita supply of dentists is projected to increase through 2035.²⁸ The unadjusted number of dentists per 100,000 in population increases from 52.0 in 2015 to 56.9 in 2035.²⁹ The per capita calculation performed in this report is a headcount of total dentists in comparison to the state's total population. The study was based on a headcount of 10,781 dentists and a state population of 20.6 million.

One drawback to a per capita count of dentists is that the study does not consider the location of the providers and any access to care issues in particular regions or the needs of special populations. For example, a shortage could be only for participation by dental health providers in public programs such as Medicaid and the Children's Health Insurance Program (CHIP), two

²⁴ *Supra* note 22.

²⁵ See chapter 2011-134, Laws of Fla.

²⁶ Agency for Health Care Administration, *Statewide Medicaid Managed Care Dental Program Overview Presentation* (October 2018), Slides 21-30, https://ahca.myflorida.com/Medicaid/statewide_mc/pdf/SMMC_Dental_Overview.pdf (visited Feb. 27, 2019).

²⁷ AHCA, Invitation to Negotiate 012-17/18 (Oct. 16, 2017). A copy of the ITN can be downloaded from http://www.myflorida.com/apps/vbs/vbs_www.ad_r2.view_ad?advertisement_key_num=137442 (last visited Feb. 27, 2019). See also Chapter 2016-109, Laws of Fla.

²⁸ American Dental Association, Health Policy Institute, *Projected Supply of Dentists: Florida*, <https://www.ada.org/~media/ADA/Science%20and%20Research/HPI/ProjectedSupplyofDentists/Florida-Projected-Supply-of-Dentists.pdf?la=en> (last visited Feb. 27, 2019).

²⁹ *Id.*

programs that serve high numbers of children and families from low and moderate income families. Florida’s dental provider participation rate in these public programs is 30 percent while the national average is 39 percent.³⁰ The HPI’s data indicates that 96 percent of publicly insured children live within 15 minutes of a Medicaid dentist.³¹

The chart below shows the current national participation rate by dental providers by type of provider.

Type of Provider	2015	2016	2017
<i>National %</i>	<i>% Public Assistance</i>	<i>% Public Assistance</i>	<i>% Public Assistance</i>
General Practitioner	36.4%	37.3%	32.9%
Specialists	35.5%	41.4%	33.5%
All Dentists	36.2%	38.2%	33.1%

Most dentists practice in general dentistry (157,676 dentists) followed by orthodontics as a distant second (10,779).³³ In many rural communities, the county health department may be the primary provider of health care services, including dental care. According to the Department of Health (DOH), Florida’s current designated dental HPSAs have only enough dentists to serve 13.22 percent of the population living within them.³⁴ According to the DOH, there are seven currently vacant dentist positions in the DOH itself.³⁵ As of December 31, 2018, HRSA estimated that 1,266 additional dentists were required to meet the state’s total need and eliminate the state’s shortage.³⁶

The ADA has also studied this issue and found that while there may be a sufficient number of dentists overall for the state’s population or the national population, there may be an inadequate number available for certain populations or geographic areas.³⁷ Children are acutely affected by

³⁰ American Dental Association, *Dentist Participation in Medicaid or CHIP*, https://www.ada.org/~media/ADA/Science%20and%20Research/HPI/Files/HPIGraphic_0318_1.pdf?la=en (last visited Feb. 27, 2019).

³¹ Health Policy Institute, American Dental Association, *Geographic Access to Dental Care: Florida*, <https://www.ada.org/~media/ADA/Science%20and%20Research/HPI/AccessToDentalCare-StateFacts/Florida-Access-To-Dental-Care.pdf> (last visited Feb. 27, 2019).

³² Health Policy Institute, American Dental Association, *Dental Practice – 2017 Characteristics of Private Dental Practice – Table 4 – Percentage of Dentists’ Practices That Had Any Patients Covered by Public Assistance, 1990-2017* (January 2016), <http://www.ada.org/en/science-research/health-policy-institute/data-center/dental-practice> (last visited Feb. 28, 2019).

³³ *Id.*

³⁴ U.S. Dep’t of Health and Human Services, Bureau of Health Workforce – HRSA, *Designated Health Professional Shortage Areas Statistics* (as of December 31, 2017), https://ersrs.hrsa.gov/ReportServer?/HGDW_Reports/BCD_HPSA/BCD_HPSA_SCR50_Qtr_Smry_HTML&rc:Toolbar=false (last visited Feb. 28, 2019).

³⁵ Email from Bryan Wendell, Office of Legislative Planning, Florida Dep’t. of Health, (Feb. 27, 2019) (on file with the Senate Committee on Health Policy).

³⁶ U.S. Dep’t of Health and Human Services, HRSA, *Shortage Areas – Explore MUSAs Dashboard-Florida*, <https://data.hrsa.gov/topics/health-workforce/shortage-areas> (report last generated Feb. 28, 2019).

³⁷ Bradley Munson, B.A., and Marko Vujicic, Ph.D.: Health Policy Institute Research Brief, American Dental Association, *Supply of Dentists in the United States Likely to Grow*, p.2. (October 2014) http://www.ada.org/~media/ADA/Science%20and%20Research/HPI/Files/HPIBrief_1014_1.ashx (last visited Feb. 27, 2019).

the shortage of dentists to serve low-income patients. For example in Florida for federal fiscal year 2016, 37.6 percent of Medicaid-enrolled children and 42.8 percent of CHIP-enrolled children received preventive dental services.³⁸ For Medicaid, this was an increase from 2012, when only 26 percent of Medicaid-enrolled children received at least one dental care service.³⁹

Future Outlook for the Dental Workforce

According to the United States Department of Labor, Bureau of Labor Statistics, the occupational outlook for dental students is growing much faster than the average for other occupations for the time period between 2016 through 2026, and an estimated 29,300 additional jobs are anticipated during this same time period.⁴⁰ Florida has one metropolitan area in the top 10 list of highest paying areas for dentists: Sebring, which pays an annual median wage of \$269,300.⁴¹ Below is a chart comparing the mean annual wages of different types of dentists nationally and for Florida.

Comparison of Dental Professions by Mean Annual Wages – May 2017		
Dental Profession Type	Mean National Annual Wage	Mean State Annual Wage
Dentist, generally ⁴²	\$176,630	\$166,610
Oral & Maxillofacial Surgeons ⁴³	\$242,740	\$288,450
Orthodontists ⁴⁴	\$229,380	\$221,990
Dentists, all other specialists ⁴⁵	\$199,980	\$166,610

Wages can vary dramatically depending on the setting in which the provider is located. Generally, a provider located in a private office setting has higher wages, for example, an annual wage of \$176,630, while a dentist located in a hospital setting or in the office of another health care practitioner who is not a dentist, might have a significantly lower average annual wage, from \$138,480 to \$132,990.⁴⁶

³⁸ Brishke, J., Gaskins, J., and Shenkman, B., *Florida KidCare: The Florida KidCare Program Evaluation Calendar Year 2016* (Dec. 1 2017), p. 141, http://ahca.myflorida.com/medicaid/Policy_and_Quality/Quality/performance_evaluation/MER/contracts/med147/FL_KidCare_MED147_Deliverable_66_12-2017_Final.pdf (last visited Feb. 27, 2019).

³⁹ Agency for Health Care Administration, *Statewide Medicaid Managed Care Dental Program Overview Presentation* (October 2018), Slide 8, https://ahca.myflorida.com/Medicaid/statewide_mc/pdf/SMMC_Dental_Overview.pdf (visited Feb. 27, 2019).

⁴⁰ U.S. Dep’t of Labor, Bureau of Labor Statistics, *Occupational Outlook Handbook – Dentists*, <https://www.bls.gov/ooh/healthcare/dentists.htm#tab-1> (last visited Feb. 27, 2019).

⁴¹ U.S. Dep’t of Labor, Bureau of Labor Statistics, *Occupational Employment Statistics, May 2017 (Florida)*, <https://www.bls.gov/oes/current/oes291021.htm#st> (last visited Feb. 27, 2019).

⁴² U.S. Dep’t of Labor, Bureau of Labor Statistics, *Occupational Employment and Wages, May 2017, Dentists, General*, <https://www.bls.gov/oes/current/oes291021.htm#st> (last visited Feb. 27, 2019).

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ U.S. Dep’t of Labor, Bureau of Labor Statistics, *Occupational Employment and Wages, May 2017, Dentists, All Other Specialists*, <https://www.bls.gov/oes/current/oes291029.htm#st> (last visited Feb. 27, 2019).

⁴⁶ *Supra* note 42.

The Cost of Dental Education

According to a survey of dental school students, the average debt for graduates in 2017 was \$287,337,⁴⁷ a 72 percent increase in the last decade.⁴⁸ Over 30 percent of the Class of 2016 reported student loan debt in excess of \$300,000.⁴⁹ For the Class of 2018, 40 percent of the graduates reported a student loan debt greater than \$300,000.⁵⁰

For in-state tuition at a state university, such as the University of Florida, one year's tuition is currently \$41,720 and non-residents pay \$68,202. When housing, books, and other costs are included, three or four years of dental school tuition can result in a total dental school bill ranging from \$226,042 to \$291,836.⁵¹ In comparison, a northern private school's tuition is listed at \$73,364 per year and with other supplies, housing and fees, the total estimated costs over four years for 2018-2019 would be \$463,490.⁵²

Dental Student Loan Repayment Assistance

Federal Initiatives

The National Health Service Corps (NHSC) programs provide scholarships and educational loan repayment to primary care providers⁵³ who agree to practice in areas that are medically underserved and are located in selected HPSAs. The chart below shows the different loan programs that dental students may be eligible for based on where the participant is placed (HPSA score) and whether the participant provides full (40 hours per week) or part-time (20 hours per week) service.

⁴⁷ American Student Dental Education Association, *Dental Student Debt*, <https://www.asdanet.org/index/get-involved/advocate/issues-and-legislative-priorities/Dental-Student-Debt> (last visited Feb. 27, 2019).

⁴⁸ American Student Dental Education Association, *Paying for Dental School*, <https://www.asdanet.org/index/get-into-dental-school/before-you-apply/paying-for-dental-school>, (last visited Feb. 27, 2019).

⁴⁹ American Dental Education Association, *Education Debt*, http://www.adea.org/GoDental/Money_Matters/Educational_Debt.aspx#sthash.rYlqVawm.dpbs (last visited Feb. 27, 2019).

⁵⁰ *Id.*

⁵¹ University of Florida, Office of Admissions – College of Dentistry, *Budgets & Costs of Attendance: DMD*, <http://admissions.dental.ufl.edu/financial-aid-2/d-m-d/budgets-cost-of-attendance-d-m-d/> (last visited Feb. 27, 2019).

⁵² Tufts School of Dental Medicine, *Financial Aid Application Forms and Costs of Attendance for D.M.D. and D.I.S. Programs*, <https://dental.tufts.edu/academics/financial-aid/forms-and-costs-dmd-and-dis-programs> (last visited Feb. 27, 2019).

⁵³ Primary care physicians, nurse practitioners, certified nurse midwives, physician assistants, dentists, dental hygienists, and behavioral and mental health providers, including health service psychologists, licensed clinical social workers, marriage and family therapists, psychiatrist nurse specialists, and licensed professional counselors.

Federal Loan Programs Applicable for Dental Students – National Health Services Corps (NHSC)				
Program Name	Time Commitment	Maximum Amount	Service Commitment Locations	Additional Time
Loan Repayment Program (LRP) ^{54,55}	2 years	Vary based on where placed Range: \$30,000 - \$50,000 (Full-time) \$15,000- \$25,000 – (Part-time)	NHSC approved sites in HPSAs ⁵⁶	Option to annually renew after 2 years
Student to Service LRP ⁵⁷	Students in last year of school must commit to serve 3 years	Up to \$120,000	At an HPSA of greatest need	Option to annually renew after 3 year commitment to pay off loan remainder
Public Service Loan Forgiveness ⁵⁸	120 qualifying on-time loan payments ⁵⁹	Forgiveness of remainder of qualified federal loan	Qualified public service employment while making 120 loan payments	Remainder of qualified federal loan amounts forgiven at end of 120 payments

All of the NHSC programs require an application process. Some require a background check depending on the setting, and all require that the applicant:

- Be a U.S. Citizen or U.S. National;
- Be eligible to participate in the Medicare, Medicaid, and the State Children’s Health Insurance Program, as appropriate;
- Be fully trained and licensed to practice in the NHSC-eligible primary care medical, dental, or mental/behavioral health discipline for which the applicant seeks approval;
- Have unpaid student loans, taken before application to the NHSC’s Loan Repayment Program to support undergraduate or graduate education; and

⁵⁴ The definition of part-time and full-time vary by discipline. The guidelines for both can be found in the *Fiscal Year 2018 Application and Program Guidance (March 2018)* beginning on pg. 24, <https://nhsc.hrsa.gov/downloads/loan-repayment/nhsc-LRP-application-program-guidance.pdf> (last viewed Feb. 28, 2019).

⁵⁵ U.S. Dep’t. of Health and Human Services, *Loan Repayment Program – Fiscal Year 2019 Application and Program Guidance* (December 2018) <https://nhsc.hrsa.gov/sites/default/files/NHSC/loan-repayment/lrp-application-guidance.pdf> (last viewed Feb. 27, 2019).

⁵⁶ NHSC-approved sites are community-based health care facilities that provide comprehensive outpatient, ambulatory, and primary health care services. Eligible dental facilities must be located in a dental HPSA and offer comprehensive primary dental health services. NHSC-approved sites (with the exception of correctional facilities and free clinics) are required to provide services free or on a sliding fee scale (SFS) or discounted fee schedule for low-income individuals.

⁵⁷ U.S. Dep’t of Health and Human Services, HRSA, *Loan Repayment – NHSC Loan Repayment Program*, <https://www.nhsc.hrsa.gov/loanrepayment/index.html> (last visited Feb. 27, 2019).

⁵⁸ 34 CFR § 685.219. A qualifying public employer is a government organization at any level (federal, state, local, or tribal), not-for-profit organizations that are tax exempt under Section 501(c)(3) of the Internal Revenue Code, or other types of not-for-profit organizations that provide certain types of qualifying public services.

⁵⁹ 34 CFR § 685.219(c)(1)(iii). To qualify for public service loan forgiveness, a borrower must make 120 separate on-time monthly payments after October, 1, 2007, on eligible Direct Subsidized, Unsubsidized, PLUS, or Consolidation student loans that are part of either an income-based repayment plan or income contingent repayment plan; a standard repayment plan; or, except for the alternative repayment plan, any other repayment plan if the monthly payment amount is not less than what would have been paid under the Direct Loan standard repayment plan. Except for borrowers in an AmeriCorps or Peace Corps position, or any other student loan administered by the Department of Defense, a payment is considered on-time if it is made within 15 days of the scheduled due date for the full scheduled installment amount.

- Be working at or have accepted an offer of employment at an NHSC-approved site by the designated date (date determined each year).⁶⁰

Participants may be eligible to continue loan repayment beyond the initial term. If a participant breaches his or her loan repayment agreement, he or she will be subject to monetary damages, which are the sum of the amount of assistance received by the participant representing any period of obligated service not completed, a penalty, and interest.

Several other federal loan repayment programs are open to most borrowers, including dental, that have certain post-graduate working conditions such as a requirement to work as a faculty member at an approved health institution, as a biomedical researcher, as a provider at an Indian health program site, as a commissioned dental officer in the U.S. Public Health Service Commissioned Corps, or with the United States Army or Navy.⁶¹

Florida Initiatives

Florida no longer has a state program to address dental health professional shortage areas or medically underserved areas through the repayment of dentists' student loans.^{62,63}

Transparency of Health Care Quality Information

Patient Safety Plan

Hospitals and ambulatory surgical centers (ASCs) are required to adopt a patient safety plan in accordance with state and federal laws and regulations.⁶⁴ Hospitals and ASCs designate an employee to serve as a patient safety officer, and establish a patient safety committee, to promote the health and safety of patients, evaluate the quality of patient safety measures utilized by the facility, and ensure the accountability of, and fidelity to, the facility's patient safety plan.⁶⁵

Hospital Compare

The federal Centers for Medicare & Medicaid Services (CMS) maintains the Hospital Compare website,⁶⁶ which provides consumers with data about the quality of care at over 4,000 Medicare-

⁶⁰ National Health Services Corps, Loan Repayment Program, *Eligibility*, <https://nhsc.hrsa.gov/loan-repayment/nhsc-loan-repayment-program.html#eligibility> (last visited Feb. 27, 2019).

⁶¹ American Dental Education Association, *State and Federal Loan Forgiveness Programs* (November 1, 2017), www.adea.org/advocacy/state/loan-forgiveness-programs.aspx (last visited Feb. 27, 2019).

⁶² See chapter 92-33, s. 111, Laws of Fla. (creating s. 381.0302, F.S., effective July 1, 1992). The Florida Health Services Corps (FHSC), administered by the DOH, encouraged medical professionals to practice in locations that are underserved because of a shortage of qualified professionals. The FHSC offered scholarships to allopathic, osteopathic, chiropractic, podiatric, dental, physician assistant, and nursing students, and loan repayment assistance and travel and relocation expenses to allopathic and osteopathic residents and physicians, chiropractic physicians, podiatric physicians, nurse practitioners, dentists, and physician assistants, in return for service in a public health care program or in a medically underserved area. All FHSC members were required to enroll in Medicaid and to accept all patients referred by the DOH.

⁶³ See chapter 2012-184, s. 45, Laws of Fla.

⁶⁴ Section 395.1012, F.S., and 42 C.F.R. § 482.21.

⁶⁵ Section 395.1012(2), F.S. At least one member of the patient safety committee must be a person who is neither employed by nor practicing in the hospital or ASC.

⁶⁶ Centers for Medicare & Medicaid Services, Hospital Compare, available at <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/hospitalcompare.html> (last visited on March 12, 2019)

certified hospitals.⁶⁷ Hospital Compare allows consumers to select multiple hospitals and directly compare performance measure information related to heart attack, heart failure, pneumonia, surgery and other conditions.⁶⁸ Performance measures are derived from consumers' responses to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey⁶⁹ which collects data on patient satisfaction and readmission, hospital-acquired infection, and mortality rates.⁷⁰ Overall hospital performance is presented to consumers through a star rating of one to five stars.⁷¹

Florida Center for Health Information and Transparency

The Florida Center for Health Information and Transparency (the Florida Center) provides a comprehensive health information system that includes the collection, compilation, coordination, analysis, indexing, dissemination, and utilization of health-related data. The Florida Center is housed within the Agency for Health Care Administration (AHCA).⁷² The Florida Center electronically collects patient data from every Florida licensed inpatient hospital, ASC, emergency department, and comprehensive rehabilitation hospital on a quarterly basis.⁷³

The Florida Center maintains www.FloridaHealthFinder.gov, which assists consumers in making informed health care decisions and leads to improvements in quality of care in Florida. The website provides a wide array of search and comparative tools to the public that allows easy access to information on hospitals, ASCs, emergency departments, hospice providers, physician volume, health plans, nursing homes, and prices for prescription drugs in Florida. Some of the features and data available on the website include a multimedia encyclopedia and symptoms navigator; hospital and ASCs performance data; data on mortality, complication, readmission, and acquired infection rates for hospitals; and a facility/provider locator.

Access to Primary and Specialist Care in a Hospital Setting

Continuity of Care

'Continuity of care' generally refers to a patient's care over time by a single individual or team of health professionals but can also include effective and timely communication of health information at different levels of care between the patient, the primary care provider, and other treating specialists.⁷⁴ This long-term patient-physician relationship in which the physician knows the patient's history from experience allows the physician to integrate new information and

⁶⁷ Medicare.gov, What is Hospital Compare? available at <https://www.medicare.gov/hospitalcompare/About/What-Is-HOS.html> (last visited March 12, 2019).

⁶⁸ *Id.*

⁶⁹ The Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey is a national survey that asks patients about their experiences during a recent hospital stay. The HCAHPS is endorsed by the National Quality Forum as a measure of hospital quality. Available at: <http://www.hcahponline.org/> (last visited March 29, 2019).

⁷⁰ Medicare.gov, Measures and current data collection periods, available at: <https://www.medicare.gov/hospitalcompare/Data/Data-Updated.html#> (last visited March 12, 2019).

⁷¹ Medicare.gov, Hospital Compare overall hospital rating, available at <https://www.medicare.gov/hospitalcompare/About/Hospital-overall-ratings.html> (last viewed March 12, 2019).

⁷² Section 408.05, F.S.

⁷³ Section 408.061, F.S., and chs. 59B-9 and 59E-7, F.A.C.

⁷⁴ Institute of Medicine Committee on the Future of Primary Care; M.S. Donaldson et. al., *Primary Care: America's Health in a New Era*, 27-51 (National Academies Press, 1996), available at: https://www.ncbi.nlm.nih.gov/books/NBK232643/pdf/Bookshelf_NBK232643.pdf (last visited Mar. 29, 2019).

decisions from a holistic perspective efficiently without extensive investigation or record review.⁷⁵

When a patient's various healthcare providers do not communicate with one another, the lack of coordination results in fragmented care. Fragmented care can have an adverse impact on the quality of care, and is associated with increased healthcare costs, medical errors,⁷⁶ and risk of re-hospitalization.⁷⁷

Patient handoff – when the patient care responsibility is transferred from one health care professional to another – is a critical moment in the continuum of care. This is especially significant during transition from an inpatient to an outpatient setting. Based on reports and studies, it is not common practice for a treating physician at a hospital to communicate with the patient's primary care provider during a patient's admission or even at discharge.⁷⁸ Primary care providers are often wholly unaware of the hospitalization or do not receive a discharge summary or information from the hospital.

A growing body of research and articles recommend that a primary care provider be informed of the patient's admission to, or discharge from, a hospital, with the most effective care being provided when information is shared between the primary care provider and treating physician throughout the course of the admission.⁷⁹ In an effort to better coordinate care, some hospitals

⁷⁵ *Id.* at 52-75; *See also*, American Academy of Family Physicians, Continuity of Care, <https://www.aafp.org/about/policies/all/definition-care.html> (last visited Mar. 29, 2019).

⁷⁶ “Medical error” generally refers to failure of a planned action to be completed as intended or a preventable adverse effect of care, and can range from documentation errors to improper diagnosis or failure to test or treat as required.

⁷⁷ Study of 86 patients seen by their primary care physicians two months after hospital discharge found 49% experienced medical errors and patients with a work-up error were 6.2 times more likely to be re-hospitalized within three months after the first outpatient visit. Carlton Moore et. al., *Medical Errors Related to Discontinuity of Care from an Inpatient to an Outpatient Setting*, 18:8 J. Gen. Internal Med. 646-51 (Aug. 2013), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1494907/> (last visited Mar. 29, 2019).

⁷⁸ Sunil Kripalani, M.D., M.Sc., et. al., *Deficits in Communication and Information Transfer Between Hospital-Based and Primary Care Physicians: Implications for Patient Safety and Continuity of Care*, 297:8 JAMA 831-41 (Feb. 2007), available at: <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.522.2320&rep=rep1&type=pdf> (last visited Mar. 29, 2019); extracted and synthesized data from existing body of research and found that direct communication between the hospital and primary care physician occurred less than 20 percent of the time, the availability of the discharge summary at the first post-discharge visit was less than 34 percent and remained poor even four weeks after discharge and affected the quality of care in 25 percent of follow-up visits.

⁷⁹ Diane Shannon, M.D., M.P.H, *Effective Physician-to-Physician Communication: An Essential Ingredient for Care Coordination*, 38(1) Physician Exec. J. 16-21 (Jan.-Feb. 2012), available at: http://www.mdwriter.com/uploads/1/8/0/3/18033585/md_to_md_communication_pej.pdf (last visited Mar. 29, 2019); *See also*, Stacey S. Brener, M.Sc., *Association Between In-Hospital Supportive Visits by Primary Care Physicians and Patient Outcomes: A Population-Based Cohort Study*, 11:6 J. Hosp. Med. 418-24 (June 2016), a retrospective cohort study of 164,059 patients, the 12 percent of patients who received visits from their primary care physicians had lower risks of adverse patient outcomes, fewer emergency room visits, and increased utilization of community health services; Carl van Walraven, M.D., M.Sc., *Effect of Discharge Summary Availability During Post-Discharge Visits on Hospital Readmission*, 17:3 J. Gen. Intern. Med. 186-92 (Mar. 2002), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1495026/> (last visited Mar. 29, 2019), studied 888 patients discharged from a single hospital after treatment for an acute illness and found that the discharge summary was only given to the primary physician in 25 percent of cases and in those cases, the patients had a decreased risk of re-hospitalization compared to their counterparts; *See generally*, Gregory A. Harlan, et. al., *Improving Transitions of Care at Hospital Discharge—Implications for Pediatric Hospitalists and Primary Care Providers*, 32:5 J. Healthcare Quality 51-60 (Sept.-Oct. 2010); Vicenza Snow, M.D., et. al., *Transitions of Care Consensus Policy Statement: American College of Physicians, Society of General Internal Medicine, Society of Hospital Medicine, American Geriatrics*

have implemented continuity visits or increased communication procedures so the primary care provider can be consulted in the patient's care.⁸⁰

Regulation of Hospitals

Hospitals are regulated by the AHCA.⁸¹ Hospitals are not required to coordinate care with patients' primary care providers or to comply with patients' request for such coordination. There is no statutory requirement that a treating physician at a hospital consult with a patient's primary care provider during the admission, or notify such provider after a patient is discharged.

Ambulatory Surgical Centers

An ambulatory surgical center (ASC) is a licensed facility not part of a hospital with the primary purpose of providing elective surgical care in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.⁸²

In Florida, ambulatory procedures are performed in two settings, hospital-based outpatient facilities and freestanding ASCs. As of January 2019, there are 458 ASCs and 308 licensed hospitals in Florida. Of the 308 licensed hospitals, 212 report providing hospital-based outpatient surgical services.⁸³

Between April 2017 and March 2018, there were 3,049,558 visits to ASCs in Florida.⁸⁴ Hospital outpatient facilities accounted for 1,419,020 visits (46.5 percent) and freestanding ASCs accounted for 1,622,013 visits (53.5 percent). Freestanding ASC average charges range from \$3,516 to \$9,347 and hospital-based ASC average charges range from \$10,522 to \$34,291 for the same time period.⁸⁵ According to 2017 utilization data submitted to the Agency for Health Care Administration (AHCA), less than five percent of all outpatient surgical visits at hospitals and ASCs were for pediatric patients (age 0 to 17 years).⁸⁶

Society, American College of Emergency Physicians, and Society for Academic Emergency Medicine, 4:6 J. Hosp. Med. 364-370 (July 2009), available at: <https://pdfs.semanticscholar.org/4d62/22d8eadfdb0e3dc7edad34cc86b1290afbd5.pdf> (last visited Mar. 29, 2019).

⁸⁰ Allan H. Goroll, M.D. and Daniel P. Hunt, M.D., *Bridging the Hospitalist-Primary Care Divide Through Collaborative Care*, 372:4 N. Engl. J. Med. 308-309 (Jan. 2015), available at: https://www.researchgate.net/publication/271222735_Bridging_the_HospitalistPrimary_Care_Divide_through_Collaborative_Care (last visited Mar. 29, 2019); *See also*, Larry Beresford, *Continuity Visits by Primary Care Physicians Could Benefit Inpatients*, *The Hospitalist* (Apr. 2015), <https://www.the-hospitalist.org/hospitalist/article/122479/continuity-visits-primary-care-physicians-could-benefit-inpatients> (last visited Mar. 29, 2019).

⁸¹ Ch. 395, F.S.

⁸² Section 395.002(3), F.S.

⁸³ Agency for Health Care Administration, *Senate Bill 434 Analysis* (January 24, 2019) (on file with the Senate Committee on Health Policy).

⁸⁴ Agency for Health Care Administration, *Florida Health Finder*, <http://www.floridahealthfinder.gov/CompareCare/CompareFacilities.aspx> (last viewed March 4, 2019).

⁸⁵ *Id.*

⁸⁶ *Id.*

Age Group	Visits	% of Visits
Age 0 (Less than 1 year old)	10,348	0.34%
1 – 4 years	48,802	1.60%
5 – 9 years	37,398	1.22%
10 – 14 years	25,958	0.85%
15 – 17 years	24,992	0.82%
Total Pediatrics	147,498	4.83%
Total All Ages	3,056,789	100%

Federal Requirements

ASCs are required to have an agreement with the federal Centers for Medicare and Medicaid Services (CMS) to participate in Medicare. ASCs are also required to comply with specific conditions for coverage. The CMS defines “ASC” as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and for whom the expected duration of services would not exceed 24 hours following an admission.⁸⁷

The CMS may deem an ASC to be in compliance with all of the conditions for coverage if the ASC is accredited by a national accrediting body or licensed by a state agency and if the CMS determines that such accreditation or licensure provides reasonable assurance that the conditions for coverage are met.⁸⁸

Florida Requirements

ASCs are licensed and regulated by the AHCA under the same regulatory framework as hospitals.⁸⁹ Applicants for ASC licensure are required to submit certain information to the AHCA prior to accepting patients for care or treatment, including:

- An affidavit of compliance with fictitious name;
- Registration of articles of incorporation; and
- The applicant’s zoning certificate or proof of compliance with zoning requirements.⁹⁰

Upon receipt of an initial ASC application, the AHCA is required to conduct a survey to determine compliance with all laws and rules. Applicants are required to provide certain information during the initial inspection, including:

- Governing body bylaws, rules, and regulations;
- A roster of registered nurses and licensed practical nurses with current license numbers;
- A fire plan; and
- A comprehensive emergency management plan.⁹¹

The AHCA is authorized to adopt rules for hospitals and ASCs.⁹² Separate standards may be provided for general and specialty hospitals, ASCs, mobile surgical facilities, and statutory rural

⁸⁷ 42 C.F.R. s. 416.2

⁸⁸ 42 C.F.R. s. 416.26(a)(1)

⁸⁹ Sections 395.001-395.1065, F.S., and part II, ch. 408, F.S.

⁹⁰ Rule 59A-5.003(4), F.A.C.

⁹¹ Rule 59A-5.003(5), F.A.C.

⁹² Section 395.1055, F.S.

hospitals, but the rules for all hospitals and ASCs are required to include minimum standards for ensuring that:

- A sufficient number of qualified types of personnel and occupational disciplines are on duty and available at all times to provide necessary and adequate patient care;
- Infection control, housekeeping, sanitary conditions, and medical record procedures are established and implemented to adequately protect patients;
- A comprehensive emergency management plan is prepared and updated annually;
- Licensed facilities are established, organized, and operated consistent with established standards and rules; and
- Licensed facility beds conform to minimum space, equipment, and furnishing standards.

The aforementioned federal CMS conditions for coverage requirements are specifically required in Rule 59A-5, F.A.C., and apply to all ASCs in Florida.⁹³

Accreditation

ASCs may seek voluntary accreditation by an accrediting organization whose standards are determined by the AHCA to be comparable to state licensure requirements. The AHCA is required to conduct a licensure inspection survey for non-accredited ASCs. The AHCA is authorized to accept survey reports of accredited ASCs from accrediting organizations if the standards included in the survey report are determined to document that the ASC is in substantial compliance with state licensure requirements. The AHCA is required to conduct annual validation inspections on a minimum of five percent of the ASCs which were inspected by an accreditation organization.⁹⁴

The AHCA is required to conduct annual life safety inspections of all ASCs to ensure compliance with life safety codes and disaster preparedness requirements. However, the life-safety inspection may be waived if an accreditation inspection was conducted on an ASC by a certified life safety inspector and the ASC was found to be in compliance with the life safety requirements.⁹⁵

American College of Surgeons: Optimal Resources for Children's Surgical Care v. 1

In 1913, the American College of Surgeons (ACS) was founded on the basic principles of improving the care of surgical patients and strengthening the education of surgeons. With these principles in mind, the ACS Children's Surgery Verification Committee was created in 2015 to continue, on a permanent basis within the ACS, the work of the ad hoc Task Force for Children's

⁹³ The conditions for coverage require ASCs to have a governing body that assumes full legal responsibility for determining, implementing, and monitoring policies governing the ASC's total operation; a quality assessment and performance improvement program; a transfer agreement with one or more acute care general hospitals, which will admit any patient referred who requires continuing care; a disaster preparedness plan; an organized medical staff; a fire control plan; a sanitary environment; an infection control program; and a procedure for patient admission, assessment, and discharge.

⁹⁴ Rule 59A-5.004, F.A.C.

⁹⁵ *Id.*

Surgical Care. The task force was first convened in 2012, and its recommendations are contained in the ACS' Standards Manual entitled, "Optimal Resources for Children's Surgical Care v. 1."⁹⁶

Specific to ASCs, the report found that:

Children's ambulatory surgical centers must have treatment protocols for resuscitation, transfer protocols, and data reporting and must participate in systems for performance improvement. Children's ambulatory centers must have good working relationships and be fully integrated with a Level I, II, or III inpatient children's surgical center⁹⁷ to be verified in this program... [i]t is essential for the children's ambulatory surgical center to have the involvement of one or more committed and appropriately trained pediatric health care providers to provide leadership and sustain the integration with other relevant components of an integrated children's health care system.⁹⁸

Pediatric Cardiac Standards of Care

Current Standards for Pediatric Cardiac Services

Hospital facilities are regulated by the Agency for Health Care Administration (AHCA) under ch. 395, F.S., and the general licensure provisions of ch. 408, F.S. Hospitals are also subject to the Certificate of Need (CON) provisions in Part I of ch. 408, F.S.

A CON is a written statement issued by the AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service. Certain specialty programs offered within a hospital may also be subject to a CON process as prescribed by statute. All health-care-related projects are subject to review and must file a CON application with the AHCA, unless specifically exempt from the process.⁹⁹ Examples of covered health-care-related projects include hospice services, skilled nursing facilities, intermediate care facilities for the developmentally disabled, organ transplantation, and level II and level III neonatal intensive care units. Additionally, programs for pediatric cardiac catheterization and pediatric open heart surgery are considered health-care-related projects.¹⁰⁰

⁹⁶ American College of Surgeons, *Optimal Resources for Children's Surgical Care v.1*, (released in 2015) available at https://www.facs.org/~media/files/quality%20programs/csv/acs%20csv_standardsmanual.ashx (last visited on March 27, 2019).

⁹⁷ *Id.* The report details such relationship on page 19. "Ideally, one hospital, typically a Level I center, would be looked upon as the resource leader within a given region. This hospital would serve as a resource to all other hospitals within the system. Outside major population centers, a Level II center may serve as the lead hospital for extended geographic areas. In some rural areas, where population densities are low and distances great, a Level III center may be the only resource for miles. Ambulatory surgical centers are considered separately but in any system will have clearly identified relationships and demonstrable integration with one or more verified Level I, II, or III children's inpatient facilities."

⁹⁸ *Id.*

⁹⁹ Section 408.036, F.S.

¹⁰⁰ See s. 408.036(1)(f), F.S. (2018) and Rule 59C-1.004, F.A.C.

Pediatric Surgery Programs

Pediatric Open Heart Surgery Programs

Pediatric open heart surgery programs are regulated through the CON process and governed by Rule 59C-1.033, F.A.C. The administrative rule establishes five service areas, defines the pediatric patient as those patients under 15 years of age, and specific services included in a pediatric open heart surgery program. To be considered for an open heart surgery program, a facility must meet certain minimum requirements and provide additional services in the event complications arise during the performance of pediatric open heart surgery.¹⁰¹

The pediatric open heart surgery team must be available for elective open heart surgery eight hours per day, five days per week and available for rapid mobilization of the surgical and medical support teams for emergency cases 24 hours a day, seven days per week.¹⁰²

For pediatric open heart surgery, any CON applicant must document an adequate number of the following properly trained personnel that can perform during surgery:

- A cardiovascular surgeon, board certified by the American Board of Thoracic Surgery, or board eligible.
- A physician to assist the operating surgeon.
- A board certified or board eligible anesthesiologist trained in open heart surgery.
- A registered nurse or certified operating room technician trained to serve in open heart surgery operations and perform circulating duties.
- A perfusionist to perform extracorporeal perfusion, or a physician or specially trained nurse, technician, or physician assistant under the supervision of the operating surgeon to operate the heart-lung machine.¹⁰³

Follow-up care after open heart surgery must be provided in an intensive care unit that provides 24 hour nursing coverage with a nurse-to-patient ratio of no less than one nurse for every two patients for the first hours of post-operative care. The facility must have at least one board-certified or board-eligible pediatric cardiac surgeon on the staff of the hospital seeking the CON for a pediatric open heart surgery.¹⁰⁴ Back-up personnel must be available for consultation to the surgical team, including a clinical cardiologist, cardiologist, anesthesiologist, pathologist, thoracic surgeon, and radiologist.

¹⁰¹ Rule 59C-1.033, F.A.C., requires a facility be able to repair or replace heart valves; repair congenital heart defects; perform cardiac revascularization; repair or reconstruct intrathoracic vessels; and treat cardiac trauma, and provide the following additional services: cardiology, hematology, nephrology, pulmonary medicine, and treatment of infectious diseases; pathology, including anatomical, clinical blood bank and coagulation laboratory services; anesthesiology, including respiratory therapy; radiology, including diagnostic nuclear medicine and magnetic resonance imaging studies; neurology; inpatient cardiac catheterization; non-invasive cardiographics, including electrocardiography, exercise stress testing, transthoracic and transesophageal echocardiography; intensive care; emergency care available 24 hours per day for cardiac emergencies; and extracorporeal life support (ECLS).

¹⁰² Rule 59C-1.033(4)(b), F.A.C.

¹⁰³ Rule 59C-1.033(5)(a), F.A.C.

¹⁰⁴ Rule 59C-1.033(5)(b), F.A.C.

Pediatric Cardiac Catheterization and Angioplasty Institutional Health Services

As with the requirements for the pediatric open heart surgery program, the pediatric cardiac catheterization program requires a hospital to have a CON before it may operate its program. A cardiac catheterization is a medical procedure requiring the passage of a catheter into one or more cardiac chambers with or without coronary arteriograms, for the purpose of diagnosing congenital or acquired cardiovascular diseases, or for determining measurement of blood pressure flow. Cardiac catheterization also includes the selective catheterization of the coronary ostia with injection of contrast medium into the coronary arteries.¹⁰⁵

A facility must demonstrate as part of the CON approval process that it is capable of providing immediate endocardiac catheter pacemaking in cases of cardiac arrest, and pressure recording to evaluate valvular disease or heart failure.¹⁰⁶ The facility must also ensure a range of additional services and equipment are available within the facility.¹⁰⁷

The cardiac catheterization team must be capable of rapidly mobilizing within 30 minutes, 24 hours a day, seven days a week for emergency procedures.¹⁰⁸ The team must be capable of providing immediate endocardiac catheter pacemaking in cases of cardiac arrest, and pressure recording for monitoring and to evaluate valvular disease or heart failure.¹⁰⁹ The team must be able to document these standards.

In addition to documentation of the required staff¹¹⁰ that is available to perform the pediatric cardiac catheterization and angiographic processes, the CON applicant facility is required to have a department, service, or other similar unit organized, directed, staffed, and integrated with the other units and departments of the hospital to assure the provision of quality of care.¹¹¹ A pediatric catheterization program must also be co-located at a facility where pediatric open heart surgeries are performed.¹¹²

Pediatric cardiac facilities granted CONs under either program are required to provide the AHCA with quarterly utilization reports within 45 days of the end of each quarter showing the number of pediatric procedures under both programs.

¹⁰⁵ Rule 59C-1.032(2), F.A.C.

¹⁰⁶ Rule 59C-1.032(3)(a), F.A.C.

¹⁰⁷ Rules 59C-1.032(3)(b) and 59C-1.032(3)(b), F.A.C. Additional services and equipment include: hematology studies or coagulation studies; electrocardiography; chest x-ray; blood gas studies; clinical pathology studies and blood chemistry analysis; a special procedure x-ray room; a film storage and darkroom for proper processing of films; x-ray equipment with the capability in cineangiocardiology, or equipment with similar capabilities; an image intensifier; an automatic injector; a diagnostic x-ray examination table for special procedures; an electrocardiograph; a blood gas analyzer; a multi-channel polygraph; emergency equipment, including but not limited to, a temporary pacemaker unit with catheters, ventilatory assistance devices, and a DC defibrillator; biplane angiography, with framing rates of 30-60 fps and injection rates of up to 40mL/s; and one or more crash carts containing the necessary medication and equipment for ventilatory support, which must be located in each pediatric cardiac catheterization procedure room.

¹⁰⁸ Rule 59C-1.032(4)(a), F.A.C.

¹⁰⁹ Rule 59C-1.032(3)(a), F.A.C.

¹¹⁰ The staff required for these programs are listed in Rule 59C-1.032(b), F.A.C.

¹¹¹ Rule 59C-1.032(5)(a), F.A.C.

¹¹² Rule 59C-1.032(6), F.A.C.

Technical Advisory Panel for Pediatric Cardiac Programs

During the 2017 Legislative Session, a Technical Advisory Panel (panel) for Pediatric Cardiac Programs was established to develop procedures and standards for measuring outcomes of pediatric catheterization programs and pediatric cardiac cardiovascular programs, and make recommendations about regulatory guidelines for pediatric open heart surgery programs. The panel is housed administratively at the AHCA, and appointments to the panel are made by the AHCA Secretary in accordance with the statutory guidelines.

To be eligible as a voting member on the panel, a hospital must maintain its pediatric CON and the individual member must have technical expertise in pediatric cardiac medicine. Members serve without compensation and are not reimbursed for any travel costs or per diem.¹¹³

The AHCA Secretary appoints three at-large members, one of whom is a cardiologist who is board certified in caring for adults with congenital heart disease and two board-certified pediatric cardiologists. None of the three at-large members may be employed by any of the named facilities who have specific representation on the panel. The panel has 10 other members who are appointed by the chief executive officer of their respective hospitals, plus an alternate member. The named member, either the voting member or the alternate, must be a pediatric cardiologist or pediatric cardiovascular surgeon.

The panel membership is composed as follows:

Cardiac Program Technical Advisory Panel Membership¹¹⁴			
Members/Type of Members:	Voting	Alternate	Non-Voting
Johns Hopkins All Children’s Hospital in St. Petersburg	■	■	
Arnold Palmer Hospital for Children in Orlando	■	■	
Joe DiMaggio Children’s Hospital in Hollywood			
Nicklaus Children’s Hospital in Miami	■	■	
St. Joseph’s Children’s Hospital in Tampa	■	■	
University of Florida Health Shands Hospital in Gainesville	■	■	
University of Miami Holtz Children’s Hospital in Miami	■	■	
Wolfson Children’s Hospital in Jacksonville	■	■	
Florida Hospital for Children in Orlando	■	■	
Nemours Children’s Hospital in Orlando	■	■	
AHCA Secretary may appoint following nonvoting members:			
Secretary, AHCA			■
Surgeon General, DOH			■
Deputy Secretary of Children’s Medical Services, DOH			■
Any current or past Director of Children’s Medical Services, DOH			■
A parent of a child with congenital heart disease			■
An adult with congenital heart disease			■
3- At Large Members			
<i>1 Cardiologist - Board Certified in caring for adults with congenital health disease</i>	■		
<i>2 Pediatric Cardiologists – Board Certified</i>	■		
A representative from each of the following organizations:			

¹¹³ Section 395.1055(9)(a) and (b), F.S.

¹¹⁴ Section 395.1055(9)(b) and (c), F.S.

Cardiac Program Technical Advisory Panel Membership¹¹⁴			
Members/Type of Members:	Voting	Alternate	Non-Voting
<i>Florida Chapter of the American Academy of Pediatrics</i>			■
<i>Florida Chapter of the American College of Cardiology</i>			■
<i>Greater Southeast Affiliate of the American Heart Association</i>			■
<i>Adult Congenital Heart Association</i>			■
<i>March of Dimes</i>			■
<i>Florida Association of Children’s Hospitals</i>			■
<i>Florida Society of Thoracic and Cardiovascular Surgeons</i>			■

The panel is required to meet at least biannually, or more frequently, upon the call of the AHCA Secretary. Meetings may be held telephonically or by other electronic means. The panel has held at least 26 meetings since its inception in 2017, and has been working toward proposed rules and policies on cardiology, surgery, public reporting and transparency, and facility standards.

At a minimum, the statute requires the panel to make recommendations for additional rules and standards for pediatric cardiac programs¹¹⁵ which must include:

- Standards for pediatric cardiac catheterization services and pediatric cardiovascular surgery services, including quality of care, personnel, physical plant, equipment, emergency transportation, data reporting, and appropriate operating hours and timeframes for mobilization for emergency procedures.
- Outcome standards consistent with nationally established levels of performance in pediatric cardiac programs.
- Specific steps to be taken by the AHCA and licensed facilities when the facilities do not meet the outcome standards within a specified time, including time required for detailed case reviews and the development and implementation of corrective action plans.

By January 1, 2020, the panel is required to submit an annual report to the Governor, President of the Senate, the Speaker of the House of Representatives, the AHCA Secretary, and the Surgeon General which summarizes the panel’s activities during the preceding fiscal year. The report must include data and performance measures on surgical morbidity and mortality for all pediatric cardiac programs.¹¹⁶

Once the panel has developed recommendations for pediatric cardiac care, the panel will forward such recommendations to the AHCA for adoption through the formal administrative rulemaking process.¹¹⁷

Liability for Good Faith Actions

Currently, the volunteer physicians and other members of the panel are not covered by any liability or immunity clauses in the panel’s implementing statute. During panel meetings, the

¹¹⁵ Chapter 395, Florida Statutes, provides standards for cardiac programs. For example, a pediatric cardiac program must be affiliated with a hospital licensed under chapter 395; have a pediatric cardiac catheterization laboratory and pediatric cardiovascular surgical program located in the hospital; and have a risk-adjusted surgical procedure protocol which follows the guidelines established by the Society of Thoracic Surgeons. *Also see* The Society of Thoracic Surgeons, <https://www.sts.org/about-sts> (last visited March 13, 2019).

¹¹⁶ Section 395.1055(9)(f), F.S.

¹¹⁷ *See* s. 395.1055(10)(a-c) and (12), F.S.

members have held discussions relating to sovereign immunity for panel members when they are engaged in activities related to the panel.¹¹⁸ Members on other panels, boards of directors, or volunteers in programs have been granted similar provisions of immunity for their official actions by the Legislature, such as individuals in the Division of Rehabilitation and Liquidation of the Department of Financial Services,¹¹⁹ guardians ad litem,¹²⁰ and employees and board of directors of the Health Maintenance Organization Consumer Assistance Plan.¹²¹

Children's Medical Services

Children's Medical Services (CMS) is a group of programs administered by the Department of Health (DOH) that serve children with special health care needs.¹²² One such program is the newborn screening program, which screens all newborns in Florida for 32 core disorders and 22 secondary disorders, unless a parent objects in writing.¹²³ The most recently added disorders to the newborn screening panel include critical congenital heart disease (CCHD), X-linked adrenoleukodystrophy (X-ALD), Pompe, Muccopolysaccharidosis Type I (MPS I), and spinal muscular atrophy (SMA). The newborn screening program currently tests for CCHD and X-ALD,¹²⁴ and the program is expected to begin testing for Pompe, MPS I, and SMA in the 2019-2010 fiscal year.¹²⁵

Patient Notification of Hospital Observation Status

When a patient enters a hospital, the physician or other practitioner responsible for a patient's care must decide whether the patient should be admitted for inpatient care. The factors considered include:

- The severity of signs and symptoms exhibited by the patient;
- The medical probability of something adverse happening to the patient;
- The need for diagnostic studies to assist in the admitting decision; and
- The availability of diagnostic procedures at the time when, and the location where, the patient presents.¹²⁶

Observation status is commonly ordered for a person who presents to the emergency department and requires treatment or monitoring to determine if he or she should be admitted or

¹¹⁸ Agency for Health Care Administration, Pediatric Cardiology Technical Advisory Panel Meeting Minutes (October 2, 2018), pg. 3, <http://ahca.myflorida.com/SCHS/PCTAP/docs/102518/PCTAPDraftMinutes100218.pdf> (last visited March 13, 2019).

¹¹⁹ See s. 631.391, F.S.

¹²⁰ See s. 61.405, F.S.

¹²¹ See s. 631.825, F.S.

¹²² See ss. 383.14 and 383.145, F.S., (newborn screening program); s. 391.301, F.S., (Early Steps Program); and ss. 391.055 and 409.974(4), F.S., (Children's Medical Services Managed Care Plan).

¹²³ Department of Health, *Newborn Screening* <http://www.floridahealth.gov/programs-and-services/childrens-health/newborn-screening/index.html> (last visited April 5, 2019).

¹²⁴ *Id.*

¹²⁵ The sum of \$3.8 million is provided in SB 2500, First Engrossed, the Senate's proposed 2019-2020 General Appropriations Bill, for the program to begin testing for Pompe, MPS I, and SMA in the 2019-2020 fiscal year, see Section, 3, Specific Appropriations 467 and 469, at page 97; 474, at page 98; 480, at page 100; and 525, at page 106.

¹²⁶ Medicare Benefit Policy Manual, ch. 1 § 10, available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html> (last visited Mar. 13, 2019).

discharged.¹²⁷ A patient receives observation services when on observation status and can spend one or more nights in the hospital. These services can occur in the hospital's emergency department or in another area of the hospital.¹²⁸

Observation services are covered under Medicare Part B, rather than Part A, so some patients with Medicare will experience an increase in out-of-pocket costs for observation services versus being admitted to the hospital.¹²⁹ For example, hospital inpatient services are covered under Medicare Part A and require the patient to pay a one-time deductible (\$1,364) for the first 60 days of his or her stay. Alternately, hospital outpatient services, including observation services, are covered under Medicare Part B and require the patient to pay a deductible (\$185) as well as 20 percent of the Medicare-approved amount for doctor services.¹³⁰ A person who is treated for an extended period of time as a hospital outpatient receiving services may incur greater financial liability. However, it can be difficult for a person to determine his or her status based purely on the type of care provided at the hospital.¹³¹

Once a person is discharged from a hospital, additional rehabilitation in a nursing home is often necessary. Hospital admission can affect a person's eligibility for other services.¹³² When a person is admitted and has a three-night inpatient stay in a hospital¹³³ and needs rehabilitative care, Medicare Part A will pay for up to 60 days in a skilled nursing facility. However, if a person is not admitted to the hospital – such as when a patient is under observation status for the duration of the hospital stay – and subsequently goes into a nursing home, the patient will have not met the requirements of a qualifying inpatient hospital stay, and Medicare will not pay for the skilled nursing facility care.¹³⁴

The federal Notice of Observation Treatment and Implication for Care Eligibility Act requires hospitals to provide the Medicare Outpatient Observation Notice (MOON) to patients when observation status services last more than 24 hours.¹³⁵ The MOON must be provided to the patient if the patient is discharged, transferred, or admitted within 36 hours. The notice informs patients that observation status may affect their health care costs.

¹²⁷ *Id.* at ch. 6 § 20.6.

¹²⁸ U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, Product No. 11435, *Are You a Hospital Inpatient or Outpatient? If You Have Medicare – Ask!* (May 2014) available at <https://www.medicare.gov/Pubs/pdf/11435-Are-You-an-Inpatient-or-Outpatient.pdf> (last visited Mar. 12, 2019).

¹²⁹ AARP Public Policy Institute, *Rapid Growth in Medicare Hospital Observation Services: What's Going On?*, p. 1 (September 2013), available at http://www.aarp.org/content/dam/aarp/research/public_policy_institute/health/2013/rapid-growth-in-medicare-hospital-observation-services-AARP-ppi-health.pdf (last visited Mar. 12, 2019).

¹³⁰ Medicare.gov., *Medicare 2015 costs at a glance*, available at <http://www.medicare.gov/your-medicare-costs/costs-at-a-glance/costs-at-a-glance.html> (last visited Mar. 12, 2019) and 42 CFR s. 419.40.

¹³¹ See Amanda Cassidy, *The Two-Midnight Rule*, Health Affairs, Health Policy Briefs (Jan. 22, 2015) available at http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=133 (last visited Mar. 12, 2019).

¹³² *Id.*

¹³³ See 42 C.F.R. § 409.30. A patient must have a qualifying inpatient hospital stay, defined as three consecutive days of inpatient care, to be covered by Medicare Part A.

¹³⁴ *Id.*

¹³⁵ Centers for Medicare and Medicaid Services, Medicare Outpatient Observation Status, available at: <https://www.cms.gov/Medicare/Medicare-General-Information/BNI/MOON.html> (last viewed Mar. 29, 2019).

Florida law requires hospitals to notify patients or a patient's proxy of their observation status through documentation in the patient's discharge papers provided when leaving the hospital.¹³⁶ The documentation is not required to inform patients that observation status may affect their health care costs.

Health Care Contracts in Restraint of Trade or Commerce

A contract in restraint of trade or commerce is generally considered unlawful in Florida,¹³⁷ however, non-competition restrictive covenants contained in employment agreements that are reasonable in time, area, and line of business are not prohibited.¹³⁸ In any action concerning enforcement of a restrictive covenant, a court may not enforce a restrictive covenant unless it is set forth in writing signed by the person against whom enforcement is sought, and the person seeking enforcement of a restrictive covenant must prove the existence of one or more legitimate business interests justifying the restrictive covenant. The term "legitimate business interest" includes, but is not limited to:

- Trade secrets;¹³⁹
- Valuable confidential business or professional information that otherwise does not qualify as trade secrets;
- Substantial relationships with specific prospective or existing customers, patients, or clients;
- Customer, patient, or client goodwill associated with:
 - An ongoing business or professional practice, by way of trade name, trademark, service mark, or "trade dress";
 - A specific geographic location; or
 - A specific marketing or trade area; or
- Extraordinary or specialized training.¹⁴⁰

Any restrictive covenant not supported by a legitimate business interest is unlawful and is void and unenforceable. A person seeking enforcement of a restrictive covenant must prove that the contractually-specified restraint is reasonably necessary to protect the legitimate business interest or interests justifying the restriction.¹⁴¹

A court must apply specified rebuttable presumptions when determining the reasonableness in time of a post-term restrictive covenant not predicated upon the protection of trade secrets. A court must presume as reasonable in time any restraint six months or less in duration, and presume as unreasonable in time any restraint more than two years in duration.¹⁴² In the case of a restrictive covenant sought to be enforced against a former distributor, dealer, franchisee, or licensee of a trademark or service mark and not associated with certain sales, a court must

¹³⁶ Section 395.301, F.S.

¹³⁷ Section 542.18, F.S.

¹³⁸ See Section 542.335, F.S.

¹³⁹ Section 688.002, F.S., defines a trade secret as information, including a formula, pattern, compilation, program, device, method, technique, or process that derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

¹⁴⁰ Section 542.335(1)(b), F.S.

¹⁴¹ Section 542.335(1)(c), F.S.

¹⁴² Section 542.335(1)(d)1., F.S.

presume as reasonable in time any restraint one year or less in duration, and presume as unreasonable in time any restraint more than three years in duration.¹⁴³ In the case of a restrictive covenant sought to be enforced against the seller of certain assets, a court must presume as reasonable in time any restraint three years or less in duration and must presume as unreasonable in time any restraint more than seven years in duration.¹⁴⁴ In determining the reasonableness in time of a post-term restrictive covenant predicated upon the protection of trade secrets, a court must presume as reasonable in time any restraint of five years or less, and presume as unreasonable in time any restraint of more than 10 years.¹⁴⁵

A court must not refuse enforcement of a restrictive covenant on the ground that the person seeking enforcement is a third-party beneficiary of such contract or is an assignee or successor to a party to such contract.¹⁴⁶ In determining the enforceability of a restrictive covenant, a court must not consider any individualized economic or other hardship that might be caused to the person against whom enforcement is sought, may consider as a defense the fact that the person seeking enforcement no longer continues in business in the area or line of business that is the subject of the action to enforce the restrictive covenant, and must consider all other pertinent legal and equitable defenses and the effect of enforcement upon the public health, safety, and welfare.¹⁴⁷

A court must construe a restrictive covenant in favor of providing reasonable protection to all legitimate business interests established by the person seeking enforcement, and must not employ any rule of contract construction that requires the court to construe a restrictive covenant narrowly, against the restraint, or against the drafter of the contract.¹⁴⁸ No court may refuse enforcement of an otherwise enforceable restrictive covenant on the ground that the contract violates public policy unless such public policy is articulated specifically by the court and the court finds that the specified public policy requirements substantially outweigh the need to protect the legitimate business interest or interests established by the person seeking enforcement of the restraint.¹⁴⁹

A court must enforce a restrictive covenant by any appropriate and effective remedy.¹⁵⁰ In the absence of a contractual provision authorizing an award of attorney's fees and costs to the prevailing party, a court may award attorney's fees and costs to the prevailing party in any action seeking enforcement of, or challenging the enforceability of, a restrictive covenant.¹⁵¹

Direct Primary Care

Direct primary care (DPC) is a primary care medical practice model that eliminates third party payers from the provider-patient relationship. A DPC contractual agreement is not considered

¹⁴³ Section 542.335(1)(d)2., F.S.

¹⁴⁴ Section 542.335(1)(d)3., F.S.

¹⁴⁵ Section 542.335(1)(e), F.S.

¹⁴⁶ Section 542.335(1)(f), F.S.

¹⁴⁷ Section 542.335(1)(g), F.S.

¹⁴⁸ Section 542.335(1)(h), F.S.

¹⁴⁹ Section 542.335(1)(i), F.S.

¹⁵⁰ Section 542.335(1)(j), F.S.

¹⁵¹ Section 542.335(1)(k), F.S.

insurance and is not subject to regulation under the Florida Insurance Code (Code).¹⁵² The agreement, however, must meet certain requirements, such as being in writing and including the scope of services, duration of the agreement, amount of the fees, and specifying what the fees cover under the agreement. A primary care provider, which includes a primary care group practice, or his or her agent, is exempted from any certification or licensure requirements in the Code for marketing, selling, or offering to sell an agreement, and establishes criteria for DPC agreements.¹⁵³

A patient generally pays a monthly retainer fee – on average \$77 per individual¹⁵⁴ – to the primary care provider for defined primary care services, such as office visits, preventative care, annual physical examination, and routine laboratory tests. An estimated 1,000 DPC practices exist in 48 states and the District of Columbia, covering over 330,000 patients, including Florida.¹⁵⁵

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

DPC agreements in Florida are currently limited to primary care services offered by primary care providers licensed under chapters 458 (allopathic medicine), 459 (osteopathic medicine), 460 (chiropractic medicine), or 464 (nursing), or a primary care group practice.

Not all states call such arrangements DPC agreements or limit the agreements to primary care physicians. In Missouri, the agreement is a *medical retainer agreement* between a physician and an individual patient or a patient's representative. The Missouri statute requires that the fees for the agreement be paid from a health savings account in compliance with federal law.¹⁵⁶ In Alabama, the agreement is specific to both primary care physicians and dentists and is known as the *Alabama Physicians and Dentists Direct Pay Act*.¹⁵⁷

¹⁵² Section 624.27, F.S.

¹⁵³ *Id.*

¹⁵⁴ A study of 141 DPC practices found the average monthly retainer fee to be \$77.38. Of the 141 practices identified, 116 (82 percent) have cost information available online. When these 116 practices were analyzed, the average monthly cost to the patient was \$93.26 (median monthly cost, \$75.00; range, \$26.67 to \$562.50 per month). Of the 116 DPCs noted, 36 charged a one-time enrollment fee and the average enrollment fee was \$78. Twenty-eight of 116 DPCs charged a fee for office visits in addition to the retainer fee, and the average visit fee was \$16. See Phillip M. Eskew and Kathleen Klink, *Direct Primary Care: Practice Distribution and Cost Across the Nation*, Journal of the Amer. Bd. of Family Med. (Nov.-Dec. 2015) Vol. 28, No. 6, p. 797, available at: <http://www.jabfm.org/content/28/6/793.full.pdf> (last viewed Mar. 12, 2019).

¹⁵⁵ Direct Primary Care Coalition, *About the Direct Primary Care Coalition* <https://www.dpcare.org/about> (last viewed Mar. 12, 2019).

¹⁵⁶ Mo. Rev. Stat. §376.1800 (2015).

¹⁵⁷ 2017 Ala. Laws 460.

Cost-Containment in Health Insurance

Step-Therapy Protocols

Insurers and health maintenance organizations (HMOs) use many cost containment and utilization review strategies to manage medical and drug spending and patient safety. For example, plans may impose clinical management or utilization management requirements on the use of certain medical treatments or drugs on their formulary. In some cases, insurers or HMOs require an insured to use a step-therapy protocol for drugs or a medical treatment, which requires the insured to try one drug or medical procedure first to treat the medical condition before the insurer or HMO will authorize coverage for another drug or procedure for that condition.

Regulation of Health Insurance

Federal Law

The federal Patient Protection and Affordable Care Act (PPACA)¹⁵⁸ requires health insurers to make coverage available to all individuals and employers without exclusions for preexisting conditions, and mandates specified essential health benefits, including prescription drugs.¹⁵⁹ Insurers are required to publish a current and complete list of all covered drugs on its formulary drug list, including any tiered structure and any restrictions on the way a drug can be obtained, in a manner that is easily accessible to insureds, prospective insureds, and the public.¹⁶⁰

Florida Regulatory Entities

The Office of Insurance Regulation (OIR) regulates the activities of insurers, HMOs, and other risk-bearing entities.¹⁶¹ The AHCA regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from the AHCA.¹⁶²

Florida State Employee Group Insurance Program

The Department of Management Services, through the Division of State Group Insurance, administers the state group insurance program by providing employee benefits such as health, life, dental, and vision insurance products under a cafeteria plan consistent with s. 125, Internal Revenue Code.¹⁶³ To administer the state group health insurance program, DMS contracts with third part administrators, HMOs, and a Pharmacy Benefits Manager for the state employees' prescription drug program.¹⁶⁴

¹⁵⁸ The Patient Protection and Affordable Care Act (Pub. L. No. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010.

¹⁵⁹ 42 U.S.C. s.18022.

¹⁶⁰ 45 C.F.R. s. 156.122(d).

¹⁶¹ Section 20.121(3)(a), F.S.

¹⁶² Section 641.21(1), F.S.

¹⁶³ Section 110.123, F.S.

¹⁶⁴ Section 110.12315, F.S.

Portability of Health Care Occupational Licensure in the United States

Occupational Licensure Compacts

Interstate compacts are authorized under the U.S. Constitution, art. I, section 10, cl. 3.¹⁶⁵ Compacts that affect a power delegated to the federal government or that affect or alter the political balance within the federal system require the consent of Congress.¹⁶⁶ There are currently more than 200 compacts between the states, including 50 national compacts of which six are for health professions.^{167,168}

The licensing of professions is predominantly a state responsibility as each state has developed its own regulations, oversight boards, and requirements for dozens of professions and occupations. More than 25 percent of the American workforce are currently in a profession that requires a professional license.¹⁶⁹

In September 2018, the Federal Trade Commission (FTC) looked at the issue of state-by-state occupational licensure and its unintended consequences. In particular, the FTC noted that state-by-state licensing can have a particularly hard effect on those in the military and their spouses who are required to move frequently, those who provide services across state lines, or deliver services through telehealth.¹⁷⁰ The FTC also suggested that improved licensed portability would enhance competition, choice, and access for consumers, especially where services may be in short supply.¹⁷¹

Interstate Medical Licensure Compact

The Interstate Medical Licensure Compact (Compact) provides an expedited pathway for medical and osteopathic physicians to qualify to practice medicine across state lines within a Licensure Compact. Currently, 24 states and one territory, which cover 31 medical and

¹⁶⁵ “No state shall, without the Consent of Congress...enter into any Agreement or Compact with another State, or with a foreign Power[.]” see U.S. Constitution, art. I, sect. 10, cl. 3. While the language of the provision says congressional approval is required, not all compacts require congressional approval.

¹⁶⁶ This issue was settled in *Virginia v. Tennessee*, 148 U.S. 503 (1893). See also *Interstate Compacts & Agencies* (1998), William Kevin Voit, Sr. Editor and Gary Nitting, Council of State Governments, pg. 7, <http://www.csg.org/knowledgecenter/docs/ncic/CompactsAgencies98.pdf> (last visited Mar. 8, 2019)

¹⁶⁷ Ann O’M. Bowman and Neal D. Woods, *Why States Join Interstate Compacts*, The Council of State Governments (March 2017) p. 19 and 20, <http://knowledgecenter.csg.org/kc/system/files/Bowman%202017.pdf>, (last visited Mar. 8, 2019).

¹⁶⁸ Federal Trade Commission, *Policy Perspectives: Options to Enhance Occupational License Portability* (September 2018), p. 9, https://www.ftc.gov/system/files/documents/reports/options-enhance-occupational-license-portability/license_portability_policy_paper.pdf (last visited Mar. 8, 2019). The six health professions are nurses, medical, emergency medical services, physical therapy, psychology, and advanced registered nurse practitioners. The only two compacts currently operational are the Enhanced Nurse Compact and the physicians compacts as the others are awaiting the completion of an administrative structure.

¹⁶⁹ Albert Downs and Iris Hentze, *License Overload? Lawmakers are questioning whether we’ve gone too far with occupational and professional licensing* (April 1, 2018), STATE LEGISLATURES MAGAZINE, [ncsl.org, http://www.ncsl.org/bookstore/state-legislatures-magazine/occupational-licensing-can-balance-safety-and-employment-opportunities.aspx](http://www.ncsl.org/bookstore/state-legislatures-magazine/occupational-licensing-can-balance-safety-and-employment-opportunities.aspx) (last visited Mar. 8, 2019).

¹⁷⁰ Federal Trade Commission, *Policy Perspectives: Options to Enhance Occupational License Portability* (September 2018), *Executive Summary*, https://www.ftc.gov/system/files/documents/reports/options-enhance-occupational-license-portability/license_portability_policy_paper.pdf (last visited Mar. 8, 2019).

¹⁷¹ *Id.*

osteopathic boards participate in the Compact, and, as of February 2019, six other states have active legislation to join the Compact.^{172, 173}

The Compact has 24 sections which establish the Compact’s administration and components and prescribe how the Interstate Medical Licensure Compact Commission will oversee the Compact and conduct its business. The table below describes, by Compact section, the components of the Compact.

Provisions of the Interstate Medical Licensure Compact		
Section	Title	Description
1	Purpose <i>Establishes prevailing standard of care</i>	The purpose of the Interstate Medical Licensure Compact (Compact) is to provide a streamlined, comprehensive process that allows physicians to become licensed in multiple states. It allows physicians to become licensed without changing a state’s Medical Practice Act(s). The Compact adopts the prevailing standard of care based on where the patient is located at the time of the patient-provider encounter. Jurisdiction for disciplinary action or any other adverse actions against a physician’s license is retained in the jurisdiction where the license is issued to the physician.
2	Definitions <i>Establishes standard definitions for operation of the Compact and the Commission.</i>	Definitions are provided for: <ul style="list-style-type: none"> - Bylaws: means those Bylaws established by the Commission pursuant to Section 11 for governance, direction, and control of its action and conduct. - Commissioner: means the voting representative appointed by each member board pursuant to Section 11 whereby each member state appoints two members to the Commission. If the member state has two medical boards, the two representatives should be split between the two boards. - Conviction: means a finding by a court that an individual is guilty of a criminal offense through adjudication, or entry of a plea of guilt or no contest to the charge by the offender. A conviction also means evidence of an entry of a conviction of a criminal offense by the court shall be considered final for the purposes of disciplinary action by a member board. - Expedited license: means a full and unrestricted medical license granted by a member state to an eligible physician through the process set forth in the Compact. - Interstate Commission: means the interstate commission created pursuant to Section 11.

¹⁷² Interstate Medical Licensure Compact, *The IMLC*, <https://imlcc.org/> (last visited Mar. 8, 2019).

¹⁷³ Interstate Medical Licensure Compact, Draft Executive Committee Meeting Minutes (February 5, 2019), <https://imlcc.org/wp-content/uploads/2019/02/2019-IMLC-Executive-Committee-Minutes-February-5-2019-DRAFT.pdf> (last visited Mar. 8, 2019).

Provisions of the Interstate Medical Licensure Compact		
Section	Title	Description
		<ul style="list-style-type: none"> - License: means authorization by a state for a physician to engage in the practice of medicine, which would be unlawful without the authorization. - Medical Practice Act: means laws and regulations governing the practice of allopathic and osteopathic medicine within a member state. (In Florida, the Medical Practice Act for allopathic medicine is under ch. 458, F.S., and for osteopathic medicine, under ch. 459, F.S.) - Member Board: means a state agency in a member state that acts in the sovereign interests of the state by protecting the public through licensure, regulation, and education of physicians as directed by the state government. (The Florida Board of Medicine and the Florida Board of Osteopathic Medicine are responsible for the licensure, regulation, and education of physicians in Florida.) - Member State: means a state that has enacted the Compact. - Practice of medicine: means the diagnosis, treatment, prevention, cure, or relieving of a human disease, ailment, defect, complaint, or other physical, or mental condition, by attendance, advise, device, diagnostic test, or other means, or offering, undertaking, attempting to do, or holding oneself out as able to do, any of these acts. - Physician means: any persons who is a graduate of medical school accredited by the Liaison Committee on Medical Education, the Commission on Osteopathic College Accreditation, or a medical school listed in the International Medical Education Directory or its equivalent; passed each component of the USMLE or the COMPLEX-USA within three attempts, or any of its predecessor examinations accepted by a state medical board as an equivalent examination for licensure purposes; successfully completed graduate medical education approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association; holds specialty certification or time-unlimited specialty certificate recognized by the American Board of Medical Specialties or the American Osteopathic Association’s Board of Osteopathic Specialties; however, the times unlimited specialty certificate does not have to be maintained once the physician is initially determined through the expedited Compact process; possess a full and unrestricted license to engage in the practice of medicine issued by a member board; has never been convicted received adjudication, community supervision, or deferred disposition for any offense by a court of appropriate jurisdiction; has never held a license authorizing the practice of medicine subjected to discipline by a licensing agency in any state, federal, or foreign

Provisions of the Interstate Medical Licensure Compact		
Section	Title	Description
		<p>jurisdiction, excluding any action related to non-payment of fees related to a license; has never had a controlled substance license or permit suspended or revoked by a state or the United States Drug Enforcement Administration; and is not under active investigation by a licensing agency or law enforcement authority in any state, federal, or foreign jurisdiction.</p> <ul style="list-style-type: none"> - Offense means: A felony, high court misdemeanor, or crime of moral turpitude. - Rule means: A written statement by the Commission promulgated pursuant to Section 12 of the Compact that is of general applicability, implements, interprets, or prescribes a policy or provision of the Compact, or an organizational, procedural, or practice requirement of the Commission, and has the force and effect of statutory law in a member state, if the rule is not inconsistent with the laws of the member state. The term includes the amendment, repeal, or suspension of an existing rule. - State means: Any state, commonwealth, district, or territory of the United States. - State of Principal License means: A member state where a physician holds a license to practice medicine and which has been designated as such by the physician for purposes of registration and participation in the Compact.
3	<p>Eligibility</p> <p><i>Provides minimum requirements to receive an expedited license</i></p>	<p>To be eligible to participate and receive an expedited license, a physician must meet the requirements of Section 2 (definition of physician).</p> <p>A physician who does not meet the requirements of Section 2 may obtain a license to practice medicine in a member state outside of the Compact if the individual complies with all of the laws and requirements to practice medicine in that state.</p>
4	<p>State of Principal License (SPL)</p> <p><i>Defines a SPL</i></p>	<p>The Compact requires participating physicians to designate a State of Principal License (SPL) for purposes of registration for expedited licensure if the physician possesses a full and unrestricted license to practice medicine in that state. The SPL must be a state where:</p> <ul style="list-style-type: none"> - The physician has his/her primary residence, or - The physician has at least 25 percent of his/her practice, or - The state where the physician’s employer is located. <p>If no state qualifies for one of the above options, then the state of residence as designated on the physician’s federal income taxes is the SPL. A SPL may be re-designated at any time as long as the physician possesses a full and unrestricted license to practice medicine in that state. The Commission is authorized to develop rules to facilitate the re-designation process.</p>

Provisions of the Interstate Medical Licensure Compact		
Section	Title	Description
5	<p>Application and Issuance of Expedited Licensure</p> <p><i>Qualifications</i></p>	<p>Section 5 of the Compact establishes the process for the issuance of the expedited license.</p> <p>A physician must file an application with the member of the state selected as the SPL. The SPL will evaluate the application to determine whether the physician is eligible for the expedited licensure process and issue a letter of qualification, either verifying or denying eligibility, to the Commission.</p> <ul style="list-style-type: none"> - Static Qualifications: Include verification of medical education, graduate medical education, results of any medical or licensing examinations and any other qualifications set by the Commission through rule. - Performance of Criminal Background Checks by the member board through FBI, with the exception of federal employees who have suitability determined in accordance with U.S. 5 CFR section 731.202. - Appeals on eligibility determinations are handled through the member state. - Upon completion of eligibility verification process with member state, applicants suitable for an expedited license are directed to complete the registration process with the Commission, including the payment of any fees. - After receipt of registration and payment of fees, the physician receives his/her expedited license. The license authorizes the physician to practice medicine in the issuing state consistent with the Medical Practice Act and all applicable laws and regulations of the issuing member board and member state. - An expedited license must be valid for a period consistent with the member state licensure period and in the same manner as required for other physicians holding a full and unrestricted license. - An expedited license obtained through the Compact must be terminated if a physician fails to monitor a license in the SPL for a non-disciplinary reason, without re-designation of a new SPL.
	<i>Commission rulemaking provisions</i>	The Commission is authorized to develop rules relating to the application process, including fees and issuing the expedited license.
6	Fees for Expedited Licensure	A member state is authorized to charge a fee for an expedited license that is issued or renewed through the Compact. The individual state fees currently vary from a low of \$75.00 in Alabama to a high of \$700 in Maine. ¹⁷⁴

¹⁷⁴ Interstate Medical Licensure Compact, *What Does It Cost?* <https://imlcc.org/what-does-it-cost/> (last visited Mar. 8, 2019).

Provisions of the Interstate Medical Licensure Compact		
Section	Title	Description
	<i>Rulemaking authority</i>	The Commission is authorized is develop rules relating to fees for expedited licenses. The rules are not permitted to limit the authority of the member states, the regulating authority of the member states, or to impose and determine the amount of the fee charged by the member states.
7	<p>Renewal and Continued Participation <i>Renewal license process created</i></p> <p><i>Continuing education required for renewal with member state</i></p> <p><i>Fees collected, if any, by member state.</i></p> <p><i>Rulemaking authority.</i></p>	<p>A physician with an expedited license in a member state must complete a renewal process with the Commission if the physician:</p> <ul style="list-style-type: none"> - Maintains a full and unrestricted license in a SPL. - Has not been convicted, received adjudication, deferred adjudication, community supervision, or deferred disposition for any offense by a court of appropriate jurisdiction. - Has not had a license authorizing the practice of medicine subject to discipline by a licensing agency in any state, federal, or foreign jurisdiction, excluding any action relating to non-payment of fees related to a license. - Has not had a controlled substance license or permit suspended or revoked by a state or the United State Drug Enforcement Administration. <p>Physicians are required to comply with all continuing education and professional development requirements for renewal of a license issued by a member state.</p> <p>The Commission must collect any renewal fees charged for the renewal of a license and distribute the fees to the appropriate member board. Upon payment of fees, a physician’s license may be renewed. Any information collected during the renewal process shall also be shared with all member boards.</p> <p>The Commission is authorized to develop rules to address the renewal of licenses.</p>
8	<p>Coordinated Information Systems <i>Authorized to create database of all applicants</i></p> <p><i>By request, may share data</i></p>	<p>The Commission is required to establish a database of all licensed physicians who have applied for licensure. Member boards are required to report disciplinary or investigatory actions as required by Commission rule. Member boards may also report any non-public complaint, disciplinary, or investigatory information not required to be reported to the Commission.</p> <p>Upon request, member boards may share complaint or disciplinary information about physicians to another member board. All information provided to the Commission or distributed by the</p>

Provisions of the Interstate Medical Licensure Compact		
Section	Title	Description
	<i>Rulemaking authority</i>	<p>member boards shall be confidential, filed under seal, and used only for investigatory or disciplinary matters.</p> <p>The Commission is authorized to develop rules for mandated or discretionary sharing of information by member boards.</p>
9	<p>Joint Investigations</p> <p><i>Permits joint investigations between the state and the member boards</i></p>	<p>Licensure and disciplinary records of physicians are deemed investigative.</p> <p>A member board may participate with other member boards in joint investigations of physicians licensed by the member boards in addition to the authority granted by the member board and its respective Medical Practice Act or other respective state law.</p> <p>Member boards may share any investigative, litigation, or compliance materials in furtherance of any joint or individual investigation initiated under the Compact. Any member state may investigate actual or alleged violations of the statutes authorizing the practice of medicine in any other member state in which a physician holds a license to practice medicine.</p>
10	<p>Disciplinary Actions</p> <p><i>Licensure actions specific actions to reinstate</i></p> <p><i>Discipline by a member state has reciprocal actions</i></p>	<p>Any disciplinary action taken by any member board against a physician licensed through the Compact is be deemed unprofessional conduct which may be subject to discipline by other member boards, in addition to any violation of the Medical Practice Act or regulations in that State.</p> <p>If the physician’s license is revoked, surrendered, or relinquished in lieu of discipline in the SPL, or suspended, then all licenses issued to that physician by member boards are automatically placed, without any further action necessary by any member board, on the same status. If the SPL subsequently reinstates the physician’s license, a license issued to the physician by any other member board remains encumbered until that respective board takes action to specifically reinstate the license in a manner consistent with the Medical Practice Act in that state.</p> <p>If a disciplinary action is taken against the physician in a member state that is the physician’s SPL, any other member state may deem the action conclusive as to matter of law and fact decided, and:</p> <ul style="list-style-type: none"> - Impose the same or lesser sanction or sanctions against the physician so long as such sanctions are consistent with the Medical Practice Act of that state; or - Pursue separate disciplinary action against the physician under the Medical Practice Act, regardless of the action taken in other member states.

Provisions of the Interstate Medical Licensure Compact		
Section	Title	Description
		If a license granted to a physician by a member board is revoked, surrendered, or relinquished in lieu of discipline, or suspended, then any license issued to the physician by any other member board or boards is be suspended, automatically, and without further action necessary by the other board(s), for ninety (90) days upon entry of the order by the disciplining board, to permit the member board(s) to investigate the basis for the action under the Medical Practice Act of that state. A member board may terminate the automatic suspension of the license it issued prior to the completion of the ninety (90) day suspension period in a manner consistent with the Medical Practice Act of that state.
11	<p>Interstate Medical Licensure Compact Commission</p> <p><i>Recognizes creation of Commission and state's representative with 2 Commissioners, one from each regulatory board</i></p> <p><i>Availability of Commission meetings, except for certain topics</i></p>	<p>The member states create the Interstate Medical Licensure Compact Commission as a joint agency of the member states and administration of the Compact. The Commission has all the duties, powers, and responsibilities set forth in the Compact, plus any other powers conferred upon it by the member states through the Compact.</p> <p>Each member state has two (2) two voting representatives appointed by each member state to serve as Commissioners. For states with separate regulatory boards for allopathic and osteopathic regulatory boards, the member appoints one representative from each member board.</p> <p>A Commissioner must be:</p> <ul style="list-style-type: none"> - An allopathic or osteopathic physician appointed to a member board. - Executive director, executive secretary, or similar executive or a member board, or - Member of the public appointed to a member board. <p>The Commission must meet at least once per calendar year and at least a portion of the meeting shall be a business meeting which shall include the election of officers. The Chair may call additional meeting and shall call for all meeting upon the request of a majority of the member states.</p> <p>Meetings are permitted via telecommunication according to the Bylaws.</p> <p>Each Commissioner is entitled to one vote. A majority of Commissioners constitutes a quorum, unless a larger quorum is required by the Bylaws of the Commission. A Commissioner may not delegate a vote to another Commissioner. In the absence of its Commissioner, a member state may delegate voting authority for a</p>

Provisions of the Interstate Medical Licensure Compact		
Section	Title	Description
	<i>Public notice required</i>	<p>specified meeting to another person from that state who meets the requirements of being a Commissioner.</p> <p>The Commission must provide public notice of all meetings and all meetings shall be open to the public. A meeting may be closed to the public, in full or in portion, when it determines by a 2/3 vote of the Commissioners present, that an issue or matter would likely to:</p> <ul style="list-style-type: none"> - Relate solely to the internal personnel practices and procedures of the Interstate Commission. - Discuss matters specifically exempted from disclosure by federal statute; - Discuss trade secrets, commercial, or financial information that is privileged or confidential; - Involve accusing a person of a crime, or formally censuring a person; - Discuss information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy; - Discuss investigative records compiled for law enforcement purposes; or - Specifically relate to the participation in a civil action or other legal proceeding.
	<i>Availability of public data from the Commission</i>	The Commission must make its information and official records, to the extent, not otherwise designated in the Compact or by its rules, available to the public for inspection.
	<i>Creates an executive committee to act on behalf of the Commission</i>	<p>An executive committee is established which has the authority to act on behalf of the Commission, with the exception of rulemaking, when the Commission is not in session. The executive committee oversees the administration of the Compact, including enforcement and compliance with the Compact, its bylaws and rules, and other such duties as necessary.</p> <p>The Commission may establish other committees for governance and administration of the Compact.</p>
12	<p>Powers and Duties of the Interstate Commission</p> <p><i>Recognizes creation of the Commission</i></p>	<p>The Commission has the duties and the powers to:</p> <ul style="list-style-type: none"> - Oversee and administer the Compact. - Promulgate rules which are binding. - Issue advisory opinions upon the request of member states concerning the meaning or interpretation of the Compact or its bylaws, rules, and actions. - Enforce compliance with the Compact, provisions, the rules, and the bylaws.

Provisions of the Interstate Medical Licensure Compact		
Section	Title	Description
		<ul style="list-style-type: none"> - Establish and appoint committees, including the executive committee, which has the power to act on behalf of the Interstate Commission. - Pay, or provide for the payment of Commission expenses. - Establish and maintain one or more offices. - Borrow, accept, hire, or contract for services of personnel. - Purchase and maintain insurance and bonds. - Employ an executive director with power to employ, select, or appoint employees, agents, or consultants, determine their duties, and fix their compensation. - Establish personnel policies and programs. - Accept donations and grants of money, equipment, supplies, materials, and services, and to receive, utilize and dispose of it consistent with conflict of interest policies as established by the Commission. - Lease, purchase, accept contributions, or donation of, or otherwise own, hold, improve or use, any property, real, personal, or mixed. - Establish a budget and make expenditures. - Adopt a seal and bylaws governing the management and operation of the Commission. - Report annually to the legislatures and governors of the members concerning the activities of the Commission during the preceding year, including reports of financial audits and any recommendations that may have been adopted by the Commission. - Coordinate education, training, and public awareness regarding the Compact, its implementation and operation. - Maintain records in accordance with bylaws. - Seek and obtain trademarks, copyrights, and patents. - Perform such functions as may be necessary or appropriate to achieve the purpose of the Compact.
13	<p>Finance Powers</p> <p><i>Provides for annual assessment</i></p> <p><i>Requires rule for any assessment</i></p> <p><i>No pledging credit without authorization</i></p>	<p>The Compact authorizes an annual assessment levied on each member state to cover the costs of operations and activities of the Commission and its staff. The assessment must be sufficient to cover the amount not provided by other sources and needed to cover the annual budget approved each year by the Commission.</p> <p>The Compact requires that the assessment be memorialized by rule binding all the member states.</p> <p>The Commission is not authorized to pledge the credit of any of the member states, except by, and with the authority of, the member states.</p>

Provisions of the Interstate Medical Licensure Compact		
Section	Title	Description
	<i>Yearly audits</i>	The Compact requires yearly financial audits conducted by a certified or licensed public accountant and the report is to be included in the Commission’s annual report.
14	<p>Organization and Operation of the Interstate Commission</p> <p><i>Annual officer election</i></p> <p><i>No officer remuneration</i></p> <p><i>Liability protection for actions within scope of duties and responsibilities only for officers, employees, and agents</i></p>	<p>The Compact creates a requirement for the Commission to adopt bylaws by a two-thirds (2/3) vote within twelve months of the first meeting which has already occurred. The first Bylaws were adopted in October 2015.¹⁷⁵</p> <p>A Chair, Vice Chair, and Treasurer are be elected or appointed each year by the Commission.</p> <p>Officers serve without remuneration. Officers and employees are immune from suit and liability, either personally or in their professional capacity, for a claim for damage to or loss of property or personal injury or other civil liability cause or arising out of, or relating to, an actual or alleged act, error or omission that occurred with the scope of Commission employment, duties, or responsibilities, provided such person should not be protected from suit or liability for damage or loss, injury or liability caused by the intentional or willful and wanton conduct of such a person.</p> <p>The liability of the executive director and Commission employees or representatives of the Commission, acting within the scope of their employment, may not exceed the limits set forth under the state’s Constitution and laws for state officials, employees, and agents. The Compact provides that the Commission is considered an instrumentality of the state for this purpose.</p> <p>The Compact provides that the Commission must defend the executive director, its employees, and subject to the approval of the state’s attorney general or other appropriate legal counsel, must defend in any civil action seeking to impose liability within scope of duties.</p> <p>The Compact provides that employees and representatives of the Commission shall be held harmless in the amount of any settlement or fees, including attorney fees and costs that occurred within the scope of employment or responsibilities and not a result of willful or wanton misconduct.</p>
15	Rulemaking Functions of	The Commission is required to promulgate reasonable rules in order to implement and operate the Compact and the Commission. The

¹⁷⁵ Interstate Medical Licensure Compact, *Annual Report 2017*, <https://imlcc.org/wp-content/uploads/2018/03/IMLCC-Annual-Report-2017-1.pdf> (last visited Mar. 11, 2019).

Provisions of the Interstate Medical Licensure Compact		
Section	Title	Description
	<p>the Interstate Commission <i>Promulgate reasonable rules</i></p> <p><i>Judicial review at U.S. Federal District Court</i></p>	<p>Compact adds that any attempt to exercise rulemaking beyond the scope of the Compact renders the action invalid. The rules should substantially conform to the “Model State Administrative Procedures Act” of 2010 and subsequent amendments thereto.</p> <p>The Compact allows for judicial review of any promulgated rule. A petition may be filed thirty (30) days after a rule has been promulgated in the U.S. District Court in Washington, D.C., or the federal court where the Commission is located.¹⁷⁶ The Compact requests deference to the Commission’s action consistent with state law.</p>
16	<p>Oversight of Interstate Contract <i>Enforcement</i></p> <p><i>Service of process</i></p>	<p>The Compact is the responsibility of each state’s own executive, legislative, and judicial branch to oversee and enforce. All courts are to take judicial notice of the Compact and any adopted administrative rules in a proceeding involving Compact subject matter.</p> <p>The Compact provides that the Commission is entitled to receive service of process in any proceeding and have standing in any proceeding. Failure to serve the Commission renders a judgment null and void as to the Commission, the Compact, or promulgated rule.</p>
17	Enforcement of Interstate Contract	The Compact provides the Commission reasonable discretion to enforce the provisions and rules of the Compact, including when and where to initiate legal action. The Commission is permitted to seek a range of remedies.
18	Default Procedures	<p>The Compact provides a number of reasons a member state may default on the Compact, including failure to perform required duties and responsibilities and the options available to the Commission.</p> <p>The Compact requires the Commission to promulgate rules to address how physician licenses are affected by the termination of a member state from the Compact. The rules must also ensure that a member state does not bear any costs when a state has been found to be in default.</p> <p>The Compact provides an appeal process for the terminating state and procedures for attorney’s fees and costs.</p>
19	Dispute Resolution	The Compact authorizes the Commission to use dispute resolution tools to resolve disputes between states, such as mediation and

¹⁷⁶ The Interstate Medical Licensure Compact Commission is currently headquartered in Littleton, Colorado. See Interstate Medical License Commission, Frequently Asked Questions (FAQS), <https://imlcc.org/faqs/>

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Section	Title	Description
		binding dispute resolution. The Commission must promulgate rules for the dispute resolution process.
20	Member States, Effective Date and Amendment	The Compact allows any state to become a member state and that the Compact is binding upon the legislative enactment of the Compact by no less than seven (7) states. ¹⁷⁷
21	Withdrawal	<p>A member state may withdraw from the Compact through repeal of this section of law which inserted the Compact into state statute. Any repeal of the Compact through repeal of the state law cannot take effect until one (1) year after the effective date of such an action and written notice has been given by the withdrawing state to the governor of each other member state.</p> <p>The Compact provision also requires that upon introduction of any repeal legislation, that the withdrawing state immediately notify the Chairperson of the Commission of the legislation.</p> <p>The Compact provides that it is the Commission's responsibility to notify the other member states within 60 (sixty) days of its receipt of information about legislation that would repeal that state's participation in the Compact. The withdrawing state would be responsible for any dues, obligations, or liabilities incurred through the date of withdrawal. Reinstatement is an option under the Compact.</p> <p>The Compact authorizes the Commission to develop rules to address the impact of the withdrawal of a member state on licenses.</p>
22	Dissolution	<p>When the membership of the Compact is reduced to one, the Compact shall be dissolved. Once dissolved, the Compact is null and void.</p> <p>Once concluded, any surplus funds of the Commission shall be distributed in accordance with the bylaws.</p>
23	Severability and Construction	<p>If any part of this Compact is not enforceable, the remaining provisions are still enforceable.</p> <p>The provisions of the Compact are to be liberally construed, and nothing is to be construed so as to prohibit the applicability of other interstate compacts to which states might be members.</p>

¹⁷⁷ The Compact is in force now. The Commission was seated for the first time in October 2015 and issued its first letters of qualification to physicians in April 2017. See Interstate Medical Licensure Compact, <https://imlcc.org/faqs/> (last Mar. 11, 2019).

Provisions of the Interstate Medical Licensure Compact		
Section	Title	Description
24	Binding Effect of Compact and Other Laws	<p>This Compact does not prohibit the enforcement of other laws which are not in conflict with this Compact. All laws which are in a member state which are inconsistent with this Compact are superseded to the point of the contact.</p> <p>The actions of the Commission are binding on the member states, including all promulgated rules and the adopted bylaws of the Commission. All agreements between the Commission and the member state are binding in accordance with their terms.</p> <p>In the event that any provision of this Compact exceeds Florida’s constitutional limits imposed on the legislature of any member state, such provision is ineffective to the extent that the conflict of the constitutional provision in question in that member state.</p>

Regulation of Physicians in Florida

Licensing of Florida Physicians

The regulation of the practices of medicine and osteopathic medicine fall under chapters 458 and 459, F.S., respectively. The practice acts for both professions establish the regulatory boards, a variety of licenses, the application process with eligibility requirements, and financial responsibilities for the practicing physicians. The boards have the authority to establish, by rule, standards of practice and standards of care for particular settings.¹⁷⁸ Such standards may include education and training, medication including anesthetics, assistance of and delegation to other personnel, sterilization, performance of complex or multiple procedures, records, informed consent, and policy and procedures manuals.¹⁷⁹ The current licensure application fee for a medical doctor is \$350 and is non-refundable.¹⁸⁰ Applications must be completed within one year. If a license is approved, the initial license fee is \$355.¹⁸¹ The entire process may take from two to six months from the time the application is received.¹⁸²

For osteopathic physicians, the current application fee is non-refundable \$200, and if approved, the initial licensure fee is \$305.¹⁸³ The same application validity provision of one year applies and the processing time of two to six months is the range of time that applicants should

¹⁷⁸ Sections 458.331(1)(v) and 459.015(1)(z), F.S.

¹⁷⁹ *Id.*

¹⁸⁰ Florida Board of Medicine, *Medical Doctor - Fees*, <https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted/> (Last visited Mar. 8, 2019).

¹⁸¹ A change to Rule 64B-3.002, F.A.C., effective March 11, 2019, modified the fee schedule for licensure applications. The fee for licensure by examination increased to \$500 and the fee for licensure by endorsement also increased to \$500. The time to complete an initial applications was reduced from one year to six months.

¹⁸² Florida Board of Medicine, *Medical Doctor Unrestricted – Process*, <https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted/> (last visited Mar. 8, 2019).

¹⁸³ Florida Board of Osteopathic Medicine, *Osteopathic Medicine Full Licensure - Fees*, <https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted/> (last visited: Mar. 8, 2019).

anticipate for a decision.¹⁸⁴ If an applicant is licensed in another state, the applicant may request that Florida “endorse” those exam scores and demonstrate that the license was issued based on those exam scores. The applicant must also show that the exam was substantially similar to any exam that Florida allows for licensure.¹⁸⁵

The general requirements for licensure under both practice acts are very similar with the obvious differences found in the educational backgrounds of the applicants. However, the practice acts are not identical in their licensure offerings as shown in the table below which compares some of the contents of the two practice acts. Where the practice acts share the most similarities are the qualifications for licensure. Both the Board of Medicine and the Board of Osteopathic Medicine require their respective applicants to meet these minimum qualifications:

- Complete an application form as designated by the appropriate regulatory board.
- Be at least 21 years of age.
- Be of good moral character.
- Have completed at least two years (medical) or three years (osteopathic) of pre-professional post-secondary education.
- Have not previously committed any act that would constitute a violation of this chapter or lead to regulatory discipline.
- Have not had an application for a license to practice medicine or osteopathic medicine denied or a license revoked, suspended or otherwise acted upon in another jurisdiction by another licensing authority.
- Must submit a set of fingerprints to the DOH for a criminal background check.
- Demonstrate that he or she is a graduate of a medical college recognized and approved by the applicant’s respective professional association.
- Demonstrate that she or he has successfully completed a resident internship (osteopathic medicine) or supervised clinical training (medical) of not less than 12 months in a hospital approved for this purpose by the applicant’s respective professional association.
- Demonstrate that he or she has obtained a passing score, as established by the applicant’s appropriate regulatory board, on all parts of the designated professional examination conducted by the regulatory board’s approved medical examiners no more than five years before making application to this state; or, if holding a valid active license in another state, that the initial licensure in the other state occurred no more than five years after the applicant obtained a passing score on the required examination.¹⁸⁶

Statutory References for Practice Acts - Licensure Medical and Osteopathic Physicians: Ch. 458 and 459, F.S.		
Issue	Medical Physicians	Osteopathic Physicians
Regulatory Board	Board of Medicine s. 458.307, F.S.	Board of Osteopathic Medicine s. 459.004, F.S.
Rulemaking Authority	s. 458.309., F.S.	s. 459.005, F.S.

¹⁸⁴ Florida Board of Osteopathic Medicine, *Osteopathic Medicine Full Licensure - Process*, <https://floridasosteopathicmedicine.gov/licensing/osteopathic-medicine-full-licensure/> (last visited Mar. 8, 2019).

¹⁸⁵ Florida Board of Osteopathic Medicine, *Osteopathic Medicine Full Licensure – Requirements*, <https://floridasosteopathicmedicine.gov/licensing/osteopathic-medicine-full-licensure/> (last visited Mar. 8, 2019).

¹⁸⁶ See ss. 458.311, F.S. and 459.0055, F.S.

Statutory References for Practice Acts - Licensure Medical and Osteopathic Physicians: Ch. 458 and 459, F.S.		
Issue	Medical Physicians	Osteopathic Physicians
General Requirements for Licensure	s. 458.311, F.S.	s. 459.0055, F.S.
Licensure Types		
<i>Restricted License</i>	s. 458.310, F.S.	No provision
<i>Restricted License Certain foreign physicians</i>	s. 458.3115, F.S.	No provision
<i>Licensure by Endorsement</i>	s. 458.313, F.S.	No provision
<i>Temporary Certificate (Approved Cancer Centers)</i>	s. 458.3135, F.S.	No provision
<i>Temporary Certificate (Training Programs)</i>	s. 458.3137, F.S.	No provision
<i>Medical Faculty Certificate</i>	s. 458.3145, F.S.	s. 459.0077, F.S.
<i>Temporary Certificate Areas of Critical Need</i>	s. 458.315, F.S.	s. 459.0076, F.S.
<i>Temporary Certificate Areas of Critical Need – Active Duty Military & Veterans</i>	s. 458.3151, F.S.	s. 459.00761, F.S.
<i>Public Health Certificate</i>	s. 458.316, F.S.	No provision
<i>Public Psychiatry Certificate</i>	s. 458.3165, F.S.	No provision
<i>Limited Licenses</i>	s. 458.317, F.S.	s. 459.0075, F.S.
<i>Expert Witness</i>	s. 458.3175, F.S.	s. 459.0066, F.S.
License Renewal	s. 458.319, F.S. \$500/max/biennial renewal	s. 459.008, F.S.
Financial Responsibility <i>Condition of Licensure</i>	s. 458.320, F.S.	s. 459.0085, F.S.
Penalty for Violations	s. 458.327, F.S.	s. 459.013, F.S.

In Florida, to practice medicine an individual must become a licensed medical doctor through licensure by examination¹⁸⁷ or licensure by endorsement.¹⁸⁸ Florida does not recognize automatically another state’s medical license or provide licensure reciprocity. Licensure by endorsement requires the medical physician to meet the following requirements:

- Be a graduate of an allopathic United States Medical School recognized and approved by the United States Office of Education (AMG) and completed at least one year of residency training;
- Be a graduate of an allopathic international medical school (IMG) and have a valid Educational Commission for Foreign Medical Graduates (ECFMG) certificate and completed an approved residency of at least two years in one specialty area; or

¹⁸⁷ Section 458.311, F.S.

¹⁸⁸ Section 458.313, F.S.

- Be a graduate who has completed the formal requirements of an international medical school except the internship or social service requirements, passed parts I and II of the National Board of Medical Examiners (NBME) or ECFMG equivalent examination, and completed an academic year of supervised clinical training (5th pathway) and completed an approved residency of at least two years in one specialty area.
- And both of the following:
 - Passed all parts of a national examination (the NBME; the Federation Licensing Examination offered by the Federation of State Medical Boards of the United States, Inc.; or the United States Medical Licensing Exam); and
 - Be licensed in another jurisdiction and actively practiced medicine in another jurisdiction for at least two of the immediately preceding four years; or passed a board-approved clinical competency examination within the year preceding filing of the application or; successfully completed a board approved postgraduate training program within 2 years preceding filing of the application.¹⁸⁹

Financial Responsibility

Florida-licensed allopathic physicians are required to maintain professional liability insurance or other financial responsibility to cover potential claims for medical malpractice as a condition of licensure, with specified exemptions.¹⁹⁰ Physicians who perform surgeries in a certain setting or have hospital privileges must maintain professional liability insurance or other financial responsibility to cover an amount not less than \$250,000 per claim.¹⁹¹ Physicians without hospital privileges must carry sufficient insurance or other financial responsibility in coverage amounts of not less than \$100,000 per claim.¹⁹² Certain physicians who are exempted from the requirement to carry professional liability insurance or other financial responsibility must provide notice to their patients.¹⁹³

Florida-licensed osteopathic physicians have similar financial responsibility requirements as allopathic physicians¹⁹⁴. With specified exceptions, the DOH must suspend, on an emergency basis, any licensed allopathic or osteopathic physician who fails to satisfy a medical malpractice claim against him or her within specified time frames.¹⁹⁵

Disciplinary Process: Fines and Sanctions

Chapter 456, F.S., contains the general regulatory provisions for health care professions and occupations under the Division of Medical Quality Assurance (MQA) in the DOH. Section 456.072, F.S., specifies 40 acts that constitute grounds for which disciplinary actions may be taken against a health care practitioner. Section 458.331, F.S., identifies 43 acts that constitute grounds for which disciplinary actions may be taken against a medical physician and s. 459.015,

¹⁸⁹ Florida Board of Medicine, *Medical Doctor-Unrestricted; Licensure by Endorsement*, <https://flboardofmedicine.gov/licensing/medical-doctor-unrestricted/> (last visited Apr. 1, 2019).

¹⁹⁰ Section 458.320, F.S.

¹⁹¹ Section 458.320(2), F.S.

¹⁹² Section 458.320(1), F.S.

¹⁹³ Section 458.320(5)(f) and (g), F.S.

¹⁹⁴ Section 459.0085, F.S.

¹⁹⁵ Sections 458.320(8) and 459.0085(9), F.S.

F.S., identifies those acts which are specific to an osteopathic physician. Some parts of the review process are public and some are confidential.¹⁹⁶

Complaints and allegations are received by the MQA unit for determination of legal sufficiency and investigation. A determination of legal sufficiency is made if the ultimate facts show that a violation has occurred.¹⁹⁷ The complainant is notified by letter as to whether the complaint will be investigated and if any additional information is needed. Complaints which involve an immediate threat to public safety are given the highest priority.

The DOH is responsible for reviewing each report to determine if discipline against the provider is warranted.¹⁹⁸ Authorization for the discipline of allopathic and osteopathic physicians can be found in state law and administrative rule.¹⁹⁹ If held liable for one of the offenses, the fines and sanctions by category and by offense are based on whether it is the physician's first, second, or third offense.²⁰⁰ The boards may issue a written notice of noncompliance for the first occurrence of a single minor violation.²⁰¹ The amount of fines assessed can vary depending on the severity of the situation, such as improper use of a substance to concealment of a material fact. A penalty may come in the form of a reprimand, a licensure suspension, or revocation followed by some designated period of probation if there is an opportunity for licensure reinstatement. Other sanctions may include supplemental continuing education requirements which require proof of completion before the license can be reinstated.

III. Effect of Proposed Changes:

Access to Dental Services

Section 1 provides legislative intent to promote programs and initiatives that make preventive and educational dental services available to Floridians and recognizes that better oral health leads to a more productive workplace and improves the cognitive abilities of schoolchildren, resulting in a reduction in the number of missed school days.

Section 2 creates the Dental Student Loan Repayment Program at the Department of Health (DOH) under s. 381.4019, F.S. The initiative is intended to promote access to dental care by encouraging dentists to practice in dental health professional shortage areas or medically underserved areas, or serve a medically underserved population.

¹⁹⁶ Fla. Department of Health, Division of Medical Quality Assurance, *Enforcement Process*, http://www.floridahealth.gov/licensing-and-regulation/enforcement/_documents/enforcement-process-chart.pdf (last updated Mar. 11, 2019).

¹⁹⁷ Fla. Department of Health, *Consumer Services – Administrative Complaint Process*, <http://www.floridahealth.gov/licensing-and-regulation/enforcement/admin-complaint-process/consumer-services.html> (last visited Mar. 11, 2019).

¹⁹⁸ See ss. 458.351(5) and 459.026(5), F.S.

¹⁹⁹ See ss. 458.307 and 459.004, F.S., for the regulatory boards, and ss. 64B8-8 and 64B15-19, F.A.C., for administrative rules relating to disciplinary procedures.

²⁰⁰ *Id.*

²⁰¹ Sections 64B8-8.011 and 64B15-19.0065, F.A.C. A minor violation is deemed to not endanger the public health, safety, and welfare and does not demonstrate a serious inability to practice.

The DOH is required to establish a Dental Student Loan Repayment Program, subject to a legislative appropriation, to benefit state-licensed dentists who demonstrate active employment in a public health program that serves Medicaid recipients and other low-income patients. The employment must be located in a dental health professional shortage area (HPSA) or a medically underserved area (MUA).

The DOH is directed to award funds from the loan program to repay student dental loans of a Florida-licensed dentist who meets these requirements; however, no award may exceed \$50,000 per year, per dentist. The DOH must limit the number of new dentists participating in the loan program to no more than 10 per fiscal year. A dentist may receive funds for at least one year and up to a maximum of five years. The dentist's period of obligated service begins when the dentist who receives the funds begins his or her employment.

Only loans taken out to pay the costs of tuition, books, dental equipment and supplies, uniforms, and living expenses may be covered under the loan program. Loan repayments are contingent upon continued proof of eligibility and must be made directly to the holder of the loan.

A dentist is not eligible to benefit from program funding if the dentist:

- Is no longer employed by a public health program that meets the requirements;
- Ceases to participate in the Florida Medicaid program; or
- Has disciplinary action taken against his or her license by the Board of Dentistry for a violation of s. 466.028, F.S.²⁰²

The DOH is required to adopt rules to administer the loan program.

Section 3 creates the Donated Dental Services Program under s. 381.40195, F.S., in the DOH. The Donated Dental Services Program is intended to provide comprehensive dental care through a network of volunteer dentists and other dental providers to needy, disabled, elderly, and medically comprised individuals who are ineligible for public assistance programs such as Medicaid or CHIP. Services under the program may be provided in a private office location or at any other suitable location. The eligible individual is not required to pay any fees or costs associated with the services for any treatments received.

The DOH is responsible for the implementation and operation of the program if an appropriation is provided by the Legislature for such purpose. The DOH is required to contract with a nonprofit organization that has experience providing and administering similar services and any such contract must delineate all of the vendor's responsibilities as provided in the statute. These responsibilities include, but are not limited to:

- Maintaining a network of volunteer providers who can provide a comprehensive range of dental services;
- Maintaining a referral system to an appropriate volunteer dentist or other participating provider;

²⁰² A violation of s. 466.028, F.S., constitutes grounds for denial of dental licensure or disciplinary action by the Board of Dentistry, as specified in s. 456.072(2), F.S.

- Developing a public awareness and marketing campaign to promote the program and to educate eligible individuals about the program;
- Providing the necessary administrative and technical support to administer the program;
- Submitting an annual report to the DOH with the required statutory components; and
- Performing any other program-related duties and responsibilities as required by the DOH.

The DOH is required to adopt rules to administer the program.

Hospital Quality Information

Section 4 amends s. 395.1012, F.S., to require each hospital to provide to any patient upon admission, upon scheduling of non-emergency care, or prior to treatment, written information on a form created by the AHCA that contains data reported for the most recent year available for the hospital and the statewide average for:

- The rate of hospital-acquired infections;
- The overall rating of the Hospital Consumer Assessment of Healthcare Providers Systems Survey; and
- The 15-day readmission rate.

The hospital must also provide the required data to any party upon request. The hospital must present the data in a manner that is easily understandable and accessible to the patient and include an explanation of the relationship between the data and patient safety.

Patient Access to Primary Care and Specialty Providers

Section 5 creates s. 395.1052, F.S., to require that a hospital notify a patient's primary care provider (PCP) within 24 hours of the patient's admission and discharge from the hospital. A hospital must also notify a patient of his or her right to request that the hospital's treating physician consult with the patient's PCP or specialist, and, if the patient so requests, the treating physician must make reasonable efforts to consult with the PCP or specialist when developing the patient's plan of care. Additionally, a hospital is required to provide the discharge summary and any related information and records to the PCP within 14 days of the patient's discharge.

Ambulatory Surgical Center Services

Section 6 amends s. 395.002, F.S., to allow a patient to stay in an ASC for 24 hours, rather than requiring that a patient be admitted and discharged on the same working day. This change complies with the federal CMS requirements for an ASC.²⁰³

Section 7 amends s. 395.1005, F.S., to require the AHCA, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules to ensure the safe and effective delivery of surgical care to children in ambulatory surgical centers. The rules must be consistent with the American College of Surgeons' 2015 Standards Manual entitled "Optimal Resources for Children's Surgical Care."

²⁰³ 42 C.F.R. s. 416.2.

The bill specifies that an ASC may provide surgical care that requires a length of stay past midnight to children younger than 18 years of age only after the AHCA authorizes such procedures in rule.

Pediatric Cardiac Standards of Care

Section 7 amends s. 395.1055, F.S., to modify the composition and duties of the Pediatric Cardiac Technical Advisory Panel (panel) as established in the AHCA by:

- Authorizing the AHCA to reimburse members of the panel for travel and per diem expenses.
- Authorizing the appointment of three alternate, at-large members from affiliations different than those of the voting at-large members.
- Adding a two-year term limit to voting panel members; however, members may be re-appointed to the panel after a two-year retirement period.
- Providing panel members sovereign immunity for the good faith performance of duties assigned to them by the Secretary of the AHCA.
- Requiring the Secretary of the AHCA to consult with the panel for an advisory recommendation on all Certificate of Need (CON) applications to establish pediatric cardiac surgical centers.
- Authorizing the Secretary of the AHCA to request announced or unannounced site visits to any existing pediatric cardiac surgical center or a facility seeking licensure as a pediatric cardiac surgical center through the CON process to ensure compliance with the process.
- Authorizing the Secretary of the AHCA to request recommendations from the panel for in-state physician experts to conduct on-site visits and permitting the Secretary to appoint up to two out-of-state physician experts for such visits.
- Establishing procedures for site visit team on-site inspections of a hospital's pediatric medical and surgical programs and requiring each team member to submit a written report of their findings to the panel.
- Authorizing the panel to discuss the written reports from review team members and present an advisory opinion and suggested actions for correction to the Secretary of the AHCA.
- Requiring each on-site inspection to include:
 - An inspection of the program's physical facilities, clinics, and laboratories.
 - Interviews with support staff and hospital administration.
 - A review of randomly selected medical records and reports, clinical outcome data from the Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC), mortality reports, and program volume data from the preceding year.
- Requiring the Surgeon General of the Department of Health to provide quarterly reports to the Secretary of the AHCA consisting of data from the Children's Medical Services' (CMS) critical congenital heart disease screening program for review by the panel.

Notification of Hospital Observation Status

Section 8 amends s. 395.301, F.S., to require a hospital to provide a patient written notice of their observation status immediately when he or she is placed upon observation status. The bill requires Medicare patients receive the notice through the Medicare Outpatient Observation Notice form adopted under 42 C.F.R. s. 489.20, and non-Medicare patients through a form adopted by rule of the AHCA. The bill also makes conforming changes.

Health Care Contracts in Restraint of Trade or Commerce

Section 9 provides that a restrictive covenant entered into with an allopathic or osteopathic physician licensed in Florida who practices a medical specialty in a county where one entity employs or contracts with all physicians who practice such specialty in that county is not supported by a legitimate business interest, and is void and unenforceable.

The restrictive covenant remains void and unenforceable until three years after the date on which a second entity that employs or contracts with one or more physicians who practice that specialty begins serving patients in that county.

Direct Health Care Agreements

Section 10 amends s. 624.27, F.S., to authorize direct care agreements with health care providers licensed under chapters 458 (medicine), 459 (osteopathic medicine), 460 (chiropractic medicine), or 464 (nursing), F.S., or a primary care group practice, for any health care service within their competency and training, and to add health care providers licensed under ch. 466, F.S., (dentistry) to the list of providers who can provide direct health care services. Additionally, all references to “primary care” are replaced with “health care” throughout the section.

Cost-Containment in Health Insurance

Sections 11 and **12** create s. 627.42393 and amend s. 641.31(45), respectively, relating to step-therapy protocols of health insurers and HMOs issuing major medical coverage, both individual and group. **Sections 11** and **12** are effective January 1, 2020, and will therefore apply to all such health insurance policies and HMO contracts issued or renewed on or after that date.

The sections prohibit an insurer or HMO from requiring a covered individual to undergo a step-therapy protocol under the policy or contract, respectively, for a covered prescription drug if the insured or subscriber has been approved previously to receive the drug through the completion of a step-therapy protocol required by a separate health coverage plan;²⁰⁴ however, an insurer or HMO is not required to add a drug to its prescription drug formulary or to cover a prescription drug that the insurer or HMO does not otherwise cover. To trigger this provision, a covered individual must provide documentation originating from the prior health coverage plan that the prescription drug was paid by the health coverage plan on behalf of the covered individual during the 90 days immediately prior to the request.

Portability of Health Care Occupational Licensure in the United States

Section 13 requires the Office of Program Policy Analysis and Government Accountability (OPPAGA) to analyze the Interstate Medical Licensure Compact (Compact) and its congruence

²⁰⁴ The bill defines the term “health coverage plan” to mean any of the following plans which previously provided coverage or is currently providing major medical or similar comprehensive coverage or benefits to the insured or subscriber: a health insurer or health maintenance organization, a plan established or maintained by an individual employer as provided by the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, a multiple-employer welfare arrangement as defined in s. 624.437, F.S., or a governmental entity providing a plan of self-insurance.

with the Florida Constitution and relevant Florida Statutes. Based on the comparative analysis, the OPPAGA must submit a report by October 1, 2019, to the Governor, the President of the Senate, and the Speaker of the House of Representatives that includes recommendations regarding Florida's prospective entrance into the Compact as a member state while remaining consistent with the Florida Constitution and relevant Florida Statutes.

Section 14 provides an effective date of July 1, 2019, except as otherwise provided in the bill.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

Section 9 provides an effective date of July 1, 2019, but does not specifically address whether the new provision deeming certain restrictive covenants void and unenforceable is to be applied retroactively to contracts already in effect on July 1, 2019, or prospectively to contracts entered into on or after July 1, 2019.

Florida courts use a two-prong test for determining whether statutes should be applied retroactively.²⁰⁵ The first is whether there is clear legislative intent to apply the statute retrospectively. The general rule is that in the absence of clear legislative intent to the contrary, a law affecting substantive rights, liabilities and duties is presumed to apply prospectively. If the legislation clearly expresses an intent that it apply retroactively, then the second inquiry is whether retroactive application is constitutionally permissible.²⁰⁶ The presumption against retroactivity is only a default rule of statutory construction; the essential purpose of statutory construction is to determine legislative intent.²⁰⁷

The United States Constitution and the Florida Constitution prohibit the state from passing any law impairing the obligation of contracts.²⁰⁸ “[T]he first inquiry must be

²⁰⁵ *Metropolitan Dade County v. Chase Federal Housing Corp.*, 737 So. 2d 494, 499 (Fla. 1999).

²⁰⁶ *Id.*

²⁰⁷ *Id.*, at 500.

²⁰⁸ U.S. Const. Article I, s. 10; Art. I, s. 10, Fla. Const.

whether the state law has, in fact, operated as a substantial impairment of a contractual relationship. The severity of the impairment measures the height of the hurdle the state legislation must clear.²⁰⁹ If a law does impair contracts, the courts will assess whether the law is deemed reasonable and necessary to serve an important public purpose.²¹⁰ The factors that a court will consider when balancing the impairment of contracts with the public purpose include:

- Whether the law was enacted to deal with a broad, generalized economic or social problem;
- Whether the law operates in an area that was already subject to state regulation at the time the parties undertook their contractual obligations, or whether it invades an area never before subject to regulation; and
- Whether the law results in a temporary alteration of the contractual relationships of those within its scope, or whether it permanently and immediately changes those contractual relationships, irrevocably and retroactively.²¹¹

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Section 2 will have an indeterminate positive fiscal impact on dentists who participate in the Dental Student Loan Repayment Program.

Section 6 may have an indeterminate positive fiscal impact on patients seeking surgical services if such patients are able to obtain the surgical services at an ASC for lower costs than the costs of receiving comparable services at a hospital. If more patients choose to have their surgical procedures performed in an ASC, hospitals may experience a negative, but indeterminate, fiscal impact.

Section 9 invalidates certain restrictive health care covenants; however, the bill does not specify whether such invalidation applies retrospectively or prospectively. Therefore, the fiscal impact on entities and physicians that are currently part of a restrictive covenant is indeterminate.

Section 10, by modifying the availability of direct patient contracting for health care services, access to expanded health care services may be extended to patients who may not otherwise have access to certain types of health care services or in underserved or rural areas of the state. Statistics also show that more than one third of current direct primary care patients nationally are Medicare patients.

²⁰⁹ *Pomponio v Claridge of Pompano Condominium, Inc.*, 378 So. 2d 774, 779 (Fla. 1979) (quoting *Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234, 244-45 (1978)). See also *General Motors Corp. v. Romein*, 503 U.S. 181 (1992).

²¹⁰ *Park Benziger & Co. v. Southern Wine & Spirits, Inc.*, 391 So. 2d 681, 683 (Fla. 1980); *Yellow Cab Co. of Dade County v. Dade County*, 412 So. 2d 395, 397 (Fla. 3rd DCA 1982) (citing *United States Trust Co. v. New Jersey*, 431 U.S. 1 (1977)).

²¹¹ *Supra* note 209.

Current Florida law allows physicians to contract only for primary care agreements. This bill removes that restriction and expands the scope of those agreements so patients may have additional options. This model is seen as a mechanism for providers to reduce their administrative burdens with payers. By adding reimbursement options for more provider types and health care services, provider access may be improved for Floridians.

C. Government Sector Impact:

Sections 2 and 3 are contingent upon a legislative appropriation to implement the Dental Student Loan Repayment Program and the Donated Dental Services Program, respectively. If an appropriation is provided to implement the Dental Student Loan Repayment Program, the DOH indicates it will require one additional other personal services employee at a cost of \$65,670, inclusive of compensation and applicable expenses.²¹² The DOH estimates the implementation of the Donated Dental Services Program will require an appropriation of \$200,000 in recurring general revenue funds.²¹³

Section 4 creates an insignificant negative fiscal impact to the Agency for Health Care Administration (AHCA) to create the form hospitals must provide to patients, and any other person upon request, pertaining to required hospital quality measures, and the additional workload for the AHCA to monitor compliance by hospitals of such requirements. The fiscal impact can be absorbed within existing resources of the AHCA.²¹⁴

Section 6. ASCs are reimbursed by Medicaid through an outpatient prospective payment reimbursement methodology called Enhanced Ambulatory Patient Groups (EAPGs). EAPGs categorize outpatient services and procedures into groups for payment based on clinical information present on an outpatient claim. ASCs are not currently reimbursed for an overnight stay. If ASCs are authorized to bill for an overnight stay through the EAPG system, an increase in the volume of ASC claims and corresponding increase in ASC expenditures may occur; however, a potential increase in claim volumes and expenditures could be offset from a corollary decrease in claims and expenditures for services provided in an outpatient or inpatient hospital setting.²¹⁵ Consequently, the fiscal impact to the Florida Medicaid program is indeterminate.²¹⁶

Section 7 authorizes, but does not require, the AHCA to reimburse members of the Pediatric Cardiac Technical Advisory Council Panel (panel) for per diem and travel expenses. The AHCA estimates an annual cost of approximately \$21,000 if it were to reimburse panel members.²¹⁷

²¹² Department of Health, *Senate Bill 716 Analysis* (January 22, 2019) (on file with the Senate Appropriations Committee).

²¹³ *Id.*

²¹⁴ Email from James Kotas, Agency for Health Care Administration (April 2, 2019) (on file with the Senate Appropriations Committee).

²¹⁵ *Supra* note 83.

²¹⁶ *Id.*

²¹⁷ *Supra* note 214.

The bill authorizes, but does not require, the Secretary of the AHCA to request announced or unannounced site visits of existing pediatric cardiac centers or facilities seeking licensure as a pediatric cardiac surgical center through the certificate of need process. At the Secretary's request, the panel must recommend in-state physician experts to conduct such on-site visit, and the Secretary may appoint up to two out-of-state physician experts. The bill does not establish a deadline nor a frequency for the site visits required of existing pediatric cardiac centers; however, the panel has recommended that experts conduct three annual site visits.²¹⁸ The increase in state expenditures as a result of the onsite visits for the existing pediatric cardiac centers is addressed through an appropriation of \$150,000 in SB 2500, First Engrossed, the Senate's proposed General Appropriations Bill for the 2019-2020 fiscal year.²¹⁹ The number of facilities seeking licensure as a pediatric cardiac surgical center is unknown; therefore, the fiscal impact of conducting onsite visits prior to the completion of the certificate of need process is indeterminate.

The Surgeon General of the Department of Health (DOH) is required to provide a quarterly report to the Secretary of the AHCA that summarizes data from the Children's Medical Services critical congenital heart disease (CCHD) newborn screening program. This data will be reviewed by the panel. The bill does not specify the data to be included in such quarterly report. According to the DOH, the current aggregate data collected and provided to the Genetic and Newborn Screening Advisory Council (GNSAC) for CCHD is minimal. To the extent that the information required in the quarterly report is the same data that is provided to the GNSAC, there would be no increase in state expenditures; however, if the requested data exceeds that which is provided to the GNSAC, then there would be an indeterminate increase in state expenditures.²²⁰

Section 8 requires the AHCA to create a form for hospitals and ambulatory surgical centers to immediately notify non-Medicare patients of their placement on observation status. The form must be adopted by the AHCA in a rule which will create an insignificant, negative fiscal impact that the AHCA can absorb within existing resources.²²¹

VI. Technical Deficiencies:

Line 449 of the bill authorizes panel members to be reimbursed for travel and per diem; however, the provision does not include a cross reference to s. 112.061, F.S., which limits travel reimbursement for individuals who travel on public business. Without the cross reference to the state guidelines, a different travel reimbursement schedule could be implemented for the panel members.

²¹⁸ Pediatric Technical Advisory Panel, Agency for Health Care Administration, *Draft Meeting Minutes*, pg. 2 (Dec. 13, 2018), available at: <http://ahca.myflorida.com/SCHS/PCTAP/docs/020719/PCTAPDraftMinutes121318.pdf> (last visited Apr. 5, 2019).

²¹⁹ See SB 2500, First Engrossed, the Senate's proposed Fiscal Year 2019-2020 General Appropriations Bill, Section 3, Specific Appropriation 226, at page 61. An appropriation of \$150,000 of nonrecurring funds from the Health Care Trust Fund is provided to the Agency for Health Care Administration for the Pediatric Cardiac Technical Advisory Panel.

²²⁰ Email correspondence from Gary Landry, Department of Health (April 5, 2019) (on file with the Senate Appropriations Committee).

²²¹ *Id.*

VII. Related Issues:

Section 2 uses the term “other low income patients” to identify other clients that could be the focus of dental graduates who are the beneficiaries of the Dental Student Loan Repayment program; however, the term is not defined in the bill.

The number of new dentists participating in the Dental Student Loan Repayment program cannot exceed 10 in a fiscal year, and the DOH is authorized to adopt rules to administer the program. Rather than rely on the DOH to develop its own process, it may be beneficial to include specific standards in the bill which will prioritize the selection of dentists to participate in the program if the DOH receives more than 10 new applications in a fiscal year.

Section 3 uses a series of terms to describe the target population for the Donated Dental Services Program that are not defined: needy, disabled, elderly, and medically compromised. These terms may need further clarification to ensure that the DOH is accurately focusing its efforts on the populations desired by the legislation.

Section 9 deems certain restrictive covenants, which might otherwise be enforceable under s. 542.335, F.S., as “void and unenforceable” until three years after a date determined by the actions of private actors and entities. In effect, the enforceability of specific restrictive covenants for medical specialties would be determined not by the law as defined by the Legislature, but would be determined by, and would require knowledge of, the actions of private actors and entities, on particular dates, on a county by county basis. The bill may create potential compliance issues related to determining where or if certain restrictive covenants are enforceable.

Section 10. The Office of Insurance Regulation suggests that several additional terms or conditions be added to the Direct Access Agreements:

- Define the term “health care group practice.” Under currently law, the term “primary care group practice” is used and is also not defined.
- Include guaranteed renewal terms or continuity of care provisions for patients who are undergoing treatment or receiving services for a condition to limit risk of a contract being canceled with 30 days’ notice and no recourse.
- Add an enforcement mechanism for violations of the statute or failure to include the mandatory provisions in the agreement.²²²

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 395.002; 395.1005; 395.1012, 395.1055, 395.301, 624.27, and 641.31.

This bill creates two undesignated sections of Florida law, and creates the following sections of the Florida Statutes: 381.4019, 381.40195, 395.1052, 542.336, and 627.42393.

²²² Office of Insurance Regulation, *2019 Agency Legislative Bill Analysis – HB 7* (February 20, 2019) (on file with the Senate Committee on Health Policy).

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

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

CS by Appropriations on April 18, 2019:

The committee substitute:

- Creates the Dental Student Loan Repayment Program and the Donated Dental Services Program within the DOH, and conditions the implementation of each program upon legislative appropriation;
- Removes the requirement that certain health care facilities provide copies of a patient's or resident's medical or clinical records within a specified timeframe upon request;
- Extends the timeframe that a hospital is required to provide the discharge summary and any related information and records to a patient's primary care provider from seven to 14 days of the patient's discharge;
- Allows a patient to stay in an ASC for 24 hours, rather than requiring that a patient be admitted and discharged on the same working day;
- Requires the AHCA, in consultation with the Board of Medicine and the Board of Osteopathic Medicine, to adopt rules to ensure the safe and effective delivery of surgical care to children in ambulatory surgical centers;
- Modifies the composition and duties of the Pediatric Cardiac Technical Advisory Panel;
- Provides members of the Pediatric Cardiac Technical Advisory Panel immunity from civil or criminal liability for the good faith performance of duties assigned to them by the Secretary of the AHCA;
- Invalidates certain restrictive health care covenants and specifies that such covenants remain void and unenforceable until certain conditions are met;
- Reduces the time period that an insurer or HMO previously paid for a prescription drug from 180 days to 90 days immediately prior to a request by an insured individual for such drug that triggers the prohibition of such insurer or HMO from requiring a step-therapy protocol of the insured;
- Clarifies step-therapy protocols such that an insurer or HMO is not required to add a drug to its prescription drug formulary or to cover a prescription drug that the insurer or HMO does not otherwise cover;
- Removes the prohibition of Medicaid managed care plans from employing step-therapy protocols under certain circumstances;
- Removes the authorization for Florida to participate in the Interstate Medical Licensure Compact; and
- Requires the Office of Program Policy Analysis and Government Accountability to perform a comparative analysis of the Interstate Medical License Compact and Florida law, and submit a report to the Governor and Legislature by October 1, 2019.

B. Amendments:

None.

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