

**HOUSE OF REPRESENTATIVES STAFF ANALYSIS  
FINAL BILL ANALYSIS**

**BILL #:** CS/HB 843 Health Care  
**SPONSOR(S):** Health & Human Services Committee, Rodriguez, A. M.  
**TIED BILLS:** IDEN./SIM. BILLS: CS/SB 7078

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Market Reform Subcommittee	13 Y, 0 N	Gilani	Crosier
2) Health Care Appropriations Subcommittee	9 Y, 0 N	Nobles	Clark
3) Health & Human Services Committee	14 Y, 0 N, As CS	Gilani	Calamas
<b>FINAL HOUSE FLOOR ACTION:</b> 115 Y's 0 N's			
<b>GOVERNOR'S ACTION:</b> Approved			

**SUMMARY ANALYSIS**

CS/HB 843 passed the House on April 11, 2019. The bill was amended in the Senate on April 26, 2019, and was returned to the House. The House concurred with the Senate amendment and subsequently passed the bill as amended on April 29, 2019. Part of the bill also passed the House and Senate in CS/HB 7 on May 2, 2019.

The bill addresses various health care programs and regulatory provisions, as follows:

- **Dental Services** – subject to an appropriation, establishes a dental student loan repayment program and donated dental services program within the Department of Health for certain underserved areas and populations.
- **Hospital Quality Report Cards** – requires hospitals to provide patients with specified information and data relating to patient quality measures under certain circumstances or upon request.
- **Patient Access to Providers** – requires hospitals to notify a patient's provider within certain timeframes of admission and discharge, transfer discharge records to the provider within a certain timeframe, and, if requested, make reasonable efforts to consult with the provider when developing the patient's plan of care.
- **Ambulatory Surgical Centers** – increases the permissible length of stay in ambulatory surgical centers from the same day to 24 hours.
- **Pediatric Cardiac Technical Advisory Panel** – revises the membership of the Pediatric Cardiac Technical Advisory Panel within the Agency for Health Care Administration (AHCA), authorizes members to inspect pediatric cardiac surgical programs in certain circumstances, and grants them personal immunity for this activity.
- **Hospital Observation Status** – requires hospitals to immediately notify a patient when placing the patient on observation status and document such notice in the medical record and discharge papers.
- **Clinical Labs** – makes conforming changes based on the 2018 repeal of clinical lab licensure requirements
- **Restrictive Covenants** – makes certain restrictive covenants related to specialty physicians void and unenforceable for a specified period.
- **Direct Health Care Agreements** – expands the insurance regulation exemption for direct primary care agreements to include specialty care and dentistry, and renames them "direct health care agreements."
- **Step Therapy Protocols** – prohibits issuers of comprehensive major medical health insurance from requiring completion of a step therapy protocol for patients who demonstrate previous completion of a related step therapy process, under certain circumstances.
- **Interstate Medical Licensure Compact** – requires the Office of Program Policy Analysis and Government Accountability to submit a report and recommendations to the Governor and Legislature on the feasibility of Florida entering into the Interstate Medical Licensure Compact.

The bill has an indeterminate, negative fiscal impact on AHCA, the Division of Management Services, and local governments. See Fiscal Comments.

The bill was approved by the Governor on June 25, 2019, ch. 2019-138, L.O.F., and will become effective July 1, 2019, except as otherwise provided.

**This document does not reflect the intent or official position of the bill sponsor or House of Representatives.**

**STORAGE NAME:** h0843z1.HMR.DOCX

**DATE:** 6/26/2019

## I. SUBSTANTIVE INFORMATION

### A. EFFECT OF CHANGES:

#### Dental Services

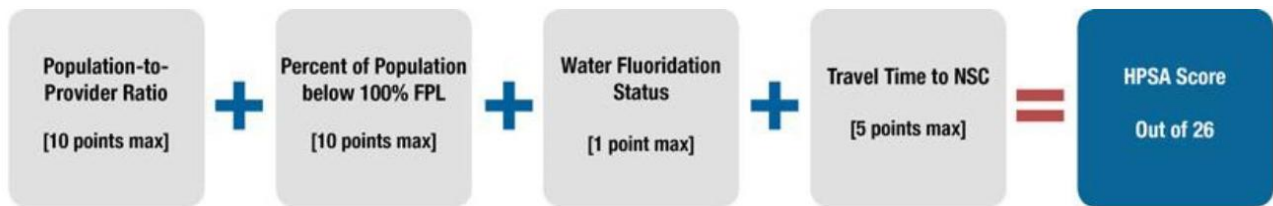
##### Background

##### Health Professional Shortage Areas

The U.S. Department of Health and Human Services' Health Resources and Services Administration (HRSA) designates Health Professional Shortage Areas (HPSAs) according to criteria developed in accordance with section 332 of the Public Health Services Act. HPSA designations are used to identify areas and population groups within the United States that are experiencing a shortage of health care provider shortages in primary care, dental health, or mental health.<sup>1</sup> The threshold for a dental HPSA is a population-to-provider ratio of at least 5,000:1.<sup>2</sup> For each discipline category, there are three types of HPSA designations based on the area or population group that is experiencing the shortage:<sup>3</sup>

- **Geographic Area:** A shortage of providers for the entire population within a defined geographic area.
- **Population Groups:** A shortage of providers for a specific population group(s) within a defined geographic area (e.g., low income, migrant farmworkers, and other groups)
- **Facilities:** A facility that primarily cares for an underserved population; examples of these include state mental hospitals, federally qualified health centers, and CMS-certified rural health clinics.

Once designated, HRSA scores HPSAs on a scale of 0-26 for dental health, with higher scores indicating greater need.<sup>4</sup>



##### Medically Underserved Areas

HRSA also designates Medically Underserved Areas (MUAs) and Medically Underserved Populations (MUPs). MUAs and MUPs identify geographic areas and populations with a lack of access to primary care services.<sup>5</sup> MUAs have a shortage of primary care health services for residents within a geographic area such as a county, a group of neighboring counties, a group of urban census tracts, or a group of county or civil divisions.<sup>6</sup> MUPs are specific sub-groups of people living in a defined geographic area with a shortage of primary care health services who may face economic, cultural, or linguistic barriers to

<sup>1</sup> HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Health Professional Shortage Areas (HPSAs)*, <https://bhwh.hrsa.gov/shortage-designation/hpsas> (last visited May 7, 2019).

<sup>2</sup> Id.

<sup>3</sup> Id.

<sup>4</sup> HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Health Professional Shortage Area (HPSA) Application and Scoring Process*, <https://bhwh.hrsa.gov/shortage-designation/hpsa-process> (last visited May 7, 2019).

<sup>5</sup> HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Medically Underserved Areas and Populations (MUA/Ps)*, <https://bhwh.hrsa.gov/shortage-designation/muap> (last visited May 7, 2019).

<sup>6</sup> Id.

health care. MUPs include, but are not limited to, those who are homeless, low-income, Medicaid-eligible, Native American, or migrant farmworkers.<sup>7</sup>

MUA and MUP designations are based on the Index of Medical Underservice (IMU), which is calculated based on four criteria:

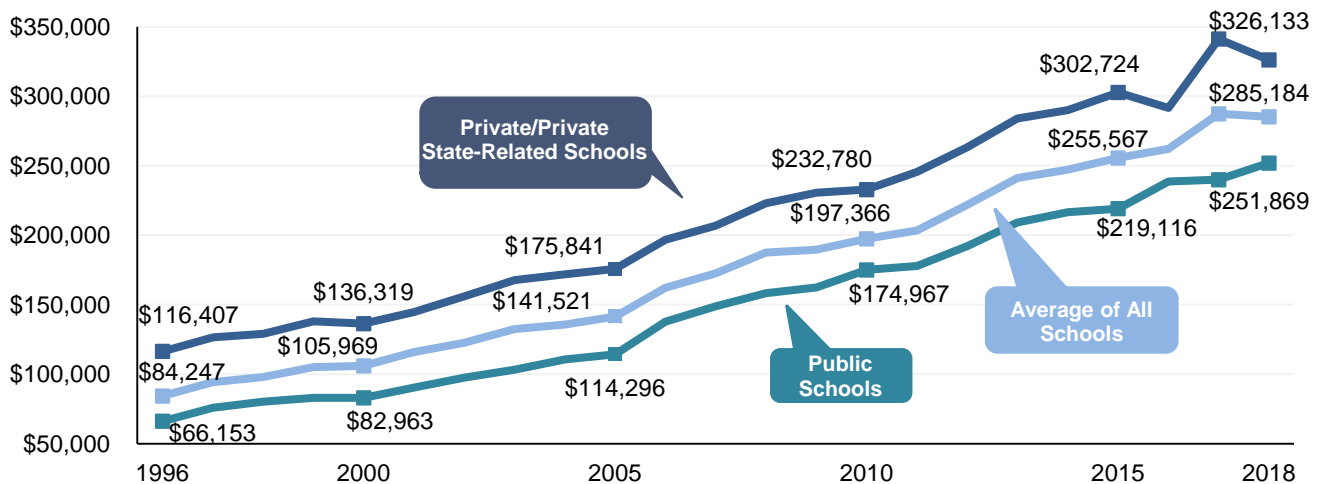
- The population to provider ratio;
- The percent of the population below the federal poverty level;
- The percent of the population over age 65; and
- The infant mortality rate.

The IMU can range from 0 to 100, where zero represents the completely underserved; areas or populations with an IMU of 62.0 or less qualify for designation as an MUA or MUP.<sup>8</sup>

### Cost of Dental Education

Students enter dental school with existing debt averaging \$35,000, and approximately 83 percent of dental students rely on student loans to finance their degrees.<sup>9</sup> In the U.S., combined undergraduate and dental school debt has jumped from \$106,000 in 2000 to \$285,000 in 2018, an increase of 169 percent in 18 years.<sup>10</sup>

**Average Student Loan Debt among Graduating Dental Students, 1996 to 2018<sup>11</sup>**



Source: Created using data derived from American Dental Education Association, Survey of Dental School Seniors, 2018 Graduating Class. Note: Debt is the sum of undergraduate and dental school debt of only the 83% of respondents who have debt.

The National Health Service Corps (NHSC) offers tax-free loan repayment assistance of up to \$50,000 to support qualified health care providers, including dentists, who work for two years at a NHSC-approved site.<sup>12</sup> Additionally, dental students who commit to serving at least three years at an approved NHSC site in a HPSA of greatest need may earn up to \$120,000 in their final year of school through the

<sup>7</sup> Id.

<sup>8</sup> Id.

<sup>9</sup> AMERICAN DENTAL EDUCATION ASSOCIATION, *ADEA Survey of Dental School Seniors, 2018 Graduating Class Tables Report*, p. 21, available at: [https://www.adea.org/ADEA\\_Survey\\_of\\_Dental\\_School\\_Seniors\\_2018\\_Tables\\_Report.pdf](https://www.adea.org/ADEA_Survey_of_Dental_School_Seniors_2018_Tables_Report.pdf) (last visited May 7, 2019).

<sup>10</sup> Id. at 25. After adjusting for inflation, the dental school loan debt increased by 84% from 2000 to 2018.

<sup>11</sup> Id.

<sup>12</sup> HEALTH RESOURCES AND SERVICES ADMINISTRATION, *NHSC Loan Repayment Program*, <https://nhsc.hrsa.gov/loan-repayment/nhsc-loan-repayment-program.html> (last visited May 7, 2019).

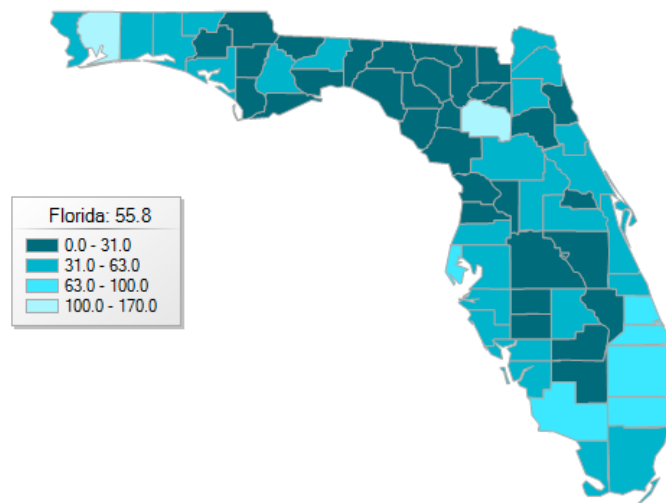
Students to Service Loan Repayment Program.<sup>13</sup>

NHSC's State Loan Repayment Program provides cost-sharing grants to states and territories that operate their own loan repayment programs for primary medical, mental and behavioral, and dental healthcare clinicians working in HPSAs.<sup>14</sup> Florida is one of nine states<sup>15</sup> that does not have an operational state-funded dental student loan repayment program.<sup>16</sup>

### Access to Dental Care and Dental Workforce in Florida

There are 5,833 dental HSPAs in the U.S., 240 of which are in Florida and affect 5.5 million people.<sup>17</sup> Additionally, there are 4,232 MAUs and MAPs in the U.S., 128 of which are in Florida.<sup>18</sup> Today, there are approximately 56 licensed dentists per 100,000 people in Florida; however, this ratio varies greatly across the state.<sup>19</sup> Most dentists are disproportionately concentrated in the more populous areas of the state. Three counties, Dixie, Glades, and Lafayette, do not have any licensed dentists, while other counties have over 150 dentists per 100,000 residents.<sup>20</sup>

**Licensed Dentists per 100,000 Floridians FY 17-18<sup>21</sup>**



<sup>13</sup> HEALTH RESOURCES AND SERVICES ADMINISTRATION, *NHSC Students to Service Loan Repayment Program* <https://nhsc.hrsa.gov/loan-repayment/nhsc-students-to-service-loan-repayment-program.html> (last visited May 7, 2019).

<sup>14</sup> HEALTH RESOURCES AND SERVICES ADMINISTRATION, *State Loan Repayment Program*, <https://nhsc.hrsa.gov/loan-repayment/state-loan-repayment-program/index.html> (last visited May 7, 2019).

<sup>15</sup> Alabama, Connecticut, Florida, Georgia, Hawaii, Indiana, Iowa, Mississippi, Puerto Rico, and Utah do not have operational state-funded dental loan repayment programs. Several of these states had programs, but they are no longer operational due to a lack of funding. Alabama no longer participates in the HRSA state loan repayment program, but has other limited programs to repay dental student loans. Connecticut's program is no longer accepting applications; Georgia's program ended in 2015; Hawaii's state loan repayment program does not include dentists or dental hygienists; Indiana's program has been suspended since 2011 due to a lack of funding; Iowa's program has ended, however, it still has a loan repayment program for individuals pursuing a graduate degree in dental public health; and Mississippi is no longer taking applicants due to a lack of funding. Additionally, New York's program did not accept applicants for several years, but it resumed in 2017 when it received new funding. *Infra* note 16.

<sup>16</sup> AMERICAN DENTAL EDUCATION ASSOCIATION, *State and Federal Loan Forgiveness Programs*, (November 2018), available at, <https://www.adea.org/WorkArea/DownloadAsset.aspx?id=40489> (last visited May 7, 2019).

<sup>17</sup> HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Designated health Professional Shortage Areas Statistics, First Quarter of Fiscal Year 2019 Designated HPSA Quarterly Summary*, [https://ersrs.hrsa.gov/ReportServer?/HGDW\\_Reports/BCD\\_HPSA/BCD\\_HPSA\\_SCR50\\_Qtr\\_Smry\\_HTML&rc:Toolbar=false](https://ersrs.hrsa.gov/ReportServer?/HGDW_Reports/BCD_HPSA/BCD_HPSA_SCR50_Qtr_Smry_HTML&rc:Toolbar=false) (last visited May 7, 2019). With a shortage of 1,266 dental practitioners, only 13% of the need is currently being met in these areas.

<sup>18</sup> Health Resources and Services Administration, *MAU Find Results*, <https://datawarehouse.hrsa.gov/tools/analyzers/MuaSearchResults.aspx> (last visited May 7, 2019).

<sup>19</sup> FLORIDA DEPARTMENT OF HEALTH, *FL Health CHARTS, Total Licensed Florida Dentists*, <http://www.flhealthcharts.com/charts/OtherIndicators/NonVitalIndNoGrpDataViewer.aspx?cid=0326> (last visited May 7, 2019).

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

There is a noticeable shortage of dentists in certain parts of the state, especially the central Panhandle counties and interior counties of south Florida.<sup>22</sup> Lower patient densities, rural income disparities, and lower dental care reimbursement levels make it difficult to recruit and retain dentists in rural communities of the state.<sup>23</sup> Lack of access to dental care can lead to poor oral health and poor overall health.<sup>24</sup> Research has shown a link between poor oral health and diabetes, heart and lung disease, stroke, respiratory illnesses, and adverse birth outcomes including the delivery of pre-term and low birth weight infants.<sup>25</sup>

### Donated Dental Services Program

Dental Lifeline Network is a national charitable organization that provides oral health services to people with disabilities or who are elderly or medical fragile, are ineligible for public funding, and cannot otherwise afford necessary treatment.<sup>26</sup> One of Dental Lifeline Network's programs is the Donated Dental Services Program (DDS), which operates through a network of volunteer dentists and dental labs to provide dental services to this indigent population.<sup>27</sup> DDS operates in each state but often has a lengthy waitlist due to limited funding and volunteers.<sup>28</sup>

Dental Lifeline Network estimates that since its inception in 1985, DDS has treated more than 120,000 people across the nation and provided over \$378 million in donated dental treatment.<sup>29</sup> In Florida, Dental Lifeline Network has 455 dentists and 215 dental labs volunteering dental services to the program.<sup>30</sup> In FY 17-18, Dental Lifeline Network donated over \$700,000 in dental services to 234 Floridians through this program.<sup>31</sup> Historically, since 1997, DDS has provided over \$8.1 million in donated dental services to over 1,800 Floridians.<sup>32</sup> However, Florida's DDS is currently not accepting new applications due to a lack of funding and a long waitlist,<sup>33</sup> and those people on the waitlist can be waiting several months to over a year before they receive services.<sup>34</sup> Florida's DDS does not receive recurring state-funding.<sup>35</sup>

### **Effect of the Bill – Dental Services**

#### Dental Student Loan Repayment Program

Subject to an appropriation, the bill creates the Dental Student Loan Repayment Program (Loan Program) within the Department of Health (DOH).

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<sup>22</sup> Id.

<sup>23</sup> Chris Collins, MSW, *Challenges of Recruitment and Retention in Rural Areas*, North Carolina Medical Journal, Vol. 77 no. 2, (March-April 2016), <http://www.ncmedicaljournal.com/content/77/2/99.full> (last visited May 7, 2019).

<sup>24</sup> Florida Department of Health, *Florida's Burden of Oral Disease Surveillance Report*, (Aug, 2016), p. 5, available at, [http://www.floridahealth.gov/programs-and-services/community-health/dental-health/reports/\\_documents/floridas-burden-oral-disease-surveillance-report.pdf](http://www.floridahealth.gov/programs-and-services/community-health/dental-health/reports/_documents/floridas-burden-oral-disease-surveillance-report.pdf) (last visited May 7, 2019).

<sup>25</sup> Id.

<sup>26</sup> DENTAL LIFELINE NETWORK, *Our Programs*, <https://dentallifeline.org/about-us/our-programs/> (last visited May 7, 2019).

<sup>27</sup> Id.

<sup>28</sup> DENTAL LIFELINE NETWORK, *State Programs*, <https://dentallifeline.org/our-state-programs/> (last visited May 7, 2019). AL, AZ, AK, CA, CT, DE, FL, GA, HI, ID, IL, IN, KS, KY, LA, ME, MA, MN, MS, MO, MT, NB, NV, NH, NJ, NY, NC, OH, OR, PA, SC, TN, TX, UT, WA, D.C., WV, and WY all have waitlists and are either not accepting any applications or only accepting them for limited counties or populations.

<sup>29</sup> *Supra* note 26.

<sup>30</sup> DENTAL LIFELINE NETWORK, *2017-2018 Annual Report*, <https://dentallifeline.org/wp-content/uploads/2018/12/2017-2018-Annual-Report-Web.pdf> (last visited May 7, 2019).

<sup>31</sup> Id.

<sup>32</sup> DENTAL LIFELINE NETWORK, *Florida*, <https://dentallifeline.org/florida/> (last visited May 7, 2019).

<sup>33</sup> Id. However, if you are a military veteran who still meets the eligibility requirements or if you have documentation from a physician stating that you cannot receive essential medical treatment due to your dental condition, you can still apply for the program.

<sup>34</sup> See the Florida DDS application, available at: <https://dentallifeline.org/wp-content/uploads/2017/08/Florida.pdf> (last visited May 7, 2019).

<sup>35</sup> Florida Department of Health, Agency Analysis of 2019 HB 465, p. 2 (Jan. 22, 2019)(on file with the House Health Quality Subcommittee staff). The Legislature appropriated \$100,000 in non-recurring funds for the program in FY 17-18. 2016 General Appropriations Act for Fiscal Year 17-18, line 447.

A Florida-licensed dentist is eligible to participate in the Loan Program if he or she maintains active employment in a public health program that serves Medicaid recipients and other low-income patients and is located in a dental HSPA or a MUA. The bill defines a "public health program" as a county health department, the Children's Medical Services program, a federally funded community health center, a federally funded migrant health center, or other publicly funded or nonprofit health care program designated by DOH.

A dentist is no longer eligible to receive funds under the Loan Program if the dentist:

- Is no longer employed by a public health program that is located in a dental HSPA or a MUA and serves Medicaid recipients and other low-income patients.
- Ceases to participate in the Florida Medicaid program.
- Has disciplinary action taken against his or her license by the Board of Dentistry for a violation of the dental practice act.<sup>36</sup>

The bill authorizes DOH to award each eligible dentist up to \$50,000 in student loan repayments per year for up to five years, for a maximum of \$250,000 per eligible dentist. DOH may approve up to 10 new dentists each fiscal year to participate in the Loan Program, in addition to those dentists already participating in the Loan Program. Therefore, if DOH awards the maximum number of awards available each year and no participating dentist loses eligibility during the five-year eligibility period, the number of dentists the Loan Program funds will increase by 10 each year until the fifth year, at which point the maximum number of awards that can be granted at any given time would be 50, due to the five-year eligibility limit. If the maximum award amount of \$50,000 is awarded to each of the 50 participating dentists, this would translate to \$2.5 million in awards per fiscal year.

The Loan Program may only cover loans to pay the costs of tuition, books, dental equipment and supplies, uniforms, and living expenses and must be made directly to the holder of the loan. The bill specifies that all repayments are contingent upon continued proof of eligibility and that the state will be not responsible for the collection of any interest charges or other remaining balance loan balances.

The bill requires DOH to adopt rules to administer the Loan Program.

#### Donated Dental Services Program

Subject to an appropriation, the bill requires DOH to establish a Donated Dental Services Program (DDS Program) to provide comprehensive dental care through a network of volunteer dentists and other dental providers to the needy, disabled, elderly, and medically compromised individuals who cannot afford necessary treatment but are ineligible for public assistance. Eligible individuals may not be charged for such dental care received under the DDS Program.

The bill requires DOH to contract with the Dental Lifeline Network, or its designee, to administer the program. Such contract must specify the Dental Lifeline Network's responsibilities, including, but not limited to:

- Maintaining a network of volunteer dentists and other dental providers, including, but not limited to, dental specialists and dental laboratories to provide comprehensive dental services;
- Maintaining a system to refer eligible individuals to the appropriate volunteer dentist or dental provider;
- Developing a public awareness and marketing campaign to promote the program;
- Providing the necessary administrative and technical support to administer the program;
- Performing any other program-related duties required by DOH; and

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<sup>36</sup> S. 466.028, F.S., grounds for disciplinary action by the Board.

- Submitting an annual report to DOH, which must include, at a minimum:
  - Financial data relating to administering the program;
  - Demographic data relating to eligible individuals who are referred to and receive treatment through the program;
  - Demographic data relating to the volunteer dentists and dental providers participating in the program; and
  - Any other data or information DOH requires.

Dental Lifeline Network currently administers Florida’s DDS Program and receives funding from the Legislature, if any, via appropriation project requests. The bill would codify this program in law, establish it within DOH, and designate Dental Lifeline Network, or its designee, as the contractor to administer it.

The bill requires DOH to adopt rules to administer the DDS Program.

## **Hospital Quality Report Cards**

### **Background**

#### **Health Care Price and Quality Transparency**

The United States is experiencing significant changes in health care payment and delivery. Record numbers of newly-insured persons are enrolled in both public and private health insurance. Americans bear a greater share of health care costs, and more participate in high deductible health plans. Clear, factual information about the cost and quality of health care is necessary for consumers to select value-driven health care options and for consumers and providers to be involved in and accountable for decisions about health and health care services. To promote consumer involvement, health care pricing and other data should be free, timely, reliable, and reflect individual health care needs and insurance coverage.

#### *Health Care Quality Transparency*

Most Americans believe that the health care they receive is the best available, but the evidence shows otherwise.<sup>37</sup> Although the U.S. spends more than \$3 trillion a year on health care,<sup>38</sup> 18 percent of the gross national product,<sup>39</sup> research shows that the quality of health care in America is, at best, imperfect, and, at worst, deeply flawed.<sup>40</sup> Issues with health care quality fall into three categories:

- Underuse. Many patients do not receive medically necessary care.
- Misuse. Each year, more than 100,000 Americans get the wrong care and are injured as a result. More than 1.5 million medication errors are made each year.
- Overuse. Many patients receive care that is not needed or for which there is an equally effective alternative that costs less money or causes fewer side effects.

Research indicates that quality of care in the U.S. is uneven. For example, Americans receive appropriate, evidence-based care when they need it only 55 percent of the time.<sup>41</sup> Similarly, more than

<sup>37</sup> NATIONAL COMMITTEE FOR QUALITY ASSURANCE, *The Essential Guide to Health Quality*, p. 6, available at: [http://www.kdheks.gov/hcf/news/download/04172007\\_NCQA\\_Health\\_Quality.pdf](http://www.kdheks.gov/hcf/news/download/04172007_NCQA_Health_Quality.pdf) (last visited May 23, 2019).

<sup>38</sup> THE HENRY J. KAISER FOUNDATION, PETERSON-KAISER HEALTH SYSTEM TRACKER, *Health Spending Explorer-U.S. Health Expenditures 1960-2017*, <https://www.healthsystemtracker.org/interactive/?display=U.S.%2520%2524%2520Billions&service=&rangeType=range&years=1960%252C2017> (last visited May 23, 2019).

<sup>39</sup> THE WORLD BANK, *Data-United States*, <http://data.worldbank.org/country/united-states> (last visited May 23, 2019).

<sup>40</sup> *Supra* note 37.

<sup>41</sup> McGlynn, E.A., et al., *The Quality of Health Care Delivered to Adults in the United States*, 348(26) NEW ENG. J. MED. 2635-45, (2003).

250,000 people die each year as a result of preventable hospital errors in the U.S.<sup>42</sup>, and more than 72,000 people died in 2015 from an infection obtained while in the hospital.<sup>43</sup>

There are hundreds of health care quality measures developed, maintained, and evaluated for relevancy and accuracy by many different organizations, including the federal Agency for Healthcare Research and Quality, the National Quality Forum, and the National Committee for Quality Assurance. In general, health quality measures can be sorted into four categories:<sup>44</sup>

- **Structure measures-** assess the aspects of the health care setting, including facility, personnel, and policies related to the delivery of care.
  - Example- What is the nurse-to-patient ratio in a neonatal intensive care unit?
- **Process measures-** determine if the services provided to patients are consistent with routine clinical care.
  - Example- Does a doctor recommend prostate-specific antigen testing for his male patients at average risk for prostate cancer beginning at age 50?
- **Outcome measures-** evaluate patient health as a result of care received.
  - Example- What is the infection rate of patients undergoing cardiac surgery at a hospital?
- **Patient experience measures-** provide feedback on patients' experiences with the care received.
  - Example- Do patients recommend their doctor to others following a procedure?

Data on health care quality measures come from a number of sources. Some of the most common source include:

- Health insurance claims and other administrative documents;
- Disease registries, such as those maintained by the Agency for Toxic Substances and Disease Registry<sup>45</sup> in the Centers for Disease Control and national disease-specific registries, like the National Amyotrophic Lateral Sclerosis (ALS) Registry<sup>46</sup> and the Kaiser Permanente Autoimmune Disorder Registry<sup>47</sup>;
- Medical records; and
- Qualitative data, including information from patient surveys, interviews, and focus groups.<sup>48</sup>

Standardized healthcare performance measures are used by a range of healthcare stakeholders for a variety of purposes. Measures help clinicians, hospitals, and other providers understand whether the care they provide their patients is optimal and appropriate, and if not, where to focus their efforts to improve. Public and private payers also use measures for feedback and benchmarking purposes, public reporting, and incentive-based payment. Lastly, measures are an essential part of making the cost and quality of healthcare more transparent to all, particularly for those who receive care or help make care decisions for loved ones. The Institute of Medicine's six domains of quality—safe, effective, patient-centered, timely, efficient, and equitable—are one way to organize the information.<sup>49</sup> Studies

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<sup>42</sup> JOHN HOPKINS MEDICINE, *Medical Error-The Third Leading Cause of Death in the U.S.*, <https://www.bmj.com/content/353/bmj.i2139.full> (last visited May 23, 2019).

<sup>43</sup> CENTERS FOR DISEASE CONTROL, *Healthcare-Associated Infections (HAI), Data and Statistics-HAI Prevalence Survey*, available at <http://www.cdc.gov/HAI/surveillance/index.html> (last viewed February 5, 2019).

<sup>44</sup> U.S. Government Accountability Office, *Health Care Transparency-Actions Needed to Improve Cost and Quality Information for Consumers*, October 2014, pgs. 6-7 (citing quality measure categories established by the U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality's National Quality Measures Clearinghouse, available at <http://qualitymeasures.ahrq.gov/tutorial/varieties.aspx>).

<sup>45</sup> For more information, visit [www.atsdr.cdc.gov/](http://www.atsdr.cdc.gov/).

<sup>46</sup> For more information, visit <https://wwwn.cdc.gov/ALS/Default.aspx>.

<sup>47</sup> For more information, visit <https://divisionofresearch.kaiserpermanente.org/research>.

<sup>48</sup> *Supra* note 44.

<sup>49</sup> Institute of Medicine, *Report: Crossing the Quality Chasm: A New Health System for the 21st Century*, Mar. 1, 2001, available at <http://ion.nationalacademies.org/~media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf> (last visited May 23, 2019).



have found patients find effectiveness, safety, and patient-centeredness to be most meaningful in their consideration of health care options.<sup>50</sup>

As more and more health care consumers shop for their health care, value becomes more important than price alone. Determining value means comparing the cost of care with information on the quality or benefit of the service. Presenting health care price information without accompanying quality information leads consumers to assume that high-priced care is high quality care.<sup>51</sup> In fact, there is no evidence of a correlation between cost and quality in health care.<sup>52</sup>

Showing cost and quality information together helps consumers clearly see variation among providers.<sup>53</sup> Further, it helps consumers understand that high costs do not necessarily mean high quality—high-quality care is available without paying the highest price.<sup>54</sup> One way to accomplish this would be to present comparative quality and cost information on one, consumer-friendly website, using several specific measures or scores so multiple metrics can be compared at the same time.<sup>55</sup>

### *Hospital Compare*

The Centers for Medicare and Medicaid Services (CMS) maintains the Hospital Compare website,<sup>56</sup> which provides consumers with data about the quality of care at over 4,000 Medicare-certified hospitals.<sup>57</sup> 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.<sup>58</sup> Performance measures include patient satisfaction survey results<sup>59</sup> and readmission, hospital acquired infection and mortality rates.<sup>60</sup> Overall hospital performance is presented to consumers through a star rating of one to five stars.<sup>61</sup> A 2015 survey of health care consumers, found that 13% of consumers were aware of the Hospital Compare website and only 3% of consumers had utilized the Hospital Compare website.<sup>62</sup>

### *Florida Center for Health Information and Transparency*

The Florida Center for Health Information and Transparency (the Florida Center) provides a comprehensive health information system (information system) that includes the collection, compilation,

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<sup>50</sup> Hibbard, JH, Greene, J, Daniel D., *What is Quality Anyway? Performance Reports That Clearly Communicate to Consumers the Meaning of Quality Care*, 67(3) MED. CARE RES. REV. 275-293 (2010).

<sup>51</sup> Public Agenda and Robert Wood Johnson Foundation, *How Much Will It Cost? How Americans Use Prices in Health Care*, Mar. 2015, p. 5, available at: [http://www.publicagenda.org/files/HowMuchWillItCost\\_PublicAgenda\\_2015.pdf](http://www.publicagenda.org/files/HowMuchWillItCost_PublicAgenda_2015.pdf) (last visited May 23, 2019).

<sup>52</sup> Carman, KL, Maurer M., et al., *Evidence That Consumers Are Skeptical About Evidence-Based Health Care*, 29(7) HEALTH AFFAIRS 1400-1406 (2010).

<sup>53</sup> American Institute of Research, The Robert Wood Johnson Foundation, *How to Report Cost Data to Promote High-Quality, Affordable Choices: Findings from Consumer Testing*, Feb. 2014, available at [https://www.rwjf.org/content/dam/farm/reports/issue\\_briefs/2014/rwjf410706](https://www.rwjf.org/content/dam/farm/reports/issue_briefs/2014/rwjf410706) (last visited May 23, 2019).

<sup>54</sup> Id.

<sup>55</sup> Id.

<sup>56</sup> MEDICARE.GOV, *Hospital Compare*, <http://www.medicare.gov/hospitalcompare> (last visited May 23, 2019).

<sup>57</sup> MEDICARE.GOV, *What is Hospital Compare?*, <https://www.medicare.gov/hospitalcompare/About/What-Is-HOS.html> (last visited May 23, 2019).

<sup>58</sup> CENTERS FOR MEDICARE & MEDICAID SERVICES, *Hospital Compare*, <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/hospitalcompare.html> (last visited May 23, 2019).

<sup>59</sup> Data is from responses to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. HCAHPS is a national survey that asks patients about their experiences during a recent hospital stay. <http://www.hcahpsonline.org/>

<sup>60</sup> MEDICARE.GOV, *Measures and Current Data Collection Periods*, <https://www.medicare.gov/hospitalcompare/Data/Data-Updated.html#> (last visited May 23, 2019).

<sup>61</sup> MEDICARE.GOV, *Hospital Compare Overall Hospital Rating*, <https://www.medicare.gov/hospitalcompare/About/Hospital-overall-ratings.html> (last visited May 23, 2019).

<sup>62</sup> Professional Research Consultants, *2015 National Consumer Report*, available at [http://cdn2.hubspot.net/hubfs/506577/national-consumer-report-prc.pdf?\\_hssc=195883955.2.1447781166730&\\_hstc=195883955.37a62d05b8cdf8e6b71584f6cedf05df.1447781166730.1447781166730.1447781166730.1&hsCtaTracking=774f2caf-e66b-42c6-820b-afad1c5653d6%7Ce405f131-f4e9-48ff-9090-5f51bfa7f04f](http://cdn2.hubspot.net/hubfs/506577/national-consumer-report-prc.pdf?_hssc=195883955.2.1447781166730&_hstc=195883955.37a62d05b8cdf8e6b71584f6cedf05df.1447781166730.1447781166730.1447781166730.1&hsCtaTracking=774f2caf-e66b-42c6-820b-afad1c5653d6%7Ce405f131-f4e9-48ff-9090-5f51bfa7f04f) (last visited May 23, 2019).

coordination, analysis, indexing, dissemination, and utilization of health-related data. The Florida Center is housed within AHCA and is funded through appropriations in the General Appropriations Act, through grants, gifts, and other payments, and through fees charged for services. Offices within the Florida Center, which serve different functions, are:

- Data Collection and Quality Assurance, which collects patient discharge data from all licensed acute care hospitals (including psychiatric and comprehensive rehabilitation units), comprehensive rehabilitation hospitals, ambulatory surgical centers and emergency departments.
- Risk Management and Patient Safety, which conducts in-depth analyses of reported incidents to determine what happened and how the facility responded to the incident.
- Data Dissemination and Communication, which maintains AHCA's health information website, provides technical assistance to data users, and creates consumer brochures and other publications.
- Health Information Exchange and Policy Analysis, which monitors innovations in health information technology, informatics, and the exchange of health information and provides a clearinghouse of technical resources on health information exchange, electronic prescribing, privacy and security, and other relevant issues.

The Florida Center electronically collects patient data from every Florida licensed inpatient hospital, ambulatory surgery center (ASC), emergency department, and comprehensive rehabilitation hospital on a quarterly basis. The data is validated for accuracy and maintained in three major databases: the hospital inpatient database, the ambulatory surgery database, and the emergency department database.

- The **hospital inpatient database** contains records for each patient stay at Florida acute care facilities, including long-term care hospitals and psychiatric hospitals. These records contain extensive patient information including discharge records, patient demographics, admission information, medical information, and charge data. This database also includes comprehensive inpatient rehabilitation data on patient-level discharge information from Florida's licensed freestanding comprehensive inpatient rehabilitation hospitals and acute care hospital distinct part rehabilitation units.
- The **ambulatory surgery database** contains "same-day surgery" data on reportable patient visits to Florida health care facilities, including freestanding ambulatory surgery centers, short-term acute care hospitals, lithotripsy centers, and cardiac catheterization laboratories. Ambulatory surgery data records include, but are not limited to, patient demographics, medical information, and charge data.
- The **emergency department database** collects reports of all patients who visited an emergency department, but were not admitted for inpatient care. Reports are electronically submitted to the AHCA and include the hour of arrival, the patient's chief complaint, principal diagnosis, race, ethnicity, and external causes of injury.

Florida statute requires the Florida Center to identify available data sets, compile new data when specifically authorized by the Legislature, and promote the use of extant health-related data and statistics. As mentioned previously, the duties and obligations were streamlined by HB 1175 in 2016 to eliminate obsolete language, redundant duties, and unnecessary functions. Now, the Florida Center must maintain any data sets in existence before July 1, 2016, unless such data sets duplicate information that is readily available from other credible sources, and may collect or compile data on:

- Health resources, including licensed health care practitioners, by specialty and type of practice, and including information collected by the Department of Health.

- Health service inventories, including acute care, long-term care, and other institutional care facilities and specific services provided by hospitals, nursing homes, home health agencies, and other licensed health care facilities.
- Service utilization for licensed health care facilities.
- Health care costs and financing, including trends in health care prices and costs, the sources of payment for health care services, and federal, state, and local expenditures for health care.
- The extent of public and private health insurance coverage in this state; and
- Specific quality-of-care initiatives involving various health care providers when extant data is not adequate to achieve the objectives of the initiative.

The Florida Center maintains [www.FloridaHealthFinder.gov](http://www.FloridaHealthFinder.gov), which was established to assist consumers in making informed health care decisions and lead 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, ambulatory surgery centers, emergency departments, hospice providers, physician volume, health plans, nursing homes, and prices for prescription drugs in Florida. The website also provides tools to researchers and professionals to allow specialized data queries, but requires users to have some knowledge of medical coding and terminology. Some of the features and data available on the website include a multimedia encyclopedia and symptoms navigator, hospital and ambulatory surgery centers performance data, data on mortality, complication, and infection rates for hospitals, and a facility/provider locator.

Hospital data for total hospitalizations, high and low charges, infection rates, readmission rates and patient satisfaction are available on the website. The public may search data for infection rates and patient satisfaction by age group and medical procedure. Data for the following hospital acquired infections is available<sup>63</sup>:

- Catheter Associated Urinary Tract Infection (CAUTI)
- Central-line Associated Bloodstream Infection (CLABSI)
- Clostridium Difficile Infections (C. diff.)
- Methicillin-resistant Staphylococcus aureus (MRSA)
- Surgical Site Infection from Abdominal Hysterectomy (SSI: Hysterectomy)
- Surgical Site Infection from Colon Surgery (SSI: Colon)

Data for patient satisfaction includes the following measures<sup>64</sup>:

- Communication with nurses
- Communication with doctors
- Responsiveness of hospital staff
- Communication about medicines
- Discharge information
- Care transition
- Cleanliness of hospital environment
- Quietness of hospital environment
- Overall hospital rating
- Recommend the hospital

Data is presented using a star rating system. For readmission rates, three stars represents fewer readmissions than expected given how sick patients were, two stars represents expected number of

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<sup>63</sup> AGENCY FOR HEALTH CARE ADMINISTRATION, *Florida Health Finder*, <http://www.floridahealthfinder.gov/CompareCare/CompareFacilities.aspx> (last visited May 23, 2019).

<sup>64</sup> Id.

readmissions given how sick patients were, and one star represents more readmissions than expected given how sick patients were.<sup>65</sup> For patient satisfaction, the HCAHPS star rating is used.<sup>66</sup> For hospital acquired infections, three stars represents better than the U.S. national benchmark, two stars represents no different than the U.S. national benchmark, and one star represents worse than the U.S. national benchmark.<sup>67</sup> The website also provides a glossary with explanations of the performance data published on the website.<sup>68</sup>

## **Effect of the Bill – Hospital Quality Report Cards**

The bill requires hospitals to provide patients or a patient's representative and any person upon request the hospital's data and the statewide average for the following quality measures:

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

The hospitals currently submit this data for these quality measures to AHCA and available to the public on [www.FloridaHealthFinder.gov](http://www.FloridaHealthFinder.gov).

The bill requires hospitals to present the data in writing on a form created by AHCA to patients upon non-emergency care scheduling or within 24 hours of stabilization of a patient. The bill also requires hospitals to provide an explanation of the quality measures and the relationship between the hospital's quality measure data and patient safety.

The bill limits who may receive the data by defining patient's representative to the statutorily enumerated list of people allowed to serve as a patient's representative for incapacitated or developmentally disabled patients without advanced directives.<sup>69</sup>

## **Patient Access to Providers**

### **Background**

#### **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.<sup>70</sup> 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 decisions from a holistic perspective efficiently without extensive investigation or record review.<sup>71</sup>

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<sup>65</sup> Id.

<sup>66</sup> Hospital Consumer Assessment of Healthcare Providers and Systems, *HCAHPS Fact Sheet*, available at [http://www.hcahponline.org/globalassets/hcahps/facts/hcahps\\_fact\\_sheet\\_november\\_2017.pdf](http://www.hcahponline.org/globalassets/hcahps/facts/hcahps_fact_sheet_november_2017.pdf) (last viewed December 12, 2018).

<sup>67</sup> *Supra* note 63.

<sup>68</sup> FLORIDA HEALTH FINDER, *Glossary*, <http://www.floridahealthfinder.gov/CompareCare/Glossary.aspx#hai> (last visited May 23, 2019).

<sup>69</sup> See, s. 765.401(1), F.S.

<sup>70</sup> 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](https://www.ncbi.nlm.nih.gov/books/NBK232643/pdf/Bookshelf_NBK232643.pdf) (last visited May 7, 2019).

<sup>71</sup> 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 May 7, 2019).

Studies suggest that continuity of care by a primary care provider is associated with greater patient satisfaction and better patient outcomes, especially in the management of chronic conditions, by decreasing hospitalizations and emergency room visits, and improving preventative services.<sup>72</sup> Conversely, fragmented care where a patient's various healthcare providers do not communicate with one another can have an adverse impact on the quality of care, and is associated with increased healthcare costs, medical errors,<sup>73</sup> and risk of re-hospitalization.<sup>74</sup>

### Care Coordination

Health care experts, policy makers, and patient advocacy groups have identified coordination of care as an integral part of improving the current health care system.<sup>75</sup> In 2010, Congress prioritized improvement of the health care delivery system through integrated care and care coordination, and created incentives for providers who communicate with one another across systems to improve patient outcomes.<sup>76</sup> The American Academy of Family Physicians supports continuity of care and recommends the primary care provider play a role in the patient's care across all settings, directly and by coordination of care with other health care professionals.<sup>77</sup> In an effort to better coordinate care, some hospitals have implemented continuity visits or increased communication procedures so that the patient's provider can be consulted in the patient's care.<sup>78</sup>

Physicians who practice a medical specialty have extensive education and training in a specific field of medicine, such as cardiology, endocrinology, orthopedics, or rheumatology. Due to their specialized skills, specialist providers are often consulted on or co-manage a patient's chronic condition.<sup>79</sup> Specialty care is critical because it provides effective diagnoses and treatment to reduce clinical

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<sup>72</sup> Michael D. Cabana, MD, MPH, and Sandra H. Jee, MD, MPH, *Does Continuity of Care Improve Patient Outcomes?*, 53:12 J. FAM. PRACTICE 974-980 (Dec. 2004), available at: <https://www.mdedge.com/jfonline/article/60297/does-continuity-care-improve-patient-outcomes> (last visited May 7, 2019), a meta-analysis reviewed existing research and narrowed its scope to 8 studies focused on the effect of continuous primary care on quality of patient care; See also, David J. Nyweide, PhD. et. al., *Continuity of Care and the Risk of Preventable Hospitalization in Older Adults*, 173:20 JAMA Intern. Med. 1879-85 (2013), available at: <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1738715> (last visited May 7, 2019), a retrospective cohort study of approximately 413,000 FFS Medicare beneficiaries over 65 with at least 4 ambulatory visits in one year observed the patients over a 2-year follow-up period. The study found that among this population, higher continuity of care is associated with lower rates of preventable hospitalizations; Eric A. Colean, M.D., M.P.H., et. al., *The Care Transitions Intervention: Results of a Randomized Controlled Trial*, 166:17 Arch. Intern. Med. 1822-28 (2006), available at:

<https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/410933?version=meter%20at%20null&module=meter-Links&pgtype=Blogs&contentId=&mediald=&referrer=&priority=true&action=click&contentCollection=meter-links-click> (last visited May 7, 2019).

<sup>73</sup> "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.

<sup>74</sup> Study of 86 patients seen by their PCPs 2 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 3 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 May 7, 2019).

<sup>75</sup> See generally, THE AMERICAN COLLEGE OF PHYSICIANS, *The Patient Centered Medical Home & Specialty Physicians*, <https://www.acponline.org/practice-resources/business-resources/payment/delivery-and-payment-models/patient-centered-medical-home/understanding-the-patient-centered-medical-home/the-patient-centered-medical-home-specialty-physicians> (last visited May 7, 2019); THE JOINT COMMISSION CENTER FOR TRANSFORMING HEALTHCARE, *Hot Topics in Health Care, Issue #2: Transitions of Care: The need for collaboration across entire care continuum* (Feb. 2013), available at: [https://www.jointcommission.org/assets/1/6/TOC\\_Hot\\_Topics.pdf](https://www.jointcommission.org/assets/1/6/TOC_Hot_Topics.pdf) (last visited May 7, 2019); THE COMMONWEALTH FUND, COMMISSION ON A HIGH PERFORMANCE HEALTH SYSTEM, *Organizing the U.S. Health Care Delivery System for High Performance*, Aug. 2008, available at: [https://www.commonwealthfund.org/sites/default/files/documents/\\_media\\_files\\_publications\\_fund\\_report\\_2008\\_aug\\_organizing\\_the\\_u\\_s\\_health\\_care\\_delivery\\_system\\_for\\_high\\_performance\\_shih\\_organizingushltcaredeliverysys\\_1155.pdf](https://www.commonwealthfund.org/sites/default/files/documents/_media_files_publications_fund_report_2008_aug_organizing_the_u_s_health_care_delivery_system_for_high_performance_shih_organizingushltcaredeliverysys_1155.pdf) (last visited May 7, 2019).

<sup>76</sup> The Patient Protection and Affordable Care Act, *Pub. L. No. 111-148*, H.R. 3590, 111th Cong. (Mar. 23, 2010).

<sup>77</sup> AMERICAN ACADEMY OF FAMILY PHYSICIANS, *Continuity of Care*, <https://www.aafp.org/about/policies/all/definition-care.html> (last visited May 7, 2019).

<sup>78</sup> 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\\_Hospitalist-Primary\\_Care\\_Divide\\_through\\_Collaborative\\_Care](https://www.researchgate.net/publication/271222735_Bridging_the_Hospitalist-Primary_Care_Divide_through_Collaborative_Care) (last visited May 7, 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 May 7, 2019).

<sup>79</sup> Christopher Forrest, M.D., Ph.D., *A Typology of Specialists' Clinical Roles*, 169(11) ARCHIVE OF INTERN. MED. 1062-8 (2009), available at: <https://static1.squarespace.com/static/52d9c6c5e4b021f2d93416db/t/53a1f295e4b0b7f569f7e388/1403122325699/Arch+Intern+Med+2009+Forrest.pdf> (last visited Apr. 4, 2019).

uncertainty and can be effective in the treatment and management of chronic conditions.<sup>80</sup> Studies show that the best patient outcomes result from co-management of conditions between specialist and primary care providers.<sup>81</sup>

### *Patient Handoff*

A critical moment in the continuum of care is during patient handoff, when the patient care responsibility is transferred from one healthcare professional to another. This is especially significant during transition from an inpatient to an outpatient setting. Based on reports and studies, it does not appear to be common practice for a hospital to communicate with the patient's providers during a patient's admission or even at discharge.<sup>82</sup> Often, the patient's providers are wholly unaware of the hospitalization or do not receive a discharge summary or information from the hospital.

Evidence suggests that when hospitals fail to communicate with the patient's providers during a patient's admission or discharge, there is an increased rate of medical errors and risk of re-hospitalization.<sup>83</sup> A growing body of research and articles recommend that a patient's provider be informed of the patient's admission to or discharge from a hospital, with most effective care being provided when information is shared between the provider and treating physician throughout the course of the admission.<sup>84</sup>

### Hospital Regulation

In Florida, the Agency for Health Care Administration (AHCA) regulates hospitals under ch. 395, F.S. Current law does not require Florida hospitals to coordinate care with primary care providers or authorize patients to request such coordination.

### **Effect of the Bill – Patient Access to Providers**

Currently, there is no statutory requirement that a hospital notify the primary care provider of a patient's admission to or discharge from the hospital. The bill requires each hospital in the state to notify a patient's primary care provider, if any, within 24 hours of the patient's admission to and discharge from

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<sup>80</sup> Id.

<sup>81</sup> Id. See also, D. J. Willison, et al., *Consultation between Cardiologists and Generalists in the Management of Acute Myocardial Infarction: Implications for Quality Care*, 158(16) ARCHIVES OF INTERN. MED. 1778-83 (1998); J.E. Lafata et al., *Provider Type and Receipt of General and Diabetes-Related Preventive Health Services Among Patients with Diabetes*, 39(5) MED. CARE 491-99 (2001); J.Z. Ayanian, *Specialty of Ambulatory Care Physicians and Mortality among Elderly Patients after Myocardial Infarction*, 347(21) N. ENGL. J. MED. 1678-86 (2002).

<sup>82</sup> 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 May 7, 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% of the time, the availability of the discharge summary at the first post-discharge visit was less than 34% and remained poor even 4 weeks after discharge and affected the quality of care in 25% of follow-up visits.

<sup>83</sup> Id. See also, *supra* note 74.

<sup>84</sup> 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](http://www.mdwriter.com/uploads/1/8/0/3/18033585/md_to_md_communication_pej.pdf) (last visited May 7, 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% of patients who received visits from their primary care physicians had lower risks of adverse patient outcomes, fewer ER 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 May 7, 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% 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 Society, American College of Emergency Physicians, and Society for Academic Emergency Medicine*, 4:6 J. HOSP. MED. 364-70 (July-Aug. 2009), available at: <https://pdfs.semanticscholar.org/4d62/22d8eadfdb0e3dc7edad34cc86b1290afbd5.pdf> (last visited May 7, 2019).

the hospital and provide the discharge summary and any related information or records to the primary care or specialist provider within 14 days after the patient's discharge summary has been completed.

Currently, there is no statutory requirement that a treating physician at a hospital consult with a patient's primary care or specialist provider during the admission. The bill requires the hospital to inform patients immediately upon admission that they may request to have the treating physician consult with the patient's primary care or specialist provider, if any, when developing the patient's plan of care. If the patient makes this request, then the treating physician must make reasonable efforts to consult with the primary care or specialist provider during the patient's admission.

## **Ambulatory Surgical Centers**

### **Background**

#### **Ambulatory Surgical Centers (ASCs)**

An ASC is a facility, that is not a part of a hospital, the primary purpose of which is to provide elective surgical care, in which the patient is admitted and discharged within the same working day and is not permitted to stay overnight.<sup>85</sup>

ASCs are licensed and regulated by the Agency for Health Care Administration (AHCA) under the same regulatory framework as hospitals.<sup>86</sup> Currently, there are 461 licensed ASCs in Florida.<sup>87</sup> Of the 308 licensed hospitals in the state, 212 report providing outpatient surgical services.<sup>88</sup>

In 2017, there were 1,636,976 visits to ASCs in Florida.<sup>89</sup> Visits occur at hospital-based outpatient facilities or freestanding ASCs. Hospital-based outpatient facilities accounted for 46 percent and freestanding ASCs accounted for 54 percent of the total number of visits.<sup>90</sup> Of the \$44 billion in total charges for ambulatory procedures in 2017, hospital-based outpatient facilities accounted for 77 percent of the charges, while freestanding ASCs accounted for 23 percent.<sup>91</sup> The average charge at the hospital-based facilities, \$23,951, was more than three times larger than the average charge at the freestanding ASCs, \$6,208.<sup>92</sup>

In Florida, for 2017, the top five medical procedures, by total charges, at a freestanding ASC and hospital-based outpatient facility were:

- Esophagogastroduodenoscopy;
- Cataract surgery with IOL implant;
- Colonoscopy and biopsy;
- Diagnostic colonoscopy; and
- Colonoscopy with lesion removal.<sup>93</sup>

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<sup>85</sup> S. 395.002(3), F.S.

<sup>86</sup> Ss. 395.001-.1065, F.S., and Part II, Chapter 408, F.S.

<sup>87</sup> AGENCY FOR HEALTH CARE ADMINISTRATION, *Facility/Provider Locator, Ambulatory Surgical Center*, available at <http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx> (last visited May 23, 2019)

<sup>88</sup> Agency for Health Care Administration, 2019 Agency Legislative Bill Analysis for HB 25, Mar. 11, 2019 (on file with Health Market Reform Subcommittee staff).

<sup>89</sup> AGENCY FOR HEALTH CARE ADMINISTRATION, *Ambulatory (Outpatient) Surgery Query Results*, available at <http://www.floridahealthfinder.gov/QueryTool/QTRResults.aspx?T=O> (last visited May 23, 2019).

<sup>90</sup> AGENCY FOR HEALTH CARE ADMINISTRATION, *Ambulatory (Outpatient) Surgery Query Results, By Facility Type*, available at <http://www.floridahealthfinder.gov/QueryTool/QTRResults.aspx?T=O> (last visited May 23, 2019).

<sup>91</sup> Id.

<sup>92</sup> Id.

<sup>93</sup> AGENCY FOR HEALTH CARE ADMINISTRATION, *Ambulatory (Outpatient) Surgery Query Results; By Current Procedural Terminology Code and Facility Type*, available at <http://www.floridahealthfinder.gov/QueryTool/QTRResults.aspx?T=O> (last visited May 23, 2019).

The following chart shows the total number of visits for each of the top five medical procedures and the average charge for each procedure in 2017<sup>94</sup>:

Procedure	Total Visits	Average Charge
Esophagogastroduodenoscopy	254,537	\$5,540
Cataract surgery with IOL implant	250,096	\$4,829
Colonoscopy and biopsy	192,133	\$4,836
Diagnostic colonoscopy	183,785	\$3,605
Colonoscopy with lesion removal	166,185	\$5,041

In 2017, payment for visits to freestanding ASCs and hospital-based outpatient facilities was made mainly by commercial insurance and regular Medicare. Commercial insurance paid \$18 billion or 41 percent of charges, while Medicare paid \$12 billion or 27 percent of charges.<sup>95</sup> The next three top payer groups, Medicare managed care, Medicaid managed care, and self-pay, accounted for a combined \$10.8 billion or 24 percent of charges.<sup>96</sup>

## Federal Requirements

### *Medicare*

ASCs are required to have an agreement with the Centers for Medicare and Medicaid Services (CMS) to participate in Medicare. ASCs are also required to comply with specific conditions for coverage. CMS defines an “ASC” as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours<sup>97</sup> following an admission.<sup>98</sup>

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 that CMS determines provides reasonable assurance that the conditions are met.<sup>99</sup> All of the CMS conditions for coverage requirements are included in Chapter 59A-5, F.A.C., and apply to all ASCs.

### ASC Cost of Care and Quality Outcomes

There has been tremendous growth in the outpatient surgery segment of health care in the U.S., facilitated by advances in technology. From 1981 through 2005, the number of outpatient surgeries increased ten-fold.<sup>100</sup> Outpatient surgeries now account for more than 80 percent of all surgeries completed in the U.S.<sup>101</sup> Research shows that procedures in ASCs are 25 percent faster on average

<sup>94</sup> Id.

<sup>95</sup> AGENCY FOR HEALTH CARE ADMINISTRATION, *Ambulatory (Outpatient) Surgery Query Results; By Principal Payer* <http://www.floridahealthfinder.gov/QueryTool/QTRResults.aspx?T=O> (last last visited May 23, 2019).

<sup>96</sup> Id.

<sup>97</sup> U.S. CENTERS FOR MEDICARE AND MEDICAID SERVICES, State Operations Manual Appendix L, *Guidance for Surveyors: Ambulatory Surgical Centers* (Rev. 137, 04-01-15), available at: [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap\\_l\\_ambulatory.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_l_ambulatory.pdf) (last visited May 23, 2019); Exceeding the 24-hour time frame is expected to be a rare occurrence and each rare occurrence is expected to be demonstrated to have been something which ordinarily could not have been foreseen. Not meeting this requirement constitutes condition-level noncompliance with regulations. In addition, review of the cases that exceed the time frame may also reveal noncompliance with conditions for coverage related to surgical services, patient admission and assessment, and quality assurance/performance improvement.

<sup>98</sup> 42 C.F.R. §416.2.

<sup>99</sup> 42 C.F.R. §416.26(a)(1).

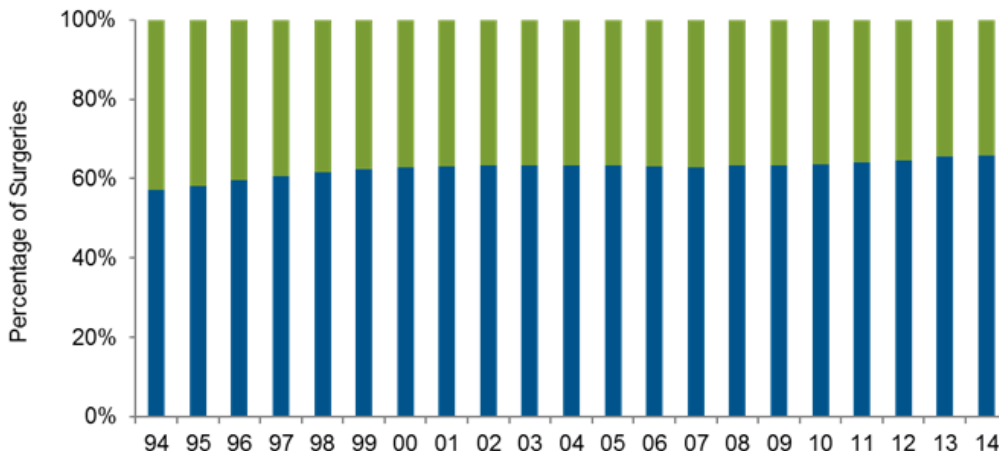
<sup>100</sup> Munnich E. and Parente S., *Procedures Take Less Time at Ambulatory Surgery Centers, Keeping Costs Down and Ability to Meet Demand Up*, 33:5 HEALTH AFFAIRS 764-69, 764 (2014).

<sup>101</sup> Munnich E. and Parente S., *Returns to Specialization: Evidence from the Outpatient Surgery Market*, pg. 1 (April 2014), available at [https://louisville.edu/faculty/elmun01/Munnich\\_Parente\\_ASC\\_Quality.pdf](https://louisville.edu/faculty/elmun01/Munnich_Parente_ASC_Quality.pdf) (last visited May 23, 2019); Chart data is from an analysis of the American Hospital Association Annual Survey data from 2014 for community hospitals.



than hospital-based outpatient facilities, driven mainly by technological, system and process efficiencies in ASCs.<sup>102</sup>

**Percentage of Inpatient vs. Outpatient Surgeries 1994-2014<sup>103</sup>**



The increased use of outpatient surgery may help lower health care costs and meet increased patient demand for outpatient surgery, which is frequently more convenient for patients and their families and allows for less stressful recovery.

#### ASC Cost of Care

Despite the volume of outpatient surgeries today, there is little research on cost savings associated with ASCs.<sup>104</sup> The study that found procedures in ASCs were completed 25 percent faster than the same procedures in hospital-based outpatient facilities also found that ASC efficiency generated a savings of \$363-\$1,000 per outpatient case.<sup>105</sup>

In 2014, the Office of the Inspector General for the U.S. Department of Health and Human Services studied the cost efficiency associated with Medicare beneficiaries obtaining surgical services in an outpatient setting.<sup>106</sup> The OIG found that Medicare saved almost \$7 billion during calendar years (CYs) 2007 through 2011 and could potentially save \$12 billion from CYs 2012 through 2017 due primarily to the lower rates for surgical procedures done in ASCs.<sup>107</sup> The OIG also found that Medicare beneficiaries realized savings of \$2 billion in the form of reduced co-payment obligations in the ASC setting.<sup>108</sup> In addition, Medicare could generate savings of as much as \$15 billion for CYs 2012 through 2017 if CMS reduced hospital outpatient department payment rates for ASC-approved procedures to ASC payment levels.<sup>109</sup> Beneficiaries, in turn, would save \$3 billion.<sup>110</sup>

<sup>102</sup> Trentman T., et al, *Outpatient Surgery Performed in an Ambulatory Surgery Center Versus a Hospital: Comparison of Perioperative Time Intervals*, 100:1 AMER. J. SURGERY 64-67 (July 2010).

<sup>103</sup> Shapiro, M.D., Presentation to the Health Innovation Subcommittee, slide 5, January 25, 2017 (on file with Health Market Reform Subcommittee staff).

<sup>104</sup> Professor Elizabeth L. Munnich, University of Louisville, Louisville, Kentucky, Presentation to the Health Innovation Subcommittee on Measuring Cost and Quality in Ambulatory Surgical Centers, slide 2, January 25, 2017 (on file with Health Market Reform Subcommittee staff).

<sup>105</sup> *Supra* note 100 at 767; The savings calculation is based on the estimated charges for operating room time, set at \$29 to \$80 per minute, not including surgeon and anesthesia provider fees. Macario A. *What does one minute of operating room time cost?*, 22(4) J CLIN ANESTH. 233-6 (2010).

<sup>106</sup> U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF INSPECTOR GENERAL, *Medicare and Beneficiaries Could Save Billions If CMS Reduces Hospital Outpatient Department Payment Rates for Ambulatory Surgical Center-Approved Procedures to Ambulatory Surgical Center Payment Rates*, Audit A-05-12-00020 (April 16, 2014), available at: <https://oig.hhs.gov/oas/reports/region5/51200020.pdf> (last visited May 23, 2019).

<sup>107</sup> *Id.* at i.

<sup>108</sup> *Id.* at ii.

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

A review of commercial medical claims data found that U.S. healthcare costs are reduced by more than \$38 billion per year due to the availability of ASCs for outpatient procedures.<sup>111</sup> More than \$5 billion of the cost reduction accrued to the patient through lower deductible and coinsurance payments.<sup>112</sup> This cost reduction is driven by the fact that, in general, ASC prices are significantly lower than hospital outpatient department prices for the same procedure in all markets, regardless of payer. The study also looks at the potential savings that could be achieved if additional procedures were redirected to ASCs. As much as \$55 billion could be saved annually depending on the percentage of procedures that migrate to ASCs and the mix of ASCs selected instead of HOPDs.<sup>113</sup>

An analysis by the Ambulatory Surgery Center Association of 2014 data from the Center for Medicaid and Medicare Services focused on the impact of Florida ASCs to Medicare. Specifically, it found:

- Medicare saved more than \$84 million on cataract procedures because beneficiaries elected to have those procedures performed in an ASC.
- Florida patients saved more than \$23.4 million by having upper GI procedures in an ASC.
- Medicare saved an additional \$42.6 million on colonoscopies performed in ASCs.<sup>114</sup>

### *ASC Quality Outcomes*

The body of evidence shows that patients undergoing outpatient surgery in an ASC have the same or better outcomes as patients undergoing surgery at a hospital-based outpatient department.<sup>115</sup> Another study showed that patients who underwent a high volume procedure in an ASC were less likely than those treated in a hospital-based outpatient department to visit an ER or be admitted to the hospital following surgery.<sup>116</sup> The finding held true across timeframe since surgery and for low and high risk patients. Researchers concluded that ASCs provide high volume services more efficiently than hospital-based outpatient departments, but not at the expense of quality of care.<sup>117</sup> One national study found patient satisfaction with care received at ASCs measured at 92 percent.<sup>118</sup>

### **Effect of the Bill – Ambulatory Surgical Centers**

Pursuant to s. 395.002(3), F.S., patients receiving services in an ASC must be discharged on the same working day that they were admitted and cannot stay overnight. Medicare reimbursement policy limits the length of stay in an ASC to 24 hours following admission. The bill amends s. 395.002(3), F.S., to permit a patient to stay at an ASC for no longer than 24 hours.

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<sup>111</sup> Healthcare Bluebook and HealthSmart, *Commercial Insurance Cost Savings in Ambulatory Surgery Centers*, p. 7 (June 2016), available at <http://www.ascassociation.org/asca/communities/community-home/librarydocuments/viewdocument?DocumentKey=61197e80-d852-4004-860a-2424968b005b> (last visited May 23, 2019).

<sup>112</sup> *Id.*

<sup>113</sup> *Id.*

<sup>114</sup> *Supra* note 104, at slide 8.

<sup>115</sup> Office of Program Policy and Government Accountability, Research Memorandum, *Ambulatory Surgical Centers and Recovery Care Centers*, Jan. 19, 2016 (on file with Health Innovation Subcommittee staff). The OPPAGA research literature review found nine studies supporting the conclusion that ASCs provide more timely service to patients and have low rates of unexpected safety events. The review also found five studies concluding that the increase in patient volume to ASCs was not associated with an increase in hospital admissions or patient mortality. *Outpatient Surgery Performed in an Ambulatory Surgery Center Versus a Hospital: Comparison of Perioperative Time Intervals* (Trentman et al., 2010); *A Comparative Study of Quality Outcomes in Freestanding Ambulatory Surgery Centers and Hospital-Based Outpatient Departments: 1997-2004* (Chukmaitov et al., 2008); *Comparing Quality at an Ambulatory Surgery Center and a Hospital-Based Facility: Preliminary Findings* (Grisel and Arjmand, 2009); *Ambulatory Surgery Centers and Their Intended Effects on Outpatient Surgery* (Hollenbeck et al., 2015); *Changing Access to Emergency Care for Patients Undergoing Outpatient Procedures at Ambulatory Surgery Centers: Evidence From Florida* (Neuman et al., 2011); and *Hospital-Based, Acute Care After Ambulatory Surgery Center Discharge* (Fox et al., 2014).

<sup>116</sup> *Supra* note 102; Fleisher LA, Pasternak LR, Herbert R, Anderson GF. *Inpatient Hospital Admission and Death After Outpatient Surgery in Elderly Patients: Importance of Patient and System Characteristics and Location of Care*, 139(1) ARCH SURG. 67-72 (Jan. 2004).

<sup>117</sup> *Supra* note 104, at slide 8.

<sup>118</sup> *Press Ganey Outpatient Pulse Report 2008*. Represents the experiences of 1,039,289 patients treated at 1,218 facilities nationwide between January 1 and December 31, 2007.

The bill requires AHCA to establish minimum standards for pediatric care in ASCs. The standards must include quality of care, staffing, and equipment standards. ASCs may not perform operative procedures on children under the age of 18 that require a length of stay past midnight until such standards are established.

## **Pediatric Cardiac Technical Advisory Panel**

### **Background**

#### **Pediatric Cardiac Services**

Currently, pediatric cardiac catheterization<sup>119</sup> and pediatric open-heart surgery<sup>120</sup> are subject to certificate of need (CON)<sup>121</sup> review and approval prior to implementation of services pursuant to ss. 408.036(1) and 408.032(17), F.S. As conditions of CON approval, AHCA requires that:

- The program director for a pediatric cardiac catheterization program be board-eligible or board-certified in pediatric cardiology;<sup>122</sup>
- Pediatric cardiac catheterization programs be located in a hospital in which pediatric open-heart surgery is being performed;<sup>123</sup> and
- Pediatric open-heart surgery programs have at least one physician who is board-eligible or board-certified as a pediatric cardiac surgeon on the staff of a hospital.<sup>124</sup>

Pediatric cardiac programs must also:

- Have a pediatric cardiology clinic affiliated with a licensed hospital;
- Have a pediatric cardiac catheterization laboratory and a pediatric cardiovascular surgery program located in the hospital;
- Have a risk adjustment surgical procedure protocol that follows national guidelines;
- Have quality assurance and quality improvement processes in place to enhance clinical operation and patient satisfaction with services; and
- Participate in clinical outcome reporting systems.

#### *Pediatric Cardiac Technical Advisory Panel*

Licensure standards for pediatric cardiac services do not include pediatric cardiac service standards that exist within the CON process. In 2017, the Legislature created the Pediatric Cardiac Technical Advisory Panel (panel) to recommend licensure standards for pediatric cardiac programs to AHCA.<sup>125</sup>

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<sup>119</sup> Pediatric cardiac catheterization is a nonsurgical procedure used in infants, children, and teens to determine if there is a problem with the heart or repair a problem. NEMOURS, *Cardiac Catheterization in Children*, <https://www.nemours.org/service/medical/delaware-valley-pediatric-cardiac-center/treatment-and-testing/cardiac-catheterization-in-children.html?location=naidhc>, (last visited May 24, 2019).

<sup>120</sup> Pediatric cardiovascular surgery may treat either congenital heart defects, which are heart diseases present at birth, or heart problems developed later in childhood, called acquired heart disease. NEMOURS, *Pediatric Cardiac Surgery*, <https://www.nemours.org/service/medical/delaware-valley-pediatric-cardiac-center/treatment-and-testing/pediatric-cardiac-surgery.html> (last visited May 24, 2019).

<sup>121</sup> A certificate of need is a written statement issued by AHCA evidencing community need for a new, converted, expanded, or otherwise significantly modified health care facility or health service. See s. 408.036, F.S.

<sup>122</sup> Rule 59C-1.032(5)(b)1., F.A.C.

<sup>123</sup> Rule 59C-1.032(6)(c)., F.A.C.

<sup>124</sup> Rule 59C-1.003(5)(b), F.A.C.

<sup>125</sup> S. 395.1055, F.S.

Members of the panel must have technical expertise in pediatric cardiac medicine, serve without compensation, and not be reimbursed for per diem and travel expenses. The panel includes three at-large members including one cardiologist who is board-certified in caring for adults with congenital heart disease and two board-certified pediatric cardiologists, appointed by the Secretary of AHCA, and 10 members, each of whom is a pediatric cardiologist or a pediatric cardiovascular surgeon, from the following pediatric cardiac centers:

- 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; and
- Nemours Children's Hospital in Orlando.

The AHCA Secretary may also appoint nonvoting members to the panel, which may include the AHCA Secretary, the Surgeon General, the Deputy Secretary of CMS, any current or past Division Director of CMS, a parent of a child with congenital heart disease, an adult with congenital heart disease, and a representative from each of the following organizations:

- Florida Chapter of the American Academy of Pediatrics;
- Florida Chapter of the American College of Cardiology;
- Greater Southeast Affiliate of the American Heart Association;
- Adult Congenital Heart Association;
- March of Dimes;
- Florida Association of Children's Hospitals; and
- Florida Society of Thoracic and Cardiovascular Surgeons.

The panel must make recommendations to AHCA for standards for quality of care, personnel, physical plant, equipment, emergency transportation, and data reporting for hospitals that provide pediatric cardiac services. Based on these recommendations from the panel, AHCA must adopt rules for pediatric cardiac programs which, at a minimum, include:

- Standards for pediatric cardiac catheterization services and pediatric cardiovascular surgery 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 agency 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.

Beginning January 1, 2020, the panel must submit an annual report to the Governor, the President of the Senate, the Speaker of the House of Representatives, the AHCA Secretary, and the State Surgeon General that summarizes its activities and includes data and performance measures on surgical morbidity and mortality for all pediatric cardiac programs.

The panel has provided its recommendations to AHCA<sup>126</sup> and the agency is currently in the process of adopting rules for pediatric cardiac program standards.<sup>127</sup>

### **Effect of the Bill – Pediatric Cardiac Technical Advisory Panel**

The bill revises the membership of the panel by adding 3 alternate at-large members to the voting membership of the panel. The bill also places a 2-year term limit on voting membership of the panel and allows a prior member to be reappointed after being retired for a full 2-year term.

The bill requires the AHCA secretary to consult the panel for an advisory recommendation on certificate of need applications for pediatric cardiac surgical centers. The bill allows the panel to perform inspections of pediatric cardiac surgical programs at the request of the AHCA secretary. The bill makes the panel agents of state and provides personal immunity from tort claims when carrying out duties assigned to them by the AHCA secretary. The bill also allows members of the Panel to be reimbursed for per diem and travel expenses.

The bill requires DOH to provide AHCA with quarterly reports of data for the Children’s Medical Services’ critical congenital heart disease program for review by the panel.

### **Hospital Observation Status**

#### **Background**

##### **Hospital Billing Transparency**

Hospitals are licensed and regulated by the Agency for Health Care Administration (AHCA) under part I of ch. 395, F.S.<sup>128</sup> Current law requires hospitals to notify each patient, upon admission and discharge, of the right to receive an itemized bill. Upon request, the hospital must provide the patient an itemized statement detailing the specific nature of the charges or expenses incurred by the patient.<sup>129</sup>

A hospital must also give a patient, prior to providing any non-emergent medical services, within 7 days of a written request, a good faith estimate of reasonably anticipated charges for the facility to treat the patient’s condition.<sup>130</sup> Upon request, the hospital must also provide revisions to the estimate.<sup>131</sup> A facility that fails to provide the estimate may be fined \$500 for each instance of the facility’s failure to provide the requested information.<sup>132</sup>

##### **Patient Status**

When a patient enters a hospital, a physician must decide whether or not to admit the individual for inpatient care. Factors to be considered when making a decision to admit a patient include:

- The severity of the signs and symptoms exhibited by the patient;

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<sup>126</sup> Pediatric Cardiac Technical Advisory Program, *Pediatric and Congenital Cardiovascular Center Standards* (September 2018), available at <http://www.ahca.myflorida.com/SCHS/PCTAP/docs/121318/DraftPCTAPWorkingDocument120418Revised.pdf> (last visited May 23, 2019).

<sup>127</sup> Agency for Health Care Administration, *Notice of Development, Pediatric Cardiac Programs Rule 59A-3.248*, Florida Administrative Registrar, Vol. 44/213 (October 31, 2018) available at: <https://www.flrules.org/gateway/ruleNo.asp?id=59A-3.248> (last visited May 23, 2019).

<sup>128</sup> S. 395.002(16), F.S., defines “licensed facility” as a hospital, ambulatory surgical center, or mobile surgical facility licensed in accordance with ch. 395, F.S. The bill applies to all three facility types because it amends part I of ch. 395, F.S., but will only affect hospitals because ambulatory surgical centers and mobile surgical facilities serve patients who are receiving elective outpatient services and know in advance that they are not going to be admitted to a hospital, barring any complications.

<sup>129</sup> S. 395.301(1), F.S.

<sup>130</sup> S. 395.301(7), F.S.

<sup>131</sup> *Id.*

<sup>132</sup> *Id.*

- The medical predictability of an adverse event;
- The need for diagnostic studies to access whether the patient should be admitted;
- The availability of diagnostic procedures at the time when, and at the location where, the patient presents; and
- Whether the patient is expected to need at least 24 hours of hospital care.<sup>133</sup>

A patient in “observation status” in a hospital is considered an outpatient and receives observation services to determine if admission is necessary.<sup>134</sup> Observation services are commonly ordered for a patient who presents to the emergency department and requires a period of treatment or monitoring in order to make a decision between admission and discharge.<sup>135</sup> Outpatient services can include laboratory tests, medication, minor procedures, x-rays, and other imaging services. Observation stays can occur anywhere in the hospital, including the emergency department, a separate observation unit, or an inpatient unit.

The federal Medicare program does not expressly limit the number of days a patient may be in “observation status,” but assumes the decision whether to admit or discharge a patient from the hospital can often be made in less than 48 hours; only in rare cases are outpatient observation services required beyond 48 hours.<sup>136</sup>

Section 1862(a)(1)(A) of the federal Social Security Act limits Medicare payments to the provision of services that are reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body.<sup>137</sup> Hospital care that is custodial, rendered for social purposes or reasons of convenience and not required for the diagnosis or treatment of illness or injury, is excluded from Medicare Part A payment.<sup>138</sup> A patient in “observation status” may experience higher costs than a patient on admission status for time spent in a hospital because Medicare covers inpatient and outpatient hospital services differently.

The federal Medicare fee-for-service program provides hospital insurance (Medicare Part A) and supplementary medical insurance (Medicare Part B) to eligible beneficiaries.<sup>139</sup> Patient liability under Medicare Part B includes not only copayments (20% of the Medicare payment amount for outpatient items and services after paying an annual Part B deductible), but also may include the cost of self-administered drugs that are not covered under Part B as well as the cost of any necessary post-hospitalization skilled nursing facility care, which requires a three-day inpatient hospital admission prior to Part A coverage.<sup>140</sup> Medicare Part A covers inpatient hospital services, which requires a one-time deductible covering all hospital services for the first 60 days a patient is in the hospital. A patient on “observation status” is covered under Medicare Part B, which covers outpatient hospital services and requires the patient to pay a 20-percent copayment for each individual outpatient hospital service.<sup>141</sup>

In addition, a patient’s hospital status may affect their Medicare coverage for care in a skilled nursing facility (SNF). The patient must have a qualifying inpatient hospital stay, defined as three consecutive days of inpatient care, to be covered by Medicare for SNF care.<sup>142</sup> A patient who qualifies for Medicare

<sup>133</sup> Centers for Medicare and Medicaid Services (CMS), *Medicare Benefit Policy Manual* (MBPM), ch. 1, § 10.

<sup>134</sup> *Id.* at ch. 6, § 20.6.

<sup>135</sup> *Id.*

<sup>136</sup> *Id.*

<sup>137</sup> CENTERS FOR MEDICARE AND MEDICAID SERVICES, *Frequently Asked Questions*, [https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/QAsforWebsitePosting\\_110413-v2-CLEAN.pdf](https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/QAsforWebsitePosting_110413-v2-CLEAN.pdf) (last visited May 23, 2019).

<sup>138</sup> *Id.*

<sup>139</sup> Jessica Gustafson and Abby Pendleton, *Be On Notice: CMS’s Proposed Rule on the Notice Act Has Been Published*, American Bar Association Health Law Section, Health eSource (June 2015-2016)(on file with the Health and Human Services Committee staff).

<sup>140</sup> *Id.* at 2.

<sup>141</sup> 42 C.F.R. § 419.40(b)

<sup>142</sup> 42 CFR § 409.30

and Medicaid will not be responsible for the copayment.<sup>143</sup> A patient under "observation status" in a hospital does not meet the requirements for a qualifying inpatient hospital stay for Medicare coverage for SNF care.

### Patient Notification of Observation Status

The Federal Notice of Observation Treatment and Implication for Care Eligibility Act of 2015 requires hospitals to provide the Medicare Outpatient Observation Notice to patients when observation status services last more than 24 hours.<sup>144</sup> The notice must be provided to the patient if the patient is discharged, transferred or admitted before 36 hours. The notice informs patients that observation status may affect their health care costs.

Florida law requires hospitals to notify patients or a patient's proxy of their observation status through documentation in the patient's discharge papers, that is, when leaving the hospital.<sup>145</sup> The documentation may include brochures, signage, or other forms of communication. The documentation is not required to inform patients that observation status may affect their health care costs.

### **Effect of the Bill – Hospital Observation Status**

The bill removes the requirement that a hospital notify a patient or patient's proxy through the patient's discharge papers that the patient was placed on observation status. The bill requires hospitals to immediately provide written notification to patients of their observation status. The bill requires the notice be given to Medicare patients through the Medicare Outpatient Observation Notice form and to non-Medicare patients through a form adopted by rule of the Agency for Health Care Administration (AHCA).

### **Clinical Labs**

#### **Background**

#### Clinical Laboratory Improvement Amendments of 1988

The federal Centers for Medicare & Medicaid Services (CMS), within the United States Department of Health and Human Services, regulates all laboratory testing performed on humans in the United States through the CLIA.<sup>146</sup> The purpose of the CLIA program is to establish quality standards for all laboratory testing to ensure accuracy, reliability, and timeliness of test results regardless of where the test was performed.<sup>147</sup> The Division of Laboratory Services, within the Survey and Certification Group, under the Center for Clinical Standards and Quality in CMS has the responsibility for implementing the CLIA Program, including laboratory registration, fee collection, onsite surveys, and enforcement.<sup>148</sup> In total, CLIA covers approximately 260,000 laboratory entities, and issues five types of certificates.<sup>149</sup>

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<sup>143</sup> 42 CFR § 440.20. Outpatient hospital services are a mandatory Medicaid benefit. For services that both Medicare and Medicaid cover, Medicare pays first, and Medicaid pays second by covering an individual's remaining costs for Medicare coinsurances and copayments.

<sup>144</sup> 42 U.S.C. § 1395cc; See also, CENTERS FOR MEDICARE AND MEDICAID SERVICES, *Medicare Outpatient Observation Status*, <https://www.cms.gov/Medicare/Medicare-General-Information/BNI/MOON.html> (last visited May 23, 2019).

<sup>145</sup> S. 395.301, F.S.

<sup>146</sup> CENTERS FOR MEDICARE & MEDICAID SERVICES, *Clinical Laboratory Improvement Amendments (CLIA)*, [https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA/10\\_Categorization\\_of\\_Tests.asp](https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/CLIA/10_Categorization_of_Tests.asp) (last visited May 23, 2019).

<sup>147</sup> DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF THE INSPECTOR GENERAL, *Enrollment and Certification Processes in the Clinical Laboratory Improvement Amendments Program* (Aug. 2001), <https://oig.hhs.gov/oei/reports/oei-05-00-00251.pdf> (last visited May 23, 2019).

<sup>148</sup> Id.

<sup>149</sup> *Supra* note 146. See also, CENTERS FOR MEDICARE AND MEDICAID SERVICES, *Clinical Laboratory Improvement Amendments (CLIA): How to Obtain a CLIA Certificate* (Mar. 2006), <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/HowObtainCLIACertificate.pdf> (last visited May 23, 2019). All certificates are effective for two years.

In 1992, the federal government required all facilities performing clinical laboratory testing, including doctor's offices, to register with the CLIA program.<sup>150</sup>

In 1993, Florida enacted legislation requiring all facilities performing clinical laboratory testing to be licensed.<sup>151</sup> Florida law exempted licensed clinical laboratories from also being licensed as a clinic. In 2018, Florida repealed the requirement for clinical laboratory licensure and replaced the licensure requirement with the requirement for clinical laboratories to be CLIA certified.<sup>152</sup>

## **Effect of the Bill – Clinical Labs**

The bill makes a conforming change to the clinic licensure exemption based upon the 2018 repeal of clinical laboratory licensure requirements. The 2018 repeal removed licensed clinical laboratories from the list of entities exempt from the clinic licensure requirements but did not exempt CLIA certified labs. The bill exempts CLIA certified labs from clinic licensure requirements.

## **Direct Health Care Agreements**

### **Background**

#### **Direct Primary Care Agreements**

Direct primary care (DPC) is a primary care medical practice model that eliminates third-party payers from the primary care provider-patient relationship. Through a contractual agreement, a patient pays a fixed monthly fee, usually between \$50 and \$100 per individual,<sup>153</sup> to the primary care provider for defined primary care services.<sup>154</sup> These primary care services may include:<sup>155</sup>

- Office visits;
- Annual physical examination;
- Routine laboratory tests;
- Vaccinations;
- Wound care (such as stiches and sterile dressings);
- Splinting or casting of fractured or broken bones;
- Other routine testing, e.g. echocardiogram and colon cancer screening; or
- Other medically necessary primary care procedures.

After paying the fee, patients generally have unrestricted access to all services under the agreement at no extra charge, which can also include 24/7 access to a physician by phone and electronically. Some DPC practices also include in-house pharmacies and routine preventative services, like laboratory tests, mammograms, Pap screenings, vaccinations, and home visits.<sup>156</sup> A primary care provider DPC

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<sup>150</sup> Id.

<sup>151</sup> See, Ch. 483, Part I, F.S. (2017).

<sup>152</sup> See, Ch. 2018-24, L.O.F.

<sup>153</sup> In 2017, over 70% of practices charged between \$25 and \$100, and less than 2% charged more than \$175. The average monthly fee was \$82.86 and the median monthly rate was \$65. HINT, *DPC Trends Report 2017*, available at: <https://cdn2.hubspot.net/hubfs/2562809/pdf-assets/dpc-trends-2017/Hint-DPC-Trends-Report-2017.pdf> (last visited May 5, 2019); In 2014, a study of 141 DPC practices found the average monthly fee to be \$77.38, Philip M. Eskew & Kathleen Klink, *Direct Primary Care: Practice Distribution and Cost Across the Nation*, 28:6 J. AM. BD. FAM. MED. 797 (Nov-Dec. 2015), available at: <https://www.jabfm.org/content/28/6/793> (last visited May 7, 2019);

<sup>154</sup> AMERICAN ACADEMY OF FAMILY PHYSICIANS, *Direct Primary Care: An Alternative Practice Model to the Fee-for-Service Framework*, [https://www.aafp.org/dam/AAFP/documents/practice\\_management/payment/DirectPrimaryCare.pdf](https://www.aafp.org/dam/AAFP/documents/practice_management/payment/DirectPrimaryCare.pdf) (last visited May 7, 2019).

<sup>155</sup> Id. See also, Dave Chase, *Direct Primary Care: Value Proposition, Scope of Practice and Pricing*, FORBES (July 8, 2013), available at: <https://www.forbes.com/sites/davechase/2013/07/08/direct-primary-care-value-proposition-scope-of-practice-and-pricing/#7511816d5ada> (last visited May 7, 2019).

<sup>156</sup> CALIFORNIA HEALTH CARE FOUNDATION, *Issue Brief, April 2013: On Retainer: Direct Primary Care Practices Bypass Insurance*, p. 4, available at: <https://www.chcf.org/wp-content/uploads/2017/12/PDF-OnRetainerDirectPrimaryCare.pdf> (last visited May 7, 2019); See also, *Direct Primary Care Journal, DPC Journal Releases Two-Year Industry Analysis of Direct Primary Care Marketplace; Shows Trends, Demographics*,



model can be designed to address the large majority of health care issues, including women's health services, pediatric care, urgent care, wellness education, and chronic disease management.

Advocates for the DPC model claim that it reduces overhead costs for the practice and increases positive patient outcomes at an affordable price to the patient.<sup>157</sup> The DPC practice model eliminates practice overhead costs associated with filing claims, coding, refiling claims, write-offs, appealing denials, and employing billing staff. The cost and time savings can be reinvested into the practice, allowing more time with patients to address their primary care needs.

Some research suggests that a high-intensity primary care model, such as the DPC practice model, that delivers care through very frequent patient-provider interactions is helpful in managing chronic conditions and preventing or delaying the occurrence of health complications.<sup>158</sup>

One study of a DPC practice in Seattle found that its patients saved 20% in costs of reduced visits to the emergency room, inpatient care, specialists, and advanced radiology, and the overall patient satisfaction of the DPC practice was above the 95th percentile nationally.<sup>159</sup> Additionally, the DPC practice found that if its patients purchased a low-premium wraparound insurance to plan to cover non-primary health care, patients could save 35% or more in the cost of comprehensive care depending on what level of deductible they chose.<sup>160</sup>

The federal Patient Protection and Affordable Care Act (PPACA)<sup>161</sup> addresses the DPC practice model. The individual responsibility provision of PPACA requires individuals to obtain health insurance coverage that meets minimum essential coverage standards in the law.

Direct primary care arrangements alone do not constitute minimum essential coverage because they do not cover catastrophic medical events. A qualified health plan under PPACA is permitted to offer coverage through a DPC medical home plan if it provides essential health benefits and meets all other criteria in the law.<sup>162</sup> Patients enrolled in a DPC medical home plan may be compliant with the individual mandate if they have coverage for other services, such as a wraparound catastrophic health policy to cover treatment for serious illnesses, like cancer, or severe injuries that require lengthy hospital stays and rehabilitation.<sup>163</sup> In Colorado and Washington, qualified health plans are offering DPC medical home coverage on each state-based health insurance exchange.<sup>164</sup>

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*DPC Hot Zones*, available at: <http://directprimarycarejournal.com/2015/08/24/dpc-journal-releases-two-year-industry-analysis-of-direct-primary-care-marketplace-shows-trends-demographics-dpc-hot-zones/> (last visited May 7, 2019).

<sup>157</sup> DIRECT PRIMARY CARE COALITION, *What Is Direct Primary Care?*, <https://www.dpcare.org/> (last visited May 7, 2019).

<sup>158</sup> One study of 17,711 senior primary care patients compared the standard care model to that of a “high-touch” model with more frequent patient-provider interactions and found that patients in the “high-touch” model took more medication, had lower healthcare costs, and had fewer hospitalizations. The study concluded that a “high-touch” preventative model with frequent and easy access to primary, specialty, pharmacy, and ancillary care can improve healthcare utilization and reduce healthcare costs in spite of higher frequency of outpatient visits, especially in senior populations. Reyan Ghany, MD, et al., *High-Touch Care Leads to Better Outcomes and Lower Costs in Senior Population*, 24:9 AM. J. MANAGED CARE e300-e304 (2018), available at: [https://ajmc.s3.amazonaws.com/media/pdf/AJMC\\_09\\_2018\\_Ghany%20final.pdf](https://ajmc.s3.amazonaws.com/media/pdf/AJMC_09_2018_Ghany%20final.pdf) (last visited May 11, 2019).

<sup>159</sup> DPC patients experienced 35% fewer hospitalizations, 65% fewer ER visits, 66% fewer specialists visits, and 82% fewer surgeries. The study compared two years of insurance claims data for 4,000 of its DPC patients compared to their coworkers that were covered by traditional fee-for-service practice models. The overall patient satisfaction was measured by the national Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. William N. Wu, et al., *A Direct Primary Care Medical Home: The Qliance Experience*, 29:5 HEALTH AFFAIRS 959, 959-62 (2010), available at: <http://content.healthaffairs.org/content/29/5/959>; See also, David Von Drehle, *Medicine is About to Get Personal*, TIME HEALTH (Dec. 20, 2014), <http://bostonshoulderinstitute.com/wp-content/uploads/2015/03/Medicine-Is-About-to-Get-Personal--TIME.pdf> (last visited May 6, 2019); See also, Leigh Page, *The Rise and Further Rise of Concierge Medicine*, 347:6465 BRIT. MED. J. 347 (Oct. 28, 2013).

<sup>160</sup> Id.

<sup>161</sup> Pub. L. No. 111-148, H.R. 3590, 111<sup>th</sup> Cong. (Mar. 23, 2010).

<sup>162</sup> 42 U.S.C. §1802 (a)(3); 45 C.F.R. §156.245

<sup>163</sup> 42 U.S.C. §18021(a)(3).

<sup>164</sup> Jay Keese, Direct Primary Care Coalition, *Direct Primary Care*, PowerPoint presentation before the House Health Innovation Subcommittee, slide 2, February 17, 2015 (on file with Health and Human Services Committee staff).

In 2017, the federal Centers for Medicare and Medicaid Services (CMS) issued a Request for Information (RFI) on direct provider contracting models seeking input from all stakeholders on direct provider contracting between payers and primary care or multi-specialty group practices so that CMS may test this approach within the Medicare fee-for-service program, Medicare Part C program, and Medicaid.<sup>165</sup> In April 2018, after reviewing all of the responses to the RFI, CMS announced that it is developing a potential model that will incorporate direct provider contracting.<sup>166</sup>

As of December 2018, 25 states, including Florida, have laws that define DPC agreements or services as outside the scope of state insurance regulation,<sup>167</sup> and at least eight of which do not limit the agreements to primary care services.<sup>168</sup> Nationwide, there are approximately 954 DPC practices, with approximately 61 DPC practices in Florida.<sup>169</sup>

### Direct Primary Care in Florida

Section 624.27, F.S., provides that a direct primary care provider may contract with individuals to provide pre-determined primary care services for a set monthly fee. Primary care providers are defined as health care providers licensed under chapter 458 (physicians), chapter 459 (osteopathic physicians), chapter 460 (chiropractors) and chapter 464 (nurses), or a primary care group practice who provide primary care services to patients.<sup>170</sup> Primary care services include the screening, assessment, diagnosis, and treatment of a patient conducted within the training of the primary care provider for the purpose of promoting health or detecting and managing disease or injury.<sup>171</sup> Currently, individuals may only contract with primary care providers for primary care services.

The direct primary care agreement between the health care provider and the individual is not insurance and entering into such an agreement is not the business of insurance.<sup>172</sup> Both the agreement and the activity of entering into the agreement are exempt from the Florida Insurance Code (Code).<sup>173</sup> Therefore, the Office of Insurance Regulation does not have authority to regulate a direct primary care agreement or entering into such an agreement. Additionally, s. 624.27(3), F.S., exempts a primary care provider, or his or her agent, from the certification or licensing requirements under the Code to market, sell, or offer to sell a direct primary care agreement.

The Code establishes criteria for direct primary care agreements. They must:<sup>174</sup>

- Be in writing;
- Be signed by the primary care provider, or his or her agent, and the patient, the patient's legal representative, or the patient's employer;
- Allow either party to terminate the agreement by giving the other party 30 days' advance written notice;

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<sup>165</sup> CENTERS FOR MEDICARE & MEDICAID SERVICES, *Innovation Center New Direction*, <https://innovation.cms.gov/initiatives/direction/index.html> (last visited May 7, 2019); RFI available here: <https://innovation.cms.gov/Files/x/dpc-rfi.pdf> (last visited May 7, 2019); Under Section 1115A of the Social Security Act, CMS is authorized to test innovative payment and service delivery models that have the potential to reduce program expenditures while preserving or enhancing the quality of care for Medicare, Medicaid, and CHIP beneficiaries.

<sup>166</sup> Press Release, Centers for Medicare & Medicaid Services, Feedback on New Direction Request for Information (RFI) Released, CMS Innovation Center's Market-Driven Reforms to Focus on Patient-Centered Care, available at: <https://www.cms.gov/newsroom/press-releases/feedback-new-direction-request-information-rfi-released-cms-innovation-centers-market-driven-reforms> (last visited May 7, 2019).

<sup>167</sup> AL, AZ, AR, CO, FL, ID, IN, IA, LA, KS, KY, ME, MI, MS, MO, NE, OK, OR, TN, TX, UT, VA, WA, WV, and WY Direct Primary Care Coalition, *2018 DPC Laws Passed in 25 States*, available at: <https://www.dpcare.org/state-level-progress-and-issues> (last visited May 4, 2019).

<sup>168</sup> [Alabama](#), [Arkansas](#), [Kansas](#), [Michigan](#), [Missouri](#), [Oklahoma](#), [Utah](#), and [Wyoming](#).

<sup>169</sup> As of Mar. 10, 2019, DPC FRONTIER, *DPC Mapper*, available at: <https://www.dpcfrontier.com/mapper/> (last visited May 7, 2019).

<sup>170</sup> S. 624.27(1)(b), F.S.

<sup>171</sup> S. 624.27(1)(c), F.S.

<sup>172</sup> S. 624.27(2), F.S.

<sup>173</sup> S. 624.27(2), F.S.

<sup>174</sup> S. 624.27(4), F.S.

- Allow immediate termination of the agreement for a violation of physician-patient relationship or a breach of the terms of the agreement;
- Describe the scope of primary care services that are covered by the monthly fee;
- Specify the monthly fee and any fees for primary care services not covered under the agreement;
- Specify the duration of the agreement and any automatic renewal provisions;
- Offer a refund to the patient of monthly fees paid in advance if the primary care provider stops offering primary care services for any reason;
- State that the agreement is not health insurance and that the primary care provider will not bill the patient's health insurance policy or plan for services covered under the agreement;
- State that the agreement does not qualify as minimum essential coverage to satisfy the individual responsibility provision of the Patient Protection and Affordable Care Act; and
- State that the agreement is not workers' compensation insurance and may not replace the employer's workers' compensation obligations.

### **Effect of the Bill – Direct Health Care Agreements**

Section 624.27, F.S., currently allows individuals to contract directly with certain health care providers outside the scope of insurance, but only for primary care services. The bill removes this limitation and expands the scope of these agreements to allow “direct health care agreements.” Under the bill, direct health care agreements will still have the same contract requirements as direct primary care agreements and will also receive the same regulatory exemptions from the Code.

The bill also adds a person licensed under ch. 466 (dentistry) to the list of health care providers recognized by this section. This allows individuals to contract directly with health care providers licensed under chs. 458 (medicine), 459 (osteopathic medicine), 460 (chiropractic medicine), 464 (nursing), or 466 (dentistry), or a health care group practice, for any health care service that is within the competency and training of the healthcare provider.

The bill revises definitions and makes other conforming changes to exchange references to “primary care,” for “health care” to reflect the broadened scope of the agreements under the bill.

### **Step Therapy Protocols**

#### **Background**

Spending on prescription drugs rose sharply in the U.S. in recent few years.<sup>175</sup> From 2013 to 2015, out-of-pocket costs for prescription drugs rose 20 percent,<sup>176</sup> to an average cost of \$44 per brand name prescription drug.<sup>177</sup> Additionally, prescription drug prices increased an average of almost 10 percent from June 2015 to May 2016.<sup>178</sup> Specialty prescription drug prices are projected to increase 14.3 percent in 2019, accounting for 35 percent of the prescription drug spending trend even though they

<sup>175</sup> Ameet Sarpatwari, Jerry Avorn, and Aaron S. Kesselheim, *State Initiatives to Control Medication Costs — Can Transparency Legislation Help?*, 374 N. ENGL. J. MED. 2301-2304 ( June 2016), available at: <http://www.nejm.org/doi/full/10.1056/NEJMp1605100#t=article> (last visited May 23, 2019).

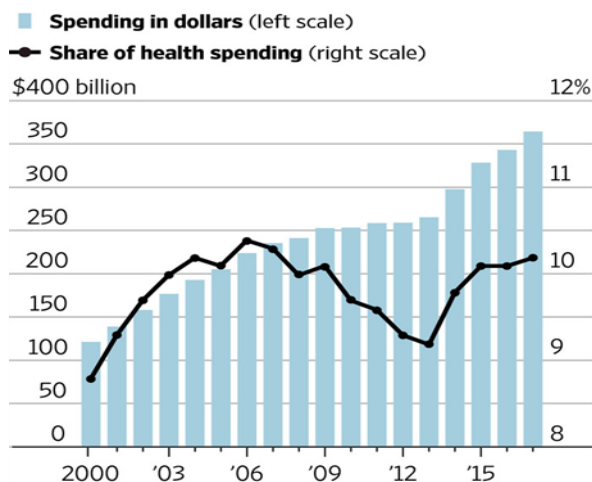
<sup>176</sup> Troy Parks, *Drug Pricing Needs Transparency, Physicians Say*, AMA WIRE, Jan. 26, 2017, <https://wire.ama-assn.org/ama-news/drug-pricing-needs-transparency-physicians-say> (last visited May 23, 2019).

<sup>177</sup> 2017 Segal Health Plan Cost Trend Survey, available at <https://www.segalco.com/media/2716/me-trend-survey-2017.pdf> (last visited May 23, 2019).

<sup>178</sup> TRUVERIS, *Americans Faced Double Digit Increases in Prescription Drug Prices in 2014, According to Truveris National Drug Index*, <https://truveris.com/press-releases/ndi-americans-faced-double-digit-increases-in-prescription-drug-prices-in-2014/> (last visited May 23, 2019).

represent a small minority of prescriptions.<sup>179</sup> Recent increases in prescription drug prices are not only an increase in spending in terms of dollars, but also as a percentage of total healthcare spending.<sup>180</sup>

### Prescription Drug Spending as a Share of Health Spending 2000-2017<sup>181</sup>



### Regulation of Insurers and Health Maintenance Organizations in Florida

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, HMOs, and other risk-bearing entities.<sup>182</sup> The Agency for Health Care Administration (agency) regulates the quality of care 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 agency.<sup>183</sup> As part of the certification process used by the agency, an HMO must provide information to demonstrate that the HMO has the ability to provide quality of care consistent with the prevailing standards of care.<sup>184</sup>

All persons who transact insurance in the state must comply with the Code.<sup>185</sup> OIR has the power to collect, propose, publish, and disseminate any information relating to the subject matter of the Code,<sup>186</sup> and may investigate any matter relating to insurance.<sup>187</sup>

### Cost Containment in Health Insurance

Insurers use many cost containment strategies to manage medical and drug spending and utilization. For example, plans may place utilization management requirements on certain procedures and therapies and on the use of certain drugs on their formulary. These requirements can include limiting the quantity of drug that they will cover over a certain period of time, requiring enrollees to obtain prior authorization from their plan before filling a prescription (prior authorization), or requiring enrollees to

<sup>179</sup> 2019 Segal Health Plan Cost Trend Survey, available at <https://www.segalco.com/annual-health-plan-cost-trend-survey/2019/#PublicSector>. (last visited May 23, 2019). Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions and often require special handling and administration.

<sup>180</sup> CENTERS FOR MEDICARE AND MEDICAID SERVICES, *National Health Expenditures by Type of Service and Source of Funds: Calendar Years 1960 to 2015*, .zip file available at, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> (last visited May 23, 2019).

<sup>181</sup> Jonathan D. Rockoff, *How Do We Deal With Rising Drug Costs?*, THE WALL STREET JOURNAL, Apr. 10, 2016, <https://www.wsj.com/articles/how-do-we-deal-with-rising-drug-costs-1460340357> (last visited May 23, 2019).

<sup>182</sup> S. 20.121(3)(a), F.S.

<sup>183</sup> S. 641.21(1), F.S.

<sup>184</sup> S. 641.495, F.S.

<sup>185</sup> S. 624.11, F.S.

<sup>186</sup> S. 624.307(4), F.S.

<sup>187</sup> S. 624.307(3), F.S.

first try a preferred drug to treat a medical condition before obtaining an alternate drug for that condition (step therapy).

### *Pharmacy Benefit Managers*

Advances in pharmaceuticals have transformed health care over the last several decades. Many health care problems are prevented, cured, or managed effectively using prescription drugs. As a result, national expenditures for prescription drugs have grown from \$121 billion in 2000 to \$324.5 billion in 2016.<sup>188</sup> Health plan sponsors, which include commercial insurers, private employers, and government plans, such as Medicaid and Medicare, spent \$277 billion on prescription drugs in 2015, while consumers paid \$45.5 billion out-of-pocket for prescription drugs that year.<sup>189</sup>

Health plan sponsors contract with pharmacy benefit managers (PBMs) to provide specified services, which may include developing and managing pharmacy networks, developing drug formularies, providing mail order and specialty pharmacy services, rebate negotiation, therapeutic substitution, disease management, utilization review, support services for physicians and beneficiaries, and processing claims.<sup>190</sup> Payments for the services are established in contracts between health plan sponsors and PBMs.<sup>191</sup> For example, contracts will specify how much health plan sponsors will pay PBMs for brand name and generic drugs. These prices are typically set as a discount off the average wholesale price<sup>192</sup> for brand-name drugs and maximum allowable cost price for generic drugs, plus a dispensing fee.<sup>193</sup>

### *Step Therapy Protocols*

In some cases, plans require an insured to try one drug first to treat his or her medical condition before they will cover another drug for that condition. For example, if Drug A and Drug B both treat a medical condition, a plan may require doctors to prescribe the most cost effective drug, Drug A, first. If Drug A does not work for a beneficiary, then the plan will cover Drug B. This form of cost containment is commonly called step therapy. Step therapy is also known as fail-first as the insurer restricts coverage of expensive therapies unless patients have already failed treatment with a lower-cost alternative.

Researchers report that there is mixed evidence on the impact of step therapy policies.<sup>194</sup> A review of the literature found that there is little good empirical evidence for or against cost savings and utilization reduction.<sup>195</sup> Some studies suggest that step therapy policies have been effective at reducing drug costs without increasing the use of other medical services,<sup>196</sup> while other studies have found that step therapy can increase total utilization costs over time because of increased inpatient admissions and emergency department visits.<sup>197</sup>

### Florida State Employee Group Insurance Program

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<sup>188</sup> CENTERS FOR MEDICARE AND MEDICAID SERVICES, *National Health Expenditure Data, Historical*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> (last visited May 23, 2019).

<sup>189</sup> *Id.*  
<sup>190</sup> Office of Program Policy Analysis & Government Accountability, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (Feb. 2007), available at <http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/0708rpt.pdf> (last visited May 23, 2019).

<sup>191</sup> *Id.*  
<sup>192</sup> Average wholesale price is the retail list price (sticker price) or the average price that manufacturers recommend wholesalers sell to physicians, pharmacies and others, such as hospitals.

<sup>193</sup> *Supra* note 190.

<sup>194</sup> Rahul K. Nayak and Steven D. Pearson, *The Ethics Of 'Fail First': Guidelines and Practical Scenarios for Step Therapy Coverage Policies*, 33:10 HEALTH AFFAIRS 1779-1785 (2014).

<sup>195</sup> Motheral, B.R., *Pharmaceutical Step Therapy Interventions: A Critical Review of the Literature*, 17: 2 J. Managed Care Pharmacy 143-55 (2011), available at <http://www.jmcp.org/doi/pdf/10.18553/jmcp.2011.17.2.143> (last visited May 23, 2019).

<sup>196</sup> *Supra* note 194, at 1780.

<sup>197</sup> *Id.*

Under the authority of s. 110.123, F.S., the Department of Management Services (DMS), 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. To administer the state group health insurance program, DMS contracts with third part administrators, HMOs, and a PBM for the state employees' prescription drug program pursuant to s. 110.12315, F.S.

## Federal Patient Protection and Affordable Care Act

### *Health Insurance Reforms*

The federal Patient Protection and Affordable Care Act (PPACA) was signed into law on March 23, 2010.<sup>198</sup> The PPACA requires health insurers to make coverage available to all individuals and employers, without exclusions for preexisting conditions and without basing premiums on any health-related factors. The PPACA also mandates required essential health benefits<sup>199</sup> and other provisions.

The PPACA requires insurers and HMOs that offer qualified health plans (QHPs) to provide ten categories of essential health benefits (EHB), which includes prescription drugs.<sup>200</sup> In Florida, the federal Health Insurance Marketplace must certify such plans of an insurer or HMO as meeting the EHB and other requirements.<sup>201</sup> Recently, the U.S. Department of Health and Human Services (HHS) proposed federal regulations that included provisions to provide states with additional flexibility in the definition of EHBs for 2019 and 2020 and increase affordability of health insurance for the individual and small group markets.<sup>202</sup>

### *Prescription Drug Coverage*

For purposes of complying with the federal EHB for prescription drugs, plans must include in their formulary drug list the greater of one drug for each U.S. Pharmacopeia (USP) category and class; or the same number of drugs in each USP category and class as the state's EHB benchmark plan. Plans must have a Pharmacy and Therapeutics Committee design formularies using scientific evidence that will include consideration of safety and efficacy, cover a range of drugs in a broad distribution of therapeutic categories and classes, and provide access to drugs that are included in broadly accepted treatment guidelines. The PPACA also requires plans to implement an internal appeals and independent external review process if an insured is denied coverage of a drug on the formulary.<sup>203</sup>

Plans 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, the state, and the public.<sup>204</sup> Restrictions include prior authorization, step therapy, quantify limits and access restrictions.<sup>205</sup>

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<sup>198</sup> 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.

<sup>199</sup> 42 U.S.C. s. 18022

<sup>200</sup> See, CENTER FOR CONSUMER INFORMATION & INSURANCE OVERSIGHT, *Insurance on Essential Health Benefits (EHB) Benchmark Plans* <https://www.cms.gov/ccio/resources/data-resources/ehb.html> (last visited May 23, 2019).

<sup>201</sup> CENTER FOR CONSUMER INFORMATION & INSURANCE OVERSIGHT, *Qualified Health Plans*, <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/ghp.html> (last visited May 23, 2019).

<sup>202</sup> See Proposed Rule, 82 FR 51052 (Nov. 2, 2017) available at <https://www.federalregister.gov/documents/2017/11/02/2017-23599/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2019> (last visited May 23, 2019).

<sup>203</sup> 45 C.F.R. § 147.136.

<sup>204</sup> 45 C.F.R. § 156.122(d).

<sup>205</sup> According to CMS, this formulary drug list website link should be the same direct formulary drug list link for obtaining information on prescription drug coverage in the Summary of Benefits Coverage, in accordance with 45 CFR § 147.00(a)(2).

## Effect of the Bill – Step Therapy Protocols

The bill creates s. 627.42393, F.S., which prohibits issuers of major medical or similar comprehensive health insurance from requiring covered individuals to repeat a step therapy protocol that was imposed previously, provided that the following conditions are met:

- The insured has previously been approved to receive the drug through a step therapy protocol imposed by a health insurer that issued major medical coverage to the insured; and,
- The insured provides documentation that an insurer made payment for the drug on the insured's behalf within the past 90 days.

The bill stipulates that a health insurer or an HMO is not required to add a drug to its drug formulary or cover a drug not currently covered in order to comply with the step therapy restriction.

The bill adds equivalent language to ch. 641, F.S., which ensures that the new restriction on step therapy protocols applies to coverage provided by an HMO operating in the state.

The bill applies to health insurance policies and HMO contracts entered into or renewed on or after January 1, 2020.

## Interstate Medical Licensure Compact

### Background

An interstate compact is an agreement between two or more states to address common problems or issues, create an independent, multistate governmental authority, or establish uniform guidelines, standards or procedures for the compact's member states.<sup>206</sup> States must pass legislation adopting an interstate compact in its entirety to become a member of a compact. Any state which passes legislation that fails to adopt a compact in its entirety or creates additional requirements within the compact will have its membership suspended, revoked or deemed void. However, member states may agree to change the terms of an interstate compact. This is commonly done to address issues identified after the adoption of a compact or to entice new states to join the compact. Each member state must pass new legislation to incorporate any such change into its statutes.

Reciprocity is a hallmark of interstate compacts. This allows member states to more efficiently regulate an issue and provide greater access to their citizens. Interstate compacts in the healthcare arena commonly create licensure reciprocity. For example, under the Nurse Licensure Compact, which currently has 34 member states,<sup>207</sup> a nurse who is issued a multistate license from a member state is permitted to practice in any other party state without obtaining a license in each of those states.<sup>208</sup>

The Interstate Medical Licensure Compact (IMLC) provides a more efficient pathway for a physician to obtain licensure. It currently consists of 29 member states, the District of Columbia and the Territory of Guam. The ILMC does not create licensure reciprocity as each physician who participates in the ILMC must obtain a separate license in each state he or she intends to practice. Rather, the ILMC functions as a facilitator for physician credentialing information (such as education, practice history and criminal

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<sup>206</sup> COUNCIL OF STATE GOVERNMENTS, CAPITOL RESEARCH, *Special Edition – Interstate Compacts*, <http://knowledgecenter.csg.org/kc/content/interstate-compacts-background-and-history> (last visited May 20, 2019). Article 1, Section 10, Clause 3 (Compact Clause) of the U.S. Constitution authorizes states to enter into agreements with each other, without the consent of Congress.

<sup>207</sup> *Nurse Licensure Compact (NLC), Current NLC States and Status*, available at <https://www.ncsbn.org/nurse-licensure-compact.htm> (last visited May 20, 2019).

<sup>208</sup> Florida is currently a party to 26 interstate compacts, including the Driver's License Compact, Compact on Adoption and Medical Assistance, the Interstate Compact on Educational Opportunity for Military Children and most recently, the Nurse Licensure Compact. OPPAGA, *2015 Nurse Licensure Compact Revisions Address Some Barriers and Disadvantages in 2006 OPPAGA Report*, Appendix D., available at: <https://floridasnursing.gov/forms/2015-oppaga-research-memo.pdf> (last visited May 20, 2019).

background checks) such that member states can rely upon other member state's verification of this information.

The IMLC requires a physician to designate a state of principal license (SPL) which reviews the physician's application including primary source verifications and state and federal criminal background check. If approved, the SPL issues a Letter of Qualification (LOQ) to the IMLC Commission (Commission), who in turn, notifies the physician. A physician may request the Commission to send the LOQ to any of the other member states that the physician is seeking licensure. This eliminates the requirement that the physician provide each state with primary source verifications and background checks, and creates a more efficient application process, which may accelerate the licensure process.

The Commission is an instrumentality of each member state in the ILMC. Section 11 of the ILMC states that the Commission is a body corporate and joint agency of the member state. Section 12 of the ILMC authorizes the Commission to promulgate rules which are binding on all physicians who utilized the ILMC to obtain a license. Section 14 of the ILMC states that the Commission is considered an instrumentality of the state for the purpose of any liability action against the Commissions or its employees or agents.

Section 11 of the ILMC appears to conflict with the Florida Constitution. The Commission is a public body subject to the open meeting requirements of the Florida Constitution. Article I, Section 24 of the Florida Constitution requires any meeting in which official acts are to be taken or at which public business of such body is to be transacted or discussed be open and noticed to the public. Section 11 of the ILMC however, allows the Commission to close a meeting, in full or in portion, if it is determined by a two-thirds vote of present commissioners that a public meeting would likely:

- Relate solely to the internal personnel practices and procedures of the 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.

Article I, Section 24 of the Florida Constitution additionally grants every person the right to inspect or copy any public record made or received in connection with the official business of any public body, officer, or employee of the state, or persons acting on their behalf. Section 8 of the ILMC however, establishes that all information provided to the Commission is confidential and may only be used for investigatory or disciplinary matters.

The ILMC also appears to conflict with the Florida Administrative Practice Act (APA). Under the APA, an agency may not revoke, suspend, amend or withdraw an individual's license without providing that individual with notice of its pending action and an opportunity to request a hearing.<sup>209</sup> However, section 10 of the ILMC requires all member states in which a physician holds a license to automatically place that license in the same status as the physician's license in his or her principal state of license, if the principal license is revoked, surrendered, relinquished or suspended. For example, a physician may designate Georgia as the principal state of licensure and also hold licenses in Florida, Alabama, Mississippi and South Carolina. If the Georgia license is revoked, then Florida, Alabama, Mississippi and South Carolina must automatically revoke their licenses without a hearing to comply with the ILMC.

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<sup>209</sup> S. 120.569, F.S. An agency may issue an emergency suspension of a license without a hearing if an immediate, serious danger to public health, safety or welfare exists.



Similarly, section 10 also requires any licenses held by a physician in other member states to be automatically suspended for 90 days without a hearing if a non-principal state license is revoked, surrendered, relinquished or suspended. Using the above example, if the physician's Florida license is revoked then his or her Georgia, Alabama, Mississippi and South Carolina licenses are automatically suspended for 90 days without a hearing in those states.

### **Effect of the Bill – Interstate Medical Licensure Compact**

The bill requires the Florida Legislature's Office of Program Policy Analysis and Government Accountability (OPPAGA) to submit a report to the Governor and Legislature by October 1, 2019, on the feasibility of Florida entering into the IMLC. Specifically, OPPAGA must research and analyze the IMLC and the relevant requirements and provisions of general law and the Florida Constitution and develop a report and recommendations addressing whether Florida can enter the IMLC while remaining consistent with such requirements and provisions. In conducting its research, OPPAGA may consult with the executive director, other executive staff, or the executive committee of the IMLC Commission.

## **II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

### **A. FISCAL IMPACT ON STATE GOVERNMENT:**

#### 1. Revenues:

None.

#### 2. Expenditures:

See Fiscal Comments.

### **B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

#### 1. Revenues:

None.

#### 2. Expenditures:

See Fiscal Comments.

### **C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:**

See Fiscal Comments.

### **D. FISCAL COMMENTS:**

#### Dental Services

Implementation of both dental services programs is subject to an appropriation, which the Legislature did not allocate this legislative session. As such, there is no fiscal impact on state or local governments.

#### Hospital Quality Report Cards

There is no fiscal impact to state or local governments.

### Patient Access to Providers

There is no fiscal impact on state or local governments. The bill's requirements for hospitals to provide patient notices, facilitate consultations between providers, and transfer discharge information to the providers may increase hospital workload, and may reduce hospital costs by reducing readmissions and other adverse incidents.

### Ambulatory Surgical Centers

There is no fiscal impact to state or local governments.

### Pediatric Cardiac Technical Advisory Panel

There may be a fiscal impact to state if the panel is reimbursed for per diem and travel expenses. There may also be a fiscal impact to the state if the state is sued for the panel's activities as agents of the state when carrying out duties assigned to them by the AHCA secretary.

### Hospital Observation Status

There is no fiscal impact to state or local governments.

### Clinical Labs

There is no fiscal impact to state or local governments.

### Restrictive Covenants

There is no fiscal impact on state or local governments.

### Direct Health Care Agreements

There is no fiscal impact on state or local governments. Health care providers authorized under the bill may establish practices that use direct health care agreements to provide health care services throughout the state without concern of facing regulatory action by OIR, which would increase access to such services.

### Step Therapy Protocols

The restriction of the use of step therapy protocols has an indeterminate negative fiscal impact on the Division of State Group Insurance (DSGI) and on managed care organizations providing coverage to individuals under the state Medicaid program.

The restrictions may also have an indeterminate negative impact on local governments that offer health plans to employees.

The restriction of the use of step therapy protocols will have an indeterminate negative fiscal impact on health insurers and HMOs, which may be passed on to consumers in the form of increased premiums or cost-sharing.

### Interstate Medical Licensure Compact

There is no fiscal impact on state or local governments.