HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 961 Health Innovation Commission
SPONSOR(S): Health Care Appropriations Subcommittee, Health Market Reform Subcommittee, Fine
TIED BILLS: **IDEN./SIM. BILLS:** SB 1348

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Market Reform Subcommittee	9 Y, 3 N	Gilani	Crosier
2) Health Care Appropriations Subcommittee	7 Y, 1 N, As CS	Nobles	Clark
3) Health & Human Services Committee	9 Y, 5 N	Gilani	Calamas

SUMMARY ANALYSIS

The United States spends increasingly more on health care each year with no noticeable improvement in health care delivery. Reduced competition and regulatory barriers to entry in the healthcare market have been identified as driving forces in increased health care costs. Two specific areas where anticompetitive regulation is impacting health care costs are in the health care workforce and provider markets.

The nation, including Florida, is facing a health care provider shortage. Government regulations reduce competition and increase health care costs by restricting health care providers from practicing to the full extent of their abilities, given their education, training, skills, and experience, consistent with the relevant standards of care. Similarly, laws that restrict entry into provider markets can stifle innovative and more cost-effective ways to provide care while limiting choice and competition. These policies allow providers to increase prices with no incentive to improve quality.

HB 961 creates a mechanism to remove regulatory barriers. The bill creates, within the Agency for Health Care Administration (AHCA), an Innovation Commission charged with facilitating implementation of innovative or alternative health care delivery or payment models that will increase efficiency, improve patient outcomes, or reduce health care costs, but which cannot be effectively or efficiently implemented due to specific regulatory barriers in law or rule. The bill gives the Commission authority to grant exemptions to these specific laws or rules, with certain conditions.

The bill authorizes the Commission to adopt rules necessary to implement the bill.

HB 961 authorizes 2.0 full-time equivalent positions, with associated salary rate of $72,137, and appropriates the sums of $174,594 in recurring and $7,144 in nonrecurring funds from the Health Care Trust Fund to AHCA to implement the bill.

The bill provides an effective date of July 1, 2019.

FULL ANALYSIS

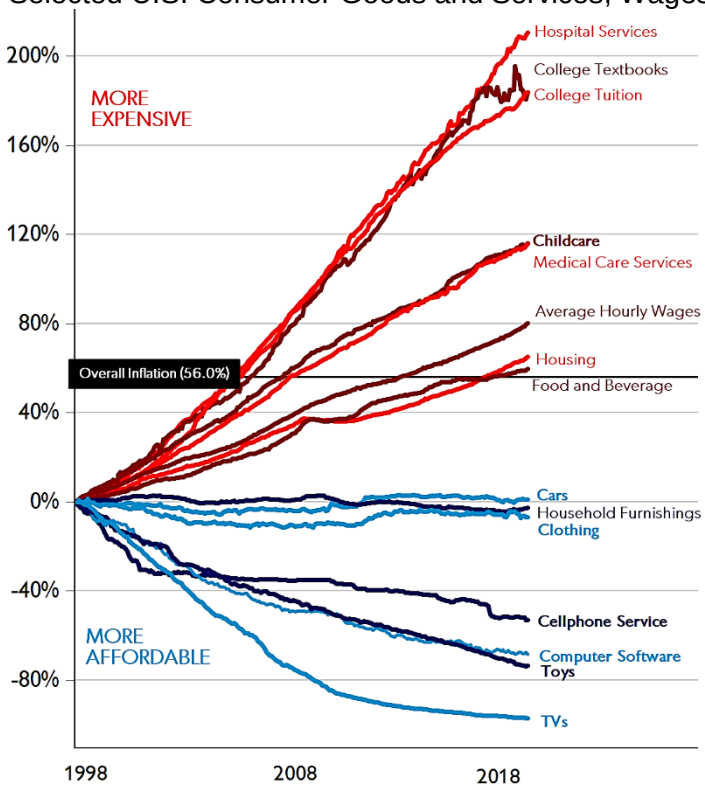
I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

The United States spends increasingly more on health care each year with no noticeable improvement in health care delivery. The federal Department of Health and Human Services, Department of the Treasury, and Department of Labor have identified reduced competition and state barriers to entry in the healthcare market as driving forces in increased health care costs.[1]

Price Changes (January 1998 to December 2018) [2]
Selected U.S. Consumer Goods and Services, Wages



Two specific areas where anticompetitive regulation negatively affects health care costs are health care workforce and provider markets.[3]

Health Care Workforce and Labor Markets: Reduced competition among clinicians leads to higher prices, reduces choice, and negatively impacts overall quality of care and efficient use of resources. Government regulations suppress competition by reducing the supply of health care providers and further restricting the range of services they can offer.

Health Care Provider Markets: State regulations that restrict entry into provider markets can stifle innovative and more cost-effective ways to provide care while limiting choice and competition. These policies allow providers to increase prices with no incentive to improve quality.

---

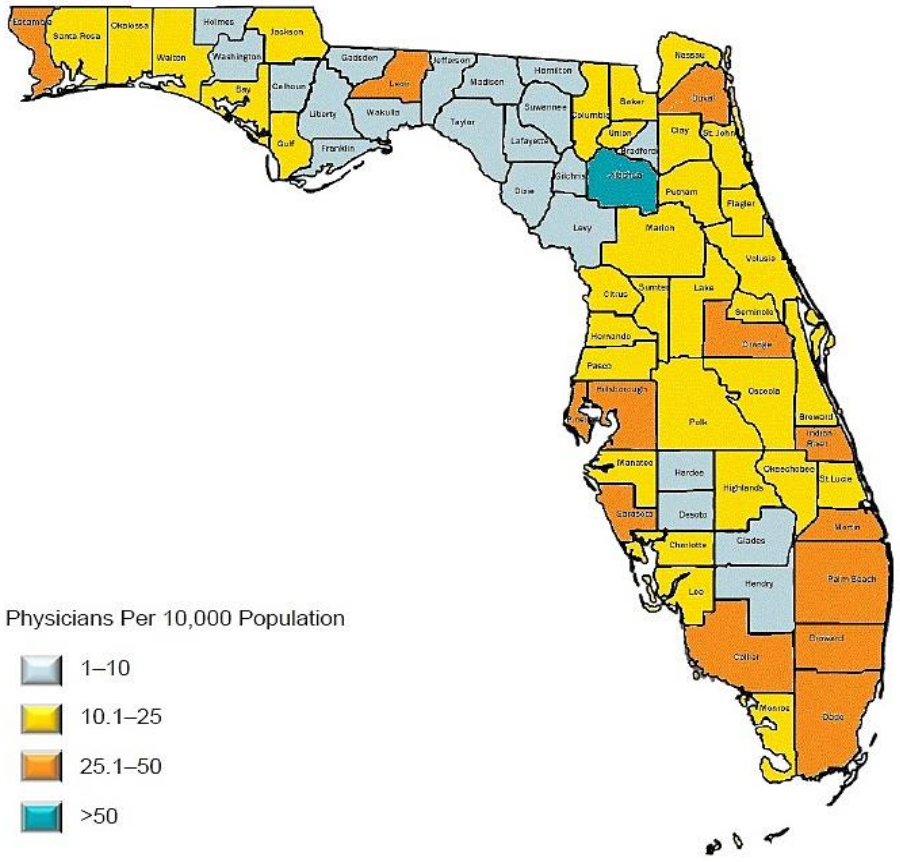
[1] *Reforming America's Healthcare System Through Choice and Competition*, U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES, U.S. DEPARTMENT OF THE TREASURY, AND U.S. DEPARTMENT OF LABOR, Dec. 3, 2018, available at: https://www.hhs.gov/sites/default/files/Reforming-Americas-Healthcare-System-Through-Choice-and-Competition.pdf (last visited Feb. 24, 2019).
[2] Chart created by American Enterprise Institute (Jan. 11, 2019) using consumer price index data released by the U.S. Bureau of Labor Statistics in January 2019, chart available at: http://www.aei.org/publication/chart-of-the-day-or-century/ (last visited Feb. 24, 2019).
[3] *Supra* note 1.

Research indicates the same: that without competitive pressure, the incentive to lower prices, innovate, or improve quality diminishes.[4] The result is high health care costs with no positive effect on patient outcomes. Other findings demonstrate the inverse to be true: that competitive health care markets have improved outcomes, increased quality, and lower prices.[5]

Barriers in Health Care Workforce

The U.S. has a health care provider shortage that is predicted to continue and worsen with time.[6] Florida is not immune from this problem and faces its own health care provider shortage. Despite being the third most populous state,[7] Florida ranks 21st in the nation for physician to population ration and 28th for primary care physician to population ratio.[8]

The following map[9] illustrates not only that Florida has a shortage of physicians, but also has a maldistribution of physicians, who are generally concentrated in urban areas.



[4] Martin Gaynor, Ph.D., et al., *Making Health Care Markets Work: Competition Policy for Health Care,* 317:13 JAMA 1313-1314 (Apr. 4, 2017), available at: https://www.brookings.edu/wp-content/uploads/2017/04/gaynor-et-al-final-report-v11.pdf (last visited Feb. 24, 2019).
[5] Id.
[6] U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Designated Health Professional Shortage Area Statistics, Fourth Quarter of Fiscal Year 2018 Designated HPSA Quarterly Summary*, (Sept. 30, 2018), available at https://ersrs.hrsa.gov/ReportServer?/HGDW_Reports/BCD_HPSA/BCD_HPSA_SCR50_Qtr_Smry_HTML&rc:Toolbar=false (last visited Feb. 24, 2019).
[7] As of July 1, 2017, the U.S. Census Bureau estimated Florida to have 20,984,400 residents, behind California (39,536,653) and Texas (28,304,596). U.S. CENSUS BUREAU, *Annual Estimates of the Resident Population: April 1, 2010 to July 1, 2017: 2017 Population Estimates*, available at: https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2014_PEPANNRES&prodType=table (last visited on Feb. 24, 2019).
[8] ASSOCIATION OF AMERICAN MEDICAL COLLEGES, *2017 State Physician Workforce Data Book,* November 2017, p. 8-9, 13-14, available at: https://www.aamc.org/data/workforce/reports/484392/2017-state-physician-workforce-data-report.html (last visited Feb. 24, 2019). The book must be downloaded to view its contents.
[9] ASSOCIATION OF AMERICAN MEDICAL COLLEGES, *The Complexities of Physician Supply and Demand: Projections from 2016 to 2030, 2018 2018 Update*, (March 2018), p. 14, available at https://aamc-black.global.ssl.fastly.net/production/media/filer_public/85/d7/85d7b689-f417-4ef0-97fb-ecc129836829/aamc_2018_workforce_projections_update_april_11_2018.pdf (last visited Feb. 23, 2019).

Government regulations restrict competition and access to care if they do not allow health care providers to practice to the full extent of their abilities, given their education, training, skills, and experience, consistent with the relevant standards of care.[10] Examples include restrictions on the use of telehealth, the ability of healthcare providers licensed in one state to work in another state, or the scope of practice of a healthcare professional whose education and training overlap with another. These types of regulations are generally justified by health and safety concerns but are often based on speculative harm and result in anticompetitive markets.[11] The risk of anticompetitive behavior is greater when the regulatory board imposing the restrictions on an occupation is controlled by another overlapping occupation that provides similar services, and whose board members are active market participants who can personally benefit from such restrictions.[12] For example, advanced practice registered nurses, physician assistants, pharmacists, and other highly trained professionals can safely and effectively provide some of the same health care services as physicians, but are often limited to providing complementary services.[13]

Governmental entities, health policy analysts, and economists alike have recommended telehealth, increased interstate licensure reciprocity, and scope of practice expansion as solutions to the health care workforce shortage that do not compromise health and safety.[14]

Telehealth

Telehealth is the use of information and communication technology to provide diagnosis, treatment, and prevention of disease and injury where distance between the provider and patient is a critical factor.[15] Telehealth is not a type of health care service but rather is a mechanism for delivery of health care services. Health care professionals use telehealth as a platform to provide traditional health care services in a non-traditional manner.

Telehealth is used to address several problems in the current health care system, including workforce shortage, inadequate access to care in rural areas, and cost barriers for the patient.[16] Telehealth reduces the impact of these issues by providing a mechanism to deliver quality health care, irrespective of the location of a patient or a health care professional, and decreasing the time and distance required to travel to the health care professional. Reutilization of health care services and hospital readmission often occur due to a lack of proper follow-up care by the patient[17] or a chronic condition.[18] Both of these issues can be addressed through telehealth and telemonitoring.

---

[10] *Occupational Licensing: A Framework for Policy Makers*, U.S. DEPARTMENT OF THE TREASURY, COUNCIL OF ECONOMIC ADVISORS, AND THE DEPARTMENT OF LABOR, July 2015, at 30, available at: https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf (last visited Feb. 24, 2019).

[11] Carolyn Cox and Susan Foster, *The Costs and Benefits of Occupational Regulation*, THE FEDERAL TRADE COMMISSION, BUREAU OF ECONOMICS (1990), available at: http://www.ramblemuse.com/articles/cox_foster.pdf (last visited Feb. 24, 2019); *Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses*, FEDERAL TRADE COMMISSION, March 7, 2014, at 14-15. https://www.ftc.gov/system/files/documents/reports/policy-perspectives-competition-regulation-advanced-practice-nurses/140307aprnpolicypaper.pdf (last visited Feb. 24, 2019).

[12] *Occupational Licensing: A Framework for Policy Makers*, U.S. DEPARTMENT OF THE TREASURY, COUNCIL OF ECONOMIC ADVISORS, AND THE DEPARTMENT OF LABOR, July 2015, at 30, available at: https://obamawhitehouse.archives.gov/sites/default/files/docs/licensing_report_final_nonembargo.pdf (last visited Feb. 24, 2019); *See also* D.J. Gilman and J. Fairman, *Antitrust and the Future of Nursing: Federal Competition Policy and the Scope of Practice*, 24 HEALTH MATRIX 157 (2014); N.C. State Bd. of Dental Exam'rs v. FTC, 135 S. Ct. 1101, 1114 (2015).

[13] *Supra* note 1.

[14] *Supra* notes 1 and 4. *See also* Thomas L. Greaney and Barak D. Richman, *Promoting Competition in Healthcare Enforcement and Policy: Framing an Active Competition Agenda,* DUKE LAW SCHOOL PUBLIC & LEGAL THEORY SERIES, Paper No. 2019-7 (Dec. 8, 2018)., available at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3267556 (last visited Feb. 24, 2019); FEDERAL TRADE COMMISSION, *Policy Perspectives: Competition and the Regulation of Advanced Practice Nurses*, (Mar. 2014), available at https://www.ftc.gov/system/files/documents/reports/policy-perspectives-competition-regulation-advanced-practice-nurses/140307aprnpolicypaper.pdf (last visited Feb. 24, 2019).

[15] WORLD HEALTH ORGANIZATION, *Telemedicine: Opportunities and Developments in Member States, Global Observatory for Ehealth Series-Volume 2,* Section 1.2, page 9 (2010), available at http://www.who.int/goe/publications/goe_telemedicine_2010.pdf (last visited Feb. 24, 2019).

[16] American Telemedicine Association, *Telemedicine Benefits*, available at http://www.americantelemed.org/main/about/about-telemedicine/telemedicine-benefits (last visited Feb. 24, 2019).

[17] Post-surgical examination subsequent to a patient's release from a hospital is a prime example. Specifically, infection can occur without proper follow-up and ultimately leads to a readmission to the hospital.

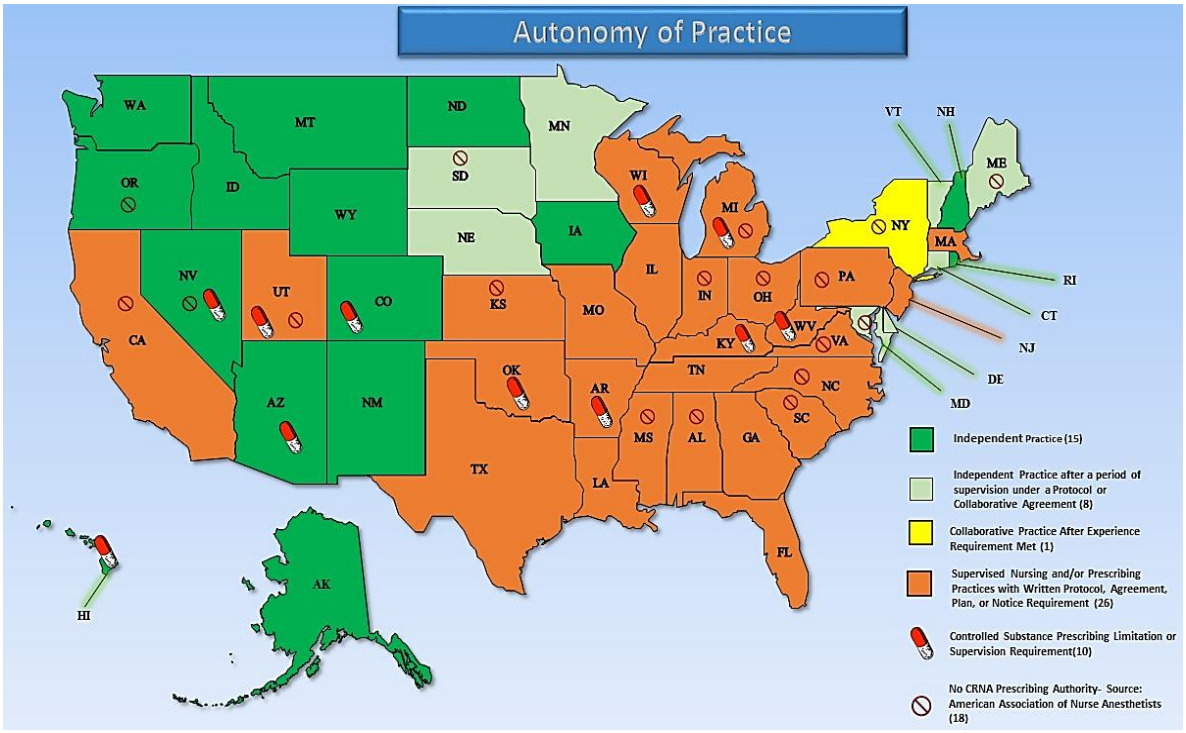
[18] For example, diabetes is a chronic condition which can benefit by treatment through telehealth.

There are currently an estimated 200 telehealth networks, with 3,500 service sites in the U.S.[19] However, due to licensure or location restrictions in some states, including Florida, licensed health care professionals cannot provide telehealth services across state lines or are limited to certain populations.[20]

Florida does not have a statutory structure for the delivery of health care services through telehealth,[21] but there are certain administrative rules that put licensure restrictions on the delivery of telehealth services.[22] In the absence of an exception or a state regulation authorizing otherwise, a health care professional must be licensed in Florida to provide telehealth services in the state. Requiring health care professionals to obtain multiple state licenses to provide health care services through telehealth is burdensome and inhibits the use of telehealth across state borders.

Scope of Practice Expansion

To address the physician shortage, many states have turned to advanced practice registered nurses (APRNs) to bridge the gap in patient access to care, allowing them to practice independently or otherwise expanding their scope of practice. In Florida, APRNs may perform only those nursing and medical practices delineated in a written physician protocol filed with the Board of Medicine.[23]



[19] AMERICAN TELEMEDICINE ASSOCIATION, *Telemedicine Frequently Asked Questions*, http://www.americantelemed.org/main/about/telehealth-faqs- (last visited Feb. 24, 2019).
[20] CENTER FOR CONNECTED HEALTH POLICY, THE NATIONAL TELEHEALTH POLICY RESOURCE CENTER, *State Telehealth Laws and Reimbursement Policies: A Comprehensive Scan of the 50 States and the District of Columbia*, (Oct. 2018), available at https://www.cchpca.org/sites/default/files/2018-10/CCHP_50_State_Report_Fall_2018.pdf (last visited Feb. 24, 2019). 9 states require out-of-state licensed health care professionals to acquire a special telehealth license or certificate to provide health care services through telehealth to patients in those states: AL, LA, ME, MN, NM, OH, OR, TN (osteopathic physicians only), and TX.
[21] The only references to telehealth in the Florida Statutes are in ss. 364.0135, 381.885, and 394.453, F.S. s. 364.0135, F.S., relates to broadband internet services and does not define or regulate telehealth in any manner. s. 381.885, F.S., relates to epinephrine auto-injectors and expressly states that consultation for the use of the auto-injector through electronic means does not constitute the practice of telemedicine. s. 394.453, F.S., provides legislative intent for the Florida Mental Health Act, in which the Legislature finds that the use of telemedicine for patient evaluation, case management, and ongoing care will improve management of patient care and reduce costs of transportation.
[22] The Florida Board of Medicine and Board of Osteopathic Medicine require a physician or physician assistant be licensed in Florida in order to provide telehealth services in the state, Rules 64B8-9.0141 and 64B15-14.0081, F.A.C.; A Child Protection Team within the Children's Medical Services(CMS) program may use a telehealth network to perform child assessments but only when performed by a CMS-approved physician or APRN at a designated site with a RN or PA located at the remote site to facilitate the evaluation, Rules 64C-8.001(5) and 64C-8.003(3), F.A.C.; Florida's Medicaid Managed Care program reimburses for telehealth services provided to its clients, Rule 59G-1.057, F.A.C.
[23] S. 464.012(3), F.S.

Despite concerns that APRNs provide a different quality of care than physicians,[24] many reports and studies suggest treatment by an APRN is just as safe as treatment by a physician.[25] More efficient use of APRNs in the provision of patient care, especially primary care, has been shown to improve patient outcomes, reduce overall health care costs, and increase access to health care.[26] Additionally, the supervision requirement for APRNs has been shown to increase the cost of APRN-provided services.[27]

Similarly, pharmacy is the third largest health profession behind nursing and medicine,[28] and often the most accessible to patients. A pharmacist dispenses medications and counsels patients on the use of both prescription and over the counter medications, but pharmacists in Florida are specifically prohibited from altering a prescriber's directions, diagnosing or treating any disease, initiating any drug therapy, and practicing medicine or osteopathic medicine, unless permitted by law.[29] Over the last few years, Florida has expanded the scope of practice for pharmacists to include the administration of vaccines and immunizations, assistance with medication management, as well as the injection of certain medications within an established protocol with a physician.[30] Other states have expanded the scope of pharmacists to include prescribing medications, either independently or pursuant to a statewide or health care practitioner protocol.[31]

Barriers in Health Care Provider Market

Research on competition in health care markets generally demonstrates that consumers will pay lower prices when the provider markets are more competitive.[32] Regulatory barriers to entry in the health care

[24] When 972 clinicians, including 467 nurse practitioners and 505 physicians were surveyed in a study as to whether physicians provide a higher quality of examination and consultation, the respondents were diametrically opposed. Approximately 66.1% of physicians agreed with the statement and 75.3% of nurse practitioners disagreed with the statement. Donelan, K., Sc.D., et al., "*Perspectives of Physicians and Nurse Practitioners on Primary Care Practice*," 368 N. ENGL. J. MED. 1898-1906 (2013), available at http://www.nejm.org/doi/full/10.1056/NEJMsa1212938 (last visited Feb. 24, 2019).

[25] A review of 25 articles comparing physician and APRN patient outcomes found that, in general, there are no appreciable differences between physicians and APRNs in health outcomes for patients, process of care, resource utilization, or cost, Laurant, M., et al., The Cochrane Collaboration, *"Substitution of Doctors by Nurses in Primary Care,"* October 18, 2004, abstract available at http://www.ncbi.nlm.nih.gov/pubmed/15846614 (last visited Feb. 24, 2019); A review of various studies to determine whether there were differences in the quality of care provided by CNPs compared to physicians found that CNPs provided at least equal quality of care to patients as compared to physicians and, in fact, CNPs were found to have equal or higher patient satisfaction rates and tended to spend more time with patients during clinical visits, National Governors Association, "*The Role of Nurse Practitioners in Meeting Increasing Demand for Primary Care*," December 2012, available at http://www.nga.org/files/live/sites/NGA/files/pdf/1212NursePractitionersPaper.pdf (last visited Feb. 24, 2019); A 2013 study found that allowing CNPs to practice and prescribe drugs without physician oversight leads to increased primary health care utilization and improvements in health outcomes, Udalova, V., Traczynski, J., "*Nurse Practitioner Independence, Health Care Utilization, and Health Outcomes*," May 4, 2014, available at http://www2.hawaii.edu/~jtraczyn/paperdraft_050414_ASHE.pdf (last visited Feb. 24, 2019).

[26] A 2012 study of APRN practice in Texas reported that utilizing APRNs more resulted in estimated savings of $16.1 billion in total expenditures and $8 billion in output (gross product) each year. Additionally, it was estimated that 97,205 permanent jobs would be added to Texas' workforce. Finally, the report estimated that Texas would receive additional tax receipts of up to $483.9 million to the state and $233.2 million to local government entities each year, The Perryman Group, "*The Economic Benefits of More Fully Utilizing Advanced Practice Registered Nurses in the Provision of Health Care in Texas*," May 2012, available at http://c.ymcdn.com/sites/www.texasnp.org/resource/resmgr/Advocacy/Perryman%20APRN%20Ultilization%20Economic%20Impact%20Report%20May%202012.pdf (last visited Feb. 24, 2019); Another study found that states that allow APRNs to practice and prescribe without physician supervision experience 16-35% increases in health care utilization, increases in care quality, and reductions in inappropriate emergency room use. The researchers concluded these advances were primarily due to elimination of supervision time (10%) and lower indirect costs (such as better appointment availability and lower patient travel costs), Udalova, V., Traczynski, J., "Nurse Practitioner Independence, Health Care Utilization, and Health Outcomes," May 4, 2014, *available at* http://www2.hawaii.edu/~jtraczyn/paperdraft_050414_ASHE.pdf (last visited Feb. 24, 2019).

[27] U.S. DEPARTMENT OF VETERAN AFFAIRS, *Economic Impact Analysis for RIN 2900-AP44, Advanced Practice Registered Nurses*, Nov. 9, 2016, available at https://www.va.gov/orpm/docs/RegMgmt_ImpactAnalysis_AP44(F)_AdvancedPracticeRegisteredNurses.docx (last visited Feb. 24, 2019).

[28] AMERICAN ASSOCIATION OF COLLEGES OF PHARMACY, *About AACP*, https://www.aacp.org/about-aacp (last visited Feb. 24, 2019).

[29] S. 465.003(13), F.S.

[30] Ss. 465.189, 465.1893, and 465.0125, F.S.

[31] Those states include California; Idaho (CPA only) Massachusetts (institutional only, no retail); Montana (CPA only); New Mexico; North Carolina; Ohio; and Washington; *See* CAL. BUS. PROF. CODE ss. 4052.6 and 4210, MONT. CODE ANN. s. 37-7-206, N.M. STAT. s. 16.19.4.17, and 21 NCAC s. 46.3101, respectively.

[32] Gaynor M., Town R., *The Impact of Hospital Consolidation—Update*, ROBERT WOOD JOHNSON FOUNDATION, THE SYNTHESIS PROJECT, Policy Brief No. 9, June 2012, available at: http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261 (last visited Feb. 24, 2019)(synthesizing research on the impact of hospital mergers on prices, cost, and quality and finding that hospital consolidation generally results in higher prices, hospital competition improves quality of care, and physician-hospital consolidation has not led to either improved quality or reduced costs); Gaynor M., Town R. *Competition in Healthcare Markets*, NATIONAL BUREAU OF ECONOMIC RESEARCH, WORKING PAPER SERIES, Working Paper No. 17208 (July 2011), available at: https://www.nber.org/papers/w17208.pdf (last visited Feb. 24, 2019). Gaynor M. et

market can lead to concentrated and inefficient markets. Specifically, state laws that require potential new participants to get government approval before entering the market can result in an anticompetitive market that increases prices for consumers with no increase in quality of care.

Certificate of Need

The Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice have urged states, including Florida, to reconsider their regulatory schemes that create market entry barriers such as the certificate of need program, finding that they are not successful in curbing health care costs, stifle innovation, and pose serious anticompetitive risk to the health care market that outweighs any purported economic benefits.[33] At least 16 states have repealed their CON programs or created variances to the program.[34]

Florida's certificate of need (CON) program requires a new general hospital, long-term care hospital, or freestanding specialty hospital to get approval from the Agency of Health Care Administration (AHCA) before it can enter the market. [35] Additionally, any existing hospital wishing to expand or add certain services must also first get approval under the CON program. In Florida, a CON 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. Unless a hospital project is exempt from the CON program, it must undergo a full comparative review, which can cost thousands of dollars and is subject to frequent litigation, often deterring or prolonging hospitals or services entering the market.

Specialty Hospitals

Similarly, Florida law bans certain types of specialty hospitals from entering the market. Specifically, Florida prohibits the licensure of hospitals that restrict their medical and surgical services to primarily or exclusively cardiac, orthopedic, surgical, or oncology specialties, or if 65% or more of the hospital's discharges are for the diagnostic care and treatment of patients with cardiac-related, orthopedic-related, or cancer-related diseases or disorders, or any combination thereof.[36]

Ambulatory Surgical Centers

One way that the health care market has been improved has been by the introduction of ambulatory surgical centers (ASCs). An ASC is a facility which provides elective surgical care on an outpatient basis. While ASCs are not part of a hospital, they are similarly regulated under ch. 395, F.S. As technology and medical knowledge advance, outpatient surgeries have increased. Outpatient surgeries now account for more than 80 percent of all surgeries completed in the U.S.[37] Research shows that procedures in ASCs are 25 percent faster on average than hospital-based outpatient facilities, due mainly to technological, system, and process efficiencies.[38] Additionally, in Florida, the average charge

---

al., *The Industrial Organization of Health-Care Markets*, 53:2 J ECON LIT. 235, 294 (2015), available at: https://www.researchgate.net/publication/278676719_The_Industrial_Organization_of_Health-Care_Markets (last visited Feb. 24, 2019).

[33] *Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice to the Virginia Certificate of Public Need Work Group*, October 26, 2015, available at https://www.ftc.gov/system/files/documents/advocacy_documents/joint-statement-federal-trade-commission-antitrust-division-u.s.department-justice-virginia-certificate-public-need-work-group/151026ftc-dojstmtva_copn-1.pdf (last viewed December 13, 2018); Federal Trade Commission and U.S. Department of Justice, *Improving Health Care: A Dose of Competition* (July 2004), available at http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf (last visited Feb. 25, 2019); Statement of the Antitrust Division, U.S. Department of Justice, Before the Florida Senate Committee on Health & Human Services. March 25, 2008, available at: https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-prepared-statement-florida-senate-concerning-florida-certificate-need-laws/v080009florida.pdf (last visited Feb. 24, 2019).

[34] CA, CO, ID, IN, KS, NH, NM, ND, PN, SD, TX, UT, and WY have repealed their CON programs; AZ, MN, and WI have variations.

[35] S. 408.036, F.S.

[36] S. 395.003(8), F.S. There is an exception for hospitals classified as an exempt cancer center hospital pursuant to 42 C.F.R. s. 412.23(f) as of December 31, 2005, and hospitals licensed as of June 1, 2004, as long as the hospital maintains the same ownership, facility street address, and range of services that were in existence on June 1, 2004. Ss. 395.003(8)(c) and 395.003(9), F.S.

[37] Munnich E. and Parente S., *Returns to Specialization: Evidence from the Outpatient Surgery Market*, pg. 1 (April 2014), available at https://louisville.edu/faculty/elmunn01/Munnich_Parente_ASC_Quality.pdf (last viewed Feb. 24, 2019).

[38] 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); 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).

for an outpatient surgery in a hospital is three times more than the average charge at an ASC.[39] The increased use of outpatient surgery may help lower health care costs and meet increased patient demand for outpatient surgery.

ASCs must have an agreement with the Centers for Medicare and Medicaid Services (CMS) to participate in Medicare, and must comply with specific conditions for coverage. CMS allows ASCs to perform outpatient surgical services that are not expected to last more than 24 hours[40] following an admission.[41] However, Florida law requires discharge the same day as admission and prohibits overnight stays,[42] thereby limiting the number of procedures that can be performed at an ASC even though they are permitted by federal standards.

Effect of the Bill:

HB 961 creates a mechanism to remove regulatory barriers to health care. The bill creates an Innovation Commission to facilitate implementation of innovative or alternative health care delivery or payment models that will increase efficiency, improve patient outcomes, or reduce health care costs, but which cannot be effectively or efficiently implemented due to regulatory barriers in law or rule.

The bill requires the Commission to solicit proposals for innovative improvements to the healthcare delivery system which would require an exemption from one of the following provisions of law or rule to effectively or efficiently implement the proposal:

- The project requirements of the certificate of need program.
- The licensure prohibition of specialty hospitals.
- The requirement that a patient be discharged from an ambulatory surgical center within the same day as admission and not be permitted to stay overnight.
- The restrictions on the practice of pharmacy.
- The prohibition on delivery of health care services to patients in the state if a person does not hold the applicable license to practice in Florida. The Commission may grant an exemption from this prohibition if the person holds a valid and active license to practice such health care profession in another state.
- The requirement that an advanced practice registered nurse practice under a supervisory protocol with a physician to: prescribe, dispense, administer, or order medication; initiate appropriate therapies for certain conditions; order diagnostic tests and physical and occupational therapy; order any medication for administration in a hospital or nursing home notwithstanding the requirements of ch. 465, F.S. or ch. 893, F.S.

The bill authorizes the Commission to grant exemptions to these provisions under certain circumstances and conditions. To be eligible for consideration for such an exemption, a proposal must, at a minimum:

- Identify an existing problem in the healthcare delivery system, which can include inefficiency, high costs, or poor patient outcomes;

---

[39] Megan Smernoff, Chief Legislative Analyst, Office of Program Policy Analysis and Government Accountability, *Ambulatory Surgical Centers and Recovery Care Centers,* A Presentation to the House Health Market Reform Subcommittee, slide 5, Feb. 6, 2019, available at: http://www.oppaga.state.fl.us/monitordocs/Presentations/P19-04.pdf (last visited Feb. 25, 2019). Of the 3 million outpatient visits in 2017, 53% of procedures were performed in an ASC, while only accounting for 23% of the charges.

[40] U.S. Centers for Medicare & 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 (last viewed Feb. 24, 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.

[41] 42 C.F.R. §416.2

[42] S. 395.002(3), F.S.

- Propose a specific alternative or innovative healthcare delivery or payment model to solve the problem the applicant will be able to implement, and describe the necessary changes to current practice that are required to effectively implement the solution;
- Demonstrate, using real data or prior experience, how and to what extent the proposed solution will either increase efficiency, improve patient outcomes, or reduce costs to the consumer, industry, or government; and
- Identify the specific barriers to implementing the proposed solution in current law or rule, request that the commission grant an exemption from such law or rule, and demonstrate the impact such exemption would have on patient health and safety.

The bill requires the Commission to perform a preliminary review of the proposals as it receives them, and authorizes the Commission to call upon relevant state agencies for any professional assistance needed on the subject matter of the proposal. The bill requires the state agencies to provide such assistance in a timely manner. Examples of relevant information the agencies may be required to provide are:

- Background information on the issue such as relevant policies, laws, rules, and data;
- Identification of what agency action, if any, would be necessary to implement the proposed solution; and
- An assessment of whether the proposed solution would achieve the Commission's purpose, and if not, recommendations for any way that the proposed solution could be amended to achieve such purpose.

Once the Commission receives all requested information from relevant state agencies, it must perform a full review of the proposal, taking into consideration any information provided by the agencies and the applicant, and make its determination. Under the bill, the Commission may only grant an exemption from one of the specified laws or rules if it finds that there is compelling evidence to show that:

- The proposal is likely to achieve the purpose of this section (i.e., increase efficiency, reduce costs, or improve patient outcomes);
- An exemption from the specified law or rule is necessary for the effective implementation of the proposal; and
- The potential benefits of the proposal outweigh any potential harm to the public health and safety that may result from such exemption.

The bill imposes certain conditions on the Commission's ability to grant exemptions. Specifically, the Commission may only grant an exemption to the extent necessary to implement the proposal. Additionally, the Commission may impose conditions on the granted exemption, but only to the extent necessary to achieve increased efficiency, reduced costs, or improved patient outcomes. Lastly, the bill prohibits the Commission from granting an exemption to a law or rule that would violate federal law or jeopardize public health and safety, or if the law or rule is required by the federal government for implementation or retention of any federally approved or delegated program unless the appropriate federal agency has authorized it.

The bill requires the Commission to adopt written findings that state the relevant facts and the rationale for granting or denying the request for an exemption. The Commission must provide a copy of its written findings and decision to the applicant within 30 days of making its decision. Similarly, if the Commission grants an exemption, it must provide a copy of its written findings and decision to the relevant state agencies.

The bill requires the Commission to meet at least quarterly or upon call of the chair and as often as necessary to carry out its duties and responsibilities under the bill. Commission members are not entitled to any compensation or reimbursement for per diem or travel expenses, but may use any method of telecommunication to conduct its meetings.

Under the bill, the Commission is housed within the Agency for Health Care Administration (AHCA) for administrative, staffing, and fiscal accountability purposes but otherwise functions independently and does not take direction from AHCA. The Commission must convene by December 1, 2019 and is comprised of 11 members with experience in the healthcare delivery system, including healthcare industry representatives, healthcare practitioners, and consumers. The Governor, President of the Senate, and Speaker of the House of Representatives shall each appoint three members to the Commission and the Governor appoints the chair. The Secretary of AHCA and the State Surgeon General will serve as ex officio nonvoting members of the Commission.

The bill requires AHCA to submit an annual report on the Commission's activities to the Governor and Legislature by November 1 of each year. The report must include, at a minimum:

- Summaries of the proposals reviewed by the Commission during the previous fiscal year, including background information, an explanation of the proposed solutions, a fiscal analysis, any barriers to implementing the proposed solutions existing in law or rule at the time the proposals were submitted, and a copy of the Commission's written findings and decisions; and
- A list of any provisions of law or rule from which the Commission granted exemptions within the previous fiscal year.

The bill allows the Commission to adopt rules necessary to implement the bill.

The bill provides an effective date of July 1, 2019.

B. SECTION DIRECTORY:

Section 1: Creates s. 381.995, F.S., relating to the Health Innovation Commission.
Section 2: Provides an effective date of July 1, 2019.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill will have a significant, negative fiscal impact on AHCA. AHCA will require 2 FTEs to administratively assist the Commission with its meetings and duties and prepare the annual reports for the Governor and the Legislature. The Commission may also require an additional FTE to provide legal advice, assist with rulemaking, and prepare the Commission's written findings. AHCA is requesting multiple FTEs and may need the additional FTEs in the future depending on the volume of proposals the Commission receives and any litigation that may result from the Commission's findings.[43]

   For the 2019-2020 fiscal year, HB 961 as amended authorizes 2.0 full-time equivalent positions, with associated salary rate of $72,137, and appropriates the sums of $174,594 in recurring and $7,144 in nonrecurring funds from the Health Care Trust Fund to the Agency for Health Care Administration for the purpose of implementing this act.

[43] Florida Agency for Health Care Administration, Agency Analysis for 2019 HB 961, Mar. 1, 2019 (on file with Health Market Reform Subcommittee staff).

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Entities that are granted exemptions under the bill will experience an indeterminate positive fiscal impact to the extent that the proposed solution is implemented and increases efficiency or reduces costs. To the extent that entities who are granted exemptions under the bill are successful in implementing their proposed solutions, patients may experience improved outcomes or reduced costs as a result.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides sufficient rulemaking authority to the Commission to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 26, 2019, the Health Care Appropriations Subcommittee adopted an amendment that authorizes 2.0 full-time equivalent positions, with associated salary rate of $72,137, and appropriates the sums of $174,594 in recurring and $7,144 in nonrecurring funds from the Health Care Trust Fund to the Agency for Health Care Administration for the purpose of implementing this act.

The bill was reported favorably as amended. This analysis is drafted to the committee substitute as passed by the Appropriations Committee.