The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Committee on Appropriations

BILL:	CS/CS/SB 212
INTRODUCER:	Appropriations Committee; Health Policy Committee; and Senator Gaetz
SUBJECT:	Health Care
DATE:	February 29, 2016
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Looke	Stovall	HP	**Fav/CS**
2.	Brown	Pigott	AHS	**Recommend: Favorable**
3.	Brown	Kynoch	AP	**Fav/CS**

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/SB 212 authorizes the creation of joint state and local dental care access accounts to promote local economic development and to encourage Florida-licensed dentists to practice in dental health professional shortage areas or medically underserved areas, or serve a medically underserved population, subject to the availability of funds.

The bill allows patients in an ambulatory surgical center (ASC) to stay in the center for up to 24 hours. Current law requires that patients in an ASC be discharged on the same working day and restricts patients from staying overnight in an ASC.

The bill also requires, as a condition of licensure, that an ASC must provide services to Medicaid and Medicare patients and to patients who qualify for charity care. The bill defines "charity care" as uncompensated care delivered to uninsured patients having incomes at or below 200 percent of the federal poverty level when such services are preauthorized by the licensee and not subject to collection procedures.

The bill creates a new section of Florida Statutes related to the application of the Florida Insurance Code for direct primary care agreements. The bill provides that a direct primary care agreement is not insurance and is not subject to the Florida Insurance Code. The bill defines the terms, "direct primary care agreement," "primary care provider," and "primary care service," and specifies certain provisions that must be included in a direct primary care agreement.

The bill creates the "Right Medicine Right Time Act" and requires Medicaid managed care plans, HMOs, and insurers that restrict medications by a step-therapy or fail-first protocol to have a clear and convenient process to request an override of the protocol, which must be granted within 24 hours if the treating physician determines that certain conditions are met.

The bill prohibits an HMO from requiring a health care provider to use a clinical decision support system or a laboratory benefits management program before the provider may order clinical laboratory services or in an attempt to direct or limit the provider's medical decision-making relating to the use of such services.

The bill allows a free clinic that engages volunteer health care providers, to receive a grant or legislative appropriation to support the delivery of services while retaining the sovereign immunity protections under existing law and allows such financial support to be used to employ providers to supplement, coordinate, or otherwise support the volunteers.

The bill expands the definition of a health care provider or provider in the Access to Health Care Act to include a pharmacy or licensed pharmacist, and a pharmacy or pharmacist providing services under the Access to Health Care Act is given sovereign immunity as an agent of the state.

The bill provides that employees and agents of the free clinics are protected from lawsuits under the state's sovereign immunity protections.

The bill has an indeterminate fiscal impact on state government.

Except as otherwise expressly provided, the bill has an effective date of July 1, 2016.

II. Present Situation:

Health Professional Shortage Areas

Health Professional Shortage Areas (HPSAs) are designated by the Health Resources and Services Administration (HRSA) within the U.S. Department of Health and Human Services 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 professionals.

There are three categories of HPSA designation: (1) primary medical; (2) dental; and (3) mental health. For each discipline category, there are three types of HPSA designations based on the area or population group that is experiencing the shortage: (1) geographic area; (2) population group; and (3) facility.[1]

A geographic HPSA indicates that the entire area may experience barriers in accessing care, while a population HPSA indicates that a particular subpopulation of an area (e.g., homeless or

[1] U.S. Department of Health and Human Services, Health Resources and Services Administration, *Shortage Designation: Health Professional Shortage Areas & Medically Underserved Areas/Population* http://www.hrsa.gov/shortage/ (last visited Sept. 21, 2015).

low-income) may be underserved. Finally, a facility HPSA is a unique facility that primarily cares for an underserved population.

The primary factor used to determine a HPSA designation is the number of health professionals relative to the population with consideration of high need. The threshold for a dental HPSA is a population-to-provider ratio of at least 5,000 to 1 (or 4,000 to 1 in high-need communities).[2]

Medically Underserved Area

Medically Underserved Areas (MUA) are also designated by the U.S. Department of Health and Human Services. These areas are designated using one of three methods and can consist of a whole county, a group of contiguous counties, or census tracts.[3]

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

The second method, Medically Underserved Populations (MUP), is based on data collected under the MUA process and reviews the ratio of primary care physicians serving the population seeking the designation. A MUP is a group of people who encounter economic or cultural barriers to primary health care services.

The third process, Exceptional MUP Designations, includes those population groups which do not meet the criteria of an IMU but may be considered for designation because of unusual conditions with a request by the governor or another senior executive level official and a local state health official.[4]

The Dental Workforce

Nationally, the pool of dentists to serve the growing population of Americans is shrinking. The American Dental Association has found that 6,000 dentists retire each year in the U.S., while only 4,000 dental school students graduate each year. The projected shortage of dentists is even greater in rural America. Of the approximately 150,000 general dentists in practice in the U.S., only 14 percent practice in rural areas, 7.7 percent practice in large rural areas, 3.7 percent practice in small rural areas, and 2.2 percent practice in isolated rural areas. In 2003, there were 2,235 federally designated dental health professional shortage areas (HPSAs).[5] Today, the number of dental HPSAs has increased to over 4,900.

While the dental workforce is projected to grow by six percent between 2012 and 2025, it is not expected to meet the overall national demand. Florida is listed as the second neediest state, with

[2] *Id.*
[3] *Id.*
[4] U.S. Department of Health and Human Services, Health Resources and Services Administration, *Medically Underserved Areas/Populations* http://www.hrsa.gov/shortage/mua/index.html (last visited Sept. 21, 2015).
[5] National Rural Health Association, *Issue Paper: Recruitment and Retention of a Quality Health Workforce in Rural Areas*, (November 2006) (on file with the Senate Committee on Health Policy).

1,152 fewer dentists than the number required to serve the population.[6] Similar to the national trend, most dentists in Florida are concentrated in the more populous areas of the state, while rural areas, especially the central Panhandle counties and interior counties of south Florida, have a noticeable lack of dentists.[7] This is true for both general dentistry as well as for dental specialists. Additionally, over 20 percent of Florida licensed dentists that responded to the 2011-2012 *Florida Workforce Survey of Dentists* (survey) currently do not practice in Florida.[8]

Most dentists – 77.8 percent – practice in general dentistry.[9] In many rural communities, the county health department may be the primary provider of health care services, including dental care. Florida currently has 220 designated dental HPSAs, which have only enough dentists to serve 17 percent of the population living within them. For 2012, HRSA estimated that 853 additional dentists were required to meet the total need. This puts Florida among the states with the highest proportion of their populations that are deemed underserved. By 2025, Florida's need grows to 1,152 dentists.[10]

The American Dental Association has also studied this issue and found that while there may be a sufficient number of dentists overall, there may be an inadequate number among certain populations or in certain geographic areas.[11] Children are acutely affected by the shortage of dentists to serve low income patients. In 2012, 26 percent of Medicaid-enrolled children in Florida received one or more dental care services, according data from the Agency for Health Care Administration (AHCA).[12] The survey noted a noticeable participation difference between private-practice dentists and those who practice in a safety-net setting. Of those in a private-office setting, only 13.7 percent report seeing Medicaid enrollees while over 60 percent of safety-net providers report Medicaid participation.[13]

In 2011, the Legislature passed HB 7107[14] creating the Statewide Medicaid Managed Care (SMMC) program as part IV of ch. 409, F.S. The program has two primary components: Managed Medical Assistance program (MMA) and Long Term Care program. To implement MMA, the law required the AHCA to create an integrated managed care program for the delivery

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[6] U.S. Department of Health and Human Services, Health Resources and Services Administration, *National and State Level Projections of Dentists and Dental Hygienists in the U.S., 2012-2015*, pp.-3-4 (February 2015) http://bhpr.hrsa.gov/healthworkforce/supplydemand/dentistry/nationalstatelevelprojectionsdentists.pdf (last visited Oct. 20, 2015).

[7] Florida Dept. of Health, *Report on the 2011-2012 Workforce Survey of Dentists*, p. 6 (April 2014) http://www.floridahealth.gov/programs-and-services/community-health/dental-health/workforce-reports/florida-workforce-survey-of-dentists-2011-2012.pdf (last visited Sept. 21, 2015). In 2009, the DOH developed this workforce survey for dentists. The survey was administered on a voluntary basis in conjunction with biennial renewal of dental licenses and 87 percent of dentists with an active Florida license responded to the survey; a drop of 2 percent points from the 2009-2010 survey.

[8] *Id.* at 46.

[9] *Id.*

[10] *Supra* note 6, at 9.

[11] Bradley Munson, B.A., and Marko Vujicic, Ph.D.: Health Policy Institute Research Brief, American Dental Association, *Supply of Dentists in the United States Likely to Grow*, p.2. (October 2014) http://www.ada.org/~/media/ADA/Science%20and%20Research/HPI/Files/HPIBrief_1014_1.ashx (last visited Sept. 21, 2015).

[12] *Supra* note 7, at 8.

[13] *Supra* note 7, at 35.

[14] *See* chapter 2011-134, Laws of Fla.

of Medicaid primary and acute care services, including dental. Medicaid recipients who are enrolled in MMA receive their dental services through managed care plans. Although most dental services are designated as a required benefit only for Medicaid recipients under age 21, many of the managed care plans also provide dental services for adults as an enhanced benefit.

The Cost of Dental Education

Among U.S. dental schools, the cost of a four-year degree has risen dramatically over the last 10 years – by 93 percent for in-state residents (from about $89,000 to $171,000) and by 82 percent for out-of-state residents (from $128,000 to $234,000). Dental school debt has increased proportionately. The average debt for dental school graduates in 2014 was $247,227.[15]

In 2013, Congress enacted the Bipartisan Student Loan Certainty Act of 2013 (Public Law 113-28) that tied student loan interest rates to the 10-year Treasury Note. For graduate and professional student loans, the interest rate is tied to 10-year Treasury Note plus 3.6 percent, but may not exceed 9.5 percent in any given year.[16] In June 2014, through a Presidential Memorandum, President Barack Obama directed the Secretary of Education to propose regulations to allow additional students with student loan debt to cap their payments at 10 percent of their income, by December 31, 2015.[17] The Presidential Memorandum called the plan, "*Pay as You Earn Plan."*[18]

Some studies indicate that increasing education costs and the prospect of indebtedness after dental school graduation could further erode access to care for vulnerable, underserved populations.[19] At least three studies, including a 2011 Florida Senate Report,[20] have

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[15] American Dental Education Association, *Federal Student Loans*, http://cqrcengage.com/adea/federalStudentLoan (last visited Sept. 21, 2015).
[16] *Id.*
[17] *Id.*
[18] The White House, Office of the Press Secretary, *Presidential Memorandum - Federal Student Loan Repayments* (June 9, 2014) https://www.whitehouse.gov/the-press-office/2014/06/09/presidential-memorandum-federal-student-loan-repayments (last visited Sept. 21, 2015).
[19] American Dental Education Association, *A Report of the ADEA Presidential Task Force on the Cost of Higher Education and Student Borrowing*, pp. 17-18 (March 2013) http://www.adea.org/uploadedFiles/ADEA/Content_Conversion_Final/publications/Documents/ADEACostandBorrowingReportMarch2013.pdf (last viewed Sept. 21, 2015). *See* also U.S. Dept. of Health and Human Services, Health Resources and Services Administration, *Financing Dental Education: Public Policy Interests, Issues and Strategic Considerations*, p. 39 (2005) http://bhpr.hrsa.gov/healthworkforce1/reports/financedentaledu.pdf (last visited Sept. 21, 2015).
[20] Comm. on Health Regulation, The Florida Senate, *Review Eligibility of Dentist Licensure in Florida and Other Jurisdictions*, p.15 (Interim Report 2012-127) (Sept. 2011) http://www.flsenate.gov/PublishedContent/Session/2012/InterimReports/2012-127hr.pdf (last visited Sept. 21, 2015). The report concluded, in part: "Florida may become more competitive in its recruitment of dentists in rural areas and may enhance Florida's dental care for underserved populations if it offers a loan forgiveness program. The program could require dentists seeking loan assistance to serve in a rural area (the Panhandle or central, south Florida) and require dentists to serve a certain percentage of Medicaid recipients or participate in the provider network of managed care entities participating in the Medicaid program for a particular period of time. Considering the current lack of state resources, it may be beneficial to limit the number of dentists that may apply to the loan forgiveness program and target resources to areas with the most need for general dentists or specialists." At the time, Florida was one of only eight states that did not have a state loan forgiveness program. According to the American Dental Association, it is one of only 11 states: Alabama, Arkansas, Connecticut, Florida, Georgia, Hawaii, Idaho, Indiana, Montana, Texas, and Utah as of July 2014.

recommended consideration of loan forgiveness programs as one strategy for addressing dental workforce shortage concerns.[21]

Florida does not have a current state program to address the dental health professional shortage areas or medically underserved areas. According to the DOH, there are 16 vacant positions (out of 82 or 19.5 percent) for dentists in the DOH.[22] Additionally, according to the Health Resources and Services Administration, there are 16 vacant dentist positions in Florida Dental Health Professional Shortage Areas as of September 16, 2015.[23]

Florida Health Services Corps

In 1992, the Legislature created the Florida Health Services Corps (FHSC), administered by the DOH, to encourage medical professionals to practice in locations that are underserved because of a shortage of qualified professionals.[24] The FHSC was defined[25] as a program that offered scholarships to allopathic, osteopathic, chiropractic, podiatric, dental, physician assistant, and nursing students, and loan repayment assistance and travel and relocation expenses to allopathic and osteopathic residents and physicians, chiropractic physicians, podiatric physicians, nurse practitioners, dentists, and physician assistants, in return for service in a public health care program[26] or in a medically underserved area.[27] Membership in the FHSC could be extended to any health care practitioner who provided uncompensated care to medically indigent patients.[28] All FHSC members were required to enroll in Medicaid and to accept all patients referred by the DOH pursuant to the program agreement.[29] In exchange for this service, an FHSC member was made an agent of the state and granted sovereign immunity under s. 768.28(9), F.S., when providing uncompensated care to medically indigent patients referred for treatment by the DOH.[30]

The statute authorized the DOH to provide loan repayment assistance and travel and relocation reimbursement to allopathic and osteopathic medical residents with primary care specialties during their last two years of residency training or upon completion of residency training, and to

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http://www.ada.org/~/media/ADA/Education%20and%20Careers/Files/dental-student-loan-repayment-resource.ashx (Last visited Mar. 2, 2015).

[21] American Dental Education Association, *supra* note 19, at 26; *Financing Dental Education*, *supra* note 19, at 40.

[22] Florida Dept. of Health, *Senate Bill Analysis SB 234*, p. 2, (Sept. 24. 2015) (on file with the Senate Health Policy Committee).

[23] *Id*.

[24] Chapter 92-33, s. 111, Laws of Fla. (creating s. 381.0302, F.S., effective July 1, 1992).

[25] Section 381.0302(2)(b)1., F.S. (2011).

[26] "Public health program" was defined to include a county health department, a children's medical services program, a federally funded community health center, a federally funded migrant health center, or other publicly funded or nonprofit health care program designated by the department. Section 381.0302(2)(e), F.S. (2011).

[27] "Medically underserved area" was defined to include: a geographic area, a special population, or a facility that has a shortage of health professionals as defined by federal regulations; a county health department, community health center, or migrant health center; or a geographic area or facility designated by rule of the department that has a shortage of health care practitioners who serve Medicaid and other low-income patients. Section 381.0302(2)(c), F.S. (2011).

[28] "Medically indigent person" was defined as a person who lacks public or private health insurance, is unable to pay for care, and is a member of a family with income at or below 185 percent of the federal poverty level. Section 381.0302(2)(d), F.S. (2011).

[29] Section 381.0302(10), F.S. (2011).

[30] Section 381.0302(11), F.S. (2011).

physician assistants and nurse practitioners with primary care specialties, in return for an agreement to serve a minimum of two years in the FHSC. During the period of service, the maximum amount of annual financial payments was limited to no more than the annual total of loan repayment assistance and tax subsidies authorized by the National Health Services Corps (NHSC) loan repayment program.[31]

During the 20 years the program was authorized by law, it was funded only three times. A total of $3,684,000 was appropriated in the 1994-1995 fiscal year, 1995-1996 fiscal year, and 1996-1997 fiscal year for loan assistance payments to all categories of eligible health care practitioners. Of that amount, $971,664 was directed to 18 dentists for an average award of $25,570 per year of service in the program.[32] The 2007 Legislature attempted to reinvigorate the program by appropriating $700,000 to fund loan repayment assistance for dentists only.[33] However, the appropriation and a related substantive bill were vetoed.[34] The Legislature repealed the program in 2012.[35]

National Health Service Corps (NHSC)

The NHSC programs provide scholarships and educational loan repayment to primary care providers[36] who agree to practice in areas that are medically underserved. NHSC loan repayment program (LRP) participants fulfill their service requirement by working at NHSC-approved sites in HPSAs. The NHSC-approved sites are community-based health care facilities that provide comprehensive outpatient, ambulatory, primary health care services. Eligible dental facilities must be located in a dental HPSA and offer comprehensive primary dental health services. NHSC-approved sites (with the exception of correctional facilities and free clinics) are required to provide services for free or on a sliding fee scale (SFS) or discounted fee schedule for low-income individuals. The SFS or discounted fee schedule is based upon the Federal Poverty Guidelines, and patient eligibility is determined by annual income and family size.[37]

The LRP provides funds to participants to repay their outstanding qualifying educational loans. Maximum loan reimbursement under the program is $50,000 for a two-year, full-time practice or up to $15,000 for a two-year, half-time clinical practice, although participants may be eligible to

[31] Section 381.0302(6), F.S. (2011).
[32] E-mail from Karen Lundberg, Florida Dept. of Health, to Joe Anne Hart, Florida Dental Association (Sept. 16, 2005) (on file with the Senate Committee on Health Policy).
[33] Chapter 2007-72, Laws of Fla. The funding was contained in Specific Appropriations 677A of the General Appropriation Act, but later vetoed pursuant to the Governor's line item veto authority.
[34] *Journal of the Florida Senate*, at 3 (June 12, 2007).
[35] Chapter 2012-184, s. 45, Laws of Fla.
[36] Primary care physicians, nurse practitioners, certified nurse midwives, physician assistants, dentists, dental hygienists, and behavioral and mental health providers, including health service psychologists, licensed clinical social workers, marriage and family therapists, psychiatrist nurse specialists, and licensed professional counselors.
[37] U.S. Dept. of Health and Human Services, Health Resources and Services Administration, *National Health Service Corps Site Reference Guide*, (April 14, 2014) http://nhsc.hrsa.gov/downloads/sitereference.pdf (last visited Mar. 2, 2015).

continue loan repayment beyond the initial term.[38,39] Participants who breach their LRP agreement are subject to monetary damages, which are the sum of the amount of assistance received by the participant representing any period of obligated service not completed, a penalty, and interest. Loan repayments are exempt from federal income and employment taxes and are not included as wages when determining benefits under the Social Security Act.[40] As of September 2015, there were 47 full-time-equivalent NHSC dentists in Florida.[41]

A second NHSC program, the State Loan Repayment Program (SLRP) offers cost-sharing grants to states to operate their own state educational loan repayment programs for primary care providers, including dental professionals, working in HPSAs within the state. The SLRP varies from state to state and may differ in eligible categories of providers, practice sites, length of required service commitment, and the amount of loan repayment assistance offered. However, there are certain statutory requirements SLRP grantees must meet. There is a minimum two-year service commitment with an additional one-year commitment for each year of additional support requested. Any SLRP program participant must practice at an eligible site located in a federally-designated HPSA. Like the NHSC loan repayment program awards, assistance provided through an SLRP is not taxable.

In addition, the SLRP requires a $1 state match for every $1 provided under the federal grant. While the SLRP does not limit award amounts, the maximum award amount per provider that the federal government will support through its grant is $50,000 per year, with a minimum service commitment of two years.

Florida does not currently participate in SLRP.

Ambulatory Surgical Centers

An ASC is a facility, that is not a part of a hospital, with a primary purpose 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.[42]

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[38] The definition of part-time and full-time vary by discipline. The guidelines for both can be found in the *Fiscal Year 2015 Application and Program Guidance* packet beginning on 19 http://www.nhsc.hrsa.gov/loanrepayment/lrpapplicationguidance.pdf (last viewed Feb, 27, 2015).

[39] U.S. Department of Health and Human Services, Loan Repayment Program - *Fiscal Year 2015 Application and Program Guidance*, pp. 4-5 (January 2015) http://www.nhsc.hrsa.gov/loanrepayment/lrpapplicationguidance.pdf (last viewed Feb. 27, 2015).

[40] U.S. Dept. of Health and Human Services, Health Resources and Services Administration, *National Health Service Corps 101* (on file in the Senate Committee on Health Policy).

[41] E-mail from Debbie Reich, Supervisor, State Primary Care Office, Health Statistics and Performance Management, Florida Dept. of Health (Sept. 22, 2015) (on file with the Senate Committee on Health Policy).

[42] Section 395.002(3), F.S, defines "Ambulatory surgical center" or "mobile surgical facility" to mean a facility the primary purpose of which is to provide elective surgical care, in which the patient is admitted to and discharged from such facility within the same working day and is not permitted to stay overnight, and which is not part of a hospital. However, a facility existing for the primary purpose of performing terminations of pregnancy, an office maintained by a physician for the practice of medicine, or an office maintained for the practice of dentistry shall not be construed to be an ambulatory surgical center, provided that any facility or office which is certified or seeks certification as a Medicare ambulatory surgical center shall be licensed as an ambulatory surgical center pursuant to s. 395.003, F.S. Any structure or vehicle in which a physician maintains an office and practices surgery, and which can appear to the public to be a mobile office because the structure or vehicle operates at more than one address, shall be construed to be a mobile surgical facility.

In Florida, ambulatory procedures are performed in two settings, hospital-based outpatient facilities and freestanding ASCs. Currently, there are 431 licensed ASCs in Florida.[43] Of these, 413 are Medicare and/or Medicaid certified, and 381 are accredited by either the Accreditation Association for Ambulatory Health Care (AAAHC) or by the Joint Commission.[44] In 2008, Medicare paid for 39.1 percent of all procedures performed in ASCs while Medicaid paid for 5.6 percent and commercial payers paid for 46.6 percent.

Between April 2014 and March 2015, there were 2,933,433 visits to ASCs or hospital outpatient facilities in Florida.[45] Hospital outpatient facilities accounted for 31 percent and free standing ASCs accounted for 59 percent. Freestanding ASC average charges range from $2,930 to $7,333 and hospital outpatient facility average charges range from $7,727 to $26,034 for the same time period.[46] Two of the most popular procedures that are performed on adults at an ASC include cataract procedures with 249,184 performed and colonoscopies with 218,745 performed, also during the same time period.[47]

In a survey of ASC research and literature, the Office of Program Policy Analysis and Government Accountability (OPPAGA) found that, generally, the impact on hospitals from competition from ASCs was limited and that ASCs can result in cost savings when performing certain procedures. Additionally, the OPPAGA did not identify any patterns associated with access to services in ASCs and found that the studies largely agree that ASCs, in general, provide timely service and had low rates of unexpected adverse safety events.[48]

ASC Licensure

ASCs are licensed and regulated by the AHCA under the same regulatory framework as hospitals.[49] Applicants for ASC licensure must submit certain information to the Agency for Health Care Administration (AHCA) prior to accepting patients for care or treatment, including registration of articles of incorporation and a zoning certificate or proof of compliance with zoning requirements.[50]

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

- The governing body's bylaws, rules, and regulations;
- The roster of registered nurses and licensed practical nurses with current license numbers;
- A fire plan; and

[43] See AHCA presentation on Ambulatory Surgical Centers, slide 10, presented to the Health Policy Committee on June 10, 2015, (on file with the Senate Committee on Health Policy).
[44] Id.
[45] Agency for Health Care Administration, Florida Health Finder Search, http://www.floridahealthfinder.gov/CompareCare/CompareFacilities.aspx (last viewed January 14, 2016).
[46] Id.
[47] Id.
[48] Ambulatory Surgical Centers and Recovery Care Centers, OPPAGA, January 19, 2016, on file with Senate Health Policy Committee staff.
[49] Sections 395.001-395.1065, F.S., and Part II, Chapter 408, F.S.
[50] Rule 59A-5.003(4), F.A.C.

- A comprehensive emergency management plan.[51]

Rules for ASCs

Pursuant to s. 395.1055, F.S., the AHCA is authorized to adopt rules for hospitals and ASCs. Separate standards may be provided for general and specialty hospitals, ASCs, and statutory rural hospitals, but the rules for all hospitals and ASCs must include minimum standards for ensuring that:

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

AHCA rule ch. 59A-5, F.A.C., implements the minimum standards for ASCs. Those rules also require policies and procedures to ensure the protection of patient rights.

Staff and Personnel Rules

ASCs are required to have written policies and procedures for surgical services, anesthesia services, nursing services, pharmaceutical services, laboratory services, and radiologic services. In providing these services, ACSs are required to have certain professional staff available, including:

- A qualified person responsible for the daily functioning and maintenance of the surgical suite;
- An anesthesiologist, physician, a certified registered nurse anesthetist under the on-site medical direction of a licensed physician, or an anesthesiologist assistant under the direct supervision of an anesthesiologist who must be in the ASC during the anesthesia and post-anesthesia recovery period until all patients are alert or discharged;
- A registered professional nurse who is responsible for coordinating and supervising all nursing services;
- A registered professional circulating nurse for a patient during that patient's surgical procedure; and
- A registered professional nurse who must be in the recovery area at all times when any patients are present.[52]

Infection Control Rules

ASCs are required to establish an infection control program involving members of the medical, nursing, and administrative staff. The program must include written policies and procedures reflecting the scope of the infection control program. The written policies and procedures must

[51] Rule 59A-5.003(5), F.A.C.
[52] Rule 59A-5.0085, F.A.C.

be reviewed at least every two years by the infection control program members. The infection control program must include:

- Surveillance, prevention, and control of infection among patients and personnel;
- A system for identifying, reporting, evaluating and maintaining records of infections;
- Ongoing review and evaluation of aseptic, isolation, and sanitation techniques employed by the ASC; and
- Development and coordination of training programs in infection control for all personnel.[53]

Emergency Management Plan Rules

ASCs are required to develop and adopt a written comprehensive emergency management plan for emergency care during an internal or external disaster or emergency. The ASC must review the plan and update it annually.[54]

Accreditation

ASCs may seek voluntary accreditation by the Joint Commission or the AAAHC. The AHCA is required to conduct an annual licensure inspection survey for non-accredited ASCs. The AHCA is authorized to accept survey reports of accredited ASCs from accrediting organizations if the standards included in the survey report are determined to document that the ASC is in substantial compliance with state licensure requirements. The AHCA is required to conduct annual validation inspections on a minimum of five percent of the ASCs which were inspected by an accreditation organization.[55]

AHCA is required to conduct annual life safety inspections of all ASCs to ensure compliance with life safety codes and disaster preparedness requirements. However, the life-safety inspection may be waived if an accreditation inspection was conducted on an ASC by a certified life safety inspector and the ASC was found to be in compliance with the life safety requirements.[56]

Medicare Requirements

ASCs are required to have an agreement with the federal Centers for Medicare & Medicaid Services (CMS) in order to participate in Medicare. ASCs are also required to comply with specific conditions for coverage. The CMS defines "ASC" as any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission.[57]

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

[53] Rule 59A-5.011, F.A.C.
[54] Rule 59A-5.018, F.A.C.
[55] Rule 59A-5.004, F.A.C.
[56] Id.
[57] 42 C.F.R. §416.2

for coverage are met.[58] All of the CMS conditions for coverage requirements are specifically required in AHCA rule ch. 59A-5, F.A.C., and apply to all ASCs in Florida. The conditions for coverage require ASCs to have:

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

Direct Primary Care

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 monthly fee, usually between $50 and $100 per individual,[59] to a primary care provider for defined primary care services, such as:

- Office visits;
- Annual physical examination;
- Routine laboratory tests;
- Vaccinations;
- Wound care;
- Splinting or casting of fractured or broken bones; or
- Other routine testing, e.g. echocardiogram and colon cancer screening.

After paying the fee, a patient can access all services under the agreement at no extra charge. Some DPC practices also include routine preventative services, like lab tests, mammograms, Pap screenings, and vaccinations. A DPC model can be designed to address most health care issues, including women's health services, pediatric care, urgent care, wellness education, and chronic disease management.

In the DPC practice model, the primary care provider eliminates overhead costs associated with insurance filing claims, coding, refiling claims, write-offs, appealing denials, and employment of billing staff.[60]

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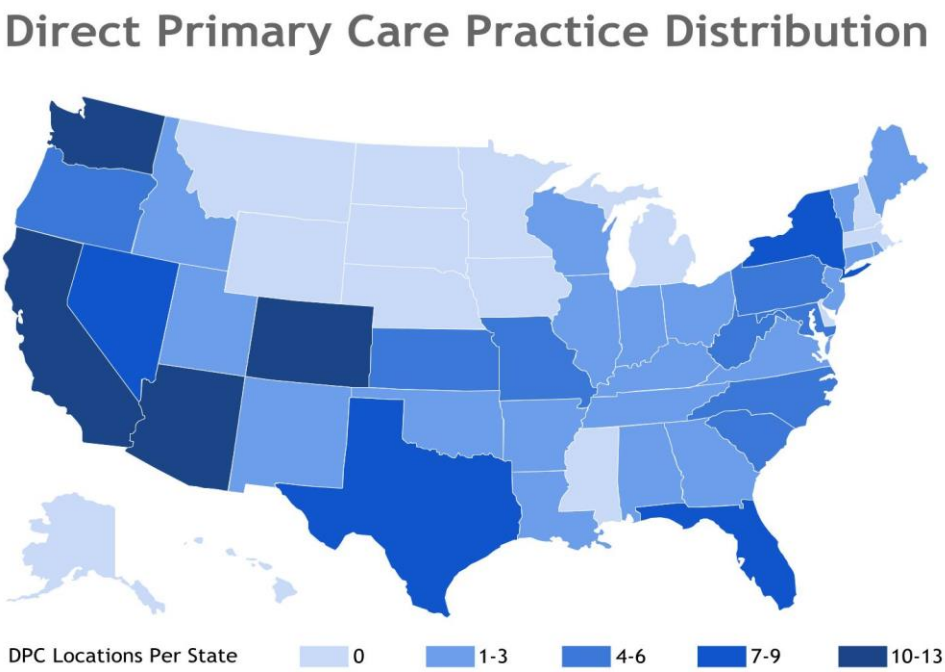
[58] 42 C.F.R. §416.26(a)(1)

[59] Approximately two-thirds of DPC practices charge less than $135 per month. *See* Jen Wieczner, *Is Obamacare Driving Doctors to Refuse Insurance?*, Wall St. J. Marketwatch, (Nov. 12, 2013) *available at:* http://www.marketwatch.com/story/is-direct-primary-care-for-you-2013-11-12 (last visited Feb. 9, 2016). A recent study of 141 DCP practices found the average monthly fee to be $77.38. *See* Phillip M. Eskew and Kathleen Klink, *Direct Primary Care: Practice Distribution and Cost Across the Nation*, Journal of the Amer. Bd. of Family Med. (Nov.-Dec. 2015) Vol. 28, No. 6, p. 797, *available at:* http://www.jabfm.org/content/28/6/793.full.pdf (last visited Feb. 9, 2016).

[60] DPC practices claim to reduce overhead by more than 40% by eliminating administrative staff resources associated with third-party billing. *See* Eskew, s*upra* note 59, p. 794.

The following chart illustrates the concentration of DPC practices in the United States:[61]



In 2014, the American Academy of Private Physicians (AAPP) estimated that approximately 5,500 physicians operate under some type of direct financial relationship with their patients, outside of standard insurance coverage. According to the AAPP that number has increased around 25 percent per year since 2010.[62]

Federal Patient Protection and Affordable Care Act

The federal Patient Protection and Affordable Care Act (PPACA) was signed into law on March 23, 2010.[63] The PPACA provides fundamental changes to the U.S. health care system by requiring 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 imposes many insurance requirements including required essential health benefits, rating and underwriting standards, review of rate increases, and internal and external appeals of adverse benefit determinations.[64]

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[61] Jay Keese, Executive Director, Direct Primary Care Coalition, *Direct Primary Care*, PowerPoint presentation before the House of Representatives Health Innovation Subcommittee (Feb. 17, 2015), slide 2, *available at:* http://www.myfloridahouse.gov/Sections/Documents/loaddoc.aspx?PublicationType=Committees&CommitteeId=2859&Session=2015&DocumentType=Meeting Packets&FileName=his 2-17-15.pdf (last visited Feb. 9, 2016).

[62] David Twiddy, *Practice Transformation: Taking the Direct Primary Care Route*, Family Practice Management, No. 3, (May-June 2014), *available at:* http://www.aafp.org/fpm/2014/0500/p10.html (last visited Feb. 9, 2016).

[63] The Patient Protection and Affordable Care Act (Pub. Law 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. Law 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. Pub. Law 111-148.

[64] Most of the insurance regulatory provisions in PPACA amend Title XXVII of the Public Health Service Act (PHSA), (42 U.S.C. s. 300gg *et seq*.).

Qualifying coverage may be obtained through an employer, the federal or state marketplaces or exchanges created under PPACA, or private individual or group coverage meeting the minimum essential benefits coverage standard off the exchange. Florida did not establish its own state exchange under PPACA. Premium credits and other cost sharing subsidies are available to U.S. citizens and legal immigrants within certain income limits for qualified coverage purchased through the exchange. Premium credits are set on a sliding scale based on a percentage of the federal poverty level and reduce the out-of-pocket costs incurred by individuals and families.

DPC and Federal Health Insurance Reform

The PPACA addresses the DPC practice model as part of health insurance reform. A qualified health plan under the PPACA is permitted to offer coverage through a DPC plan if it provides essential health benefits and meets all other criteria in the law.[65] Patients who are enrolled in a DPC plan may be exempt from the individual mandate if they have coverage for other services, such as a wrap-around catastrophic health policy to cover treatment for serious illnesses, like cancer, or severe injuries that require lengthy hospital stays and rehabilitation.[66] In Colorado and Washington, qualified health plans offer DPC medical home coverage on the state-based health insurance exchange.[67]

Currently, there are no state laws regulating direct primary care agreements in Florida.

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.[68] The AHCA regulates the quality of care provided by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a health care provider certificate from the AHCA.[69] As part of the certification process used by the AHCA, an HMO must provide information to demonstrate that it has the ability to provide quality of care consistent with the prevailing standards of care.[70]

Florida's Statewide Medicaid Managed Care

Medicaid is a joint federal and state funded program that provides health care for low income Floridians. In Florida, the AHCA administers the program. Over 3.9 million Floridians are current enrolled in Medicaid, and the program's estimated expenditures for the 2015-2016 fiscal year are over 24.9 billion.[71]

Part IV of ch. 409, F.S., was created in 2011 by ch. 2011-134, L.O.F., and governs the Statewide Medicaid Managed Care program (SMMC). The program, authorized under federal Medicaid

[65] 42 U.S.C. s. 18021(a)(3); 45 C.F.R. s. 156.245.
[66] *See* 42 U.S.C. ss. 18021(a)(3) and 18022.
[67] Keese, s*upra* note 60, slide 4.
[68] Section 20.121(3)(a), F.S.
[69] Section 641.21(1), F.S.
[70] Section 641.495, F.S.
[71] Office of Economic and Demographic Research, *Social Services Estimating Conference of January 7, 2016,* http://edr.state.fl.us/Content/conferences/medicaid/medltexp.pdf (last visited Jan. 26, 2016).

waivers, is designed for the AHCA to issue invitations to negotiate[72] and competitively procure contracts with managed care plans in 11 regions of the state to provide comprehensive Medicaid coverage for most of the state's enrollees in the Medicaid program. SMMC has two components: managed medical assistance (MMA) and long-term care managed care (LTCMC).

The LTCMC component began enrolling Medicaid recipients in August 2013 and completed its statewide roll-out in March 2014. The MMA component began enrolling Medicaid recipients in May 2014 and finished its roll-out in August 2014. As of December 2015, 3.19 million Medicaid recipients were enrolled in an SMMC plan while 793,515 were enrolled in Medicaid on a fee-for-service basis.[73]

Managed care plans have the ability to implement service authorization and utilization management requirements for the services they provide under SMMC. However, Medicaid managed care plans are required to ensure that: service authorization decisions are based on objective, evidenced-based criteria, utilization management procedures are applied consistently, and all decisions to deny or limit a requested service are made by health care professionals who have the appropriate clinical expertise in treating the enrollee's condition. The managed care plans are also required to adopt practice guidelines that:

- Based on valid and reliable clinical evidence or a consensus of health care professionals in a particular field;
- Consider the needs of the enrollees; and
- Adopted in consultation with providers; and are reviewed and updated periodically, as appropriate.

The guidelines above are consistent with requirements found in federal regulations.[74]

The AHCA maintains coverage and limitations policies for most Florida Medicaid services. Medicaid managed care plans cannot be more restrictive than these policies or the Florida Medicaid State Plan (which is approved by the federal Centers for Medicare & Medicaid Services, or CMS) in providing services to their enrollees. Managed care plans must notify enrollees and providers of the services they provide and inform them of any prior authorization requirements or coverage limitations in their respective handbooks.

Section 409.91195, F.S., establishes the Pharmaceutical and Therapeutics (P&T) Committee within the AHCA for the development of a Florida Medicaid preferred drug list (PDL). The P&T Committee meets quarterly, reviews all drug classes included in the formulary at least every 12 months, and may recommend additions to and deletions from the AHCA's Medicaid PDL, such that the PDL provides for medically appropriate drug therapies for Medicaid recipients and an array of choices for prescribers within each therapeutic class.

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[72] An "invitation to negotiate" is a written or electronically posted solicitation for vendors to submit competitive, sealed replies for the purpose of selecting one or more vendors with which to commence negotiations for the procurement of commodities or contractual services. *See* s. 287.012(17), F.S.

[73] The Agency for Health Care Administration, "Florida Statewide Medicaid Monthly Enrollment Report," December 2015, available at http://ahca.myflorida.com/Medicaid/Finance/data_analytics/enrollment_report/index.shtml (last visited Dec. 23, 2015).

[74] 42 CFR s. 438.236(b).

The AHCA also manages the federally required Medicaid Drug Utilization Board, which meets quarterly, develops, and reviews clinical prior authorization criteria, including step-therapy protocols for drugs that are not on the AHCA's Medicaid PDL.

Managed care plans serving MMA enrollees are required to provide all prescription drugs listed on the AHCA's Medicaid PDL for at least the first year of operation,[75] and the AHCA is continuing to enforce that requirement in the program's second year. As such, MMA managed care plans have not implemented their own plan-specific formularies or PDLs, and a managed care plan's prior authorization criteria and protocols related to prescribed drugs cannot be more restrictive than the criteria established by the AHCA.

The AHCA posts prior authorization protocols, step-edit criteria and protocols, and updates to the list of drugs that are subject to prior authorization on the AHCA's Internet Web site within 21 days after the prior authorization and step-edit criteria and protocol and updates are approved by the AHCA, in accordance with s. 409.912, F.S. MMA plans may adopt the Medicaid prior authorization criteria or develop their own criteria. Prior authorization and step-therapy protocols for PDL may not be more restrictive than protocols posted on the AHCA's website.[76]

Section 409.967, F.S., currently requires managed care plans to publish any prescribed drug formulary or PDL on the plan's web site in a manner that is accessible to and searchable by enrollees and providers. The plan must update the list within 24 hours after making a change. Each plan must ensure that the prior authorization process for prescribed drugs is readily accessible to health care providers, including posting appropriate contact information on its web site and providing timely responses to providers.

Florida's State Group Insurance Program

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 section 125, Internal Revenue Code. To administer the state group health insurance program, the DMS contracts with third party administrators, HMOs, and a pharmacy benefits manager (PBM) for the state employees' prescription drug program pursuant to s. 110.12315, F.S.

The health plan administrators, HMOs, and PBM each have their respective clinical coverage guidelines and utilization management practices to ensure appropriateness of care and to manage plan costs. These coverage guidelines are based on clinical evidence and recommendations from clinical and pharmacy and therapeutics committees comprising practicing physicians and pharmacists. The National Committee for Quality Assurance and other national accreditation

[75] See Agency for Health Care Administration, *SMMC Plans, Model Contract, Attachment II, Core Contract Provisions,* p. 34 (effective November 1, 2015) *available at* http://ahca.myflorida.com/Medicaid/statewide_mc/plans.shtml and the *Pharmacy Snapshot* (August 27, 2014) *available at* https://ahca.myflorida.com/Medicaid/statewide_mc/pdf/mma/Pharmacy_Snapshot_2014-08-27.pdf (last visited Jan. 26, 2016).

[76] Agency for Health Care Administration, *Senate Bill 1084 Analysis* (Jan.13, 2016) (on file with the Senate Committee on Banking and Insurance).

organizations define the structure and function of these committees, which have the same duties described for the proposed commission.

The state employees' self-insured prescription drug program has three cost-sharing categories for members: generic drugs, preferred brand name drugs (those brand name drugs on the preferred drug list), and non-preferred brand name drugs (those brand name drugs not on the preferred drug list). Contractually the PBM for the state employees' self-insured prescription drug program updates the preferred drug list quarterly as brand drugs enter the market and as the PBM negotiates pricing, including rebates with manufacturers.[77]

Prescription Drug Coverage under the PPACA

Prior to an insurer offering a plan through a PPACA exchange, the exchange must certify that the plan meets certain federal essential health benefits and other requirements to be deemed a qualified health plan (QHP). Section 1302 of the PPACA requires QHPs to provide coverage of essential health benefits (EHB), meet cost-sharing limits and actuarial value requirements. The law directs that EHBs cover at least 10 specified categories, which includes prescription drugs.[78]

Final HHS Notice of Benefit and Payment Parameters for 2016

On March 20, 2014, the final HHS regulations relating to notice of benefit and payment parameters was released, which establishes key standards for issuers and marketplaces for 2016. These regulations include provisions relating to prescription drug coverage, formulary drug lists, and the drug exception process.[79]

Prescription Drug Coverage: Currently, for purposes of complying with the essential health benefits, insurers and HMOs 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 essential health benefit (EHB) benchmark plan. For plan years beginning on or after January 1, 2017, plans must also use a P&T committee process that meets certain requirements. The P&T committee must 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.[80]

Formulary Drug List: The regulations require that a health plan must publish an up-to-date and complete list of all covered drugs on its formulary drug list, including any tiered structure and any restrictions on the manner in which a drug can be obtained, in a manner that is easily accessible to plan enrollees, prospective enrollees, the state, the exchange, HHS, and the public.

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[77] Footnote 1A of s.110.12315, F.S., prohibits the state's prescription drug program from implementing a prior authorization program or step-therapy program for non-HMO members. Step-therapy is currently not in place for any state-group health plan member.

[78] See Centers for Medicare and Medicaid Services, *Florida's Benchmark Plan* https://www.cms.gov/cciio/resources/data-resources/ehb.html (last visited Jan.26, 2016).

[79] HHS, *Final HHS Notice of Benefit and Payment Parameters for 2016*, Factsheet, *available at* http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/2016-PN-Fact-Sheet-final.pdf (last visited Jan. 26, 2016).

[80] 45 C.F.R. s. 156.122.

Additionally, insurers and HMOs must also make this information available in a standard-readable format to provide the opportunity for third parties to create resources that aggregate information on different plans.

Drug Exceptions Process: Under current HHS regulations, plans providing EHBs must have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not included on the plan's formulary drug list. Such procedures must include a process to request an expedited review based on exigent circumstances. Under this expedited process, the issuer must make its coverage determination no later than 24 hours after it receives the request. This requirement, commonly referred to as the "exceptions process," applies to drugs that are not included on the plan's formulary drug list. For plan years beginning in 2016, these processes must also include certain processes and timeframes for the standard review process, and have an external review process if the internal review request is denied. The costs of the non-formulary drug provided through the exceptions process count towards the annual limitation on cost sharing and actuarial value of the plan.[81]

Cost Containment Measures Used by Insurers and HMOs

Prior Authorization and Step Therapy or Fail First Therapy

Insurers use many cost containment and utilization review strategies to manage medical and drug spending and patient safety. For example, plans may place utilization management requirements on the use of certain drugs on their formulary. This may include requiring enrollees to obtain prior authorization from their plan before being able to fill a prescription, requiring enrollees to try first a preferred drug to treat a medical condition before being able to obtain an alternate drug for that condition, or limiting the quantity of drugs that they cover over a certain period.

Under prior authorization, a health care provider is required to seek approval from an insurer before a patient may receive a specified diagnostic or therapeutic treatment or specified prescription drugs under the plan. A PDL is an established list of one or more prescription drugs within a therapeutic class deemed clinically equivalent and cost effective. In order to obtain another drug within the therapeutic class, not part of the PDL, prior authorization is required. Prior authorization for emergency services is not required. Preauthorization for hospital inpatient services is generally required.

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 Drug A first. If Drug A does not work for a beneficiary, then the plan will cover Drug B. Advocates of step therapy state that a step therapy approach requires the use of a clinically recognized first-line drug before approval of a more complex and often more expensive medication where the safety, effectiveness, and values has been well established before a second-line drug is authorized.

[81] 45 C.F.R. s. 156.122(c). The drug exception process is distinct from the coverage appeals process, which applies if an enrollee receives an adverse benefit determination for a drug that is included on the plan's formulary drug list. The coverage appeals process has separate requirements for its external review process and allows for a secondary level of internal review before the final internal review determination for group plans. [45 C.F.R. s. 147.136]

According to a published report by researchers affiliated with the National Institutes of Health, there is mixed evidence on the impact of step therapy policies.[82] A review of the literature by Brenda Motheral found that there is little good empirical evidence,[83] but other studies[84] suggest that step therapy policies have been effective at reducing drug costs without increasing the use of other medical services. However, some studies have found that the policies can increase total utilization costs over the long run because of increased inpatient admissions and emergency department visits.[85] One-step therapy policy for a typical antipsychotic medication in a Medicaid program was associated with a higher rate of discontinuity in medication use, an outcome that was linked to increased risk for hospitalization.[86]

Clinical Decision Support Systems and Laboratory Benefit Management Programs

Clinical decision support (CDS) systems are designed to improve clinical decision-making and to provide a platform for integrating evidence based knowledge into health care delivery.[87] The CDS systems encompass a variety of tools to enhance decision-making in the clinical workflow. These tools include computerized alerts and reminders to care providers and patients; clinical guidelines; condition-specific order sets; focused patient data reports and summaries; documentation templates; diagnostic support, and contextually relevant reference information, among other tools.

Laboratory Benefit Management Program

The Laboratory Benefit Management Program (LBMP) [88] was developed to help manage appropriate utilization for outpatient laboratory services.[89] A pilot program, instituted in 2014, is limited to fully insured commercial members in Florida, excluding Neighborhood Health Partnership members. As part of the program, all outpatient laboratory services for these members are subject to new requirements, including advance notification and new medical policies. If a provider orders laboratory services and its practice is located in Florida, the provider must use BeaconLBS Physician Decision Support when ordering any of the decision support tests for members who are part of the program. The Physicians Decision Support system is an on-line tool that helps physicians select tests and laboratories using evidence-based guidelines and following insurer's policies. These tests are listed in the system's administrative protocol.

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[82] The Ethics Of "Fail First": Guidelines and Practical Scenarios for Step Therapy Coverage Policies, Rahul K. Nayak and Steven D. Pearson *Health Affairs* 33, No.10 (2014):1779-1785.
[83] Pharmaceutical Step Therapy Interventions: A Critical Review of the Literature, Brenda R. Motheral, *Journal of Managed Care Pharmacy* 17, no. 2 (2011) 143-55.
[84] *Supra* note 82, at 1780.
[85] *Id*.
[86] I*d*.
[87] See Health IT.Gov, *What is Clinical Decision Support* (updated January 15, 2013) *available at* https://www.healthit.gov/policy-researchers-implementers/clinical-decision-support-cds (last visited Jan. 26, 2016).
[88] Beacon Laboratory Benefit Solutions, Inc. (BeaconLBS®), a subsidiary of LabCorp®, administers the Laboratory Benefit Management Program for UnitedHealthcare.
[89] UnitedHealthcare, *UnitedHealthcare Laboratory Benefit Management Program Frequently Asked Questions* (June 29, 2015) (on file with the Senate Committee on Banking and Insurance).

Access to Health Care Act

Section 766.1115, F.S., is entitled "The Access to Health Care Act" (Access Act). It was enacted in 1992 to encourage health care providers to provide care to low-income persons.[90] The Access Act is administered by the Department of Health (DOH) through the Volunteer Health Services Program.[91] Volunteers complete an enrollment application with the DOH which requires a personal reference and background checks.[92]

The Access Act extends sovereign immunity to health care providers who execute a contract with a governmental contractor and who, as agents of the state, provide volunteer, uncompensated health care services to low-income individuals. These health care providers are considered agents of the state under s. 768.28(9), F.S., for purposes of extending sovereign immunity while acting within the scope of duties required under the Access Act.

A contract issued under the Access Act must pertain to volunteer, uncompensated services. For services to qualify as volunteer, uncompensated services, the health care provider must receive no compensation from the governmental contractor for any services provided under the contract and must not bill or accept compensation from the recipient or any public or private third-party payer for the specific services provided to the low-income recipients covered by the contract.[93]

Health care providers under the Access Act include:[94]

- A birth center licensed under ch. 383, F.S.[95]
- An ambulatory surgical center licensed under ch. 395, F.S.[96]
- A hospital licensed under ch. 395, F.S.[97]
- A physician or physician assistant licensed under ch. 458, F.S.[98]
- An osteopathic physician or osteopathic physician assistant licensed under ch. 459, F.S.[99]
- A chiropractic physician licensed under ch. 460, F.S.[100]
- A podiatric physician licensed under ch. 461, F.S.[101]

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[90] Low-income persons are defined in the act as a person who is Medicaid-eligible, a person who is without health insurance and whose family income does not exceed 200 percent of the federal poverty level, or any eligible client of the Department of Health who voluntarily chooses to participate in a program offered or approved by the department. Section 766.1115(3)(e), F.S. A single individual whose annual income does not exceed $23,540 is at 200 percent of the federal poverty level using Medicaid data. *See 2015 Poverty Guidelines, Annual Guidelines* (September 3, 2015), *available at* http://aspe.hhs.gov/poverty/15poverty.cfm.

[91] *See* Florida Dep't of Health, Division of Public Health Statistics and Performance Management, *Volunteer Health Services, available at* http://www.floridahealth.gov/provider-and-partner-resources/getting-involved-in-public-health/volunteerism-volunteer-opportunities/index.html (last visited Jan. 8, 2016); and Rule Chapter 64I-2, F.A.C.

[92] Florida Dep't of Health, Division of Public Health Statistics and Performance Management, *Volunteer Services Policy*, pp. 12-13, *available at* http://www.floridahealth.gov/provider-and-partner-resources/getting-involved-in-public-health/volunteer-health-services-opportunities/VHS2PolicyDOHP380-7-14.pdf (last visited Feb. 5, 2016).

[93] Section 766.1115(3)(a), F.S.

[94] Section 766.1115(3)(d), F.S.

[95] Section 766.1115(3)(d)1., F.S.

[96] Section 766.1115(3)(d)2., F.S.

[97] Section 766.1115(3)(d)3., F.S.

[98] Section 766.1115(3)(d)4., F.S.

[99] Section 766.1115(3)(d)5., F.S.

[100] Section 766.1115(3)(d)6., F.S.

[101] Section 766.1115(3)(d)7., F.S.

- A registered nurse, nurse midwife, licensed practical nurse, or advanced registered nurse practitioner licensed or registered under part I of ch. 464, F.S., or any facility that employs nurses licensed or registered under part I of ch. 464, F.S., to supply all or part of the care delivered under the act.[102]
- A dentist or dental hygienist licensed under ch. 466, F.S.[103]
- A midwife licensed under ch. 467, F.S.[104]
- A health maintenance organization certificated under part I of ch. 641, F.S.[105]
- A health care professional association and its employees or a corporate medical group and its employees.[106]
- Any other medical facility the primary purpose of which is to deliver human medical diagnostic services or which delivers nonsurgical human medical treatment, and which includes an office maintained by a provider.[107]
- A free clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to all low-income recipients.[108]
- Any other health care professional, practitioner, provider, or facility under contract with a governmental contractor, including a student enrolled in an accredited program that prepares the student for licensure as a physician, physician assistant, nurse, or midwife.[109]
- Any nonprofit corporation qualified as exempt from federal income taxation under s. 501(a) of the Internal Revenue Code, and described in s. 501(c) of the Internal Revenue Code, that delivers health care services provided by the listed licensed professionals, any federally funded community health center, and any volunteer corporation or volunteer health care provider that delivers health care services.

A governmental contractor is defined in the Access Act as the DOH, a county health department, a special taxing district having health care responsibilities, or a hospital owned and operated by a governmental entity.[110]

The Access Act further specifies additional contract requirements which must provide that:
- The governmental contractor retains the right of dismissal or termination of any health care provider delivering services under the contract;
- The governmental contractor has access to the patient records of any health care provider delivering services under the contract;
- The health care provider must report adverse incidents and information on treatment outcomes;
- The governmental contractor or the health care provider must make patient selection and initial referrals;

[102] Section 766.1115(3)(d)8., F.S.
[103] Section 766.1115(3)(d)13., F.S.
[104] Section 766.1115(3)(d)9., F.S.
[105] Section 766.1115(3)(d)10., F.S.
[106] Section 766.1115(3)(d)11., F.S.
[107] Section 766.1115(3)(d)12., F.S.
[108] Section 766.1115(3)(d)14., F.S.
[109] Section 766.1115(3)(d)15., F.S.
[110] Section 766.1115(3)(c), F.S.

- The health care provider is subject to supervision and regular inspection by the governmental contractor;[111] and
- The health care provider must accept all referred patients; however, the contract may specify limits on the number of patients to be referred.[112]

The governmental contractor must provide written notice to each patient, or the patient's legal representative, receipt of which must be acknowledged in writing, that the provider is covered under s. 768.28, F.S., for purposes of legal actions alleging medical negligence.[113]

According to the DOH, from July 1, 2014, through June 30, 2015, 12,569 licensed health care volunteers (plus an additional 9,938 clinic staff volunteers) provided 373,588 health care patient visits with a total value of donated goods and services of more than $271 million, under the Access Act.[114] The Florida Department of Financial Services, Division of Risk Management, reported that as of January 7, 2015, 10 claims had been filed against the Volunteer Health Care Provider Program under s. 766.1115, F.S., since February 15, 2000.[115]

Legislative Appropriations to Free and Charitable Clinics

Expenditures of legislative appropriations to the Florida Association of Free and Charitable Clinics has been restricted to clinic capacity-building purposes via the association's contract with the DOH, which has distributed such appropriations. Clinic capacity-building has been limited to products or processes that increase skills, infrastructure, and resources of clinics. The DOH has not authorized these funds to be used to build capacity through the employment of clinical personnel.

The DOH has cautiously interpreted the provision in the Access Act relating to volunteer, uncompensated services, which states that a health care provider must receive no compensation from the governmental contractor for any services provided under the contract. Accordingly, the DOH's interpretation precluded the use of legislative appropriation for payment of compensation to clinical personnel.

The Florida Association of Free and Charitable Clinics received a $9.5 million appropriation in the 2015-2016 General Appropriations Act through the DOH.[116] However, this fiscal year's appropriation was vetoed by the Governor "because the funds could not be used for services, and therefore it is not a statewide priority for improving cost, quality, and access in healthcare."[117]

[111] Section 766.1115(4), F.S.
[112] Rule 64I-2.003(2), F.A.C.
[113] Section 766.1115(5), F.S.
[114] Florida Dep't of Health, *Volunteer Health Services 2014-2015 Annual Report* (December 1, 2015), *available at* http://www.floridahealth.gov/provider-and-partner-resources/getting-involved-in-public-health/volunteer-health-services-opportunities/VHS1415annualreport.pdf (last visited Jan. 7, 2016).
[115] Id at A-1.
[116] Chapter 2015-232, Laws of Fla., line item 441.
[117] Governor Rick Scott, *Veto Message to Secretary of State Ken Detzner* (June 23, 2015), p. 35, *available at* http://www.flgov.com/wp-content/uploads/2015/06/Transmittal%20Letter%206.23.15%20-%20SB%202500-A.pdf (last visited Jan. 7, 2016).

Sovereign Immunity

The term "sovereign immunity" originally referred to the English common law concept that the government may not be sued because "the King can do no wrong." Sovereign immunity bars lawsuits against the state or its political subdivisions for the torts of officers, employees, or agents of those governments unless the immunity is expressly waived.

Article X, section 13 of the Florida Constitution recognizes the concept of sovereign immunity and gives the Legislature the power to waive immunity in part or in full by general law. Section 768.28, F.S., contains the limited waiver of sovereign immunity applicable to the state. Under this statute, officers, employees, and agents of the state will not be held personally liable in tort or named as a party defendant in any action for any injury or damage suffered as a result of any act, event, or omission of action in the scope of her or his employment or function. However, personal liability may result from actions committed in bad faith or with malicious purpose or in a manner exhibiting wanton and willful disregard of human rights, safety, or property.

Instead, the state steps in as the party litigant and defends against the claim. The recovery by any one person is limited to $200,000 for one incident and the total for all recoveries related to one incident is limited to $300,000.[118] The sovereign immunity recovery caps do not prevent a plaintiff from obtaining a judgment in excess of the caps, but the plaintiff cannot recover the excess damages without action by the Legislature.[119]

Whether sovereign immunity applies in any specific case turns on the degree of control of the agent of the state retained by the state.[120] In *Stoll v. Noel*, the Florida Supreme Court explained that independent contractor physicians may be agents of the state for purposes of sovereign immunity:

> One who contracts on behalf of another and subject to the other's control except with respect to his physical conduct is an agent and also independent contractor.[121]

The court examined the employment contract between the physicians and the state to determine whether the state's right to control was sufficient to create an agency relationship and held that it did.[122] The court explained:

> Whether CMS [Children's Medical Services] physician consultants are agents of the state turns on the degree of control retained or exercised by CMS. This Court has held that the right to control depends upon the terms of the employment contract. . . . CMS requires each consultant, as a condition of participating in the CMS program, to agree to abide by the

[118] Section 768.28(5), F.S.
[119] *Id.*
[120] *Stoll v. Noel*, 694 So. 2d 701, 703 (Fla. 1997).
[121] *Id.* at 703, quoting from the *Restatement (Second) of Agency* s. 14N (1957).
[122] *Id.* at 703.

terms published in its HRS[123] Manual and CMS Consultant's Guide which contain CMS policies and rules governing its relationship with the consultants. The Consultant's Guide states that all services provided to CMS patients must be authorized in advance by the clinic medical director. The language of the HRS Manual ascribes to CMS responsibility to supervise and direct the medical care of all CMS patients and supervisory authority over all personnel. The manual also grants to the CMS medical director absolute authority over payment for treatments proposed by consultants. The HRS Manual and the Consultant's Guide demonstrate that CMS has final authority over all care and treatment provided to CMS patients, and it can refuse to allow a physician consultant's recommended course of treatment of any CMS patient for either medical or budgetary reasons.

Our conclusion is buttressed by HRS's acknowledgement that the manual creates an agency relationship between CMS and its physician consultants, and despite its potential liability in this case, HRS has acknowledged full financial responsibility for the physicians' actions. HRS's interpretation of its manual is entitled to judicial deference and great weight.[124]

III. Effect of Proposed Changes:

Dental Care Access Accounts Initiative

The bill creates the dental care access accounts initiative at the Department of Health (DOH). The initiative is conditioned on the availability of funds and is intended to encourage dentists to practice in dental health professional shortage areas or medically underserved areas or serve a medically underserved population. The bill defines several key terms:

- Dental health professional shortage area: A geographic area so designated by the Health Resources and Services Administration of the U.S. Department of Health and Human Services;
- Medically underserved area: A designated health professional shortage area that lacks an adequate number of dental health professionals to serve Medicaid and other low income patients; and
- Public health program: A county health department, the Children's Medical Services program, a federally qualified community health center, a federally-funded migrant health center, or other publicly-funded or not-for-profit health care program designated by the DOH.

The initiative will be developed by the DOH to benefit dentists licensed to practice in this state who demonstrate, as required by DOH rule:

[123] Florida Department of Health and Rehabilitative Services.
[124] *Stoll*, 694 So. 2d at 703 (Fla. 1997) (internal citations omitted).

- Active employment by a public health program in a dental health professional shortage area or a medically underserved area; or
- A commitment to opening a private practice in a dental health professional shortage area or medically underserved area by residing in the area, maintaining a Medicaid provider agreement, enrolling with one or more Medicaid managed care plans, expending capital to open an office to serve at least 1,200 patients, and obtaining community financial support.

The DOH is required to establish dental access accounts for dentists who meet the requirements in the bill and to implement an electronic benefits transfer system. The bill requires that no more than 10 new dental care access accounts may be established per fiscal year. Funds from an account may be used only for specific purposes, such as payment of student loans; investment in property, facilities, or equipment necessary to establish an office and payment of transitional expenses related to relocating or opening a dental practice.

Subject to available appropriations, the DOH is required to distribute funds to the dental access accounts in amounts not to exceed $100,000 and no less than $10,000. A state award may not exceed three times the amount contributed to an account in the same year from a local source. The DOH is authorized to accept funds for deposit from local sources.

If a dentist qualifies for an account on the basis of his or her employment with a public health program, the dentist's salary and associated employer expenditures may count as local match for a state award if the salary and employer expenditures are not state funds. State funds may not be used to calculate amounts contributed from local sources.

Accounts may be terminated if the dentist no longer works for a public health program and does not open a dental practice in a designated area within 30 days of terminating employment, the dentist's practice is no longer located in a dental professional shortage area or a medically underserved area, the provider has been terminated from Medicaid, or the provider has participated in any fraudulent activity. The DOH is directed to close an account five years after the first deposit or upon a dentist's termination from the program.

Any remaining funds after five years or from terminated accounts may be awarded to another account or returned to the donor. A dentist is required to repay any funds withdrawn from the account after the occurrence of an event which requires account closure, if the dentist fails to maintain eligibility for the program through employment in a public health program or establishing a dental practice for a minimum of two years, or uses the funds for unauthorized purposes. The DOH is authorized to recover the withdrawn funds through disciplinary enforcement actions and other methods authorized by law.

The DOH is authorized to adopt rules for application procedures that:

- Limit the number of applicants;
- Incorporate a documentation process for evidence of sufficient capital expenditures in opening a dental practice, such as contracts or leases or other acquisitions of a practice location of at least 30 percent of the value of equipment or supplies necessary to operate a practice; and
- Give priority to those applicants practicing in the areas receiving higher rankings by the Department of Economic Opportunity.

The DOH may also establish by rule a process to verify that funds withdrawn from an account have been used for the purposes authorized.

The Department of Economic Opportunity is directed to rank the dental professional shortage areas and medically underserved areas based on the extent to which limited access to dental care is impeding economic development.

The DOH must develop a marketing plan for the dental care access account initiative with the University of Florida's College of Dentistry, the Nova Southeastern College of Dental Medicine, the Lake Erie College of Osteopathic Medicine's School of Dental Medicine, and the Florida Dental Association.

Beginning in January 2018, the DOH is required to issue a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives which must include:

- The number of patients served by dentists who receive funding under the bill;
- The number of Medicaid recipients served by dentists who receive funding under the bill;
- The average number of hours worked and patients served per week by dentists who receive funding under the bill;
- The number of dentists in each dental health professional shortage area or medically underserved area who receive funding under the bill;
- The amount and source of local matching funds received by the DOH;
- The amount of state funds awarded to dentists under the bill; and
- A complete accounting of the use of funds, by categories identified by the DOH, including, but not limited to, loans, supplies, equipment, rental property payments, real property purchases, and salary and wages.

The DOH is directed under the bill to adopt rules to require dentists to report information to the DOH that is necessary for the DOH to fulfill the reporting requirement.

Ambulatory Surgical Centers

The bill amends the definition of "ambulatory surgical center" in s. 395.002, F.S., to allow a patient to be admitted and discharged from an ASC within 24 hours. Current law requires that patients be discharged from an ASC within the same working day and restricts patients from staying at an ASC overnight.

The bill also amends s. 395.003, F.S., to require, as a condition of licensure, that ASCs provide services to Medicaid and Medicare patients and to patients who qualify for charity care. The bill defines "charity care" as uncompensated care delivered to uninsured patients having incomes at or below 200 percent of the federal poverty level when such services are preauthorized by the licensee and not subject to collection procedures.

The bill also includes conforming changes for statutory cross-references.

Direct Primary Care

The bill creates s. 624.27, F.S., relating to the application of the Florida Insurance Code (code) to direct primary care agreements. The bill creates the following definitions:

- "Direct primary care agreement" is a contract between a primary care provider and a patient, the patient's legal representative, or an employer which must satisfy certain requirements within the bill and does not indemnify for services provided by a third party.
- "Primary care provider" is a licensed health care practitioner under ch. 458 (medical doctor or physician assistant), ch. 459 (osteopathic doctor or physician assistant), ch. 460 (chiropractic physician), or ch. 464, F.S., (nurses and advanced registered nurse practitioners), or a primary care group practice that provides medical services which are commonly provided without referral from another health care provider.
- "Primary care service" is the screening, assessment, diagnosis, and treatment of a patient for the purpose of promoting health or detecting and managing disease or injury within the competency and training of the primary care provider.

The bill provides that a direct primary care agreement is not insurance and entering into such an agreement is not the business of insurance. The bill exempts both the agreement and the activity of entering into a direct primary care agreement from the code. Through the exemption, the bill eliminates any authority of Office of Insurance Regulation to regulate a direct primary care agreement or the act of entering into such an agreement. The bill also exempts a primary care provider, or his or her agent, from certification or licensing requirements under the code to market, sell, or offer to sell a direct primary care agreement.

The bill requires a direct primary care agreement to:

- Be in writing;
- Be signed by the primary care provider, or his or her agent, and the patient, or the patient's legal representative, or an employer;
- Allow a party to terminate the agreement by giving the other party at least 30 days advanced written notice;
- Provide for the immediate termination of the agreement if the physician-patient relationship is violated or a party breaches the terms of the agreement;
- Describe the scope of services that are covered by the monthly fee;
- Specify the monthly fee and any fees for primary care services not covered by the monthly fee;
- Specify the duration of the agreement and any automatic renewal provisions; and
- Provide for a refund to the patient of monthly fees paid in advance if the primary care provider stops offering primary care services for any reason.

The bill also requires the agreement to contain in contrasting color and 12-point or larger type, and on the same page as the applicant's signature, the following statements:

- The agreement is not health insurance and the primary care provider will not file any claims against any health insurance or reimbursement plans the patient may have for any primary care services covered by the agreement; and
- The agreement does not qualify as minimum essential coverage to satisfy the individual shared responsibility provision of the PPACA.

Right Medicine Right Time Act

The bill specifies that the amendments made by the bill to ss. 409.967, 627.42392, 641.31, and 641.394, F.S., may be known as the "Right Medicine Right Time Act."

The bill amends s. 409.967, F.S., and creates ss. 627.42392 and 641.394, F.S., respectively, relating to Medicaid managed care plans, insurers, and HMOs, that utilize a fail-first protocol. The bill requires Medicaid managed care plans, HMOs, and insurers that restrict medications by a step-therapy or fail-first protocol to have a clear and convenient process to request an override of the protocol. The bill requires these entities to grant an override of the protocol within 24 hours if, based on sound clinical evidence or medical and scientific evidence, the prescribing provider:

- Concludes that the preferred treatment required under the fail-first protocol has been ineffective in the treatment of the enrollee's disease or medical condition; or
- Believes that the preferred treatment required under the fail-first protocol is likely to be ineffective given the known relevant physical or mental characteristics and medical history of the enrollee and the known characteristics of the drug regimen, or will cause or is likely to cause an adverse reaction or other physical harm to the enrollee.

The bill requires that the duration of treatment may not exceed a period deemed appropriate by the prescribing provider, if the provider follows the fail-first protocol recommended by the managed care plan for an enrollee. Following such period, if the prescriber deems the treatment provided under the protocol clinically ineffective, the enrollee is entitled to receive the course of therapy that the prescribing provider recommends, and the provider is not required to seek approval of an override of the fail-first protocol.

The bill amends s. 641.31, F.S., to prohibit an HMO from requiring a health care provider to use a clinical decision support system or a laboratory benefits management program before the provider may order clinical laboratory services or in an attempt to direct or limit the provider's medical decision-making relating to the use of such services. The term, "clinical decision support system," means software designed to direct or assist clinical decision-making by matching the characteristics of an individual patient to a computerized clinical knowledge base and providing patient-specific assessments or recommendations based on the match. The term, "laboratory benefits management program," means an HMO protocol that dictates or limits health care provider decision-making relating to the use of clinical laboratory services. Further, the term, "clinical laboratory services" is defined. The bill specifies that this provision does not prohibit prior authorization requirements that the HMO has regarding the provision of clinical laboratory services.

Free and Charitable Clinics

The bill authorizes a free clinic to receive and use appropriations or grants from a governmental entity or nonprofit corporation to support the delivery of contracted services by volunteer health care providers under the Access to Health Care Act without those funds being deemed compensation which might jeopardize the sovereign immunity protections afforded in the act. The bill authorizes these appropriations or grants to be used for the employment of health care

providers to supplement, coordinate, or support the delivery of services by volunteer health care providers. The receipt and use of the appropriation or grant, according to the bill, does not constitute the acceptance of compensation for the specific services provided to the low-income recipients covered by the contract.

The bill inserts the phrase "employees or agents" in several provisions in the act to clarify that employees and agents of a health care provider, which typically are paid by a health care provider, fall within the sovereign immunity protections of the contracted health care provider when acting pursuant to the contract.

Additionally, a pharmacy or pharmacist licensed under chapter 465, the pharmacy act, is granted sovereign immunity under the bill. This is done by including a pharmacy or pharmacist in the definition of a "health care provider" or "provider."

Current law requires the governmental contractor to provide written notice to each patient, or the patient's legal representative that the provider is an agent of the governmental contractor and that the exclusive remedy for injury or damage suffered as the result of any act or omission of the provider or of any employee or agent thereof acting within the scope of duties pursuant to the contract, is by commencement of an action pursuant to the provisions of s. 768.28, F.S.

The bill requires the patient, or the patient's legal representative, to acknowledge in writing receipt of the notice of agency relationship between the government contractor and the health care provider at the initial visit only. Thereafter, the notice requirement is met by posting the notice in a place conspicuous to all persons. According to a DOH analysis of this provision, patients are currently informed that the provider is an agent of a governmental contractor at each visit.

Section 768.28, F.S., which pertains to the waiver of sovereign immunity in tort actions, is amended to specifically include a health care provider's employees or agents in the definition of an "officer, employee, or agent." This is done to avoid any potential ambiguity between the provisions in that section of law and the Access to Health Care Act.

Except as otherwise expressly provided, the bill has an effective date of July 1, 2016.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Dental Care Access Accounts Initiative

Under CS/CS/SB 212, Floridians living in those areas identified as medically underserved and have little or no access to dental care could benefit from this initiative. The program could bring additional dental professionals to underserved communities. The initiative also permits the grantees to utilize the funds to transition or relocate to new areas and to build or renovate office space in rural communities, which would generate economic growth for small towns and cities. Additionally, dentists who qualify for loan repayment assistance will benefit from a reduction in their student loan debt.

Ambulatory Surgical Centers (ASCs)

The bill may have an indeterminate positive fiscal impact on patients in Florida who are able to have a surgical procedure performed in an ASC if the costs are less in these settings than in a hospital.

The bill may have an indeterminate negative fiscal impact on hospitals if more patients choose to have their procedures performed in an ASC rather than in a hospital.

The bill may have a negative fiscal impact on ASCs that are required to provide services to Medicare and Medicaid patients as well as patients who qualify for charity care if the ASCs do not currently provide such services.

Direct Primary Care

The bill removes regulatory uncertainty for health care providers by stating that the direct primary care agreement is not insurance and as a result not regulated by the Office of Insurance Regulation. Additional primary care providers may elect to pursue a direct primary care model and establish direct primary care practices which may increase access to affordable primary care services.

Right Medicine Right Time Act

Implementation of the bill may provide health care providers with a greater number of prescription drugs to meet the unique medical needs of their patients and reduce the administrative burden associated with current step therapy or fail first therapy protocols.

To the extent that current step therapy policies contribute to increased costs from increased inpatient admissions and hospital emergency visits, the bill may serve to reduce those costs.

Medicaid managed care plans, insurers, and Health Maintenance Organizations may experience an indeterminate increase in costs associated with changes in the step therapy protocols provided in the bill. These cost increases are likely to pass through to the purchasers of health insurance, such as individuals and employers.

The provisions of the bill would not apply to self-insured health plans since plans are preempted from state regulation under the Employee Retirement Income Security Act of 1974. In Florida, an estimated 60 percent of private-sector enrollees obtain coverage through a self-insured plan.

Free and Charitable Clinics

Contracted free clinics may receive governmental funding in the form of an appropriation or grant without the concern of restrictions on such funding for certain uses that might be imposed by the act. The receipt of any such funding is speculative at this point, and therefore, the amount is indeterminate.

Private health care providers currently delivering services to uninsured individuals may see a reduction in their uncompensated care costs as these individuals seek care in these clinics with expanded resources.

C. Government Sector Impact:

Dental Care Access Accounts Initiative

If the dental care access accounts initiative receives an appropriation, the bill will create a fiscal impact to the Department of Health (DOH) in order to implement and manage the initiative. The estimated cost is $306,064 for the 2016-2017 fiscal year with a recurring cost of $277,296 beginning with Fiscal Year 2017-2018. These costs would need to be funded with general revenue.

The initial cost for the electronic benefit transfer (EBT) contract/vendor is estimated at $100,000 for the first year and $50,000 for the second year. The DOH reports that there is a current EBT system that could be used to implement this system, but it is unknown if it could accommodate all of the provisions of this bill. The EBT systems charge a nominal fee of approximately $0.50 per participant per month as a maintenance fee. The DOH also anticipates a withdrawal fee of at least $1 per transaction when a dentist makes a withdrawal from his or her account.

The number of dentists qualifying for this initiative is unknown.[125] However, the DOH estimates at least 32 dentists could be served annually. The cost of the EBT system would have to be negotiated based on the number of dentists participating in the program.

[125] Florida Dept. of Health, *Senate Bill Analysis 234,* pp.4-5, (Sept. 24, 2015) (on file with the Senate Committee on Health Policy).

The DOH also reports the bill will create a workload impact that current staff is unable to meet. Two additional full-time equivalent (FTE) staff members would be required to develop the application process and adopt rules. Staff will also be needed to monitor activity, dentist conduct, dentist membership status, and rulings by the Board of Dentistry on recipients.

The following are the estimated expenditures for the DOH:[126]

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

*The DOH is also directed to develop a marketing plan with Florida-based dental schools.

[126] *Id., at p 2.*

Right Medicine Right Time Act

Medicaid

The Agency for Health Care Administration indicates that the fiscal impact to Florida Medicaid under the provisions and language of the bill is indeterminate. If the bill is enacted, it may have an operational and fiscal impact on the Florida Medicaid program, as it establishes an enrollee entitlement to a prescription after one use of the fail-first protocol and exempts the provider from seeking an override of the fail-first protocol. It is unclear how the bill applies if the health plans themselves do not have restrictions. This will not allow managed care plans to apply the medical necessity definition or utilization management criteria for any prescribed treatment subsequent to the first prescription utilized under the fail-first protocol.[127]

Division of State Group Insurance

According to the Department of Management Services, with regard to the fail-first protocol (step-therapy) override process requirement for insurers and HMOs, the bill does not affect the state group insurance prescription drug program, as step-therapy is not currently a provision of the plan design.

Further, the DMS states that the provision in the bill that prohibits HMOs from requiring health care providers to use a clinical decision support system or a laboratory benefits management program, to direct or limit provider's decision-making ability could affect the state group health insurance program. Changes to current medical management procedures that cause an HMO's medical costs to increase would result in higher negotiated premiums for the state-contracted HMOs.[128]

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates the following sections of the Florida Statutes: 381.4019, 624.27, 627.42392, and 641.394.

This bill substantially amends the following sections of the Florida Statutes: 395.002, 395.003, 409.967, 641.31, 766.1115, and 768.28.

[127] Agency for Health Care Administration, *Senate Bill 1084 Fiscal Analysis* (Jan. 13, 2016) (on file with the Senate Committee on Banking and Insurance).
[128] Department of Management Services, *Senate Bill 1084 Fiscal Analysis* (Jan. 14, 2016) (on file with the Senate Committee on Banking and Insurance).

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS/CS by Appropriations on February 25, 2016:
The committee substitute:

- Authorizes the creation of joint state and local dental care access accounts to promote local economic development and to encourage Florida-licensed dentists to practice in dental health professional shortage areas or medically underserved areas, or serve a medically underserved population, subject to the availability of funds;
- Creates a new section of the Florida Statutes relating to direct primary care, provides that a direct primary care agreement is not insurance and is not subject to the Florida Insurance Code, and specifies certain provisions that must be included in a direct primary care agreement;
- Requires Medicaid managed care plans, Health Maintenance Organizations (HMOs), and insurers that restrict medications by a step-therapy or fail-first protocol to have a clear and convenient process to request an override of the protocol, which must be granted within 24 hours if the treating physician determines that certain conditions are met;
- Prohibits an HMO from requiring a health care provider to use a clinical decision support system or a laboratory benefits management program before the provider may order clinical laboratory services or in an attempt to direct or limit the provider's medical decision-making relating to the use of such services;
- Allows a free clinic that engages volunteer health care providers, to receive a grant or legislative appropriation to support the delivery of services while retaining the sovereign immunity protections under existing law and allows such financial support to be used to employ providers to supplement, coordinate, or otherwise support the volunteers;
- Expands the definition of a health care provider or provider in the Access to Health Care Act to include a pharmacy or licensed pharmacist, and a pharmacy or pharmacist providing services under the Access to Health Care Act is given sovereign immunity as an agent of the state; and
- Provides that employees and agents of the free clinics are protected from lawsuits under the state's sovereign immunity protections.

CS by Health Policy on January 19, 2016:
The CS amends SB 212 to remove all provisions of the bill except a change to the definition of "ambulatory surgical center" which allows patients to recover in an ASC for 24 hours, rather than requiring that patients be released on the same business day. The CS also requires that ASCs provide services to Medicaid and Medicare patients as well as patients who qualify for charity care. The CS defines "charity care" as uncompensated care delivered to uninsured patients having incomes at or below 200 percent of the federal poverty level when such services are preauthorized by the licensee and not subject to collection procedures.

B. Amendments:

None.