Health Innovation Subcommittee

Wednesday, February 22, 2017
3:30 PM – 6:00 PM
Mashburn Hall

Richard Corcoran
Speaker

MaryLynn Magar
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Innovation Subcommittee

Start Date and Time:	Wednesday, February 22, 2017 03:30 pm
End Date and Time:	Wednesday, February 22, 2017 06:00 pm
Location:	Mashburn Hall (306 HOB)
Duration:	2.50 hrs

Consideration of the following bill(s):

HB 95 Consumer Protection from Nonmedical Changes to Prescription Drug Formularies by Massullo
HB 449 Health Insurance by Renner
HB 543 Regulation of Nursing by Pigman
HB 589 Prescription Drug Price Transparency by Yarborough

Consideration of the following proposed committee bill(s):

PCB HIS 17-01 -- Medicaid Block Grants

Pursuant to rule 7.11, the deadline for amendments to bills on the agenda by non-appointed members shall be 6:00 p.m., Tuesday, February 21, 2017.

By request of the Chair, all committee members are asked to have amendments to bills on the agenda submitted to staff by 6:00 p.m., Tuesday, February 21, 2017.

NOTICE FINALIZED on 02/15/2017 4:01PM by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: PCB HIS 17-01 Medicaid Block Grants
SPONSOR(S): Health Innovation Subcommittee
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
Orig. Comm.: Health Innovation Subcommittee		Calamas	Poche

SUMMARY ANALYSIS

The Medicaid program is a partnership between the federal government and the states in which the federal government makes matching funds available for state health care expenditures for certain low-income residents. The program design is largely prescribed by federal laws and regulations, which may be waived in certain, limited circumstances.

The proposed memorial urges the U.S. Congress to implement the Medicaid program through per capita block grants to the states, including a rate of growth and various adjustments for risk and enrollee income, and including state authority to design programs without reference to current federal Medicaid laws and regulations.

Copies of the memorial will be sent to the President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, and to each member of the Florida delegation to the United States Congress.

Legislative memorials are not subject to the Governor's veto power and are not presented to the Governor for review. Memorials have no force of law, as they are mechanisms for formally petitioning the federal government to act on a particular subject.

The proposed memorial does not have a fiscal impact on state or local governments.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Medicaid Overview

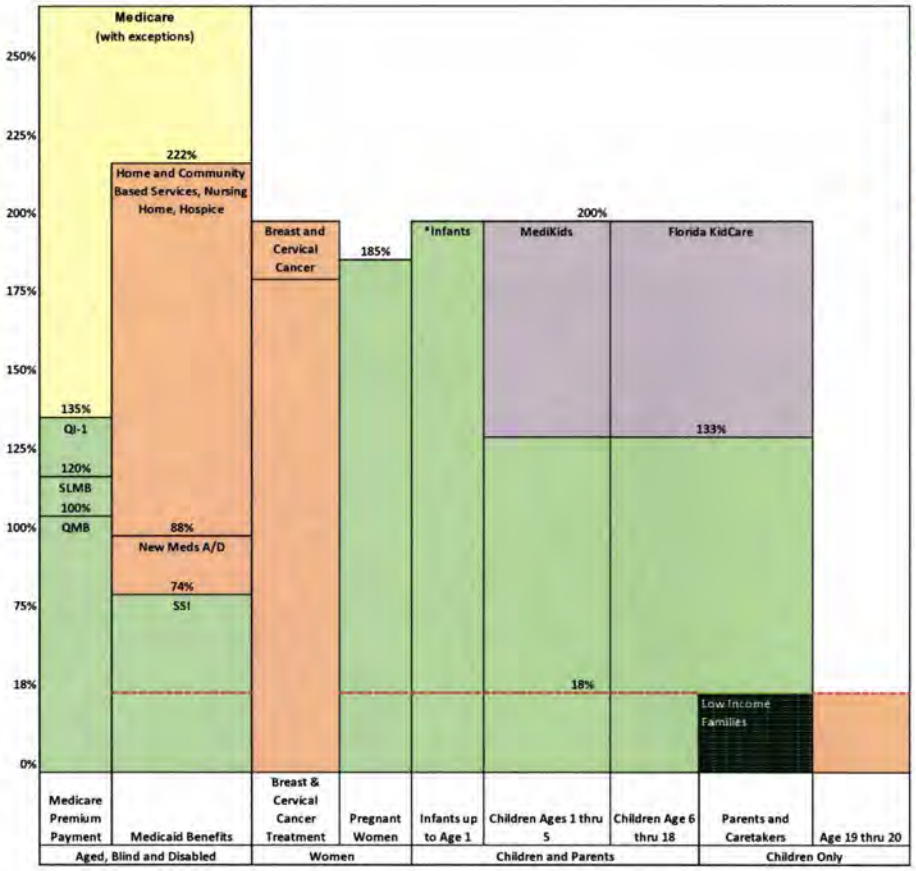
Medicaid is the health care safety net for low-income Floridians. Medicaid is a partnership of the federal and state governments established to provide coverage for health services for eligible persons. The program is administered by the Agency for Health Care Administration (AHCA) and financed by federal and state funds. AHCA delegates certain functions to other state agencies, including the Department of Children and Families, the Agency for Persons with Disabilities, and the Department of Elderly Affairs.

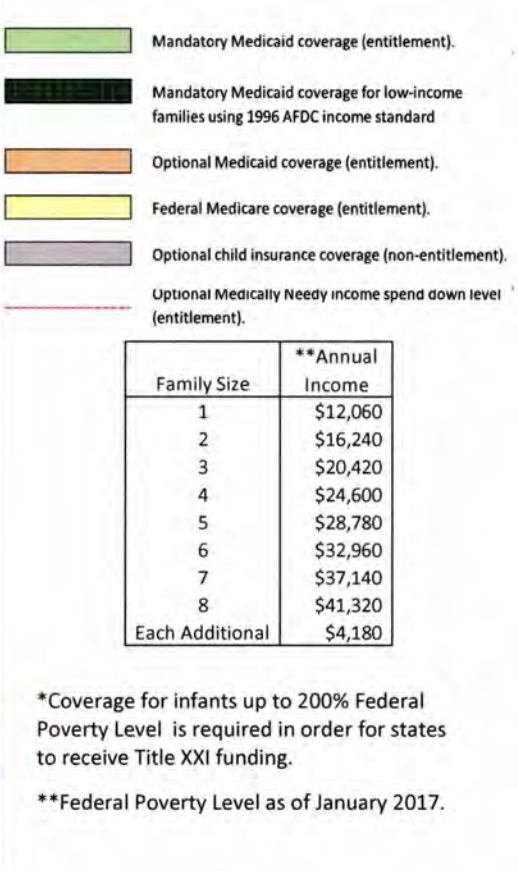
The Florida Medicaid program covers 1.7 million low-income adults (parents, aged and disabled) and 2.3 million children, or 46.8% of the children in Florida. Approximately 85% of the Medicaid population is enrolled in Medicaid Managed Care. Approximately 61% of all nursing home days are covered by Medicaid, and 62.8% of childbirths/deliveries are covered by Medicaid.

The structure of each state's Medicaid program varies and what states must pay for is largely determined by the federal government, as a condition of receiving federal funds.[1] Federal law sets the amount, scope, and duration of services offered in the program, among other requirements. These federal requirements create an entitlement that comes with constitutional due process protections. The entitlement means that two parts of the Medicaid cost equation – people and utilization – are largely predetermined for the states: Some populations are entitled to enroll in the program; and enrollees are entitled to certain benefits.

The federal government sets the minimum mandatory populations to be included in every state Medicaid program. In the chart below, the yellow and light green sections are mandatory populations by federal law. States can add eligibility groups, with federal approval. In the chart below, the orange sections show the groups Florida has added over the years. Once these optional groups are part of the Medicaid program the entitlement applies to them as well.

[1] See, Title 42 U.S.C. §§ 1396-1396w-5; Title 42 C.F.R. Part 430-456 (§§ 430.0-456.725) (2016).





Family Size	**Annual Income
1	$12,060
2	$16,240
3	$20,420
4	$24,600
5	$28,780
6	$32,960
7	$37,140
8	$41,320
Each Additional	$4,180

*Coverage for infants up to 200% Federal Poverty Level is required in order for states to receive Title XXI funding.

**Federal Poverty Level as of January 2017.

The federal government sets the minimum mandatory benefits to be covered in every state Medicaid program. These benefits include physician services, hospital services, home health services, and family planning.[2] States can add benefits, with federal approval. Florida has added many optional benefits, including prescription drugs, adult dental services, and dialysis.[3]

States do have some flexibility. States can ask the federal government to waive federal requirements to expand populations or services, or to try new ways of service delivery. For example, Florida has an 1115 waiver to use a comprehensive managed care delivery model for primary and acute care services, so-called because it is authorized by Section 1115 of the federal Social Security Act. Similarly, Florida also has a waiver under Sections 1915(b) and 1915(c) of the Social Security Act for the long-term care managed care program. However, waiver authorities are limited and federal laws and regulations are extensive; states do not have the flexibility to design any type of low-income health care program they choose. In addition, waivers require extensive negotiation with the federal Centers for Medicare and Medicaid Services, which depending on the waiver type, is not obligated to respond on any specific timeline.

Florida Medicaid is the second largest single program in the state, behind public education, representing 31 percent of the total FY 2016-2017 budget. Medicaid expenditures represent over 19 percent of the total state funds appropriated in FY 2016-2017. **Florida's program is the 4th largest in the nation** by enrollment, and the 6th largest in terms of expenditures.[4]

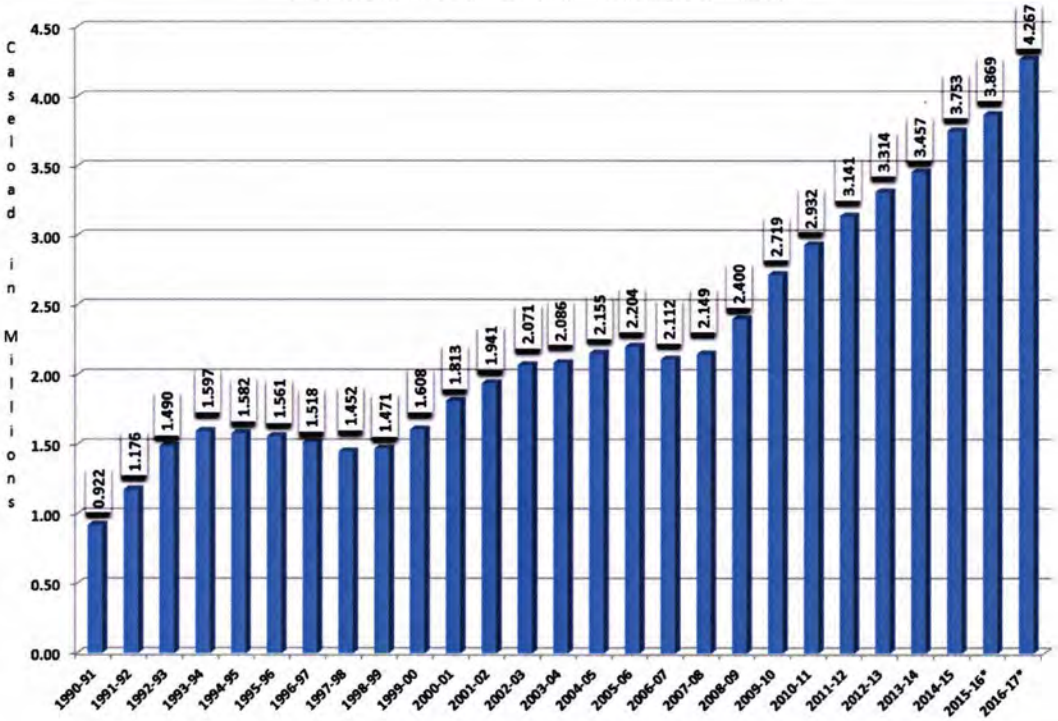
[2] S. 409.905, F.S.

[3] S. 409.906, F.S.

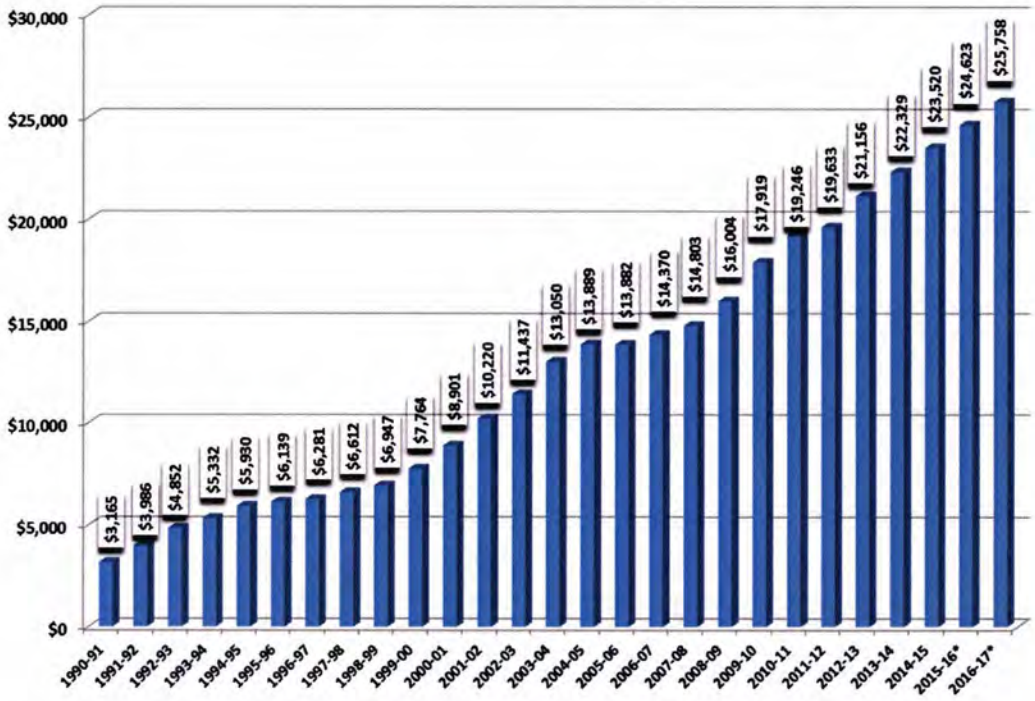
[4] The Henry J. Kaiser Family Foundation, State Health Facts, Total Medicaid Spending FY 2015 and Total Monthly Medicaid and CHIP Enrollment Nov. 2016, available at http://kff.org/statedata/.

Florida's Medicaid costs have increased significantly since its inception in 1967, due to substantial eligibility expansion as well as the broad range of services and programs funded by Medicaid expenditures. The growth in Florida's Medicaid population and expenditures since 1990 is shown in the figures below.

Growth in Medicaid Caseload[5], 1990-2017



Growth in Medicaid Expenditures[6], 1990-2017



[5] Caseloads budgeted in the General Appropriations Act.

[6] General Appropriations Act.

Medicaid Financing

In addition to prescribing the terms of the program, the federal government provides significant funding for state Medicaid programs. Federal funds come in the form of a match for state expenditures. The matching rate, called the Federal Medical Assistance Percentage (FMAP), is set annually by the federal government based on each state's per capita income relative to the national average. States with lower per capita incomes receive higher FMAP, while states with higher per capita incomes receive a lower FMAP. Nationally, the 2017 FMAPs range from 50% (13 states) to 74.63% (Mississippi).[7] Florida's 2017 FMAP is 61%: the federal government pays 61 cents and Florida pays 39 cents of every dollar spent.

The FMAP funding mechanism has no upper limit; whatever amount states choose to spend, the federal government will match. Some policy analysts indicate that this incentivizes states to move state health care expenditures into the Medicaid program, to draw down federal funds and reduce state costs.[8] Conversely, the FMAP funding mechanism means states must share spending reductions with the federal government. This reduces state incentives to pursue improved delivery models that reduce catastrophic or unnecessary spending[9], even assuming such models would be approved by the federal government.

Medicaid Block Grants and Per Capita Spending Models

In general, a block grant is a finite sum of federal funds granted to states for a particular purpose. Unlike mandatory, or entitlement, programs, which obligate the federal government to provide funding for a benefit with no limit on that funding, a block grant is a mechanism to fund a non-entitlement program that provides the federal government greater budget certainty and increases state incentives to control costs[10], while giving states complete flexibility to design the program. Rather than funding increasing (or decreasing) according to state need, the fixed-amount nature of a traditional block grant means benefits and enrollment increase or decrease, rather than funding.

Traditional block grant proposals control costs by imposing hard caps on federal investments.[11] Critiques of such proposals assume they will result in reduced enrollment and benefits, and in cost-shifting to states.[12] However, whether block grants succeed at reducing the rate of cost growth while maintaining an acceptable level of enrollment and service depends on their design.[13]

A variant of a block grant is a per capita funding model. Rather than setting a match rate based on state per capita income, the federal government would set a per enrollee defined contribution. The

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[7] U.S. Dept. of Health & Human Svcs., FY2017 Federal Medical Assistance Percentages, available at https://aspe.hhs.gov/basic-report/fy2017-federal-medical-assistance-percentages (last viewed Feb. 18, 2017).

[8] Joseph Antos, et al., *Improving Health and Health Care: An Agenda for Reform*, AM. ENTERPRISE INST. (Dec. 9 2015), http://www.aei.org/publication/improving-health-and-health-care/; John C. Goodman & Peter Ferrara, *Health Care for All without the Affordable Care Act*, NAT'L CENTER FOR POL'Y ANALYSIS (Oct. 17, 2012), http://www.ncpa.org/pub/ib116; Linda Gorman, *Medicaid Block Grants and Medicaid Performance*, INDEPENDENCE INST. (Mar. 2012), https://www.i2i.org/medicaid-block-grants-and-medicaid-performance/.

[9] Id.

[10] Lambrew, Jeanne M., *Making Medicaid a Block Grant Program: An Analysis of the Implications of Past Proposals*, MILBANK Q. 2005 Mar; 83(1): 41–63 at 41.

[11] See, e.g., S 1377, 97th Congress; H.R. 2425, 104th Congress; Bush FY 2004 Medicaid and SCHIP Budget, White House Office of Management and Budget, February 2003, available at http://www.policyalmanac.org/health/archive/medicaid_budget_FY04.shtml.

[12] See, e.g., Edwin Park, *Medicaid Block Grant Would Slash Federal Funding, Shift Costs to States, and Leave Millions More Uninsured*, Center on Budget and Policy Priorities, Nov. 30, 2016, available at http://www.cbpp.org/research/health/medicaid-block-grant-would-slash-federal-funding-shift-costs-to-states-and-leave.

Caroline Pearson, *Capped Funding in Medicaid Could Significantly Reduce Federal Spending*, Avalere Health, Feb. 6, 2017, available at http://avalere.com/expertise/managed-care/insights/capped-funding-in-medicaid-could-significantly-reduce-federal-spending.

[13] Lambrew at 55.

defined contribution could vary by eligibility group, such that a larger contribution would be made for higher-cost enrollees (like disabled persons and frail elders), and a smaller contribution would be made for lower-cost enrollees (like children). The defined contribution could vary by enrollee income, as well, to incentivize states to provide for the most vulnerable low-income people before higher income groups.

In a per capita block grant model, states could supplement the federal contribution in any manner they choose, without affecting the federal contribution. States could vary the state investment by eligibility group, adjust the investment each year, or choose to pay more for one service or type of coverage than another.

A per capita block grant model would allow the program to accommodate variations in state demographics, such as Florida's disproportionately expanding elderly population. Similarly, states would not be harmed by economic downturns that increase enrollment as might occur with a capped block grant model; states could accommodate such events at the level they choose.

A reasonable, predictable funding mechanism that no longer incentivizes state cost-shifting to the federal government, with significant flexibility as to program design could encourage states to make more rational, efficient spending choices, which could reduce the rate of cost growth more naturally than a hard federal cap. In this model, federal cost savings would result not from hard caps, but from state innovation.

Currently, federal Medicaid laws do not authorize block grants, in traditional or per capita form. They can only be authorized by action of the U.S. Congress.

Effect of Proposed Memorial

The proposed memorial urges the U.S. Congress to establish Medicaid block grants. The proposed memorial outlines a broad structure for such block grants, requesting Congress to provide block grants based on risk-adjusted, income-adjusted per capita amounts. The proposed memorial requests Congress to index such per capita amounts for inflation, which builds in a rate of growth separate from enrollment. The proposed memorial does not specify the type of inflation to be used for indexing; possible options for negotiation include (but are not limited to) general inflation and medical inflation.

Consumer Price Index Annual Percent Change (U.S. City Average)[14]

Year	Medical Care	All Items
2007	4.4	2.8
2008	3.7	3.8
2009	3.2	-0.4
2010	3.4	1.6
2011	3.0	3.2
2012	3.7	2.1
2013	2.5	1.5
2014	2.4	1.6
2015	2.6	0.1
2016	3.8	1.3
Jan. 2017	3.9	2.5

The proposed memorial urges Congress to allow states to design state Medicaid programs without reference to the requirements of current federal Medicaid laws and regulations, but which would be subject to monitoring by the federal government by measuring state progress at achieving mutually agreed-to outcome measures.

[14] U.S. Dept. of Labor, Bureau of Labor Statistics Data Series, available at https://www.bls.gov/data/ (data extracted Feb. 17, 2017).

The proposed memorial urges Congress to implement the block grants over several years. Copies of the memorial will be sent to the President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, and to each member of the Florida delegation to the United States Congress.

Legislative memorials are not subject to the Governor's veto power and are not presented to the Governor for review. Memorials have no force of law, as they are mechanisms for formally petitioning the federal government to act on a particular subject.

B. SECTION DIRECTORY:

Not applicable.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The proposed memorial contains a typographical error. It references Title XXI of the Social Security Act, rather than Title XIX, which is the correct reference to the Medicaid program.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

House Memorial

A memorial to the Congress of the United States, urging Congress to establish Medicaid block grants.

WHEREAS, the Florida Medicaid program covers over four million people at a cost of $25.8 billion in Fiscal Year 2016-2017, or 31 percent of the total state budget, and grows in cost and enrollment each year, and

WHEREAS, nationally, the vast majority of the increase in insurance coverage under the federal Patient Protection and Affordable Care Act is due to increased enrollment in Medicaid, not employer-based or other private coverage, and

WHEREAS, nationally, the Medicaid program is a stigmatizing welfare program that achieves poor quality outcomes and segregates taxpayer-supported, low-income patients from the health coverage market used by privately-supported patients, and

WHEREAS, the Medicaid program is a federally-proscribed, complex system of eligibility, financing, and service delivery models, subject to extensive, complicated, prescriptive and outdated federal laws and regulations, and

WHEREAS, opportunities for innovation and modernization are limited and only available through waivers of federal law awarded in an unpredictable manner after lengthy bureaucratic negotiations, and

WHEREAS, the current financing model of federal matching

funds encourages states to shift state spending into the Medicaid program, which both drives up costs and creates a perverse economic incentive such that states gain little benefit from efficiency and bear little risk for wasteful expenditures; and

WHEREAS, a reasonable, predictable funding mechanism that does not incentivize state spending increases will force states to make more rational, efficient spending choices, naturally reducing the rate of cost growth, and

WHEREAS, granting states complete flexibility with regard to eligibility, benefits and state investment, while holding states to mutually agreeable quality outcomes, will help states transform the Medicaid program into an innovative consumer-driven, free-market program that integrates enrollees into the larger health care system, NOW, THEREFORE,

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

That the Congress of the United States establish Medicaid block grants in lieu of Title XXI funding; and

That the Medicaid block grants shall consist of risk-adjusted, income-adjusted, per capita amounts for each state based on current federal funding and annually indexed for inflation; and

That the Medicaid block grants shall allow states to design

new Medicaid programs not subject to the requirements of Title XXI and regulations adopted thereunder, but which shall be subject to quality monitoring by the federal government based on mutually agreed-to outcome measures; and

That the Medicaid block grants shall be implemented in a multi-year transition to eliminate funding disparities between states.

BE IT FURTHER RESOLVED that copies of this memorial be dispatched to the President of the United States, to the President of the United States Senate, to the Speaker of the United States House of Representatives, and to each member of the Florida delegation to the United States Congress.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 95 Consumer Protection from Nonmedical Changes to Prescription Drug Formularies
SPONSOR(S): Massullo, MD and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 182

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Tuszynski	Poche
2) Insurance & Banking Subcommittee			
3) Appropriations Committee			
4) Health & Human Services Committee			

SUMMARY ANALYSIS

Spending on prescription drugs has risen sharply in the United States over the past few years. From 2013 to 2015, out-of-pocket costs for prescription drugs increased 20 percent. Additionally, prescription drug prices surged an average of almost 10 percent from June 2015 to May 2016.

In an attempt to contain prescription drug costs, insurers and pharmacy benefits managers (PBMs) manage lists of preferred drug products, known as formularies, in their plans. These formularies are typically three "tiered" formularies, meaning that the health plan enrollee or member would pay the lowest copayment for the first tier of prescription drugs, which are usually generics, a somewhat higher copayment for the second tier of prescription drugs, which are usually preferred brand name drugs without a generic equivalent, and the highest copayment for the third tier of drugs, usually non-preferred brand drugs or brand drugs with a generic equivalent. Insurers and PBMs employ a variety of formulary management techniques to contain prescription drug costs.

For most medicines, there exists several similar or alternative products; these can be either generic or a therapeutically equivalent drug. Therapeutic interchange, or non-medical switching, is the practice of switching or dispensing drugs that are chemically distinct but therapeutically similar in terms of their efficacy, safety, and tolerability. The stated goal of non-medical switching is to achieve an improved or neutral outcome with the new drug while reducing overall treatment costs. However, some studies show that non-medical switching can cause increased side-effects and lower efficacy for prescribed conditions, leading to increased health care utilization and an overall increase in health care costs.

HB 95 prohibits an individual or small group health insurer and a health maintenance organization (HMO) from removing a prescription drug from the formulary during the policy year. The bill provides two exceptions to this restriction: a prescription drug may be removed from the formulary during the policy year if the Food and Drug Administration (FDA) issues a statement questioning the safety of the drug or the manufacturer of a drug notifies the FDA that it is no longer manufacturing the drug or potentially plans on not manufacturing the drug.

The bill prohibits during a policy year an individual or small group health insurer or HMO from reclassifying a prescription drug to a more restrictive drug tier, increasing the amount that an insured must pay out-of-pocket for a copayment, coinsurance, or deductible for a prescription drug, or reclassifying a drug to a higher cost-sharing tier. The bill permits prescription drugs to be added to the list of prescription drugs covered during the policy year

The provisions of the bill do not apply to grandfathered health plans as defined under s. 627.402, F.S., or to limited benefit insurance products listed in s. 627.6513, F.S. Finally, the bill does not inhibit a pharmacist from substituting a generically equivalent drug for a brand name drug or dispensing a substitute biological product for the prescribed biological product.

The bill is expected to have a significant negative fiscal impact on the State Group Health Insurance Plan.

The bill provides an effective date of January 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

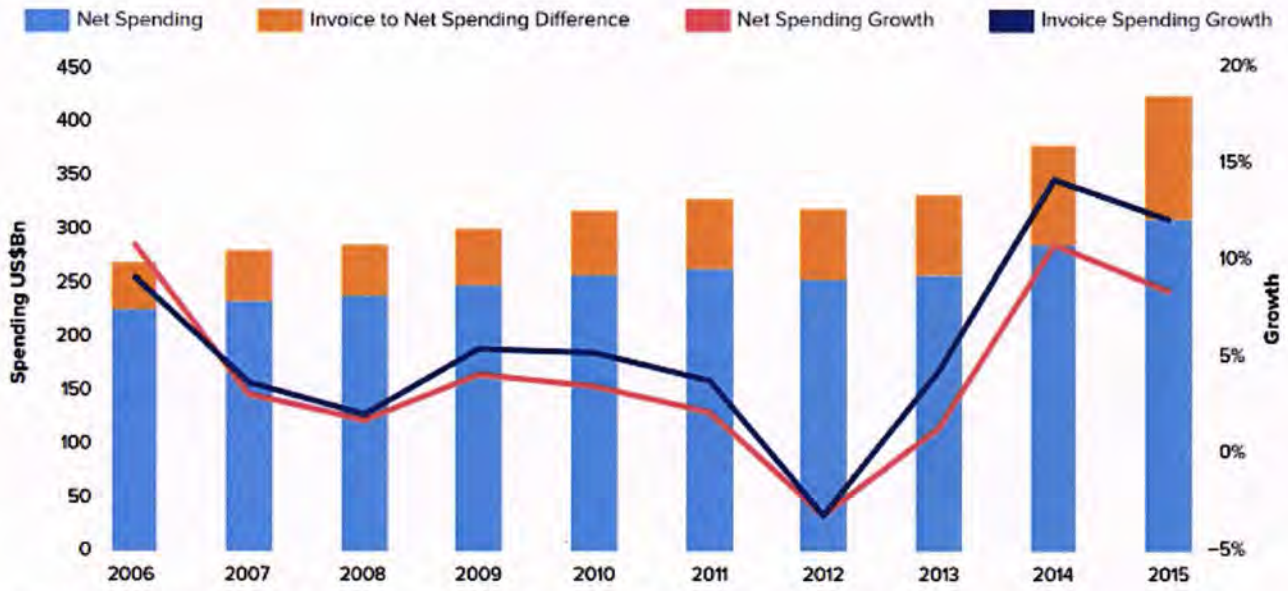
A. EFFECT OF PROPOSED CHANGES:

Present Situation

Prescription Drug Cost and Pricing

Spending on prescription drugs has risen sharply in the United States over the past few years.[1] From 2013 to 2015, out-of-pocket costs for prescription drugs surged 20 percent,[2] rising to an average cost of $44 per brand name prescription drug.[3] Additionally, prices increased an average of almost 10 percent from June 2015 to May 2016.[4] Specialty prescription drug prices are projected to increase 18.7 percent in 2017, accounting for 35 percent of the prescription drug spending trend even though they account for less than one percent of prescriptions.[5] Recent increases are not only an increase in spending in terms of dollars, but also as a percentage of total healthcare spending.[6]

Total Spending on Prescription Drugs[7]



Source: IMS Health, National Sales Perspectives, Jan 2016; U.S. Census Bureau; U.S. Bureau of Economic Analysis

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[1] Ameet Sarpatwari, Jerry Avorn, and Aaron S. Kesselheim, *State Initiatives to Control Medication Costs — Can Transparency Legislation Help?*, N. ENGL. J. MED. 2016; 374:2301-2304 Jun. 16, 2016, http://www.nejm.org/doi/full/10.1056/NEJMp1605100#t=article (last visited February 18, 2017).

[2] Troy Parks, *Drug pricing needs transparency, physicians say*, AMA WIRE, Jan. 26, 2017, https://wire.ama-assn.org/ama-news/drug-pricing-needs-transparency-physicians-say (last visited February 18, 2017).

[3] Beth Braverman, *Prescription Drug Prices Headed for Double-Digit Increases in 2017*, THE FISCAL TIMES, Oct. 24, 2016, http://www.thefiscaltimes.com/2016/10/24/Prescription-Drug-Prices-Headed-Double-Digit-Increases-2017 (last visited February 18, 2017).

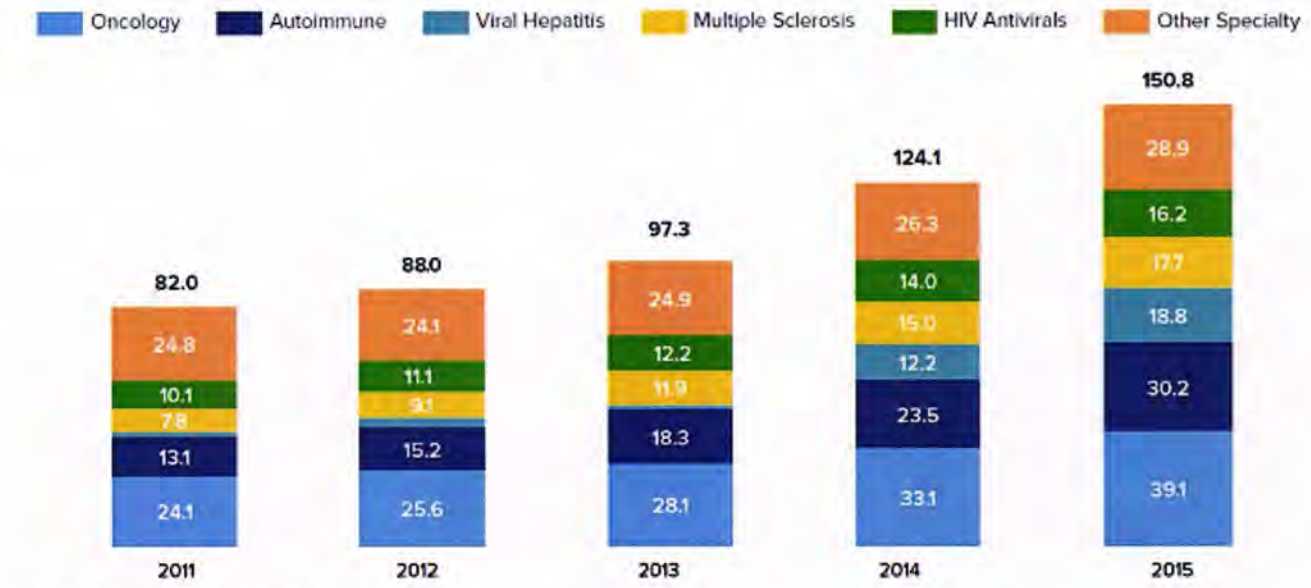
[4] Brad Tuttle, *Prescription Drug Prices in America Are Rising Like No Other Industry*, TIME, Jul. 14, 2016, http://time.com/money/4406167/prescription-drug-prices-increase-why/ (last visited February 18, 2017)

[5] Supra, FN 3. Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions and often require special handling and administration.

[6] Jonathan D. Rockoff, *How Do We Deal With Rising Drug Costs?,* THE WALL STREET JOURNAL, Apr. 10, 2016, https://www.wsj.com/articles/how-do-we-deal-with-rising-drug-costs-1460340357 (last visited February 18, 2017).

[7] *Medicines Use and Spending in the U.S. – A Review of 2015 and Outlook to 2020,* QUINTILESIMS, APR. 2016, http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020 (last visited February 18, 2017).

Spending on Specialty Prescription Drugs[8]



Source: IMS Health, National Sales Perspectives, Jan 2016

Pharmaceutical companies take into account a number of factors, including the market for the particular drug, the cost of comparative treatments, research and development costs, the price of manufacturing and ingredients, and profit maximization when deciding what price to set for their drugs.[9] The costs associated with developing a new prescription drug can be very high. A recent analysis by the Tufts Center for the Study of Drug Development of the average cost to develop and gain marketing approval for a new drug estimated the cost at $2.558 billion, and noted that when post-approval research and development activities were included, the cost rose to $2.870 billion.[10] The following factors increased clinical costs for prescription drug development:

- Increased clinical trial complexity;
- Larger clinical trial sizes;
- Higher input costs from the medical sector;
- Changes in protocol design to include efforts to gather health technology assessment information; and
- Testing on comparator drugs to accommodate payer demands for comparative effectiveness data.[11]

Per capita prescription drug spending in the United States exceeds that in all other countries, largely driven by brand-name drug prices that have been increasing in recent years at rates far beyond the consumer price index.[12]

In recent years, many innovative treatments for diseases that affect large populations, such as cancer, hepatitis C, diabetes, and multiple sclerosis have been approved. Some of the benefits of these

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[8] Id.
[9] *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System*, Special Committee On Aging, United States Senate (Dec. 2016), *available at,* https://www.collins.senate.gov/sites/default/files/DP%20Report.pdf (last visited February 18, 2017).
[10] Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, *Innovation in the pharmaceutical industry: New estimates of R&D costs*, Journal of Health Economics, Volume 47, pp. 20-33 (May 2016).
[11] Id.
[12] Aaron S. Kesselheim, Jerry Avorn, and Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform,* JAMA. 2016;316(8):858-871. doi:10.1001/jama.2016.11237.

innovative drugs include fewer side effects, convenience, and greater efficacy.[13] However, the financial burden from out-of-pocket drug costs can lead patients with chronic illnesses to forgo prescribed drugs, ultimately affecting their health.

Prescription Drug Cost Containment

Formularies

Employers, labor unions, and managed care companies that offer insurance coverage for prescription drugs often hire pharmacy benefit managers (PBMs) to manage the benefits.[14] A PBM uses many techniques to manage prescription drug insurance coverage, which are included in the contract between the PBM and the employer, union, or managed care company. For example, a PBM assembles networks of retail pharmacies so that plan members can fill prescriptions easily and in multiple locations. A PBM will also consult with a plan sponsor to decide which drugs to include in the coverage benefit to treat each medical condition.[15]

A PBM also manages a list of preferred drug products, known as a formulary, to contain the cost of prescription drugs. A formulary is typically divided into three "tiers", meaning that a member would pay the least amount of copayment for the first tier of drugs, which are usually generics, a somewhat higher copayment for the second tier of drugs, usually preferred brand drugs without a generic equivalent, and the highest copayment for the third tier of drugs, usually non-preferred brand drugs or those brand drugs with a generic equivalent.[16]

Non-Medical Switching of Prescription Drugs

For most medicines, there exists several similar or alternative products which can be either a generic or a therapeutically equivalent drug.[17] Therapeutic interchange, or non-medical switching, is the practice of switching or dispensing drugs that are chemically distinct but therapeutically similar in terms of their efficacy, safety, and tolerability profiles.[18] Non-medical switching is designed to achieve an improved or neutral outcome by using the new drug, while reducing overall treatment costs.[19]

Non-medical switching may include substituting a brand-name drug for its generic equivalent. Generic drugs are copies of brand-name drugs with the same dosage form, safety, strength, route of administration, performance characteristics, and intended use.[20] Non-medical switching may also involve products that have been deemed to have therapeutic equivalence with an originally prescribed medicine or therapy.[21] These drugs will have a different chemical composition and use a different active ingredient than the originally prescribed drug.[22]

One study reviewed reasons for adjusting anti-tumor necrosis (TNF) agents involving patients with rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, or ulcerative

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[13] *See* HEALTH AFFAIRS 35, No. 9 (2016): 1595-1603, http://content.healthaffairs.org/content/35/9/1595.full.
[14] Federal Trade Commission, *Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies*, August 2005, pg. 1, available at https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf (last accessed February 18, 2017).
[15] Id.
[16] Id. at pg. 11.
[17] Rachel Chu, et al, *Patient Safety and Comfort - The Challenges of Switching Medicines* (2010), pg 8, *available at* http://www.patients-rights.org/uploadimages/Patient_Safety_and_Comfort_The_Challenges_of_Switching.pdf (last visited February 18, 2017).
[18] Flood, J., Mihalik, C., Fleming, R., Strober, B., Zucker, D. & Burgoyne, D., The Use of Therapeutic Interchange for Biologic Therapies, Managed Care Magazine, January 2007, p. 51. http://www.managedcaremag.com/archives/0701/0701.peer_switch.html (last accessed February 18, 2017).
[19] Id.
[20] Federal Food and Drug Administration, *Understanding Generic Drugs* (last updated January 13, 2017) *available at* http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/default.htm (last visited February 18, 2017).
[21] Id.
[22] Supra, FN 17 at pg. 9.

colitis. The study found that non-medical switching of anti-TNF agents was associated with an increase in side effects and lack of efficacy that led to an increase in health care utilization.[23]

Patients with rheumatic or immune disease who were identified as having switched anti-TNF agents for cost-based reasons showed a 62 percent greater likelihood for additional treatment related to side effects from the new drug compared to 20 percent for patients who remained on the previous treatment.[24] For patients that were switched within the first 90 days of treatment, the study found an increase, from 5.8 to 13, in the mean number of health care provider visits required for those patients.[25]

In 2007, a small national survey of nursing home administrators was conducted about the Medicare Part D prescription drug benefit and policies related to the potential clinical and cost implications of managing a pharmacy benefit for the long-term care population. More than 76 percent of the respondents said it was common for a resident's new drug to be less effective after a non-medical switch for formulary reasons.[26] Additionally, in 37 percent of switching situations, the side effects from the new drug created the need for a completely new medication to treat the side effect.[27] Non-medical switches also increased administrative time and raised the overall risk of more costly outcomes.[28]

Federal Patient Protection and Affordable Care Act

Health Insurance Reforms

The federal Patient Protection and Affordable Care Act (PPACA) was signed into law on March 23, 2010.[29] PPACA requires health insurers to make coverage available to all individuals and employers, without exclusions for preexisting conditions and without basing premiums on any health-related factors and mandates required essential health benefits,[30] cost-sharing limits, rating and underwriting standards, and appeals of adverse benefit determinations.[31] PPACA also requires issuers (insurers and HMOs) of qualified health plans (QHPs) to provide essential health benefits (EHB), which includes prescription drugs.[32]

Prescription Drug Coverage

For purposes of meeting EHBs for prescription drugs, issuers must include in the formulary the greater of one drug for each U.S. Pharmacopeia (USP) category and class; or the same number of drugs in each USP category and class as the state's EHB benchmark plan. Issuers must have a Pharmacy and Therapeutics Committee design a formulary using scientific evidence, including the consideration of safety and efficacy, coverage for a range of drugs in a broad distribution of therapeutic categories and classes, and providing access to drugs that are included in broadly accepted treatment guidelines. Plans providing EHBs must have procedures in place that allow an enrollee to request and gain access

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[23] D.T. Rubin, et al, *Analysis of outcomes after non-medical switching of anti-tumor necrosis factor agents,* European Crohn's and Colitis Organisation (2015) *available at* https://www.ecco-ibd.eu/index.php/publications/congress-abstract-s/abstracts-2015/item/p354-analysis-of-outcomes-after-non-medical-switching-of-anti-tumor-necrosis-factor-agents.html?category_id=430 (last visited February 18, 2017).

[24] Gibofsky A, et al., *Non-medical switch of anti-TNF agents may result in increased side effects, lack of efficacy,*(Paper #SAT0139), Presented at: European League Against Rheumatism Annual European Congress of Rheumatology; June 10-13, 2015; Rome), http://www.healio.com/rheumatology/psoriatic-arthritis/news/online/%7B4d3c5bb3-c81b-4f16-bf9c-6614e281f1d6%7D/non-medical-switch-of-anti-tnf-agents-may-result-in-increased-side-effects-lack-of-efficacy (last accessed February 18, 2017).

[25] Id.

[26] Bryan R. Cote, M.A., et al, *Impact of Therapeutic Switching in Long Term Care,* American Journal of Managed Care, (November 15, 2008) http://www.ajmc.com/journals/issue/2008/2008-11-vol14-n11sp/nov08-3703psp23-sp28/ (last visited February 18, 2017).

[27] Id.

[28] Id.

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

[30] 42 U.S.C. s.18022.

[31] Id.

[32] See Centers for Medicare & Medicaid Services, The Center for Consumer Information & Insurance Oversight, *Information on Essential Health Benefits Benchmark Plans*, https://www.cms.gov/cciio/resources/data-resources/ehb.html (last visited February 18, 2017).

to clinically appropriate drugs not included on the plan's formulary. Such procedures must include a process to request an expedited review.[33]

Changes in Medicare Part D Formularies

Medicare Part D[34] plans may alter their formularies from year to year and, in limited circumstances, make changes within a plan year.[35] Plans may not change therapeutic categories and classes of drugs within a plan year, except to account for new therapeutic uses or to add newly approved Part D drugs.[36] The following formulary changes are allowed: [37]

- Plans may immediately remove drugs from their formularies that are deemed unsafe by the FDA or are pulled from the market by their manufacturers.
- Plans may make formulary maintenance changes after March 1, such as replacing a brand-name drug with a new generic drug or modifying formularies because of new information on safety or effectiveness.

These changes require CMS approval and 60 days' notice to appropriate parties.[38]

If Part D plans remove drugs from their formularies during a plan year or change cost-sharing or access requirements, they must provide timely notice to the Centers for Medicare and Medicaid Services (CMS), affected enrollees, physicians, pharmacies, and pharmacists.[39] Plans may only remove drugs from a formulary, move covered drugs to a less-preferred tier status, or add utilization management requirements in accordance with approved procedures and after 60 days' notice to appropriate parties. Plans may make such changes only if enrollees currently taking the affected drugs are exempt from the formulary change for the remainder of the plan year.

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.[40] The Agency for Health Care Administration (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 AHCA.[41]

Under the Insurance Code, an HMO may increase the copayment for any benefit, or delete, amend, or limit any of the benefits under a group contract only upon written notice to the contract holder at least 45 days in advance of the time of coverage renewal. The HMO may amend the contract with the contract holder, with such amendment to be effective immediately at the time of coverage renewal. The written notice to the contract holder must specifically identify any deletions, amendments, or limitations to any of the benefits provided in the group contract during the current contract period, which will be included in the group contract upon renewal. This provision does not apply to any increases in benefits. The notice requirements do not apply if benefits are amended, deleted, or limited, pursuant to a request of the contract holder.[42]

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[33] 45 C.F.R. s. 156.122.
[34] The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108-173) established a voluntary, outpatient prescription drug benefit under Medicare Part D, effective January 1, 2006. Medicare Part D provides coverage through private prescription drug plans (PDPs) that offer only drug coverage, or through Medicare Advantage (MA) prescription drug plans (MA-PDs) that offer coverage as part of broader, managed care plans.
[35] Centers for Medicare and Medicaid, *Medicare Prescription Drug Benefit Manual*, Chapter 6, (Jan. 15, 2016) available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf. (last viewed February 18, 2017).
[36] Id.
[37] Id. at pg. 37.
[38] Id.
[39] Id.
[40] S. 20.121(3), F.S.
[41] S. 641.21(1), F.S.
[42] S. 641.31(36), F.S.

Florida' State Group Insurance Program

The Department of Management Services (DMS), through the Division of State Group Insurance (DSGI), administers the state group health insurance program (Program) under a cafeteria plan consistent with section 125 of the Internal Revenue Code.[43] To administer the Program, DMS contracts with third party administrators for self-insured health plans, insured HMOs, and a PBM for the state employees' self-insured prescription drug program (prescription drug program).[44]

The prescription drug program has three cost-share categories for members: generic drugs, preferred brand name drugs, which are those brand name drugs on the preferred drug list, and non-preferred brand name drugs, which are those brand name drugs not on the preferred drug list.[45] The PBM for the 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.[46]

The prescription drug program covers all federal legend drugs[47] for covered medical conditions, and employs very limited utilization review and clinical review for traditional or specialty prescription drugs.[48] Copayments and coinsurance for high deductible plans for each drug tier are the same for all members, as follows:[49]

State Group Health Prescription Drug Co-payments		
Drug Tier	**Retail Up to 30-Day Supply**	**Retail and Mail Up to 90-Day Supply and Specialty Medications**
Generic	$7	$14
Preferred Brand	$30	$60
Non-Preferred Brand	$50	$100

The Program typically makes benefits changes on a plan year basis, which is January 1 through December 31.[50] The following chart illustrates the estimated impact of preferred drug list tier changes implemented by the Program's PBM for calendar years 2015 and 2016:[51]

CALENDAR YEAR 2015 [6]					
Impact Type	**Unique Drugs Impacted**	**Total Rxs Impacted**	**$ Added Cost to Plan**	**$ Cost Savings to Plan**	**# Members Impacted**
Positive (Tier 3 to Tier 2)	43	5,779	($114,694)	$0	1,669
Negative (Tier 2 to Tier 3)	80	4,001	$0	$70,454	1,416
Total	**123**	**9,780**	**($114,694)**	**$70,454**	**3,081**

CALENDAR YEAR 2016 [7]					
Impact Type	**Unique Drugs Impacted**	**Total Rxs Impacted**	**$ Added Cost to Plan**	**$ Cost Savings to Plan**	**# Members Impacted**
Positive (Tier 3 to Tier 2)	42	9,918	($189,900)	$0	1,628
Negative (Tier 2 to Tier 3)	71	23,367	$0	$445,100	4,101
Total	**113**	**33,285**	**($189,900)**	**$445,100**	**5,772**

[43] S. 110.123, F.S.
[44] SS. 110.123(3) and 110.12315, F.S.
[45] S. 110.12315(a), F.S.
[46] Department of Management Services, *2017 Agency Analysis of House Bill 182,* pg. 2, (February 6, 2017) .
[47] "Legend drug" means a drug that is approved by the FDA and is available by prescription only. These drugs historically contained an inscription, or legend, denoting them as prescribed. Today, they typically state "Rx Only."
[48] Supra, FN 46.
[49] Id.
[50] Id.
[51] The Program PBM is CVS/Caremark, which became the PBM on January 1, 2015, so the estimated quarterly impacts for the 2015 calendar year do not include the first quarter of that year. Information received from an email from Program staff dated February 17, 2017 (on file with Health Innovation Subcommittee staff).

Effect of the Bill

HB 95 prohibits an individual or small group health insurer and a health maintenance organization HMO from removing a prescription drug from the formulary during the policy year. The bill provides two exceptions to this restriction: a prescription drug may be removed from the formulary during the policy year if the FDA issues a statement questioning the safety of the drug or the manufacturer of a drug notifies the FDA that it is no longer manufacturing the drug or potentially plans on not manufacturing the drug. The bill will prevent insurers and HMOs, and their PBMs, from utilizing certain formulary management techniques during the plan year. The prohibition may increase prescription drug plan costs for insureds and members of insurers and HMOs that implement those management techniques. However, insureds and members will benefit from unchanged prescription drug coverage during the entire plan year.

The bill prohibits during a policy year an individual or small group health insurer or HMO from reclassifying a prescription drug to a more restrictive drug tier, increasing the amount that an insured must pay out-of-pocket for a copayment, coinsurance, or deductible for a prescription drug, or reclassifying a drug to a higher cost-sharing tier. Insureds and members can plan for consistent prescription drug costs during the policy year. The bill permits prescription drugs to be added to the list of prescription drugs covered during the policy year, which may provide insureds and members with access to additional prescription drugs during the policy year.

The provisions of the bill do not apply to grandfathered health plans, as defined under s. 627.402, F.S., or to limited benefit insurance products listed in s. 627.6513, F.S., such as limited scope dental or vision benefits, hospital indemnity or other fixed indemnity insurance, or automobile medical payment insurance. Finally, the bill does not inhibit a pharmacist from substituting a generically equivalent drug for a brand name drug or dispensing a substitute biological product for the prescribed biological product.

The bill provides for an effective date of January 1, 2018.

B. SECTION DIRECTORY:

Section 1: Creates s. 627.42393, F.S., relating to insurance policies; limiting changes to prescription drug formularies.
Section 2: Amends s. 627.6699, F.S., relating to the Employee Health Care Access Act.
Section 3: Amends s. 641.31, F.S., relating to health maintenance contracts.
Section 4: Provides an effective date of January 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   Division of State Group Insurance

   The DSGI reports that the bill will have an indeterminate but substantial negative fiscal impact. The severity of the impact would be contingent on the number of brand drugs that are required to remain on the preferred drug list when other less expensive, interchangeable and clinically appropriate brand and generic drugs are available. The DSGI notes that maintaining brand name drugs on the preferred list when other less expensive drugs are available would not only increase the cost of

medication for the prescription drug program, but would also significantly reduce rebates from manufacturers to the Program.

The following estimates regarding the recurring impact on the DSGI were provided by the PBM:

- An increase in the cost of drugs of $50,000.
- A reduction in manufacturers' rebates of $9.2 million.

Florida Medicaid Program

The Agency for Healthcare Administration reports that the bill has no fiscal impact on the Florida Medicaid program as it does not amend ch. 409, F.S., Florida Medicaid, nor does it require any change to current Medicaid policies or procedures.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   Local governments could see an increase in the cost prescription drug coverage for their employees.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

By limiting changes to the prescription drug formulary, the bill would allow insureds to maintain their prescribed brand drugs at a preferred cost for the policy year.

The prohibition on changes to drug formularies in the middle of a plan year could increase prescription drug costs for health insurers and HMOs, and lead to higher costs for insureds and members.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not Applicable. This bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities

2. Other:

   The bill would not apply to self-insured plans that are covered under ERISA (Employee Retirement Income Security Act of 1974). ERISA preempts the regulation of such plans by the state.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

At lines 112-113, the bill requires a small employer carrier to provide continuity of care for medically stable patients as required under s. 627.42393, F.S., which is created by the bill. The new section of law does not address continuity of care or medically stable patients. It is recommended that the language be amended to refer to the limits on prescription drug formulary management outlined in the new statute.

To eliminate any impact to the State Group Insurance Program, it is recommended that language be included in the bill to make clear that the provisions of the bill do not apply to the Program.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to consumer protection from nonmedical changes to prescription drug formularies; creating s. 627.42393, F.S.; limiting changes to a health insurance policy prescription drug formulary during a policy year; providing applicability; amending s. 627.6699, F.S.; requiring small employer carriers to provide continuity of care with respect to prescription drug coverage; amending s. 641.31, F.S.; limiting changes to a health maintenance contract prescription drug formulary during a contract year; providing applicability; providing an effective date.

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

Section 1. Section 627.42393, Florida Statutes, is created to read:

627.42393 Insurance policies; limiting changes to prescription drug formularies.—

(1) Other than during an open enrollment period, an individual or group insurance policy that is delivered, issued for delivery, renewed, amended, or continued in this state that provides medical, major medical, or similar comprehensive coverage may not:

(a) Remove a covered prescription drug from its list of

covered drugs during the policy year unless the United States Food and Drug Administration has issued a statement about the drug which calls into question the clinical safety of the drug, or the manufacturer of the drug has notified the United States Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by s. 506C of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c.

(b) Reclassify a drug to a more restrictive drug tier or increase the amount that an insured must pay for a copayment, coinsurance, or deductible for prescription drug benefits, or reclassify a drug to a higher cost-sharing tier during the policy year.

(2) This section does not prohibit the addition of prescription drugs to the list of drugs covered under the policy during the policy year.

(3) This section does not apply to a grandfathered health plan as defined in s. 627.402 or to benefits set forth in s. 627.6513(1)-(14).

(4) This section does not alter or amend s. 465.025, which provides conditions under which a pharmacist may substitute a generically equivalent drug product for a brand name drug product.

(5) This section does not alter or amend s. 465.0252, which provides conditions under which a pharmacist may dispense a substitute biological product for the prescribed biological

product.

Section 2. Paragraph (e) of subsection (5) of section 627.6699, Florida Statutes, is amended to read:

627.6699 Employee Health Care Access Act.—

(5) AVAILABILITY OF COVERAGE.—

(e) All health benefit plans issued under this section must comply with the following conditions:

1. For employers who have fewer than two employees, a late enrollee may be excluded from coverage for no longer than 24 months if he or she was not covered by creditable coverage continually to a date not more than 63 days before the effective date of his or her new coverage.

2. Any requirement used by a small employer carrier in determining whether to provide coverage to a small employer group, including requirements for minimum participation of eligible employees and minimum employer contributions, must be applied uniformly among all small employer groups having the same number of eligible employees applying for coverage or receiving coverage from the small employer carrier, except that a small employer carrier that participates in, administers, or issues health benefits pursuant to s. 381.0406 which do not include a preexisting condition exclusion may require as a condition of offering such benefits that the employer has had no health insurance coverage for its employees for a period of at least 6 months. A small employer carrier may vary application of

minimum participation requirements and minimum employer contribution requirements only by the size of the small employer group.

3. In applying minimum participation requirements with respect to a small employer, a small employer carrier shall not consider as an eligible employee employees or dependents who have qualifying existing coverage in an employer-based group insurance plan or an ERISA qualified self-insurance plan in determining whether the applicable percentage of participation is met. However, a small employer carrier may count eligible employees and dependents who have coverage under another health plan that is sponsored by that employer.

4. A small employer carrier shall not increase any requirement for minimum employee participation or any requirement for minimum employer contribution applicable to a small employer at any time after the small employer has been accepted for coverage, unless the employer size has changed, in which case the small employer carrier may apply the requirements that are applicable to the new group size.

5. If a small employer carrier offers coverage to a small employer, it must offer coverage to all the small employer's eligible employees and their dependents. A small employer carrier may not offer coverage limited to certain persons in a group or to part of a group, except with respect to late enrollees.

6. A small employer carrier may not modify any health benefit plan issued to a small employer with respect to a small employer or any eligible employee or dependent through riders, endorsements, or otherwise to restrict or exclude coverage for certain diseases or medical conditions otherwise covered by the health benefit plan.

7. An initial enrollment period of at least 30 days must be provided. An annual 30-day open enrollment period must be offered to each small employer's eligible employees and their dependents. A small employer carrier must provide special enrollment periods as required by s. 627.65615.

8. A small employer carrier must provide continuity of care for medically stable patients as required by s. 627.42393.

Section 3. Subsection (44) is added to section 641.31, Florida Statutes, to read:

641.31 Health maintenance contracts.—

(44)(a) Other than during an open enrollment period, a health maintenance contract that is delivered, issued for delivery, renewed, amended, or continued in this state that provides medical, major medical, or similar comprehensive coverage may not:

1. Remove a covered prescription drug from its list of covered drugs during the contract year unless the United States Food and Drug Administration has issued a statement about the drug which calls into question the clinical safety of the drug,

or the manufacturer of the drug has notified the United States Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by s. 506C of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c.

2. Reclassify a drug to a more restrictive drug tier or increase the amount that an insured must pay for a copayment, coinsurance, or deductible for prescription drug benefits, or reclassify a drug to a higher cost-sharing tier during the contract year.

(b) This subsection does not prohibit the addition of prescription drugs to the list of drugs covered during the contract year.

(c) This subsection does not apply to a grandfathered health plan as defined in s. 627.402 or to benefits set forth in s. 627.6513(1)-(14).

(d) This subsection does not alter or amend s. 465.025, which provides conditions under which a pharmacist may substitute a generically equivalent drug product for a brand name drug product.

(e) This subsection does not alter or amend s. 465.0252, which provides conditions under which a pharmacist may dispense a substitute biological product for the prescribed biological product.

Section 4. This act shall take effect January 1, 2018.

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	____	(Y/N)
ADOPTED AS AMENDED	____	(Y/N)
ADOPTED W/O OBJECTION	____	(Y/N)
FAILED TO ADOPT	____	(Y/N)
WITHDRAWN	____	(Y/N)
OTHER		

Committee/Subcommittee hearing bill: Health Innovation Subcommittee

Representative Massullo offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Paragraph (k) is added to subsection (3) of section 110.123, Florida Statutes, to read:

110.123 State group insurance program.—

(3) STATE GROUP INSURANCE PROGRAM.—

(k) Sections 627.42393 and 641.31(36)(a) do not apply to the state group insurance program.

Section 2. Section 627.42393, Florida Statutes, is created to read:

627.42393 Insurance policies; limiting changes to prescription drug formularies.—

(1) Other than at the time of coverage renewal, an individual or group insurance policy that is delivered, issued for delivery, renewed, amended, or continued in this state and that provides medical, major medical, or similar comprehensive coverage may not:

(a) Remove a covered prescription drug from its list of covered drugs during the policy year unless the United States Food and Drug Administration has issued a statement about the drug which calls into question the clinical safety of the drug, or the manufacturer of the drug has notified the United States Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by s. 506C of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c.

(b) Reclassify a drug to a more restrictive drug tier or increase the amount that an insured must pay for a copayment, coinsurance, or deductible for prescription drug benefits, or reclassify a drug to a higher cost-sharing tier during the policy year.

(2) This section does not prohibit the addition of prescription drugs to the list of drugs covered under the policy during the policy year.

(3) This section does not apply to a grandfathered health plan as defined in s. 627.402 or to benefits set forth in s. 627.6513(1)-(14).

(4) This section does not alter or amend s. 465.025, which

provides conditions under which a pharmacist may substitute a generically equivalent drug product for a brand name drug product.

(5) This section does not alter or amend s. 465.0252, which provides conditions under which a pharmacist may dispense a substitute biological product for the prescribed biological product.

Section 3. Paragraph (e) of subsection (5) of section 627.6699, Florida Statutes, is amended to read:

627.6699 Employee Health Care Access Act.—

(5) AVAILABILITY OF COVERAGE.—

(e) All health benefit plans issued under this section must comply with the following conditions:

1. For employers who have fewer than two employees, a late enrollee may be excluded from coverage for no longer than 24 months if he or she was not covered by creditable coverage continually to a date not more than 63 days before the effective date of his or her new coverage.

2. Any requirement used by a small employer carrier in determining whether to provide coverage to a small employer group, including requirements for minimum participation of eligible employees and minimum employer contributions, must be applied uniformly among all small employer groups having the same number of eligible employees applying for coverage or receiving coverage from the small employer carrier, except that

a small employer carrier that participates in, administers, or issues health benefits pursuant to s. 381.0406 which do not include a preexisting condition exclusion may require as a condition of offering such benefits that the employer has had no health insurance coverage for its employees for a period of at least 6 months. A small employer carrier may vary application of minimum participation requirements and minimum employer contribution requirements only by the size of the small employer group.

3. In applying minimum participation requirements with respect to a small employer, a small employer carrier shall not consider as an eligible employee employees or dependents who have qualifying existing coverage in an employer-based group insurance plan or an ERISA qualified self-insurance plan in determining whether the applicable percentage of participation is met. However, a small employer carrier may count eligible employees and dependents who have coverage under another health plan that is sponsored by that employer.

4. A small employer carrier shall not increase any requirement for minimum employee participation or any requirement for minimum employer contribution applicable to a small employer at any time after the small employer has been accepted for coverage, unless the employer size has changed, in which case the small employer carrier may apply the requirements that are applicable to the new group size.

5. If a small employer carrier offers coverage to a small employer, it must offer coverage to all the small employer's eligible employees and their dependents. A small employer carrier may not offer coverage limited to certain persons in a group or to part of a group, except with respect to late enrollees.

6. A small employer carrier may not modify any health benefit plan issued to a small employer with respect to a small employer or any eligible employee or dependent through riders, endorsements, or otherwise to restrict or exclude coverage for certain diseases or medical conditions otherwise covered by the health benefit plan.

7. An initial enrollment period of at least 30 days must be provided. An annual 30-day open enrollment period must be offered to each small employer's eligible employees and their dependents. A small employer carrier must provide special enrollment periods as required by s. 627.65615.

8. A small employer carrier must limit changes to prescription drug formularies as required by s. 627.42393.

Section 4. Subsection (36) of section 641.31, Florida Statutes, is amended to read:

641.31 Health maintenance contracts.—

(36) A health maintenance organization may increase the copayment for any benefit, or delete, amend, or limit any of the benefits to which a subscriber is entitled under the group

contract only, upon written notice to the contract holder at least 45 days in advance of the time of coverage renewal. The health maintenance organization may amend the contract with the contract holder, with such amendment to be effective immediately at the time of coverage renewal. The written notice to the contract holder must ~~shall~~ specifically identify any deletions, amendments, or limitations to any of the benefits provided in the group contract during the current contract period which will be included in the group contract upon renewal. This subsection does not apply to any increases in benefits. The 45-day notice requirement does ~~shall~~ not apply if benefits are amended, deleted, or limited at the request of the contract holder.

(a) Other than at the time of coverage renewal, a health maintenance organization that provides medical, major medical, or similar comprehensive coverage may not:

1. Remove a covered prescription drug from its list of covered drugs during the contract year unless the United States Food and Drug Administration has issued a statement about the drug which calls into question the clinical safety of the drug, or the manufacturer of the drug has notified the United States Food and Drug Administration of a manufacturing discontinuance or potential discontinuance of the drug as required by s. 506C of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. s. 356c.

2. Reclassify a drug to a more restrictive drug tier or increase the amount that an insured must pay for a copayment,

coinsurance, or deductible for prescription drug benefits, or reclassify a drug to a higher cost-sharing tier during the contract year.

(b) This subsection does not:

1. Prohibit the addition of prescription drugs to the list of drugs covered during the contract year.

2. Apply to a grandfathered health plan as defined in s. 627.402 or to benefits set forth in s. 627.6513(1)-(14).

3. Alter or amend s. 465.025, which provides conditions under which a pharmacist may substitute a generically equivalent drug product for a brand name drug product.

4. Alter or amend s. 465.0252, which provides conditions under which a pharmacist may dispense a substitute biological product for the prescribed biological product.

Section 5. The Legislature finds that this act fulfills an important state interest.

Section 6. This act shall take effect January 1, 2018.

T I T L E A M E N D M E N T

Remove everything before the enacting clause and insert:

A bill to be entitled

An act relating to consumer protection from nonmedical changes to prescription drug formularies; amending s. 110.123, F.S.; providing that certain provisions

prohibiting nonmedical changes to prescription drug formularies do not apply to the state group insurance program; creating s. 627.42393, F.S.; limiting, under specified circumstances, changes to a health insurance policy prescription drug formulary during a policy year; providing construction and applicability; amending s. 627.6699, F.S.; requiring small employer carriers to limit changes to prescription drug formularies under certain circumstances; amending s. 641.31, F.S.; limiting, under specified circumstances, changes to a health maintenance contract prescription drug formulary during a contract year; providing construction and applicability; providing a declaration of important state interest; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 449 Health Insurance
SPONSOR(S): Renner
TIED BILLS: **IDEN./SIM. BILLS:** SB 528

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Tuszynski	Poche
2) Insurance & Banking Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The United States is experiencing significant changes in health care payment and delivery. Record numbers of newly-insured persons are enrolled in both public and private health insurance. Consumers are bearing a greater share of health care costs, and more people are enrolling in consumer-directed health plans with high deductibles.

Clear, factual information about the cost and quality of health care is necessary for consumers to select value-driven health care options and for consumers and providers to be involved in and accountable for decisions about health and health care services. To promote consumer involvement, health care pricing and other data needs to be free, timely, reliable, and reflect individual health care needs and insurance coverage. Price transparency creates better-informed shoppers, and there is evidence that incentivizing the shopping of health care services can increase consumer involvement and avoid health care costs.

HB 449 creates the Patient Savings Act, which requires health insurers to create a shared savings incentive program (Program) to encourage insured individuals to shop for high quality, lower cost health care services and share any savings realized as a result of the insured's choice.

The bill requires health insurers to provide a method for an insured to request information on the contracted amount with a health care provider for certain health care services, called shoppable health care services, and the average price for those same services. Upon the request of an insured, an insurer must provide within 2 working days a good faith estimate of the contracted amount for the shoppable health care service, as well as an estimate of copayments, deductibles, and other cost-sharing responsibilities.

Using the information from the health insurer, if the insured obtains a shoppable health care service for less than the average price for the service, the bill requires the savings to be shared by the health insurer and the insured. The cash payment can be calculated as a percentage between the contracted amount and the average price, or by an alternative method approved by the Office of Insurance Regulation (OIR). The bill requires the cash payment be at least 50 percent of the health insurer's saved cost as compared to the average price. The Program must be a component part of the policy, contract, or certificate of insurance provided by the health insurer, and the health insurer must notify its insureds of the Program annually and at the time of enrollment and renewal.

The bill provides significant enforcement provisions, including granting an insured a civil cause of action against a health insurer which violates the Program statute. In addition, the bill permits OIR to impose an administrative fine, or revoke or suspend the certificate of authority for health insurers who fail to comply with the requirements of the section.

The bill does not appear to have a fiscal impact on state or local governments.

The bill takes effect upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Health Care Price Transparency

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

Price transparency in health care can have different definitions. The term can refer to the availability of provider-specific information on the price for a specific health care service or set of services to consumers and other interested parties.[1] Price can be defined as an estimate of a consumer's complete cost of a health care service or services that reflects any negotiated discounts; is inclusive of all costs to the consumer associated with a service or services, including hospital, physician, and lab fees; and identifies a consumer's out-of-pocket cost.[2] Further, price transparency can be considered "readily available information on the price of health care services that, together with other information, helps define the value of those services and enables patients and other care purchasers to identify, compare, and choose providers that offer the desired level of value."[3] Indeed, the definition of the price or cost of health care has different meanings depending on who is incurring the cost.[4]

Price Waterhouse Cooper's Health Research Institute projects health care costs to rise 6.5 percent in 2017.[5] While this is the same rise in cost as 2016, the rate is still expanding faster than inflation.[6]

As health care costs continue to rise, most health insurance buyers are asking their consumers to take on a greater share of their costs, increasing both premiums and out-of-pocket expenses. According to the Kaiser Family Foundation, more than one in four Americans with private insurance is enrolled in a high deductible health plan (HDHP). Enrollment in HDHPs has increased 8 percent since 2014. According to Mercer's latest survey of employer health plans, nearly 3 in 10 employees were enrolled in an HDHP in 2016.[7]

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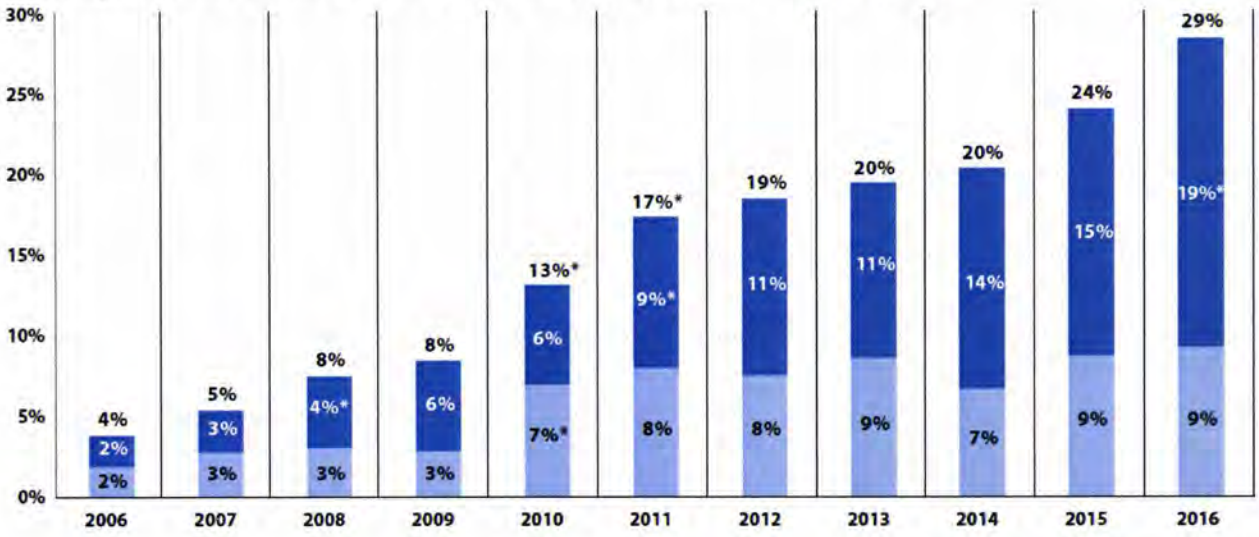
[1] Government Accounting Office, *Meaningful Price Information is Difficult for Consumers to Obtain Prior to Receiving Care*, September 2011, page 2, available at http://www.gao.gov/products/GAO-11-791.
[2] Id.
[3] Healthcare Financial Management Association, *Price Transparency in Health Care: Report from the HFMA Price Transparency Task Force*, page 2, 2014, available at http://www.hfma.org/WorkArea/DownloadAsset.aspx?id=22279.
[4] Id.
[5] PwC, Health Research Institute, *Behind the Numbers, 2017*, available at http://www.pwc.com/us/en/health-industries/behind-the-numbers.html (last accessed February 19, 2017).
[6] Here's Why You'll Likely Pay More for Your Employer-Sponsored Health Insurance, Fortune Health, June, 21, 2016, available at http://fortune.com/2016/06/21/health-care-rising-costs/ (last accessed February 19, 2017).
[7] Mercer, *Mercer survey: Health benefit cost growth slows to 2.4% in 2016 as enrollment in high-deductible plans climbs*, October 26, 2016, available at https://www.mercer.com/newsroom/national-survey-of-employer-sponsored-health-plans-2016.html (last viewed February 19, 2017).

Percentage of Covered Workers Enrolled in an HDHP/HRA or HSA-Qualified HDHP, 2006-2016



*Estimate is statistically different from estimate for the previous year shown ($p < .05$).

NOTE: Covered Workers enrolled in an HDHP/SO are enrolled in either an HDHP/HRA or a HSA-Qualified HDHP. For more information, see the Survey Methods Section. The percentages of covered workers enrolled in an HDHP/SO may not equal the sum of HDHP/HRA and HSA-Qualified HDHP enrollment estimates due to rounding.

SOURCE: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2006-2016.

Most covered workers face additional out-of-pocket costs when they use health care services, such as co-payments or coinsurance for physician visits and hospitalizations. Eighty-three percent of covered workers have a general annual deductible for single coverage that must be met before most services are paid for by the plan.[8]

Among covered workers with a general annual deductible, the average deductible amount for single coverage is $1,478.[9] The average annual deductible is similar to last year ($1,318), but has increased from $1,077 in 2015.[10] Deductibles differ by firm size; for workers in plans with a deductible, the average deductible for single coverage is $2,069 in small firms, compared to $1,238 for workers in large firms.[11] Sixty-five percent of covered workers in small firms are in a plan with a deductible of at least $1,000 for single coverage compared to 45 percent in large firms; a similar pattern exists for those in plans with a deductible of at least $2,000 (41 percent for small firms vs. 16 percent for large firms).[12]

Looking at the increase in deductible amounts over time does not capture the full impact of health care coverage for workers because the share of covered workers in plans with a general annual deductible also has increased significantly, from 55 percent in 2006 to 70 percent in 2010 to 83 percent in 2016. The average deductible for all covered workers in 2016 is $1,318, up 28 percent from $1077 in 2015, up 104 percent from $646 in 2010, and up 335 percent from $303 in 2006.

Sixty-five percent of covered workers employed by a firm of 3 to 199 employees are in a plan with a deductible of $1,000 or more, while 45 percent of covered workers employed by a firm with 200 or more employee are in such a plan, more than four times the average in 2006.[13] The chart below shows the percent of workers enrolled in employer-sponsored insurance with an annual deductible of $1,000 or more for single coverage by employer size for 2006 through 2016.[14]

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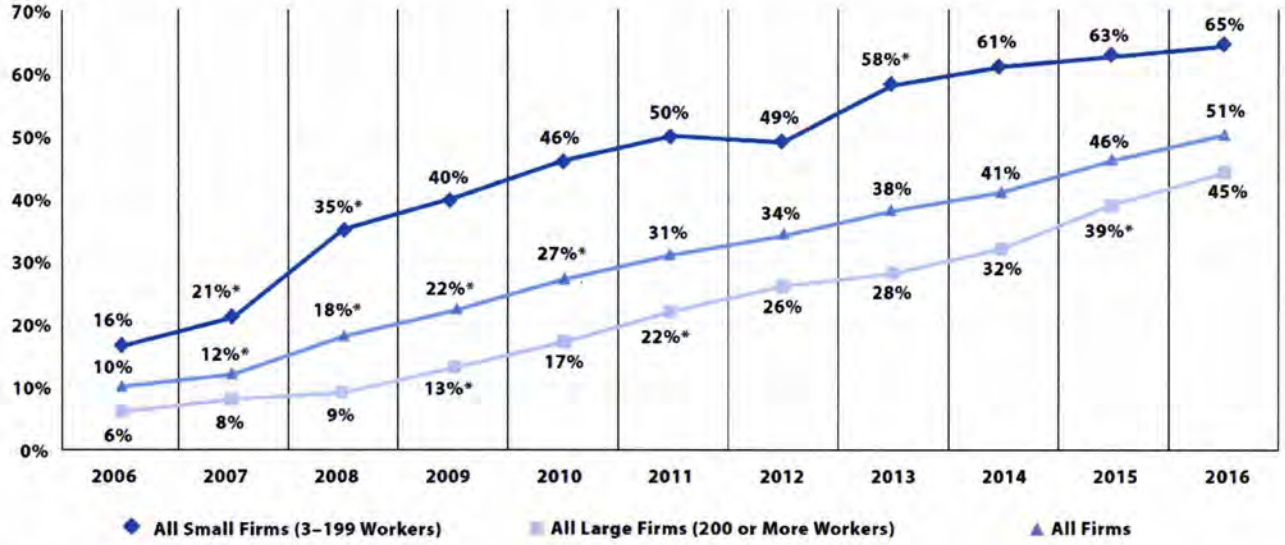
[8] The Henry J. Kaiser Family Foundation, *2016 Employer Health Benefits Survey*, September 2016, page 3, available at http://files.kff.org/attachment/Report-Employer-Health-Benefits-2016-Annual-Survey (last accessed February 19, 2017).
[9] Id. at pg. 4.
[10] Id.
[11] Id.
[12] Id.
[13] Id.
[14] Supra, FN 5, Exhibit G.

Percentage of Covered Workers Enrolled in a Plan with a General Annual Deductible of $1,000 or More for Single Coverage, By Firm Size, 2006-2016



* Estimate is statistically different from estimate for the previous year shown ($p < .05$).

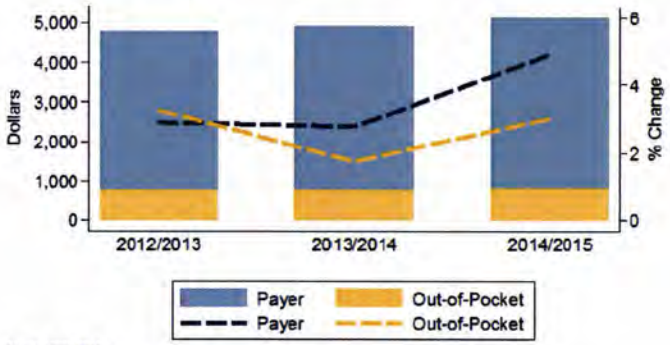
NOTE: These estimates include workers enrolled in HDHP/SO and other plan types. Average general annual health plan deductibles for PPOs, POS plans, and HDHP/SOs are for in-network services.

SOURCE: Kaiser/HRET Survey of Employer-Sponsored Health Benefits, 2006-2016.

According to the 2016 Mercer National Survey of Employer-Sponsored Health Plans, 61 percent of employers with 500 or more employees currently offer consumer-driven health plans (CDHPs), up from 39 percent in 2013, while 80 percent of jumbo employers, those with 20,000 or more employees, offer CDHPs, up from 63 percent the previous year.[15] Further, according to the survey, more employers planned on offering CHDPs in 2017.

These trends, coupled with overall increases in health care expenditures, mean consumers now spend $338.1 billion out-of-pocket annually.[16] Out-of-pocket medical spending by adults with employer-sponsored health insurance rose from $810 per capita in 2014 to $813 per capita in 2015.[17] Such spending accounted for 15.8 percent of total per capita health care expenditures in 2015.[18]

Payer and Out-of-Pocket Spending Per Capita for Insureds Younger than Age 65, 2012-2015



Source: HCCI, 2016.
Notes: All data weighted to reflect the national, younger than 65 ESI population. Data from 2014 and 2015 adjusted using actuarial completion.

[15] Supra, FN 7.
[16] U.S. Dept. of Health and Human Services, Centers for Medicaid and Medicare Services, *National Health Expenditure Data Fact Sheet-Historical National Health Expenditures, 2015*, available at https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html (last accessed February 19, 2017).
[17] Health Care Cost Institute, *2015 Health Care Cost and Utilization Report*, November 2016, page 6, available at http://www.healthcostinstitute.org/report/2015-health-care-cost-utilization-report/ (last viewed February 19, 2017).
[18] Id.

National Price Transparency Studies

To explore how expanding price transparency efforts could produce significant cost savings for the healthcare system, the Gary and Mary West Health Policy Center funded an analysis, "Healthcare Price Transparency: Policy Approaches and Estimated Impacts on Spending." This report, conducted in collaboration with researchers from the Center for Studying Health System Change and RAND, found that implementation of three policy changes could save $100 billion over ten years.

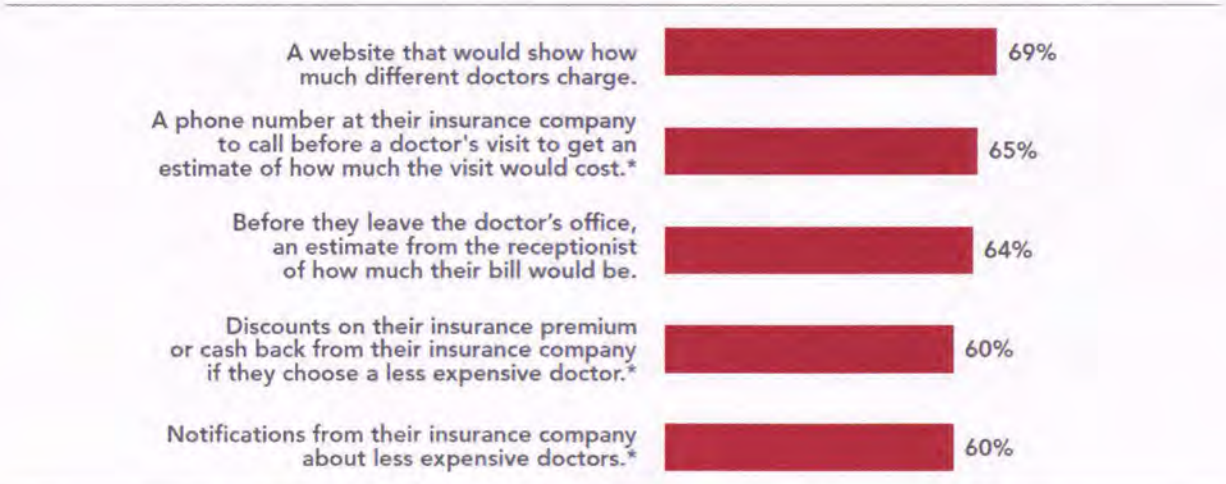
- Provide personalized out-of-pocket expense information to patients and families before receiving care.
- Provide prices to physicians through electronic health record systems when ordering treatments and tests.
- Expand state-based all-payer health claims databases (APCDs), which could save up to $55 billion by collecting and providing data and analytics tools that supply quality, efficiency and cost information to policy makers, employers, providers, and patients.[19]

The report specifically found that requiring all private health insurance plans to provide personalized out-of-pocket price data to enrollees would reduce total health spending by an estimated $18 billion over the next 10 years.[20]

As Americans shoulder more health care costs, research suggests that they are looking for more and better price information.[21]

Many Americans want help managing their health care spending.

Figure 16: Percent who say the following resources would help them a lot or some with their health care spending:



Base: All respondents, N=2,010.

*Base: Currently have health insurance, n=1,736.

[19] White, C., Ginsburg, P., et al., Gary and Mary West Health Policy Center, *Healthcare Price Transparency: Policy Approaches and Estimated Impacts on Spending*, May 2014, available at: http://www.westhealth.org/wp-content/uploads/2015/05/Price-Transparency-Policy-Analysis-FINAL-5-2-14.pdf.

[20] Id. at pg. 1.

[21] Public Agenda and Robert Wood Johnson Foundation, *How Much Will It Cost? How Americans Use Prices in Health Care*, March 2015, page 34, available at https://www.publicagenda.org/files/HowMuchWillItCost_PublicAgenda_2015.pdf (last viewed February 19, 2017).

One study in 2014, which conducted a nationally representative survey of more than 2,000 adults, found that 56 percent of Americans actively searched for price information before obtaining health care, including 21 percent who compared the price of health care services across multiple providers.[22] The chart below illustrates the finding that, as a consumer's health plan deductible increases, the consumer is more likely to seek out price information.[23]

People with deductibles over $500 are more likely to seek price information.

Figure 2: Percent who say they have tried to find price information before getting care, by deductible amount:

Base: Currently have health insurance, n=1,736.

Estimates for groups indicated by * are not statistically different from each other, and groups indicated by † are not statistically different from each other; groups indicated by * are statistically different from groups indicated by † at the p<.05 level.

The individuals who compared prices stated that such research impacted their health care choices and saved them money.[24] In addition, the study found that most Americans do not equate price with quality of care. Seventy one percent do not believe higher price impart a higher level care quality and 63 percent do not believe that lower price is indicative of lower level care quality.[25] Because of the high level of cost-sharing associated with CDHPs, these consumers are more price-sensitive than consumers with plans that have much lower cost-sharing obligations. In fact, these consumers find an estimate of their individual out-of-pocket costs more useful than any other kind of health care price transparency tool.[26] Another study found that when they have access to well-designed reports on price and quality, 80 percent of health care consumers will select the highest value health care provider.[27]

Additional research has found the use of price transparency tools to be associated with lower total claims payments for common medical services and procedures.[28] A recent study sought the measure the impact of consumer access to health care price data on the cost of three of the most common health services- laboratory tests, advanced imaging services, and clinician office visits.[29] Medical claims from 2010 to 2013 of more than 500,000 patients insured in the U.S. by 18 employers who

[22] Id. at pg. 3.
[23] Id. at pg. 13.
[24] Id. at pg. 4.
[25] Supra, FN 23.
[26] American Institute for Research, *Consumer Beliefs and Use of Information About Health Care Cost, Resource Use, and Value*, Robert Wood Johnson Foundation, October 2012, page 4, available at http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf402126.
[27] Hibbard, JH, et al., *An Experiment Shows That a Well-Designed Report on Costs and Quality Can Help Consumers Choose High-Value Health Care*, Health Affairs 2012; 31(3): 560-568.
[28] Whaley, C., Schneider Chafen, J., et al., *Association Between Availability of Health Service Prices and Payments for These Services*, Journal of the American Medical Association. 2014;312(16): 1670-1676.
[29] Id.

provided a health care price transparency platform were reviewed to determine the total claims payment for the three services.[30]

Researchers accessed the price transparency platform to determine which claims were associated with a prior search of the platform. In the study sample, 6 percent of lab test claims, 7 percent of advanced imaging claims, and nearly 27 percent of clinician office visit claims were associated with a search.[31] Prior to accessing the price transparency platform, searchers had higher claim payments than non-searchers for each of the services. After using the price transparency platform, searchers paid nearly 14 percent less for lab test services, 13 percent less for advanced imaging services, and 1 percent less for doctor office visits than non-searchers.[32] The study concluded that patient access to pricing information before obtaining clinical services may result in lower overall payments made for clinical care.[33]

Florida Efforts in Health Care Price Transparency

Florida Patient's Bill of Rights and Responsibilities

In 1991, s. 381.026, F.S., enacted the Florida Patient's Bill of Rights and Responsibilities (Patient's Bill of Rights).[34] The statute established the right of patients to expect medical providers to observe standards of care in providing medical treatment and communicating with their patients.[35] The standards of care include, but are not limited to, the following aspects of medical treatment and patient communication:

- Individual dignity;
- Provision of information;
- Financial information and the disclosure of financial information;
- Access to health care;
- Experimental research; and
- Patient's knowledge of rights and responsibilities.

Under s. 381.026(4)(c), F.S., a patient has the right to request certain financial information from health care providers and facilities.[36] Specifically, upon request, a health care provider or health care facility must provide a person with a reasonable estimate of the cost of medical treatment prior to the provision of treatment.[37] Estimates must be written in language "comprehensible to an ordinary layperson."[38] The reasonable estimate does not preclude the health care provider or health care facility from exceeding the estimate or making additional charges as the patient's needs or medical condition warrant.[39] A patient has the right to receive a copy of an itemized bill upon request and to receive an explanation of charges upon request.[40]

Currently, under the Patient's Bill of Rights financial information and disclosure provisions:

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[30] Id.
[31] Id.
[32] Id.
[33] Id.
[34] S. 1, Ch. 91-127, Laws of Fla. (1991); s. 381.026, F.S.; The Florida Patient's Bill of Rights and Responsibilities is intended to promote better communication and eliminate misunderstandings between the patient and health care provider or health care facility. The rights of patients include standards related to individual dignity; information about the provider, facility, diagnosis, treatments, risks, etc.; financial information and disclosure; access to health care; experimental research; and patient's knowledge of rights and responsibilities. Patient responsibilities include giving the provider accurate and complete information regarding the patient's health, comprehending the course of treatment and following the treatment plan, keeping appointments, fulfilling financial obligations, and following the facility's rules and regulations affecting patient care and conduct.
[35] S. 381.026(3), F.S.
[36] S. 381.026(4)(c), F.S.
[37] S. 381.026(4)(c)3., F.S.
[38] Id.
[39] Id.
[40] S. 381.026(4)(c)5., F.S.

- A request is necessary before a health care provider or health care facility must disclose to a Medicare-eligible patient whether the provider or facility accepts Medicare payment as full payment for medical services and treatment rendered in the provider's office or health care facility.
- A request is necessary before a health care provider or health care facility is required to furnish a person an estimate of charges for medical services before providing the services. The Florida Patient's Bill of Rights and Responsibilities does not require that the components making up the estimate be itemized or that the estimate be presented in a manner that is easily understood by an ordinary layperson.
- A licensed facility must place a notice in its reception area that financial information related to that facility is available on the Agency's website.
- The facility may indicate that the pricing information is based on a compilation of charges for the average patient and that an individual patient's charges may vary.
- A patient has the right to receive an itemized bill upon request.

Health care providers and health care facilities are required to make available to patients a summary of their rights. The applicable regulatory board or Agency may impose an administrative fine when a provider or facility fails to make available to patients a summary of their rights.[41]

In 2011, the Legislature passed HB 935,[42] which amended the Patient's Bill of Rights to authorize, but not require, primary care providers[43] to publish a schedule of charges for the medical services offered to patients.[44] The schedule must include certain price information for at least the 50 services most frequently provided by the primary care provider.[45] The law also requires the posting of the schedule in a conspicuous place in the reception area of the provider's office and at least 15 square feet in size.[46] A primary care provider who publishes and maintains a schedule of charges is exempt from licensure fees for a single renewal of a professional license and from the continuing education requirements for a single 2-year period.[47]

The law also requires urgent care centers to publish a schedule of charges for the medical services offered to patients.[48] The schedule requirements are the same as those established for primary care providers.[49] An urgent care center that fails to publish and post the schedule of charges is subject to a fine of not more than $1,000 per day (until the schedule is published and posted).[50]

In 2012, the Legislature passed HB 787,[51] which built upon the transparency requirements established by HB 935. The law amended the definition of "urgent care center" to include any entity that holds itself

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[41] S. 381.0261, F.S.
[42] Ch. 2011-122, Laws of Fla.
[43] S. 381.026(2)(d), F.S., defines primary care providers to include allopathic physicians, osteopathic physicians, and nurses who provide medical services that are commonly provided without referral from another health care provider, including family and general practice, general pediatrics, and general internal medicine.
[44] S. 381.026(4)(c)3., F.S.
[45] Id.
[46] Id.
[47] S. 381.026(4)(c)4., F.S.
[48] S. 395.107(1), F.S.
[49] S. 395.107(2), F.S.
[50] In 2012, the Legislature considered, but did not pass, HB 1329. The bill required ambulatory surgical centers and diagnostic-imaging centers to comply with the provisions of s. 395.107, F.S., established by HB 935 in 2011, and required physicians to publish, in writing, a schedule of medical charges. The bill would have imposed a fine of $1,000, per day, on an urgent care center, ambulatory surgical center, or diagnostic-imaging center that fails to post the schedule of medical charges. The failure of a practitioner to publish and distribute a schedule of medical charges subjected the practitioner to discipline under the applicable practice act and s. 456.072, F.S. Lastly, the bill addressed balance billing by requiring health insurers, hospitals, and medical providers to disclose contractual relationships among the parties and to disclose, in advance of the provision of medical care or services, whether or not the patient will be balance billed as a result of the contractual relationship, or lack thereof, among the insurer, hospital, and medical provider. Failure to provide disclosure to the insured as required by this provision of the bill resulted in a $500 fine, per occurrence, to be imposed by the AHCA.
[51] SS. 1-3, Ch. 2012-160, Laws of Fla.

out to the general public, in any manner, as a facility or clinic where immediate, but not emergent, care is provided, expressly including offsite facilities of hospitals or hospital-physician joint ventures; and licensed health care clinics that operate in three or more locations in the definitions.

The law requires a schedule of charges for medical services posted by an urgent care center to describe each medical service in language comprehensible to a layperson. This provision prevents a center from using medical or billing codes, Latin phrases, or technical medical jargon as the only description of each medical service. The law also requires the text of the schedule of medical charges to fill at least 12 square feet of the total 15 square feet area of the posted schedule, and allows use of an electronic device for the posting. The device must measure at least three square feet in size and be accessible to all consumers during business hours.

In 2016, the Legislature passed, and the Governor signed, HB 1175, which requires the greatest amount of health care price and quality transparency in Florida to date. The law ensures greater consumer access to health care price and quality information by requiring certain heath care providers, insurers and health maintenance organizations HMOs to give that information to patients. The law also required the Agency for Health Care Administration (AHCA) to contract with a vendor for an all-payer claims database (APCD), which provides an online, searchable method for consumers to compare provider price and quality, and a Florida-specific data set for price and quality research purposes. On January 3, 2017, AHCA recommended that the Health Care Cost (HCCI) Institute be awarded the contract to build and maintain the APCD and the Florida-specific data set. AHCA and HCCI continue to discuss the terms of the contract necessary to implement the provisions of the law. The law requires insurers and HMOs to submit data to the APCD.

The law creates pre-treatment transparency obligations for hospitals, ambulatory surgery centers, health care practitioners providing non-emergency services in these facilities, and insurers and HMOs. Facilities must post online the average payments and payment ranges received for bundles of health care services defined by AHCA. This information must be searchable by consumers. Facilities must provide, within 7 days of a request, a written, good faith, personalized estimate of charges, including facility fees, using either bundles of health care services defined by AHCA or patient-specific information. Failure to provide the estimate results in a daily licensure fine of $1,000, up to $10,000. Facilities must inform patients of health care practitioners providing their nonemergency care in hospitals and these practitioners must provide the same type of estimate, subject to a daily fine of $500, up to $5,000.

Facilities and facility practitioners must publish information on their financial assistance policies and procedures. Insurers and HMOs must create online methods for patients to estimate their out-of-pocket costs, both using the service bundles established by AHCA and HCCI and based on patient-specific estimates using the personalized estimate the patient obtains from facilities and practitioners. In addition, diagnostic-imaging centers owned by a hospital but located off of the premises must publish and post charges for services pursuant to s. 395.107, F.S., which currently requires urgent care centers to do the same.

Post-treatment, facilities must provide an itemized bill within 7 days of discharge or request, whichever is later, meeting certain requirements for comprehension by a layperson, and identifying any providers who may bill separately for the care received in the facility.

Florida Center for Health Information and Transparency

The Florida Center for Health Information and Transparency (the Florida Center) provides a comprehensive health information system (information system) that includes the collection, compilation, coordination, analysis, indexing, dissemination, and utilization of health-related data. The Florida Center is housed within AHCA and is funded through appropriations in the General Appropriations Act, through grants, gifts, and other payments, and through fees charged for services. Offices within the Florida Center, which serve different functions, are:

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

The Florida Center electronically collects patient data from every Florida licensed inpatient hospital, ambulatory surgery center (ASC), emergency department, and comprehensive rehabilitation hospital on a quarterly basis. The Florida Center must maintain any data sets in existence before July 1, 2016, unless such data sets duplicate information that is readily available from other credible sources, and may collect or compile data on:

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

The Florida Center maintains www.FloridaHealthFinder.gov, which was established to assist consumers in making informed health care decisions and lead to improvements in quality of care in Florida. The website provides a wide array of search and comparative tools to the public which allow easy access to information on hospitals, ambulatory surgery centers, emergency departments, hospice providers, physician volume, health plans, nursing homes, and prices for prescription drugs in Florida. The website also provides tools to researchers and professionals to allow specialized data queries, but requires users to have some knowledge of medical coding and terminology. Some of the features and data available on the website include a multimedia encyclopedia and symptoms navigator, hospital and ambulatory surgery centers performance data, data on mortality, complication, and infection rates for hospitals, and a facility/provider locator. AHCA is frequently improving the functionality of the website by adding more information and search capabilities.

The New Hampshire State Employee SmartShopper Incentive Program

In 2010, the State of New Hampshire began offering state employees a new pilot program called Compass SmartShopper.[52] The program was designed to lower healthcare costs by providing consumers cost information for common elective procedures, and providing cash incentives when they chose to receive care from a cost-effective provider as identified by Compass Healthcare Advisers.[53]

[52] State of New Hampshire, Department of Administrative Services, Vitals SmartShopper Program, available at https://das.nh.gov/hr/Vitals_SmartShopper.html (last accessed February 19, 2017).
[53] Id.

The program rewarded employees for being more engaged in the cost of their healthcare decisions, while also helping the state avoid unnecessary claims costs.[54] The incentives are tied to choosing the "most cost-effective", "2nd most cost-effective," or "3rd most cost-effective" option for a list of particular services. The chart below provides an example of the options available for a variety of services within the program:[55]

Incentive Reward Services	Incentive Amount		
	Most Cost-Effective	2nd Most Cost-Effective	3rd Most Cost-Effective
Back Surgery (inpatient laminectomy)	$500	$250	n/a
CT Scan	$150	$75	$50
Hernia Repair	$250	$100	$50
Mammogram	$50	$25	n/a
Tonsillectomy	$150	$75	$50
Ultrasound (non-maternity)	$50	$25	n/a

With three years of education and outreach, the program had produced $12 million in savings and over $1 million paid in incentives.[56] The data shows that:

- Consumers are 11 times more likely to use a transparency program when incentives are included;
- Roughly 90 percent of enrollees have shopped at least once, and 66 percent repeatedly shop and earn incentives;
- The program averages approximately $650 in savings each time an employee shops; and
- In 2015, the program achieved a 13:1 return on investment.

Insurance Regulation

The regulatory oversight of insurance companies is generally reserved to the states. In Florida, the Office of Insurance Regulation (OIR), within the Department of Financial Services, is responsible for all activities concerning insurers and other risk bearing entities, including licensing, rates, policy forms, market conduct, claims, issuance of certificates of authority, solvency, viatical settlements, premium financing, and administrative supervision, as provided under the insurance code.[57]

All persons who transact insurance in the state must comply with the Insurance Code (Code).[58] Under the Code, OIR has the power to collect, propose, publish, and dissemintate any information relating to the subject matter of the Code,[59] and may investigate any matter relating to insurance.[60] OIR also has

[54] Compass SmartShopper Program Personnel Memo, June 28, 2010, available at https://das.nh.gov/hr/documents/compass%20memo.pdf (last accessed February 19, 2017).
[55] State of New Hampshire, Department of Administrative Services, Incentive List, available at https://das.nh.gov/hr/documents/VitalsSmartShopperIncentiveList.pdf (last accessed February 19, 2017).
[56] Right to Shop: The Next Big Thing in Health Care, Forbes: The Apothecary, August 5, 2016, available at http://www.forbes.com/sites/theapothecary/2016/08/05/right-to-shop-the-next-big-thing-in-health-care/ (last accessed February 19, 2017).
[57] s. 20.121(3)(a)1., F.S. The OIR's commissioner is the agency head for purposes of final agency action, and its rulemaking body is the Financial Services Commission (the Governor and the Cabinet).
[58] S. 624.11, F.S. The Insurance Code consists of chapters 624-632, 634, 635, 636, 641, 642, 648, and 651, F.S.
[59] S. 624.307(4), F.S.
[60] S. 624.307(3), F.S.

the power to levy administrative fines against insurers who violate the Code,[61] as well as deny, suspend, or revoke any certificates of authority, license, or permit.[62]

Civil Remedy under the Insurance Code

Any person may bring a civil action against an insurer that is in violation of one of the following:[63]

- Section 626.9541(1)(l), (o), or (x) – relating to unfair claim settlement, illegal dealings in premiums and excess charges, or the refusal to insure.
- Section 626.9551 – relating to favored agents or insurers; coercion of debtors.
- Section 626.9705 – relating to illegal dealings in life or disability insurance.
- Section 626.9706 – relating to discrimination in life insurance.
- Section 626.9707 – relating to discrimination in disability insurance.
- Section 627.7283 – relating to the return of unearned premiums.

These private causes of action enable a person, who can show damages in court, to collect directly from an insurer.

Effect of the Bill

HB 449 creates the Patient Savings Act, which requires health insurers to create a shared savings incentive program (Program) to encourage insured individuals to shop for high quality, lower cost health care services and share any savings realized as a result of the insured's choice. The bill requires implementation of these incentive programs for plan years beginning January 1, 2018

Definitions

The bill defines the following terms:

- "Average price" is means the average amount paid to an in-network health care provider for a shoppable health care service within a 1-year period or as determined by another method approved by OIR.
- "Contracted amount" means the amount agreed to be paid by the health insurer to a health care provider for shoppable health care services, including any facility fees charged by the provider.
- "Health care provider" is defined as a comprehensive list of more than 25 individual entities or groups that provide a health care service.
- "Health insurer" means an insurer offering health insurance, an HMO, and a person offer a self-insurance policy that provides health benefits.
- "Shared savings incentive program" means the program established by a health insurer that shares any savings with an insured based on that insured's choice of a high quality, lower-cost shoppable health care service compared to the average price of the service.
- "Shoppable health care service" include nonemergency health services received by an insured and for which the insured may be eligible to share savings under the Program. The services include:
    - Clinical laboratory services.
    - Infusion therapy.
    - Inpatient and outpatient surgical procedures.
    - Obstetrical and gynecological services.
    - Outpatient nonsurgical diagnostic tests and procedures.
    - Physical and occupational therapy services.
    - Radiology and imaging services.

[61] S. 624. 310(5), F.S.
[62] S. 624.310(5)(c), F.S.
[63] S. 624.155, F.S.

Shared Savings Incentive Program

The bill requires a health insurer to provide a method for an insured to request information on the contracted amount with a health care provider for shoppable health care services, and the average price for those same services. Upon the request of an insured, an insurer must provide within 2 working days a good faith estimate of the contracted amount for the shoppable health care service, as well as an estimate of copayments, deductibles, and other cost-sharing responsibilities.

Using the information from the health insurer, if the insured obtains a shoppable health care service for less than the average price for the service, the bill requires the savings to be shared by the health insurer and the insured. The cash payment can be calculated as a percentage between the contracted amount and the average price, or by an alternative method approved by the Office of Insurance Regulation (OIR). The bill requires the cash payment be at least 50 percent of the health insurer's saved cost as compared to the average price. If an insured elects to receive a shoppable healthcare service from an out-of-network provider for less than the average in-network price, that service must be treated as in-network for purposes of calculating the incentive payment. The bill does not require a cash incentive payment to an insured for cost savings less than $50, and incentive payments are not considered administrative expenses for purposes of rate development or filing.

The Program must be a component part of the policy, contract, or certificate of insurance provided by the health insurer, and the health insurer must notify its insureds of the Program annually and at the time of enrollment and renewal.

Reports

The bill requires a health insurer to file a description of its Program for review by OIR, on a form prescribed by OIR, and requires an annual report to OIR that must include the:

- Total number of incentive payments made for the calendar year;
- Shoppable health care services by category for which payments were made;
- Average amount of incentive payments;
- Total amount saved by the health insurer when compared with the average prices for each shoppable health service; and
- Total number of insured and the percentage of total insured who participated in the program.

The bill requires OIR to submit an annual report to the President of the Senate and the Speaker of the House by April 1, 2019, and each year thereafter, which summarizes the annual Program reports submitted by the health insurers.

Enforcement

The bill allows a private cause of action against an insurer for failure to comply with the Program. As a result, an insured can sue a health insurer for failing to comply with the Program and, if successful, collect a judgement directly from the health insurer.

The bill also permits OIR to impose an administrative penalty of no more than $2,500 per day against a health insurer which fails to comply with s. 627.6387, F.S. In addition, OIR is specifically authorized to suspend for 6 months or revoke the certificate of authority for a health insurer which fails to comply with the section. For health insurers that fail to meet the required filing deadline, the bill also allows OIR to order the health insurer to discontinue the issuance of policies, contracts, or certificates of insurance until the filing requirement has been fulfilled.

Finally, the bill provides OIR with rulemaking authority to implement the provisions of the bill.

The bill provides an effective date of upon becoming law.

B. SECTION DIRECTORY:

Section 1: Amends s. 624.155, F.S., relating to civil remedies.
Section 2: Creates s. 627.6387, F.S., relating to shared savings incentive program.
Section 3: Provides an effective date of upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   OIR may realize an increase in workload as a result of ensuring compliance with the Program by health insurers and imposing the specific penalties for those health insurers that are not in compliance. There may be additional increased workload associated with compiling the Program reports from each health insurer and compiling the summary report for the President of the Senate and the Speaker of the House of Representatives each year.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health insurers must develop and implement a Program beginning with the 2018 plan year. Each health insurer must include specific information on their website that allows an insured to research certain cost information associated with health care providers, such as the average price for a shoppable health care services. Health insurers must also provide a good faith estimate, upon request from an insured, that includes contracted amounts for services from health care providers, including any copayments or other coinsurance obligations of the insured.

Health insurers are required to share any savings realized as a result of the treatment options chosen by their insureds for shoppable health care services. Insureds will receive cash payments for health care treatment options that are at least $50 less than the average price noted by their health insurer.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to require counties or municipalities to spend funds or take action requiring the expenditures of funds; reduce the authority that counties or municipalities have to raise revenues in the aggregate; or reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

OIR is granted sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to health insurance; amending s. 624.155, F.S.; providing a civil remedy for a health insurer who violates the Patient Savings Act; creating s. 627.6387, F.S.; providing a short title; providing definitions; providing health insurer website requirements; requiring an insurer to provide good faith estimates of costs for certain health care services upon request by an insured; requiring an insurer to implement a shared savings incentive program by a specified date; providing procedures and requirements; providing notification requirements; providing procedures for an insurer to obtain approval for its program; providing reporting requirements; providing penalties; requiring the Office of Insurance Regulation to make and submit an annual report; authorizing the office to adopt rules; providing an effective date.

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

Section 1. Subsection (1) of section 624.155, Florida Statutes, is amended to read:

624.155 Civil remedy.—

(1) Any person may bring a civil action against an insurer

when such person is damaged:

(a) By a violation of any of the following provisions by the insurer:

1. Section 626.9541(1)(i), (o), or (x);

2. Section 626.9551;

3. Section 626.9705;

4. Section 626.9706;

5. Section 626.9707; ~~or~~

6. Section 627.7283; or

7. Section 627.6387.

(b) By the commission of any of the following acts by the insurer:

1. Not attempting in good faith to settle claims when, under all the circumstances, it could and should have done so, had it acted fairly and honestly toward its insured and with due regard for her or his interests;

2. Making claims payments to insureds or beneficiaries not accompanied by a statement setting forth the coverage under which payments are being made; or

3. Except as to liability coverages, failing to promptly settle claims, when the obligation to settle a claim has become reasonably clear, under one portion of the insurance policy coverage in order to influence settlements under other portions of the insurance policy coverage.

Notwithstanding the provisions of the above to the contrary, a person pursuing a remedy under this section need not prove that such act was committed or performed with such frequency as to indicate a general business practice.

Section 2. Section 627.6387, Florida Statutes, is created to read:

627.6387 Shared savings incentive program.—

(1) This section may be cited as the "Patient Savings Act".—

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

(a) "Average price" means the average amount paid to an in-network health care provider for a shoppable health care service within a 1-year period or as determined by another method approved by the Office of Insurance Regulation.

(b) "Contracted amount" means the amount agreed to be paid by the health insurer pursuant to a policy, contract, or certificate of insurance to a health care provider for shoppable health care services covered by the policy, contract, or certificate of insurance, including any facility fees charged by the provider.

(c) "Health care provider" means hospitals, ambulatory surgical centers, and other medical facilities licensed under chapter 395; home health agencies licensed under chapter 400; physicians licensed under chapter 458; physician assistants licensed under chapter 458 or chapter 459; osteopathic

physicians licensed under chapter 459; chiropractic physicians licensed under chapter 460; podiatric physicians licensed under chapter 461; naturopaths licensed under chapter 462; dentists licensed under chapter 466; nurses licensed under part I of chapter 464; midwives licensed under chapter 467; occupational therapists licensed under chapter 468; radiological personnel certified under chapter 468; clinical laboratories licensed under chapter 483; physical therapists and physical therapist assistants licensed under chapter 486; blood banks, plasma centers, industrial clinics, and renal dialysis facilities; or professional associations, partnerships, corporations, joint ventures, or other associations for professional activity by health care providers.

(d) "Health insurer" means an authorized insurer offering health insurance as defined in s. 624.603 or a health maintenance organization as defined in s. 641.19(12). The term includes a person with a self-insurance plan that provides health insurance benefits.

(e) "Shared savings incentive program" means a cash incentive program established by a health insurer pursuant to this section.

(f) "Shoppable health care service" means a nonemergency health care service for which an insured may receive a cash payment under a shared savings incentive program. Shoppable health care services include:

1. Clinical laboratory services.

2. Infusion therapy.

3. Inpatient and outpatient surgical procedures.

4. Obstetrical and gynecological services.

5. Outpatient nonsurgical diagnostic tests and procedures.

6. Physical and occupational therapy services.

7. Radiology and imaging services.

(3) A health insurer's website must provide a method for an insured or prospective insured to request and obtain information on the contracted amount for shoppable health care services from a health care provider and to compare the average price among health care providers.

(4) Upon the request of an insured, a health insurer must provide a good faith estimate of the contracted amount and the estimated amount of copayments, deductibles, and other cost-sharing responsibilities for health care services and procedures within 2 working days after the request for both in-network and out-of-network providers. The health insurer must notify the insured that the estimate may differ from the actual amount the insured will be responsible to pay due to unforeseen circumstances that arise out of the proposed nonemergency service or procedure.

(5) For the plan year beginning January 1, 2018, a health insurer must implement a shared savings incentive program to provide cash payments to an insured when the insured obtains a

shoppable health care service at a price that is less than the average price for that service.

(a) The amount of the shared savings incentive program payment may be calculated as a percentage between the contracted amount and the average price, or by an alternative method approved by the office.

(b) The amount of the cash payment to the insured must be at least 50 percent of the health insurer's saved costs for each shoppable health care service paid to the health care provider as compared with the average price.

(c) If an insured elects to receive a shoppable health care service from an out-of-network health care provider for a price that is less than the average price, the health insurer must treat such service as if the service is provided by an in-network health care provider for purposes of calculating the shared savings incentive program payment.

(d) A health insurer is not required to provide a cash payment under the shared savings incentive program to an insured when the health insurer's saved cost is $50 or less.

(e) A cash payment made by an insurer in accordance with this section is not an administrative expense of the insurer for rate development or rate filing purposes.

(6) The shared savings incentive program must be a component part of the policy, contract, or certificate of insurance provided by the health insurer. Annually and at the

time of enrollment or renewal, a health insurer must notify its insureds of the shared savings incentive program.

(7) A health insurer must file a description of the shared savings incentive program with the office on a form prescribed by the office. The office must review the filing to determine if the program complies with the requirements of this section.

(8) A health insurer must file an annual report to the office of its shared savings incentive program. The report must include:

(a) The total number of payments made pursuant to this section for the calendar year.

(b) The shoppable health care services by category for which payments were made.

(c) The average amount of payments.

(d) The total amount saved by the health insurer when compared with the average prices for each shoppable health service category.

(e) The total number of insured and the percentage of total insured who participated.

(9)(a) The office may impose an administrative penalty of no more than $2,500 per violation per day upon a health insurer for failure to comply with this section. A fine imposed under this section may be in addition to other penalties or fines authorized by the insurance code.

(b) If a health insurer fails to meet the filing

requirements under this section and does not submit the filing within 30 days after the date the filing is due, the office may order the insurer to discontinue the issuance of policies, contracts, or certificate of insurance until the filing requirements have been fulfilled.

(c) The office may revoke or suspend for at least 6 months the certificate of authority of a health insurer for failure to comply with this section.

(10) The office must submit an annual report that summarizes the reports filed by health insurers required by subsection (8). The report must be delivered to the President of the Senate and the Speaker of the House of Representatives by April 1, 2019, and each year thereafter.

(11) The office may adopt rules necessary to implement and enforce this section.

Section 3. This act shall take effect upon becoming a law.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Innovation Subcommittee

Representative Renner offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 627.6387, Florida Statutes, is created to read:

627.6387 Shared savings incentive program.—

(1) This section may be cited as the "Patient Savings Act".—

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

(a) "Average price" means the average amount paid to an in-network health care provider for a shoppable health care service within a 1-year period or as determined by another method approved by the office.

(b) "Contracted amount" means the amount agreed to be paid by the health insurer pursuant to a policy, contract, or certificate of insurance to a health care provider for shoppable health care services covered by the policy, contract, or certificate of insurance, including any facility fees charged by the provider.

(c) "Health care provider" means a hospital, ambulatory surgical center, and other medical facility licensed under chapter 395; a home health agency licensed under chapter 400; a physician licensed under chapter 458; a physician assistant licensed under chapter 458 or chapter 459; an osteopathic physician licensed under chapter 459; a chiropractic physician licensed under chapter 460; a podiatric physician licensed under chapter 461; a naturopath licensed under chapter 462; a dentist licensed under chapter 466; nurses licensed under part I of chapter 464; a midwife licensed under chapter 467; an occupational therapist licensed under chapter 468; radiological personnel certified under chapter 468; a clinical laboratory licensed under chapter 483; a physical therapist and a physical therapist assistant licensed under chapter 486; a blood bank, plasma center, industrial clinic, and renal dialysis facility; or a professional association, partnership, corporation, joint venture, or other association for professional activity by health care providers.

(d) "Health insurer" means an authorized insurer offering health insurance as defined in s. 624.603 or a health maintenance organization as defined in s. 641.19(12).

(e) "Shared savings incentive program" means a cash incentive program established by a health insurer pursuant to this section.

(f) "Shoppable health care service" means a nonemergency health care service for which an insured may receive a cash payment under a shared savings incentive program. Shoppable health care services include:

1. Clinical laboratory services.

2. Infusion therapy.

3. Inpatient and outpatient surgical procedures.

4. Obstetrical and gynecological services.

5. Outpatient nonsurgical diagnostic tests and procedures.

6. Physical and occupational therapy services.

7. Radiology and imaging services.

(3) A health insurer's website must provide a method for an insured or prospective insured to request and obtain information on the contracted amount for a shoppable health care service from a health care provider and to compare the average price among health care providers. The website shall provide quality information for each shoppable health care service from each health care provider, if available.

(4) Upon the request of an insured, a health insurer must provide a good faith estimate of the contracted amount and the estimated amount of copayments, deductibles, and other cost-sharing responsibilities for health care services and procedures within 2 working days after the request for both in-network and out-of-network providers. The health insurer must notify the insured that the estimate may differ from the actual amount the insured will be responsible to pay due to unforeseen circumstances that arise out of the proposed nonemergency service or procedure.

(5) For the plan year beginning January 1, 2018, and for each plan year thereafter, a health insurer must implement a shared savings incentive program to provide a cash payment to an insured when the insured obtains a shoppable health care service at a price that is less than the average price for that service.

(a) The amount of the shared savings incentive program payment may be calculated as a percentage between the contracted amount and the average price, or by an alternative method approved by the office.

(b) The amount of the cash payment to the insured must be at least 50 percent of the health insurer's saved costs for each shoppable health care service paid to the health care provider as compared with the average price.

(c) If an insured elects to receive a shoppable health care service from an out-of-network health care provider for a

price that is less than the average price, the health insurer must treat such service as if it is provided by an in-network health care provider for purposes of calculating the shared savings incentive program payment.

(d) A health insurer is not required to provide a cash payment under the shared savings incentive program to an insured when the health insurer's saved cost is less than $50.

(e) A cash payment made by a health insurer in accordance with this section is not an administrative expense for rate development or rate filing purposes.

(6) The shared savings incentive program must be a component part of the policy, contract, or certificate of insurance provided by the health insurer. Annually and at the time of enrollment or renewal, a health insurer must notify each insured of the shared savings incentive program.

(7) A health insurer must file a description of the shared savings incentive program on a form prescribed by the office. The office must review the filing to determine if the program complies with the requirements of this section.

(8) A health insurer must file an annual report to the office of its shared savings incentive program. The report must include:

(a) The total number of cash payments made pursuant to this section for the calendar year.

(b) Each shoppable health care service, by category, for which a cash payment was made.

(c) The average amount of cash payments.

(d) The total amount saved by the health insurer when compared with the average price for each shoppable health service category.

(e) The total number of insureds and the percentage of total insureds who participated.

(9)(a) The office may impose an administrative penalty of no more than $5,000 per violation per day upon a health insurer for failure to comply with this section. A fine imposed under this section may be in addition to other penalties or fines authorized by the insurance code.

(b) If a health insurer fails to meet the filing requirements under this section and does not submit the filing within 30 days after the due date, the office may order the health insurer to discontinue issuing policies, contracts, or certificate of insurance until the filing requirements have been fulfilled.

(c) The office may revoke or suspend for at least 12 months the health insurer's certificate of authority for failure to comply with this section.

(10) The office must submit an annual report to the President of the Senate and the Speaker of the House of

Representatives by April 1, 2019, and each year thereafter, which summarizes the reports required by subsection (8).

(11) The office may adopt rules necessary to implement and enforce this section.

Section 2. This act shall take effect upon becoming a law.

T I T L E A M E N D M E N T

Remove lines 2-4 and insert:

An act relating to health insurance; creating

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 543 Regulation of Nursing
SPONSOR(S): Pigman
TIED BILLS: **IDEN./SIM. BILLS:** SB 328

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Siples	Poche
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

To address a nursing shortage in Florida, legislation has been enacted over the past several years to ensure the availability of quality nursing education programs. HB 543 continues to build on this legislation.

Current law requires a nursing education program to meet a certain graduate passage rate on the licensure examination. If the program fails to do so, it may be placed on probation for up to two years. HB 543 authorizes the Board of Nursing (BON) to grant a one year extension to a nursing education program that is on probation for failure to meet the graduate passage rate if the program is progressing towards meeting the rate. However, the BON retains the authority to terminate a program after the two year probation period, or any extension thereof.

The bill requires any nursing education program that is on probation to notify its students and applicants of its status in writing. The notice must also provide information on the implications of the program's probationary status on the student or applicant and his or her employment and educational opportunities.

The bill removes a requirement that a nursing school must require a student who does not take the licensure examination within six months of graduation to enroll in and successfully complete a licensure examination preparatory course.

The bill also prohibits a nursing education program that was terminated or closed from reapplying for approval for 3 years. This also applies to a nursing education program that is terminated for failing to obtain the required accreditation by July 2019 or within 5 years after the date of enrollment of its first students. The bill authorizes the BON to adopt rules regarding the reapplication process for terminated or closed nursing education programs.

The bill authorizes the BON to perform an on-site evaluation of a nursing education program applicant to verify its compliance with application requirements.

The bill eliminates the annual reports required by the Office of Program Policy Analysis and Government Accountability (OPPAGA) on the status of nursing education programs, but retains the requirement that the Florida Center on Nursing issue the annual report and include an assessment of the progress towards accreditation for certain nursing programs.

Advanced Registered Nurse Practitioners (ARNPs) must complete 3 hours of continuing education related to the safe and efficient prescription of controlled substances. The bill broadens who may offer such continuing education to any entity approved by the Board of Nursing. The bill also deletes obsolete language related to the certification of ARNPs.

The bill authorizes the BON to adopt rules related to nursing curriculum, nursing program implementation, and reapplication procedures for terminated or closed programs.

The bill has an indeterminate, negative fiscal impact on state government.

The bill provides an effective date of July 1, 2017, except as otherwise expressly provided.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Advance Registered Nurse Practitioners

Regulation of Advanced Registered Nurse Practitioners

Part I of ch. 464, F.S., governs the licensure and regulation of advanced registered nurse practitioners (ARNPs) in Florida. Nurses are licensed by the Department of Health (DOH) and are regulated by the Board of Nursing (BON).[1] There are 26,691 actively licensed ARNPs in Florida.[2]

In Florida, an ARNP is a licensed nurse who is certified in advanced or specialized nursing practice and may practice as a certified registered nurse anesthetist, a certified nurse midwife, or a nurse practitioner.[3] Advanced or specialized nursing practice includes the performance of advanced-level nursing acts approved by the BON, which by virtue of postbasic specialized education, training, and experience are appropriately performed by an ARNP.[4] In addition to advanced or specialized nursing practices, ARNPs are authorized to practice certain medical acts, as opposed to nursing acts, as authorized within the framework of an established supervisory physician's protocol.[5]

The BON establishes the eligibility criteria for an applicant to be certified as an ARNP and the applicable regulatory standards for ARNP nursing practices.[6] To be certified as an ARNP, the applicant must be licensed as a registered nurse, have a master's degree in a clinical nursing specialty area with preparation in specialized practitioner skills, and submit proof that the applicant holds a current national advanced practice certification from a board-approved nursing specialty board.[7] The nursing specialty board must:

- Attest to the competency of nurses in a clinical specialty area;
- Require nurses to take a written examination prior to certification;
- Require nurses to complete a formal program prior to eligibility for examination;
- Maintain program accreditation or a review mechanism that adheres to criteria which are substantially equivalent to requirements in Florida; and
- Identify standards or scope of practice statements appropriate for each nursing specialty.[8]

All ARNPs must carry malpractice insurance or demonstrate proof of financial responsibility.[9] An applicant for certification is required to submit proof of coverage or financial responsibility within sixty days of certification and with each biennial renewal.[10] An ARNP must have professional liability

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[1] Pursuant to s. 464.004, F.S., the Board of Nursing is comprised of 13 members appointed by the Governor and confirmed by the Senate who serve 4-year terms. The Board is comprised of three licensed practical nurses who have practiced for at least four years, seven members who are registered numbers who have practiced for at least 4 years; three Florida residents who have never been licensed as nurses, are not connected to the practice of nursing, and have no financial interest in any health care facility, agency, or insurer; and seven members who are registered nurses who have practiced at least four years. Among the seven members who are registered nurses, there must be at least one must be an ARNP, one nurse educator of an approved program, and one nurse executive.
[2] E-mail correspondence with the Department of Health on February 2, 2017 (on file with the staff of the Health Innovation Subcommittee). This number includes all active licenses, including out of state practitioners.
[3] S. 464.003(3), F.S.
[4] S. 464.003(2), F.S.
[5] Id.
[6] S. 464.012(2), F.S.
[7] S. 464.012(1), F.S., and Rule 64B9-4.002, F.A.C.
[8] Rule 64B9-4.002(3), F.A.C.
[9] S. 456.048, F.S.
[10] Rule 64B9-4.002(5), F.A.C.

coverage of at least $100,000 per claim with a minimum annual aggregate of at least $300,000, or an unexpired irrevocable letter of credit, which is payable to the ARNP as beneficiary, in the amount of at least $100,000 per claim with a minimum aggregate availability of at least $300,000.[11]

ARNP Scope of Practice

Within the framework of the written protocol, an ARNP may:

- Prescribe, dispense, administer, or order any drug;[12]
- Initiate appropriate therapies for certain conditions;
- Perform additional functions as may be determined by board rule;
- Order diagnostic tests and physical and occupational therapy;
- Order any medication for administration to a patient in certain licensed health care facilities;
- Perform certain acts within his or her specialty; and
- Perform medical acts authorized within the framework of an established protocol.[13]

Continuing Education

All nurses are required to complete at least 30 hours of continuing education biennially as a condition of license or certificate renewal.[14] As a part of these 30 hours, ARNPs must complete 3 hours of continuing education on the safe and effective prescription of controlled substances, offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit, the American Nurses Credentialing Center, the American Association of Nurse Anesthetists, or the American Association of Nurse Practitioners.

Nursing Education Programs

To be licensed as a registered nurse (RN) or a practical nurse (LPN) in this state, an individual must, among other things, graduate from an accredited or a BON-approved nursing program or its equivalent.[15] A registered nurse is authorized to practice professional nursing[16] and an LPN is authorized to practice practical nursing.[17]

Nursing programs in Florida are offered by public school districts, Florida colleges, state universities, private institutions licensed by the Commission for Independent Education, private institutions that are members of the Independent Colleges and Universities of Florida (ICUF), and Pensacola Christian College, which is statutorily authorized by s. 1005.06(1)(e), F.S.[18]

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[11] Id.
[12] Controlled substances may only be prescribed or dispensed if the ARNP has graduated from a program leading to a master's or doctoral degree in a clinical specialty area with training in specialized practitioner skills.
[13] S.s 464.012(3),(4), and 464.003(2), F.S.
[14] S. 464.013(3), F.S.
[15] S. 464.008(1)(c), F.S.
[16] The practice of professional nursing means the performance of those acts requiring substantial specialized knowledge, judgment, and nursing skills, including observation, assessment, nursing diagnosis, planning, intervention, and evaluation of care; teaching and counseling of the ill, injured, or infirm; promotion of wellness, maintenance of health, prevention of illness in others; and the administration of medication and treatment as authorized or prescribed. A RN is responsible and accountable for making decisions that are based upon the individual's educational preparation and experience in nursing. (Ss. 464.003(20) and (22), F.S.)
[17] The practice of practical nursing means the performance of selected acts in the care of the ill, injured, or infirm; the promotion of wellness, maintenance of health, and prevention of illness of others under the direction of a registered nurse, a licensed physician, or a licensed dentist. An LPN is responsible and accountable for making decisions that are based upon the individual's educational preparation and experience in nursing (Ss. 464.003(16) and (19), F.S.).
[18] This section of law exempts schools from the Commission for Independent Education's licensure requirements if the institution: had been so exempted prior to 2001; is incorporated in this state; the institution's credits or degrees are accepted for credit by at least three colleges that are fully accredited by an agency recognized by the U.S. Department of Education; the institution was exempt under that category prior to July 1, 1982; and the institution does not enroll any students who receive state or federal financial aid. Only two

A nursing education program is considered an accredited program if it is accredited by a specialized nursing accrediting agency that is nationally recognized by the United States Secretary of Education to accredit nursing education programs.[19] A program that is approved by the BON that is not accredited is considered an approved program.[20] Chapter 464, F.S., recognizes and distinguishes between approved programs and accredited programs.

Approved Programs

Approval of Nursing Education Programs

An educational institution may apply to the DOH to become an approved nursing program. The DOH reviews the application for completeness. An application to become an approved program must document compliance with the following program standards: faculty qualifications, clinical training requirements, written policies for faculty, signed agreements with clinical training sites in the curriculum plan, and curriculum and instruction requirements.[21]

An application deemed complete by the DOH is forwarded to the BON for approval. Within 90 days of receipt of the application by the DOH, the BON must approve the application or notify the applicant of the intent to deny the application. If noticed of the intent to deny, the applicant may request a hearing under chapter 120, F.S.[22]

An approved program's curriculum must consist of at least 50 percent clinical training for an associate's degree RN program or at least 40 percent clinical training for a bachelor's degree RN program.[23] No more than 50 percent of an approved program's clinical training may consist of clinical simulation.[24]

Approved programs must submit an annual report by November 1 of each year to the BON. The report must document application and enrollment, student retention rates, and accreditation status.[25] The BON must publish on its website for each program its:

- Accreditation status;
- Probationary status;
- Graduate passage rate on the National Council on State Boards of Nursing Licensing Examination (NCLEX) for the most recent two calendar years;
- Student retention rates;
- Annual report summary; and
- Application documentation.[26]

If the nursing education program fails to submit its annual report, the director of the nursing education program must appear before the BON, at its next regularly scheduled meeting, to explain the reason for the delay. If the annual report is not submitted within six months of its due date, the BON must terminate the program.[27]

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institutions in Florida, Pensacola Christian College and Landmark Baptist College, are subject to this exemption. Landmark Baptist College does not offer a nursing program.

[19] S. 464.003(1), F.S.
[20] Id.
[21] S. 464.019(1), F.S.
[22] S. 464.019(2), F.S.
[23] S. 464.019(1)(b), F.S.
[24] S. 464.019(1)(c), F.S.
[25] S. 464.019(3), F.S.
[26] S. 464.019(4), F.S.
[27] S. 464.019(5), F.S.

Accountability Requirements

An approved program may not have a graduate passage rate for first time takers who sit for the licensure examination within six months of graduation that is 10 percentage points or more below the national average for two consecutive years.[28] If a program fails to meet the required graduate passage rate, the program is placed on probation by the BON and the program must present a plan for remediation to the BON, which includes specific benchmarks for achieving the required graduate passage rate. If a program on probation does not achieve the required graduate passage rate for any one calendar year during the two calendar years it is on probation, the BON must terminate the program.[29] However, the BON is authorized to extend the probationary status for an additional year if the program demonstrates progress toward the graduate passage rate goal by meeting the majority of the benchmarks established in the remediation plan.[30]

Accredited Programs

Because accredited programs have to meet stringent criteria to maintain program accreditation, many of the statutory requirements for approved programs are not applicable to accredited programs.[31] However, an accredited program is subject to the accountability requirements. If an accredited program ceases to be accredited, it must, within 10 business days, provide written notice to the BON, its students and applicants, and its clinical training sites.

In 2014, legislation was enacted that required all nursing education programs that prepare students to be RNs to become accredited by July 1, 2019, or within 5 years after the enrollment of the program's first students.[32]

Accredited programs' accreditation status and graduate NCLEX passage rates must be published on the BON website.[33]

Reform of Nursing Education Programs

In 2009, the Legislature created a statutory framework for the approval of nursing education programs.[34] Prior to 2009, the BON had the authority to prescribe the process by rule. The new law:

- Established standards for faculty qualifications, clinical training and clinical simulation requirements, and curriculum and instruction requirements;
- Required all nursing education programs to submit an annual report to the BON, including information that the BON must publish on its website;
- Required the BON to place an approved nursing education program on probation if its graduate passage rate fell 10 percent or more below the national average passage rate on the NCLEX for two consecutive years;
- Required the BON to terminate a program if the approved nursing education program's graduates failed to achieve compliance within the next two consecutive years; and
- Required the Florida Center on Nursing and the Office of Program Policy Analysis and Government Accountability (OPPAGA) to monitor the implementation of the new approval process and to annually report to the Governor and the Legislature regarding the approval process, nursing program availability and quality, and the BON's compliance with the law.

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[28] Id.
[29] Id.
[30] Id.
[31] S. 464.019(9), F.S.
[32] Chapter 2014-92, Laws of Fla.
[33] Supra, note 26.
[34] Chapter 2009-168, Laws of Fla.

In 2010, the Legislature made additional changes to the nursing education program approval process to address implementation issues.[35] These changes included:

- Requiring the BON to approve or deny a nursing education program application within 90 days after receipt of a complete application;
- Specifying that a program may be removed from probation if its graduates attain the required passage rate after one calendar year during the probation period;
- Making the passage rate requirement adopted in 2009 prospective so that it would apply beginning with the 2010 calendar year; and
- Clarifying that the graduate passage rate must be 10 percentage points or more below the national average passage rate on the NCLEX for two consecutive years, rather than 10 percent below the national average passage rate.

In 2014, the Legislature made additional revisions to the requirements for nursing education programs.[36] These revisions included:

- Authorizing the BON to adopt rules for documenting nursing education program accreditation;
- Requiring all nursing education programs that prepare students as RNs to be accredited by a nationally recognized accreditation agency by July 2019, or within 5 years of the date of enrollment of the program's first students;
- Requiring the Florida Center for Nursing and OPPAGA to submit the annual report to the Governor and the Legislature until January 2020;
- Limiting the graduate passage rate requirement to only those students who take the licensure examination for the first time within six months of graduation;
- Requiring an approved program to require any graduate who does not take the licensure examination within six months of graduation to enroll in and successfully complete a licensure examination preparatory course;
- Requiring programs on probation to develop and submit a remediation plan for attaining the required graduate passage rate, including benchmarks; and
- Authorizing the BON to extend a nursing education program's probationary status for one additional year if the program shows adequate progress towards the achieving the graduate passage rate by meeting a majority of the benchmarks established in the remediation plan.

Current Status of Nursing Education Programs

Since 2009, the BON has approved 303 new nursing programs, increasing the total number of nursing education programs to 350.[37] However, in the last year, this number has trended down. There were 369 nursing programs in 2015. Overall, there has been a 105 percent increase in the number of nursing education programs since 2009. Of the nursing education programs in this state, 93 are accredited.[38]

In 2015, 128 nursing education programs (or 42 percent) had graduate passage rates that were 10 percent or below the national average rate.[39] The majority of these programs were associate degree programs; however, 27 percent were practical nursing programs and 10 percent were Bachelor of Science in nursing programs. Of the 128 programs that failed to meet the graduate passage rate:

- 14 were placed on probation;

[35] Chapter 2010-37, Laws of Fla.
[36] Chapter 2014-92, Laws of Fla.
[37] OPPAGA, *Review of Florida's Nursing Education Programs, 2016*, Report No. 17-03 (January 2017), *available at* http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/1703rpt.pdf (last visited February 15, 2017). The total number takes into account new approvals, terminations, and closures of nursing education programs that have occurred since 2009.
[38] Id. 40 bachelor's degree programs, 43 associate degree programs, and 10 practical nursing programs are accredited.
[39] OPPAGA, *Approximately 42% of Nursing Programs Had a Licensure Exam Passage Rate Below the Required Legislative Standard in 2015*, Report No. 16-05 (July 2016), *available at* http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/1605rpt.pdf (last visited February 18, 2017).

- 11 were terminated by the BON;
- 11 were exempt from being placed on probation because they were accredited;
- 55 were not on probation, but were at risk of being placed on probation if their graduate passage rate continues to be 10 percent or more below the national average in 2016; and
- 37 closed.[40]

According to OPPAGA, the majority of the nursing programs that failed to meet the graduate passage rate requirement were relatively new and unaccredited.[41]

In 2016, there were 42 programs on probation for failing to meet the graduate exam passage rate and 50 nursing education programs closed. [42] Of those 50 closed programs, 37 programs closed voluntarily and 13 programs were terminated by the BON; 22 of these programs were on probation immediately prior to their termination or closure.

Effect of Proposed Changes

Advanced Registered Nurse Practitioners

The bill deletes an obsolete provision of law that permitted a nurse to be certified as an ARNP if he or she completed a formal postbasic educational program of at least one academic year, the primary purpose of which is to prepare a nurse for advanced or specialized practice. Currently, to obtain certification as an ARNP in this state, an applicant must have a master's degree in a nursing clinical specialty area and hold a current national advanced practice certification from a board-approved nursing specialty board.[43] Due to the current graduate education and certification standards, the option to obtain certification as an ARNP by completing an additional postbasic educational program of at least one academic year is no longer in use.[44]

The bill eliminates the requirement that specific entities offer the continuing education course on safe and effective prescription of controlled substances and requires such courses to be approved by the BON. As a result, ARNPs will likely have more opportunities to satisfy this continuing education requirement as more BON-approved entities provide the course.

Nursing Education Programs

For a nursing education program applicant, the bill authorizes the Board of Nursing (BON) to perform an onsite inspection of the nursing education program to document the applicant's compliance with program requirements.

The bill amends the accountability requirements for nursing schools by:

- Including all first-time test takers in the calculation of the graduate passage rate, rather than limiting it to only those that are within six months of graduation;
- Eliminating a requirement that an approved program require a graduate who does not take the licensure examination within six months of graduate to complete a licensure examination preparatory course;
- Clarifying that the BON has the authority to extend a nursing education program's probationary status for another calendar year if, during the two calendar years following its placement on probationary status, it fails to achieve the required passage rate but has demonstrated progress toward meeting the graduate passage rate goal;

[40] Id.
[41] Id.
[42] Supra, FN 37.
[43] The bills provides that the proposed provision is effective after the Nurse Licensure Compact takes effect on December 31, 2018, or upon enactment of the Nurse Licensure Compact into law by 28 states, whichever occurs first.
[44] DOH, *Agency Legislative Bill Analysis for HB 543*, dated January 15, 2017, (on file with the Health Innovation Subcommittee).

- Clarifying that the BON retains the authority to terminate a nursing education program if it declines to grant an extension of probationary status or if the program fails to achieve the required graduation passage rate at the end of any such extension.
- Authorizing the BON to terminate a program if the program director fails to appear before the BON to explain the reason for the delay in submitting the required annual report, or if the program fails to submit an annual report within six months after it is due; and
- Requiring a nursing education program, whether accredited or non-accredited, that is on probationary status to disclose the program's status, in a written format, to students and applicants. The written notification must include an explanation of the implication of the program's probationary status on employment and educational opportunities, as well as the prospects for a student wishing to matriculate to university.

The bill prohibits a nursing education program that is terminated or closed from seeking program approval under its original name or a new name for at least 3 years after the program is closed or terminated.

If a nursing education program fails to meet the accreditation requirements, the program must be terminated and may not apply for reapproval under its original name or a new program name for at least 3 years after the program is termination.

The BON is authorized to adopt rules related to the nursing curriculum and nursing program implementation plans, which may include a description of the various types and uses of simulation technology and limitations on its use. The bill also authorizes the BON to adopt rules related to program termination or closure under this section and the procedure for the subsequent approval of a program that was terminated or closed.

The bill eliminates the annual reports due to the Governor and the Legislature by OPPAGA related to nursing education programs; however, the Florida Center on Nursing must continue to provide such reports until January 2020. Additionally, the Florida Center for Nursing must include in its annual report an assessment of the compliance of nursing programs that are required to be accredited.

The bill provides an effective date of July 1, 2017, except as otherwise expressly provided in the bill.

B. SECTION DIRECTORY:

Section 1: Amends s. 464.012, F.S., relating to certification of advanced registered nurse practitioners; fees; controlled substance prescribing.
Section 2: Amends s. 464.012, F.S., relating to certification of advanced registered nurse practitioners; fees; controlled substance prescribing.
Section 3: Amends s. 464.013, F.S., relating to renewal of license or certificate.
Section 4: Amends s. 464.019, F.S., relating to approval of nursing education programs.
Section 5: Provides an effective date of July, 1, 2017, except as otherwise expressly provided in the bill.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

The DOH may experience a recurring increase in workload associated with conducting optional on-site evaluations of nursing education programs. The DOH indicates that it is unable to calculate the fiscal impact at this time.[45]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Nursing students that do not take the licensure exam within six months of graduation may realize cost savings by no longer being subject to a mandatory licensure examination preparatory course.

A nursing education program that is terminated or closed may incur costs or experience economic losses due to the 3-year waiting period imposed by the bill before it may reapply for approval.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill authorizes the BON, within the Department of Health, to adopt rules related to nursing curriculum and nursing program implementation plans, the closure and termination of nursing programs, and the subsequent approval of a nursing program that has been closed or terminated.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

[45] Id.

A bill to be entitled

An act relating to the regulation of nursing; amending s. 464.012, F.S.; removing an obsolete qualification to satisfy certification requirements for an advanced registered nurse practitioner; amending s. 464.013, F.S.; requiring certain continuing education courses to be approved by the Board of Nursing; removing a requirement that certain continuing education courses be offered by specified entities; amending s. 464.019, F.S.; authorizing the board to conduct certain on-site evaluations; removing a limiting criterion from the requirement to measure graduate passage rates; removing a requirement that certain nursing program graduates complete a specific preparatory course; clarifying circumstances when programs in probationary status must be terminated; providing that accredited and nonaccredited nursing education programs must disclose probationary status; requiring notification of probationary status to include certain information; prohibiting a terminated or closed program from seeking program approval for a certain time; authorizing the board to adopt certain rules; requiring accredited programs to meet program accountability requirements and requirements to provide notification of probationary status; removing

requirements that the Office of Program Policy Analysis and Government Accountability perform certain tasks; requiring the Florida Center for Nursing to make an annual assessment of compliance by nursing programs with certain accreditation requirements; requiring the center to include its assessment in a report to the Governor and the Legislature; removing the requirement that the Office of Program Policy Analysis and Government Accountability perform specified duties under certain circumstances; requiring the termination of a program under certain circumstances; providing effective dates.

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

Section 1. Subsection (1) of section 464.012, Florida Statutes, is amended to read:

464.012 Certification of advanced registered nurse practitioners; fees; controlled substance prescribing.—

(1) Any nurse desiring to be certified as an advanced registered nurse practitioner shall apply to the department and submit proof that he or she holds a current license to practice professional nursing and that he or she meets one or more of the following requirements as determined by the board:

~~(a) Satisfactory completion of a formal postbasic~~

~~educational program of at least one academic year, the primary purpose of which is to prepare nurses for advanced or specialized practice.~~

(a) ~~(b)~~ Certification by an appropriate specialty board. Such certification shall be required for initial state certification and any recertification as a registered nurse anesthetist, psychiatric nurse, or nurse midwife. The board may by rule provide for provisional state certification of graduate nurse anesthetists, psychiatric nurses, and nurse midwives for a period of time determined to be appropriate for preparing for and passing the national certification examination.

(b) ~~(c)~~ Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills. For applicants graduating on or after October 1, 1998, graduation from a master's degree program shall be required for initial certification as a nurse practitioner under paragraph (4)(c). For applicants graduating on or after October 1, 2001, graduation from a master's degree program shall be required for initial certification as a registered nurse anesthetist under paragraph (4)(a).

Section 2. Effective December 31, 2018, or upon enactment of the Nurse Licensure Compact into law by 26 states, whichever occurs first, subsection (1) of section 464.012, is amended to read:

464.012 Certification of advanced registered nurse

practitioners; fees; controlled substance prescribing.—

(1) Any nurse desiring to be certified as an advanced registered nurse practitioner shall apply to the department and submit proof that he or she holds a current license to practice professional nursing or holds an active multistate license to practice professional nursing pursuant to s. 464.0095 and that he or she meets one or more of the following requirements as determined by the board:

~~(a) Satisfactory completion of a formal postbasic educational program of at least one academic year, the primary purpose of which is to prepare nurses for advanced or specialized practice.~~

(a)~~(b)~~ Certification by an appropriate specialty board. Such certification shall be required for initial state certification and any recertification as a registered nurse anesthetist, psychiatric nurse, or nurse midwife. The board may by rule provide for provisional state certification of graduate nurse anesthetists, psychiatric nurses, and nurse midwives for a period of time determined to be appropriate for preparing for and passing the national certification examination.

(b)~~(c)~~ Graduation from a program leading to a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills. For applicants graduating on or after October 1, 1998, graduation from a master's degree program shall be required for initial certification as a nurse

practitioner under paragraph (4)(c). For applicants graduating on or after October 1, 2001, graduation from a master's degree program shall be required for initial certification as a registered nurse anesthetist under paragraph (4)(a).

Section 3. Subsection (3) of section 464.013, Florida Statutes, is amended to read:

464.013 Renewal of license or certificate.—

(3) The board shall by rule prescribe up to 30 hours of continuing education biennially as a condition for renewal of a license or certificate.

(a) A nurse who is certified by a health care specialty program accredited by the National Commission for Certifying Agencies or the Accreditation Board for Specialty Nursing Certification is exempt from continuing education requirements. The criteria for programs must be approved by the board.

(b) Notwithstanding the exemption in paragraph (a), as part of the maximum 30 hours of continuing education ~~hours~~ required under this subsection, advanced registered nurse practitioners certified under s. 464.012 must complete at least 3 hours of continuing education on the safe and effective prescription of controlled substances. Such continuing education courses must be approved by the board and ~~must be offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award~~

~~Category 1 credit, the American Nurses Credentialing Center, the American Association of Nurse Anesthetists, or the American Association of Nurse Practitioners and~~ may be offered in a distance learning format.

Section 4. Paragraph (b) of subsection (2), subsection (5), subsection (8), paragraph (a) of subsection (9), and subsection (10) of section 464.019, Florida Statutes, are amended, paragraph (d) is added to subsection (7) of that section, and paragraph (e) is added to subsection (11) of that section, to read:

464.019 Approval of nursing education programs.—

(2) PROGRAM APPROVAL.—

(b) Following the department's receipt of a complete program application, the board may conduct an on-site evaluation if necessary to document the applicant's compliance with subsection (1). Within 90 days after the department's receipt of a complete program application, the board shall:

1. Approve the application if it documents compliance with subsection (1); or

2. Provide the educational institution with a notice of intent to deny the application if it does not document compliance with subsection (1). The notice must specify written reasons for the board's denial of the application. The board may not deny a program application because of an educational institution's failure to correct an error or omission that the

department failed to provide notice of to the institution within the 30-day notice period under paragraph (a). The educational institution may request a hearing on the notice of intent to deny the program application pursuant to chapter 120.

(5) ACCOUNTABILITY.—

(a)1. An approved program must achieve a graduate passage rate for first-time test takers which ~~who take the licensure examination within 6 months after graduation from the program that~~ is not more than 10 percentage points lower than the average passage rate during the same calendar year for graduates of comparable degree programs who are United States educated, first-time test takers on the National Council of State Boards of Nursing Licensing Examination, as calculated by the contract testing service of the National Council of State Boards of Nursing. ~~An approved program shall require a graduate from the program who does not take the licensure examination within 6 months after graduation to enroll in and successfully complete a licensure examination preparatory course pursuant to s. 464.008.~~ For purposes of this subparagraph, an approved program is comparable to all degree programs of the same program type from among the following program types:

a. Professional nursing education programs that terminate in a bachelor's degree.

b. Professional nursing education programs that terminate in an associate degree.

c. Professional nursing education programs that terminate in a diploma.

d. Practical nursing education programs.

2. Beginning with graduate passage rates for calendar year 2010, if an approved program's graduate passage rates do not equal or exceed the required passage rates for 2 consecutive calendar years, the board shall place the program on probationary status pursuant to chapter 120 and the program director shall appear before the board to present a plan for remediation, which shall include specific benchmarks to identify progress toward a graduate passage rate goal. The program must remain on probationary status until it achieves a graduate passage rate that equals or exceeds the required passage rate for any 1 calendar year. The board shall deny a program application for a new prelicensure nursing education program submitted by an educational institution if the institution has an existing program that is already on probationary status.

3. Upon the program's achievement of a graduate passage rate that equals or exceeds the required passage rate, the board, at its next regularly scheduled meeting following release of the program's graduate passage rate by the National Council of State Boards of Nursing, shall remove the program's probationary status. If the program, during the 2 calendar years following its placement on probationary status, does not achieve the required passage rate for any 1 calendar year, the board

~~shall terminate the program pursuant to chapter 120. However, the board~~ may extend the program's probationary status for 1 additional year, provided ~~if~~ the program has demonstrated ~~demonstrates~~ adequate progress toward the graduate passage rate goal by meeting a majority of the benchmarks established in the remediation plan. If the program is not granted the 1-year extension or fails to achieve the required passage rate by the end of such extension, the board shall terminate the program pursuant to chapter 120.

(b) If an approved program fails to submit the annual report required in subsection (3), the board shall notify the program director and president or chief executive officer of the educational institution in writing within 15 days after the due date of the annual report. The program director shall appear before the board at the board's next regularly scheduled meeting to explain the reason for the delay. The board shall terminate the program pursuant to chapter 120 if the program director fails to appear before the board, as required under this paragraph, or if the program ~~it~~ does not submit the annual report within 6 months after the due date.

(c) A nursing education ~~An approved~~ program, whether accredited or nonaccredited, which has been placed on probationary status shall disclose its probationary status in writing to the program's students and applicants. The notification must include an explanation of the implications of

the program's probationary status on student and applicant employment and educational opportunities, including the prospects a student wishing to matriculate at a university will face.

(d) If students from a program that is terminated pursuant to this subsection transfer to an approved or an accredited program under the direction of the Commission for Independent Education, the board shall recalculate the passage rates of the programs receiving the transferring students, excluding the test scores of those students transferring more than 12 credits.

(7) PROGRAM CLOSURE.—

(d) A program that is terminated or closed under this section may not seek program approval under its original name or a new program name for a minimum of 3 years after the date of termination or closing.

(8) RULEMAKING.—The board does not have rulemaking authority to administer this section, except that the board shall adopt rules that prescribe the format for submitting program applications under subsection (1) and annual reports under subsection (3), and to administer the documentation of the accreditation of nursing education programs under subsection (11). The board may adopt rules related to the nursing curriculum and nursing program implementation plans, which may include definitions of the various types and uses of simulation technology and limitations on the technology's use. The board

may also adopt rules related to program termination or closure under this section and the procedure for a program that is terminated or closed under this section to seek subsequent program approval. The board may not impose any condition or requirement on an educational institution submitting a program application, an approved program, or an accredited program, except as expressly provided in this section.

(9) APPLICABILITY TO ACCREDITED PROGRAMS.—

(a) Subsections (1)-(3), paragraph (4)(b), and paragraphs (5)(b) and (d) ~~subsection (5)~~ do not apply to an accredited program.

(10) IMPLEMENTATION STUDY.—The Florida Center for Nursing ~~and the education policy area of the Office of Program Policy Analysis and Government Accountability~~ shall study the administration of this section and submit reports to the Governor, the President of the Senate, and the Speaker of the House of Representatives annually by January 30, through January 30, 2020. The annual reports shall address the previous academic year; provide data on the measures specified in paragraphs (a) and (b), as such data becomes available; and include an evaluation of such data for purposes of determining whether this section is increasing the availability of nursing education programs and the production of quality nurses. The department and each approved program or accredited program shall comply with requests for data from the Florida Center for Nursing ~~and~~

~~the education policy area of the Office of Program Policy Analysis and Government Accountability~~.

(a) The Florida Center for Nursing ~~education policy area of the Office of Program Policy Analysis and Government Accountability~~ shall evaluate program-specific data for each approved program and accredited program conducted in the state, including, but not limited to:

1. The number of programs and student slots available.

2. The number of student applications submitted, the number of qualified applicants, and the number of students accepted.

3. The number of program graduates.

4. Program retention rates of students tracked from program entry to graduation.

5. Graduate passage rates on the National Council of State Boards of Nursing Licensing Examination.

6. The number of graduates who become employed as practical or professional nurses in the state.

(b) The Florida Center for Nursing shall evaluate the board's implementation of the:

1. Program application approval process, including, but not limited to, the number of program applications submitted under subsection (1); the number of program applications approved and denied by the board under subsection (2); the number of denials of program applications reviewed under chapter

120; and a description of the outcomes of those reviews.

2. Accountability processes, including, but not limited to, the number of programs on probationary status, the number of approved programs for which the program director is required to appear before the board under subsection (5), the number of approved programs terminated by the board, the number of terminations reviewed under chapter 120, and a description of the outcomes of those reviews.

(c) The Florida Center for Nursing shall complete an annual assessment of compliance by programs with the accreditation requirements of subsection (11), include in the assessment a determination of the accreditation process status for each program, and submit the assessment as part of the report required by this subsection ~~For any state fiscal year in which The Florida Center for Nursing does not receive legislative appropriations, the education policy area of the Office of Program Policy Analysis and Government Accountability shall perform the duties assigned by this subsection to the Florida Center for Nursing~~.

(11) ACCREDITATION REQUIRED.—

(e) A nursing education program that fails to meet the accreditation requirements shall be terminated and is ineligible for reapproval under its original name or a new program name for a minimum of 3 years after the date of termination.

Section 5. Except as otherwise expressly provided in this

act, this act shall take effect July 1, 2017.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 543 (2017)

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	__ (Y/N)
ADOPTED AS AMENDED	__ (Y/N)
ADOPTED W/O OBJECTION	__ (Y/N)
FAILED TO ADOPT	__ (Y/N)
WITHDRAWN	__ (Y/N)
OTHER	_____

Committee/Subcommittee hearing bill: Health Innovation Subcommittee

Representative Pigman offered the following:

Amendment

Remove line 260 and insert:

(5)(b) ~~subsection (5)~~ do not apply to an accredited

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 589 Prescription Drug Price Transparency
SPONSOR(S): Yarborough
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee		Langston	Poche
2) Health & Human Services Committee			

SUMMARY ANALYSIS

Spending on prescription drugs has risen sharply in the United States over the past few years. From 2013 to 2015, out-of-pocket costs for prescription drugs rose 20 percent, rising to an average cost of $44 per brand name prescription drug. Specialty prescription drug prices are projected to increase 18.7 percent in 2017, accounting for 35 percent of the prescription drug spending trend even though they account for less than one percent of prescriptions.

In Florida, consumers can research prescription drug prices at www.MyFloridaRx.com (MyFloridaRx). MyFloridaRx is a joint effort between the Office of the Attorney General (AG) and the Agency for Health Care Administration (AHCA). The website lists the usual and customary prices charged by pharmacies for 150 of the most commonly prescribed brand name drugs and associated generic equivalents.

MyFloridaRx shows price data for retail pharmacies dispensing at least one prescription drug to a Medicaid beneficiary. The retail pharmacies appearing on the website are those that dispensed at least one of the top 150 posted prescription drugs to a Medicaid beneficiary. The statute requires participating pharmacies to provide AHCA with their pricing levels quarterly, including the usual and customary retail price for a 30-day supply of the prescription drug at a standard dose. Once AHCA receives the data, it is submitted to the AG's office, which maintains the website and updates it monthly.

When a consumer queries MyFloridaRx, search results provide the pharmacy name, address and phone number, the prescription drug name and strength, the most commonly dispensed quantity, and price. These results can be sorted by pharmacy name, zip code, drug name, drug quantity, or price.

HB 589 doubles the number of prescription drugs that must be posted to MyFloridaRx, from 150 to 300. Additionally, the bill codifies the current practice by which prescription drug pricing information is reported to AHCA, from quarterly to monthly. As a result, patients who query MyFloridaRx will have access to pricing information for more prescription drugs.

Finally, the bill removes obsolete language referencing deadlines for implementation that have already passed.

The bill does not appear to have a fiscal impact on state government.

The bill provides an effective date of upon becoming law.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

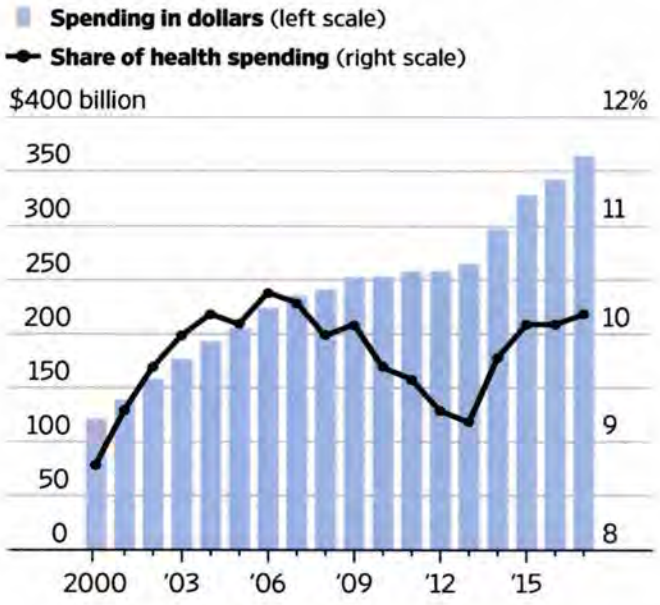
Background

Prescription Drug Cost and Pricing

Spending on prescription drugs has risen sharply in the United States over the past few years.[1] From 2013 to 2015, out-of-pocket costs for prescription drugs rose 20 percent,[2] rising to an average cost of $44 per brand name prescription drug.[3] Additionally, prescription drug prices increased an average of almost 10 percent from June 2015 to May 2016.[4] Specialty prescription drug prices are projected to increase 18.7 percent in 2017, accounting for 35 percent of the prescription drug spending trend even though they account for less than one percent of prescriptions.[5]

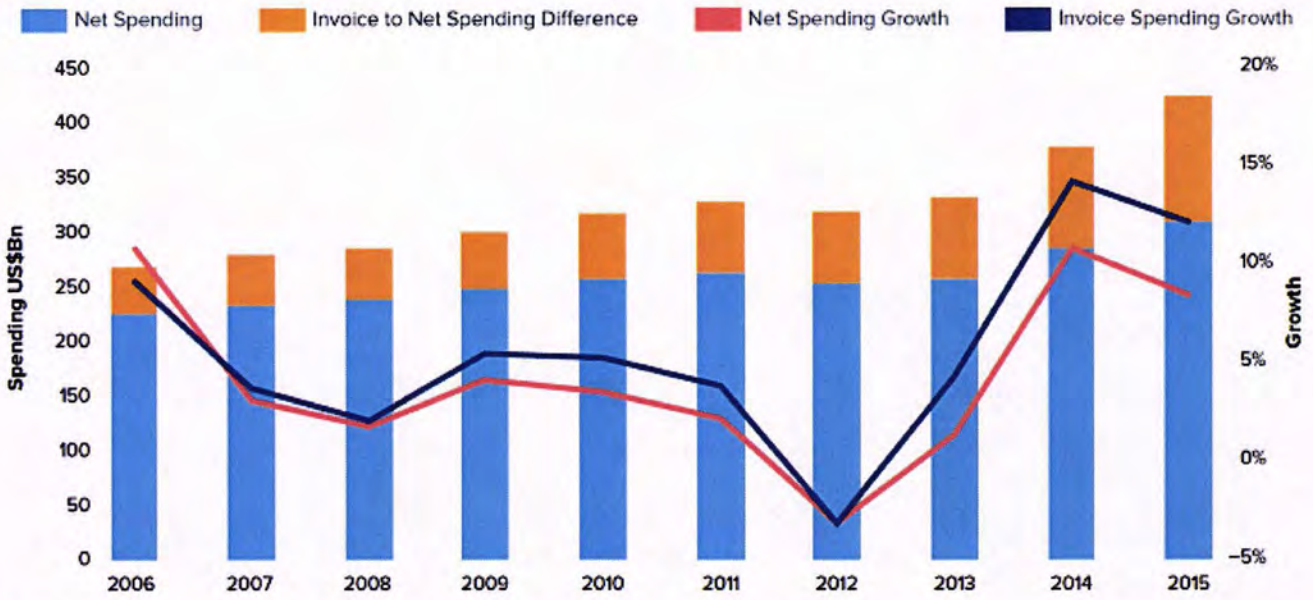
Recent increases in prescription drug prices are not only an increase in spending in terms of dollars, but also as a percentage of total healthcare spending.[6]

Prescription Drug Spending 2000-2017[7]



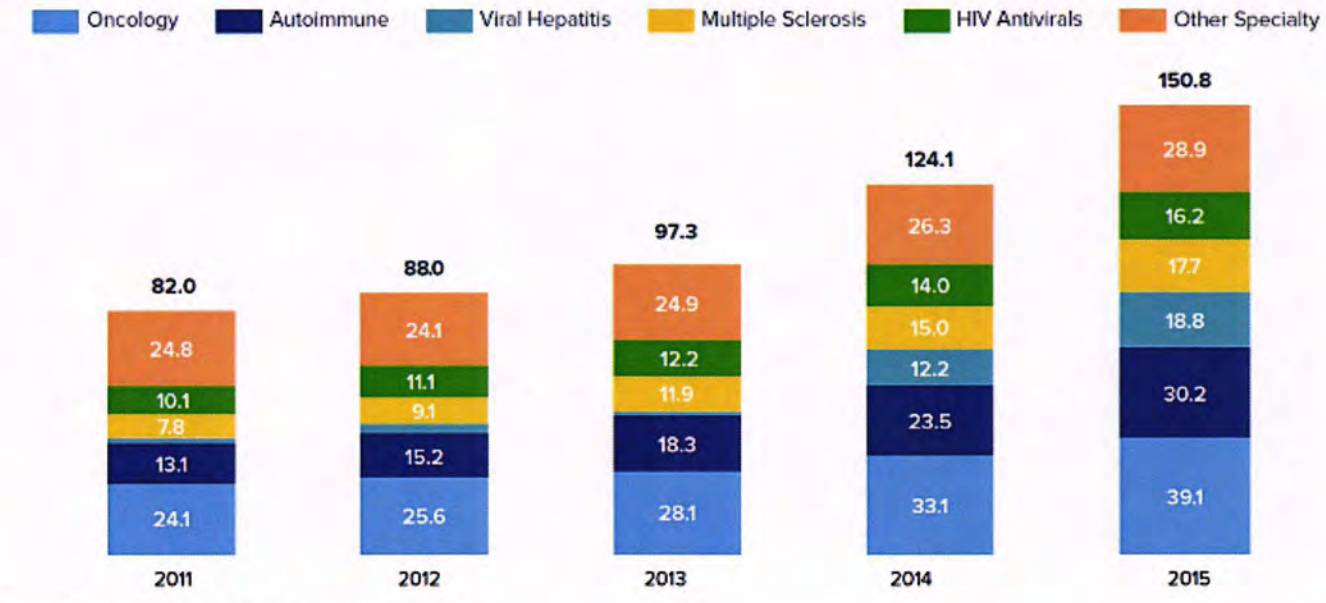
[1] Ameet Sarpatwari, Jerry Avorn, and Aaron S. Kesselheim, *State Initiatives to Control Medication Costs — Can Transparency Legislation Help?*, N. ENGL. J. MED. 2016; 374:2301-2304 Jun. 16, 2016, http://www.nejm.org/doi/full/10.1056/NEJMp1605100#t=article (last visited February 17, 2017).
[2] Troy Parks, *Drug pricing needs transparency, physicians say*, AMA WIRE, Jan. 26, 2017, https://wire.ama-assn.org/ama-news/drug-pricing-needs-transparency-physicians-say (last visited February 17, 2017).
[3] Beth Braverman, *Prescription Drug Prices Headed for Double-Digit Increases in 2017*, THE FISCAL TIMES, Oct. 24, 2016, http://www.thefiscaltimes.com/2016/10/24/Prescription-Drug-Prices-Headed-Double-Digit-Increases-2017 (last visited February 1, 2017).
[4] Brad Tuttle, *Prescription Drug Prices in America Are Rising Like No Other Industry*, TIME, Jul. 14, 2016, http://time.com/money/4406167/prescription-drug-prices-increase-why/ (last visited February 1, 2017)
[5] *Supra*, note 3. Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions and often require special handling and administration.
[6] Jonathan D. Rockoff, *How Do We Deal With Rising Drug Costs?,* THE WALL STREET JOURNAL, Apr. 10, 2016, https://www.wsj.com/articles/how-do-we-deal-with-rising-drug-costs-1460340357 (last visited February 17, 2017).
[7] Id.

Total Spending on Prescription Drugs[8]



Source: IMS Health, National Sales Perspectives, Jan 2016; U.S. Census Bureau; U.S. Bureau of Economic Analysis

Spending on Specialty Prescription Drugs[9]



Source: IMS Health, National Sales Perspectives, Jan 2016

[8] *Medicines Use and Spending in the U.S. – A Review of 2015 and Outlook to 2020,* QUINTILESIMS, APR. 2016, http://www.imshealth.com/en/thought-leadership/quintilesims-institute/reports/medicines-use-and-spending-in-the-us-a-review-of-2015-and-outlook-to-2020 (last visited February 17, 2017).

[9] Id.

Pharmaceutical companies take into account a number of factors, including the market for the particular prescription drug, the cost of comparative treatments, cost of research and development, the price of the manufacturing and ingredients, and maximization of profits when deciding to set drug price.[10] The costs associated with developing a new prescription drug can be very high. A recent analysis by the Tufts Center for the Study of Drug Development of the average cost to develop and gain marketing approval for a new prescription drug estimated the cost at $2.558 billion, and noted that when post-approval research and development activities were included, the cost rose to $2.870 billion.[11] The following factors increased clinical costs of prescription drug development:

- Increased clinical trial complexity;
- Larger clinical trial sizes;
- Higher input costs from the medical sector;
- Changes in protocol design to include efforts to gather health technology assessment information; and
- Testing on comparator drugs to accommodate payer demands for comparative effectiveness data.[12]

Per capita prescription drug spending in the United States exceeds that in all other countries, largely driven by brand-name prescription drug prices that have been increasing in recent years at rates far beyond the consumer price index.[13] Prescription drug sales are larger than the gross domestic product of 15 countries, combined.[14] Additionally, per capita spending on prescription drugs in the United States is more than double that of 19 other industrialized nations and accounts for an estimated 17 percent of overall personal health care services.[15] Depending upon the health issue being treated, the price can be far higher; for example, of the ten prescription drugs costing more than $30,000 for a 30 day supply, half are used to treat Hepatitis C.

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[10] *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System*, Special Committee On Aging, United States Senate (Dec. 2016), *available at,* https://www.collins.senate.gov/sites/default/files/DP%20Report.pdf (last visited February 17, 2017).
[11] Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, *Innovation in the pharmaceutical industry: New estimates of R&D costs*, Journal of Health Economics, Volume 47, pp. 20-33 (May 2016).
[12] Id.
[13] Aaron S. Kesselheim, Jerry Avorn, and Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform,* JAMA. 2016;316(8):858-871. doi:10.1001/jama.2016.11237.
[14] Kathlyn Stone, The Most Expensive Prescription Drugs in the World, THE BALANCE, Aug. 9, 2016, https://www.thebalance.com/the-8-most-expensive-prescription-drugs-in-the-world-2663232 (last visited February 17, 2017).
[15] *Supra*, note 13

20 Most Expensive Drugs in the United States[16]

Drug Name	Cost for 30 day supply	Condition	Manufacturer
1. Sovaldi	$75,600	Hepatitis C	Gilead Sciences, Inc.
2. Harvoni	$74,000	Hepatitis C	Gilead Sciences, Inc.
3. Cinryze	$72,100	Hereditary Angioedema	Shire
4. HP Acthar	$51,600	Systemic Lupus Erythematosus	Mallinckrodt[17]
5. Daklinza	$50,700	Hepatitis C	Bristol-Myers Squibb Company
6. Olysio	$41,800	Hepatitis C	Janssen Therapeutics
7. Orkambi	$41,200	Cystic Fibrosis	Vertex Pharmaceuticals
8. Cuprime	$39,800[18]	Wilson's Disease	Valient
9. Firazyr	$35,800	Hereditary Angioedema	Shite
10. Viekira Pak	$34,600	Hepatitis C	AbbVie
11. Kalydeco	$29,700	Cystic Fibrosis	Vertex Pharmaceuticals
12. Syprine	$29,300	Wilson's Disease	Valeant Pharmaceuticals
13. Cosentyx	$29,300	Plaque Psoriasis, Psoriatic Arthritis	Novartis Pharmaceuticals
14. Daraprim	$26,000	Toxoplasmosis	Turing Pharmaceuticals
15. Kynamro	$25,300	High Cholesterol	Kastle Therapeutics
16. Pomalyst	$15,800	Multiple Myeloma	Celgene Corporation
17. Zytiga	$15,400	Prostate Cancer	Janssen Biotech
18. Jakafi	$13,200	Myelofibrosis, Polycythemia Vera	Incyte
19. Copaxone	$12,300	Multiple Sclerosis	Teva Neuroscience
20. Tecfidera	$10,400	Multiple Sclerosis	Biogen

Prescription Drug Price Transparency in Florida

MyFloridaRx

MyFloridaRx is a joint effort between the Office of the Attorney General (AG) and the Agency for Health Care Administration (AHCA) that lists the usual and customary prices of 150 of the most commonly prescribed brand name drugs and associated generic equivalents.[19] Prescription drug prices are reported for a 30-day supply at a standard dose.[20] The data must be reported for each prescription drug by pharmacy and by metropolitan statistical area or region and updated quarterly.[21] AHCA receives the data and submits it to the AG's office; AG staff maintains the website and updates it monthly.[22]

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[16] Beth Braverman, *The 20 Most Expensive Prescription Drugs in America,* THE FISCAL TIMES, Oct. 17, 2016, http://www.thefiscaltimes.com/Media/Slideshow/2016/10/17/10-Most-Expensive-Prescription-Drugs-America (last visited February 17, 2017).

[17] Under the initial manufacturer, Questcor, the price increased to more than $28,000 a vial from $40 in the decade leading up to when it was acquired by Mallinckrodt. Andrew Pollack and Chad Bray, *Mallinckrodt Pharmaceuticals to Buy Questcor for $5.6 Billion*, THE NEW YORK TIMES, Apr. 7, 2014, https://dealbook.nytimes.com/2014/04/07/mallinckrodt-to-buy-californias-questcor-for-5-6-billion/?_r=0 (last visited February 17, 2017).

[18] According to statistics released by the Senate Special Committee on Aging, the drug's price rose by a staggering 5,786% in a little more than five years following the company's acquisition of Aton Pharma in 2010. The price of Cuprimine over the past ten years has risen from $93 to $26,188.64, with a 300% increase in the month of July 2015 alone. Zachary Brennan, *Senate Committee Offers Inside Look at the Rise and Fall of Valeant Pharmaceuticals*, REGULATORY AFFAIRS PROFESSIONAL SOCIETY, May 9, 2016, http://raps.org/Regulatory-Focus/News/2016/05/09/24897/Senate-Committee-Offers-Inside-Look-at-the-Rise-and-Fall-of-Valeant-Pharmaceuticals/#sthash.LfFt9C1R.dpuf (last visited February 17, 2017).

[19] S. 408.062(1)(h), F.S., requires AHCA to report data on the retail prices charged by pharmacies for the 100 most frequently prescribed medicines.

[20] S. 408.062(1)(h), F.S.

[21] Id.

[22] Presentation by Molly McKinstry, Agency for Health Care Administration, and Cindy Rutledge, Office of the Attorney General, *MyFloridaRx: Prescription Drug Pricing Website*, presentation to the Health Innovation Subcommittee, Feb. 8, 2017, slide 3. (On file with Health Innovation Subcommittee staff).

MyFloridaRX allows consumers to search available prescription drugs by selecting a county, selecting one or all cities within that county, and then selecting the drug.[23] The results provide the pharmacy name, address and phone number, the prescription drug name and strength, the most commonly dispensed quantity, and price. Results can be sorted by pharmacy name, zip code, prescription drug name, quantity, or price.[24] Depending on the selected prescription drug, it may be available at a number of pharmacies, or just a few, and the price may vary greatly or not at all.

Example Prescription Drug Price Comparison[25]
ProAir HFA 90mcg Inhaler

City (County)	Lowest Price	Highest Price	% Diff
Monticello (Jefferson County)	$69.99	$70.99	1.4%
Niceville (Okaloosa County)	$63.74	$70.99	11.4%
Okeechobee (Okeechobee County)	$64.05	$349.25	445.3%
Belle Glade (Palm Beach County)	$69.99	$74.14	5.9%
West Palm Beach (Palm Beach County)	$59.98	$74.99	25.0%
Jacksonville (Duval County)	$62.25	$108.10	73.7%

MyFloridaRx shows only retail pharmacies dispensing at least one prescription drug to a Medicaid beneficiary. Therefore, the retail pharmacies appearing on the website are those that dispensed at least one of the top 150 posted prescription drugs to someone using Medicaid assistance to purchase that medication.[26] Participating pharmacies provide the state with all pricing levels, including the "usual and customary" retail price.[27]

Usual and Customary Price

AHCA is required to reimburse Medicaid providers in accordance with state and federal law.[28] Medicaid reimbursement methodologies differ based upon what type of services or goods are being provided; however, these methodologies often include a prohibition against reimbursement in excess of the provider's "usual and customary" rate for the service or good. Typically, the reimbursement is the amount billed by the provider, the provider's usual and customary charge, or the Medicaid maximum allowable fee, whichever is less.[29]

In order to receive payment from AHCA, a provider must certify that the service or good has been completely furnished to the Medicaid recipient and that the amount billed does not exceed the provider's usual and customary charge.[30] The term "usual and customary" is not defined in Florida law,[31] but in the context of prescription drugs, it is understood to mean the average charge to all other customers in any quarter for the same prescription drug, quantity, and strength.[32] This price, however, is self-reported and may vary from the price charged at the time a medication is dispensed.[33]

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[23] *Rx Drug Price Finder*, MYFLORIDARX, http://myfloridarx.com/rx.nsf/finder (last visited February 17, 2017).
[24] Id.
[25] *Supra*, note 22, slide 10.
[26] *Frequently Asked Questions - FAQs*, MYFLORIDARX, http://www.myfloridarx.com/RX.nsf/pages/FAQs (last visited February 17, 2017).
[27] Id.
[28] S. 409.908, F.S. Requirements for reimbursement are established according to methodologies set forth in AHCA's administrative rules and in policy manuals and handbooks incorporated by reference.
[29] Id; see also ss. 409.912(8)(a), F.S.; 409.9128(5), F.S.; and 409.967, F.S.; 42 C.F.R. 447.512; Florida Medicaid Provider General Handbook, as promulgated in Rule 59G-5.020, F.A.C.; and Florida Medicaid Prescribed Drug Services Handbook, as promulgated in Rule 59G-4.250, F.A.C.
[30] Id.
[31] Usual and customary is identified as a payment methodology in chapters 394, 400, 409, 440, 627, 641, and 817; however, the term is not defined.
[32] *Supra*, note 22, slide 3.
[33] Id.

National Trends in Prescription Drug Price Transparency Laws

Policymakers at the state and federal levels are working to improve prescription drug price transparency. The Unites States Congress has recognized that prescription drug price transparency could provide useful information to address the issue.[34] Similarly, a workgroup of the National Academy for State Health Policy suggests that promoting greater transparency in prescription drug pricing and payment may help to address rising prescription drug costs.[35] In an effort to increase price transparency, the workgroup recommended pricing documentation for select high-priced drugs, justification for price increases above a specific threshold, and disclosures of price discounts and rebates.[36]

Federal Trends

During the 114th Congress in 2016, proposed federal legislation required prescription drug manufacturers to justify certain price increases in a report to the Department of Health and Human Services (HHS). The Fair Accountability and Innovative Research Drug Pricing Act of 2016 (the FAIR Act)[37] required manufacturers to notify HHS and submit a transparency and justification report 30 days before a price increase of more than 10 percent during a 12-month period was implemented. Manufacturers also had to justify each price increase that took place during the year.[38] The FAIR Act imposed a $100,000 daily penalty on manufacturers that failed to submit a report.[39]

Other proposed legislation created an interagency drug price review board to collect data on drug and device prices and manufacturing costs and, if necessary, take enforcement action against manufacturers that charge consumers excessive prices.[40] The Prescription Drug and Medical Device Price Review Board Act of 2016 (the Act) created a board to review reports of each manufacturer of prescription drugs or medical devices sold in the United States and prescribe a formula for determining whether the average manufacturer price for a drug or device over an annual quarter is an excessive price.[41] The Act imposed civil penalties and reduced patent terms for manufacturers found to be charging excessive prices for prescription drugs or devices.[42]

Neither of these legislative proposals became law. However, the current Congress has proposed similar legislation. In January 2017, the Lower Drug Costs through Competition Act was filed in the House of Representatives.[43] The bill amends the Federal Food, Drug, and Cosmetic Act by revising review and approval provisions of certain generic drug applications or supplements to generic drug applications for certain drugs.[44] The House Energy and Commerce Committee is expected to take up this legislation this month as part of its effort to increase transparency around the backlog of generic drug applications and promote increased generic drug development to address high prescription drug prices.[45]

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[34] *Supra*, note 1.
[35] *States and the Rising Cost of Pharmaceuticals: A Call to Action*, NATIONAL ACADEMY FOR STATE HEALTH POLICY WORK GROUP, Oct. 2016, *available at*, http://nashp.org/wp-content/uploads/2016/10/Rx-Paper.pdf (last visited February 17, 2017).
[36] Id.
[37] Fair Accountability and Innovative Research Drug Pricing Act of 2016, S. 3335 114th Cong. (Sept. 15, 2016), *available at*, https://www.congress.gov/114/bills/s3335/BILLS-114s3335is.pdf (last visited February 17, 2017).
[38] Id.
[39] Id.
[40] Prescription Drug and Medical Device Price Review Board Act of 2016, H.R. 6501 114th Cong. (Dec. 8, 2016), *available at*, https://www.congress.gov/bill/114th-congress/house-bill/6501/text (last visited February 17, 2017).
[41] Id.
[42] Id.
[43] Lower Drug Costs through Competition Act, H.R. 749 114th Cong. (Jan. 30, 2017), available at, https://www.congress.gov/bill/115th-congress/house-bill/749/text (last visited February 17, 2017).
[44] Id.
[45] *U.S. House panel to take up bill to spur generic drug development*, REUTERS, Feb. 2, 2017, http://www.reuters.com/article/us-usa-congress-genericdrugs-idUSKBN15H21B (Last visited February 17, 2017).

State Trends

State legislation proposing prescription drug manufacturer transparency and pricing requirements was filed in at least 16 states[46] during the 2015–2016 legislative sessions.[47] Common elements included imposing annual reporting requirements on manufacturers of higher-cost drugs,[48] imposing a cap on prices determined to be excessive, and establishing drug review boards or programs to review drug prices.[49]

In 2016, Vermont passed a law requiring the Attorney General to identify and report on up to 15 state-purchased prescription drugs on which the state spends a significant amount and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or 15 percent or more over the past 12 months.[50] The law requires drug manufacturers to provide a justification for the increase in the wholesale acquisition cost of the drug and provides fines for failure to do so of up to $10,000.[51] The law also requires insurers to provide information about the State Health Benefit Exchange plan's drug formularies.[52] The first report was published on December 1, 2016.[53] The report identified ten drugs[54] subject to the new law.[55] In the report, manufacturers identified a number of factors they consider in making pricing decisions, including the economic value to patients given the effectiveness of the drug compared to other drugs in the same class, investments made in creating the drug, including in research and development, and the risks associated with manufacturing the drug.[56]

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[46] Legislation was introduced in California, Colorado, Louisiana, Massachusetts, Minnesota, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Texas, Vermont, Virginia, Washington and West Virginia.

[47] National Conference of State Legislatures, Richard Cauchi, *2015-2016 State Legislation to Require Prescription Drug Cost and Price Transparency*, Nov. 7, 2016, https://comm.ncsl.org/productfiles/83403539/2015-16_Leg_Cost_Trans_PresDrugs.pdf (last visited February 17, 2017).

[48] Id.; *see, e.g.,* S 7686, New York State Senate, https://www.nysenate.gov/legislation/bills/2015/s7686/amendment/original (last visited February 17, 2017); and SB 1010, California Senate, February 11, 2016, https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160SB1010 (last visited February 17, 2017). New York SB 7686, which sought to require drug manufacturers to file a an annual report on costs for prescription drugs with a price of $1,000 or more for a 30 day supply or an increased prices within a 3-month period of 3 times the consumer price index. The report required detailed statistics on fifteen segments of actual costs including research, clinical trials, production, marketing, direct-to-consumer advertising, and prescriber education, and required the state to make that information available online. Similarly, California SB 1010 would have required health plans to report detailed information on prescription drug costs, such as the most prescribed and most costly medicines, to the Department of Managed Health Care and Department of Insurance, which would then compile specified reported information into a consumer-friendly report addressing the overall impact of drug costs on health care premiums. Under SB 1010, drug manufacturers would have had to notify specified state purchasers, health plans, and health insurers, at least 60 days prior to the planned effective date, if the wholesale acquisition cost of a prescription drug was increasing by more than 10% during any 12-month period or if a prescription drug was being introduced to market that has a wholesale acquisition cost $10,000 or more annually or per course of treatment, and justify that cost.

[49] *See, e.g.,* A 762, New Jersey Assembly, Nov. 16, 2015, available at http://www.njleg.state.nj.us/2014/Bills/A5000/4722_I1.PDF (last visited February 17, 2017). New Jersey A. 762 sought to establish the Prescription Drug Review Commission that would develop a list of prescription drugs for which there was substantial public interest in understanding the development of pricing for the drugs and require the manufacturer of the drug to report on total costs for the drug, research and development costs, marketing cost, price for the drug in other countries, and the net typical price charged to pharmacy benefit managers.

[50] Act 165 (SB 216), Vermont General Assembly, 2016, *available at* http://legislature.vermont.gov/assets/Documents/2016/Docs/ACTS/ACT165/ACT165%20As%20Enacted.pdf (last visited February 2, 2017).

[51] Id.

[52] Id.

[53] *Report of Attorney General to the Legislature Regarding Pharmaceutical Cost Transparency Pursuant to 18 V.S.A. § 4635*, Vermont Attorney General's Office, Dec. 1, 2016, *available at*,http://ago.vermont.gov/assets/files/Consumer/AGO%20Report%20-%20Pharma%20Cost%20Transparency.pdf (last visited February 17, 2017).

[54] *Drug List Per Act 165*, Vermont Attorney General's Office, *available at* http://ago.vermont.gov/assets/files/Consumer/Drug%20List%20Per%20Act%20165.pdf (last visited February 17, 2017).

[55] *Supra*, note 53.

[56] Id.

A ballot initiative in California, the California Drug Price Relief Act, (Proposition 61), which appeared on the 2016 ballot, proposed to cap the amount that any state agency could pay for prescription drugs at the cost paid by the U.S. Department of Veterans Affairs.[57] The initiative was rejected with 54 percent of voters opposed to the initiative.[58] There is a similar ballot initiative slated for the November 2017 general election in Ohio.[59]

Effect of the Bill

Current law requires MyFloridaRx to list the top 100 most frequently prescribed drugs, although the website provides the top 150 most frequently prescribed drugs. HB 589 doubles the number of prescription drugs to be listed on the website to 300. Additionally, the bill codifies the current practice of monthly reporting of prescription drug pricing information to AHCA.

Consumers who query MyFloridaRx will have access to more pricing information for more prescription drugs as a result of the bill. Better-informed consumers can find and purchase lower-priced prescription drugs, thereby changing market demand and likely lowering overall prices. As retail pharmacies realize what their competitors are charging for the same prescription drug, prices will likely stabilize at the median price.

The bill also removes obsolete language referencing deadlines for implementing s. 408.062(1)(h), Fla. Stat., which have already passed.

The bill provides an effective date of upon becoming a law.

B. SECTION DIRECTORY:

Section 1: Amends s. 408.062, F.S., relating to research, analyses, studies, and reports.
Section 2: Provides an effective date of upon becoming law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

[57] *California Proposition 61, Drug Price Standards (2016),* BALLOTPEDIA, https://ballotpedia.org/California_Proposition_61,_Drug_Price_Standards_(2016) (last visited February 17, 2017)
[58] *California Proposition 61 – Drug Price Standards Initiative – Results: Rejected*, THE NEW YORK TIMES, Dec. 13, 2016, http://www.nytimes.com/elections/results/california-ballot-measure-61-state-agency-drug-prices (last visited February 17, 2017).
[59] The measure is nearly identical to Proposition 61. *Drug price reduction campaign will return to Ohio in 2017,* THE COLUMBUS DISPATCH, Aug. 16, 2016, http://www.dispatch.com/content/stories/local/2016/08/16/drug-price-reduction-campaign-will-return-to-ohio-in-2017.html (last visited February 17, 2017).

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Consumers will have access to the usual and customary retail prices for 300 of the most frequently dispensed prescription drugs, which will help them make informed financial decisions on prescription drug purchases.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to prescription drug price transparency; amending s. 408.062, F.S.; requiring the Agency for Health Care Administration to collect data on the retail prices charged by pharmacies for the 300 most frequently prescribed medicines; requiring the agency to update its website monthly; providing an effective date.

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

Section 1. Paragraph (h) of subsection (1) of section 408.062, Florida Statutes, is amended to read:

408.062 Research, analyses, studies, and reports.—

(1) The agency shall conduct research, analyses, and studies relating to health care costs and access to and quality of health care services as access and quality are affected by changes in health care costs. Such research, analyses, and studies shall include, but not be limited to:

(h) The collection of a statistically valid sample of data on the retail prices charged by pharmacies for the 300 ~~100~~ most frequently prescribed medicines from any pharmacy licensed by this state ~~as a special study authorized by the Legislature to be performed by the agency quarterly~~. If the drug is available generically, price data shall be reported for the generic drug

and price data of a brand-named drug for which the generic drug is the equivalent shall be reported. The agency shall make available on its Internet website for each pharmacy~~, no later than October 1, 2006,~~ drug prices for a 30-day supply at a standard dose. The data collected shall be reported for each drug by pharmacy and by metropolitan statistical area or region and updated monthly ~~quarterly~~.

Section 2. This act shall take effect upon becoming a law.