Health Innovation Subcommittee

Wednesday, January 17, 2018
12:30 PM – 2:00 PM
Mashburn Hall (306 HOB)

Richard Corcoran
Speaker

MaryLynn Magar
Chair

Committee Meeting Notice

HOUSE OF REPRESENTATIVES

Health Innovation Subcommittee

Start Date and Time:	Wednesday, January 17, 2018 12:30 pm
End Date and Time:	Wednesday, January 17, 2018 02:00 pm
Location:	Mashburn Hall (306 HOB)
Duration:	1.50 hrs

Consideration of the following bill(s):

HB 199 Health Insurer Authorization by Harrison
HB 351 Pharmacy Benefits Managers by Santiago
HB 443 Nursing Home and Assisted Living Facility Resident Rights by Slosberg
HB 1021 Florida Insurance Code Exemption for Nonprofit Religious Organizations by Altman

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, January 16, 2018.

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, January 16, 2018.

NOTICE FINALIZED on 01/12/2018 3:40PM by Iseminger.Bobbye

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 199 Health Insurer Authorization
SPONSOR(S): Harrison
TIED BILLS: **IDEN./SIM. BILLS:** SB 98

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

SUMMARY ANALYSIS

Insurers and health maintenance organizations (HMOs) use many cost containment strategies to manage drug spending and utilization. For example, plans may limit the quantity of a drug that they will cover over a certain period of time, require enrollees to obtain prior authorization from the plan before obtaining certain prescriptions, procedures or treatments, or require enrollees to first try a preferred drug before obtaining a more expensive drug.

Currently, s. 627.42393, F.S., requires health insurers and PBMs to use a form approved by the Office of Insurance Regulation for prior authorization determinations if they do not provide an electronic prior authorization form. This form must include certain information. The statute does not require notification if an insurer or HMO modifies any prior authorization guidelines or any timeline for processing prior authorization.

HB 199 amends s. 627.42392, F.S., to revise criteria for prior authorization forms, requirements for prior authorization information, restrictions on prior authorization procedures, and timeframes for prior authorization request approval or denial. The bill requires PBMs to publish changes to prior authorization forms on a public website at least 60 days prior to the change.

The bill also creates s. 627.42393, F.S, which requires a health insurer or HMO to publish on its website, and provide in writing, a procedure for an insured and health care provider to request an exception to a fail-first protocol. The bill requires timeframes for the authorization or denial of a fail-first protocol exception request and details situations in which a fail-first protocol exception request must be granted.

The bill would have an indeterminate negative impact on the Medicaid program and on the state employee group insurance program.

The bill has an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Health Insurance

Health insurance is the insurance of human beings against bodily injury or disablement by accident or sickness, including the expenses associated with such injury, disablement, or sickness.[1] Individuals purchase health insurance coverage with the purpose of managing anticipated expenses related to health or protecting themselves from unexpected medical bills or large health care costs. Managed care is the most common delivery system for medical care today by health insurers.[2] Managed care systems combine the delivery and financing of health care services by limiting the choice of doctors and hospitals.[3] In return for this limited choice, however, medical care is less costly due to the managed care network's ability to control health care services. Some common forms of managed care are preferred provider organizations[4] (PPO) and health maintenance organizations[5] (HMO).

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.[6] The Agency for Health Care Administration (agency) regulates the quality of care by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from the agency.[7] As part of the certification process used by the agency, an HMO must provide information to demonstrate that the HMO has the ability to provide quality of care consistent with the prevailing standards of care.[8]

All persons who transact insurance in the state must comply with the Code.[9] OIR has the power to collect, propose, publish, and disseminate any information relating to the subject matter of the Code,[10] and may investigate any matter relating to insurance.[11]

Cost Containment in Health Insurance

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

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[1] S. 624.603, F.S.
[2] Florida Department of Financial Services, *Health Insurance and Health Maintenance Organizations, A Guide for Consumers,* available at: http://www.myfloridacfo.com/Division/Consumers/understandingCoverage/Guides/documents/HealthGuide.pdf (last visited December 28, 2017).
[3] Id.
[4] S. 627.6471, F.S.
[5] Part I of chapter 641, F.S.
[6] S. 20.121(3)(a), F.S.
[7] S. 641.21(1), F.S.
[8] S. 641.495, F.S.
[9] S. 624.11, F.S.
[10] S. 624.307(4), F.S.
[11] S. 624.307(3), F.S.

Pharmacy Benefit Managers

Advances in pharmaceuticals have transformed health care over the last several decades. Many health care problems are prevented, cured, or managed effectively using prescription drugs. As a result, national expenditures for prescription drugs have grown from $121 billion in 2000 to $324.5 billion in 2016.[12] Health plan sponsors, which include commercial insurers, private employers, and government plans, such as Medicaid and Medicare, spent $277 billion on prescription drugs in 2015, while consumers paid $45.5 billion out-of-pocket for prescription drugs that year.[13]

Health plan sponsors contract with pharmacy benefit managers (PBMs) to provide specified services, which may include developing and managing pharmacy networks, developing drug formularies, providing mail order and specialty pharmacy services, rebate negotiation, therapeutic substitution, disease management, utilization review, support services for physicians and beneficiaries, and processing claims.[14] Payments for the services are established in contracts between health plan sponsors and PBMs.[15] For example, contracts will specify how much health plan sponsors will pay PBMs for brand name and generic drugs. These prices are typically set as a discount off the average wholesale price[16] for brand-name drugs and maximum allowable cost price for generic drugs, plus a dispensing fee.[17]

Prior Authorization

Under prior authorization, a health care provider is required to seek approval from an insurer before a patient may receive a specified diagnostic or therapeutic treatment or specified prescription drugs under the plan. For example, most insurers or PBMs will have a preferred drug list (PDL), which is an established list of one or more prescription drugs within a therapeutic class deemed clinically equivalent and cost effective. Prior authorization would limit an insured's ability to obtain another drug within the therapeutic class that is not part of the PDL without the insurer or PBM authorizing that drug.

Section 627.42392, F.S., requires health insurers and HMOs to use an approved form[18] for prior authorization determinations, if they do not provide an electronic prior authorization process. This form can be no longer than 2 pages and at a minimum must include:

- Sufficient patient information to identify the member, date of birth, full name, and Health Plan ID number;
- Provider name, address and phone number;
- The medical procedure, course of treatment, or prescription drug benefit being requested, including the medical reason therefor, and all services tried and failed;
- Any laboratory documentation required; and
- An attestation that all information provided is true and accurate.

Rule 69O-161.010, Florida Administrative Code (F.A.C.), details the guidelines for a prior authorization form and rule 69O-161.011, F.A.C., incorporates by reference and requires the use of Form OIR-B2-2180[19] by insurers and HMOs that do not provide an electronic process for prior authorization.

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[12] Centers for Medicare and Medicaid Services, *National Health Expenditure Data, Historical,* available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (last accessed December 28, 2017).
[13] Id.
[14] Office of Program Policy Analysis & Government Accountability, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (Feb. 2007), available at: http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/0708rpt.pdf (last visited December 28, 2017).
[15] Id.
[16] Average wholesale price is the retail list price (sticker price) or the average price that manufacturers recommend wholesalers sell to physicians, pharmacies and others, such as hospitals.
[17] Supra, FN 14.
[18] Rule 69O-161.011, F.A.C.
[19] Form OIR-B2-2180, available at: https://www.flrules.org/gateway/readRefFile.asp?refId=7606&filename=Form%20OIR-B2-2180.docx (last accessed December 29, 2017).

Notification to policyholders or healthcare providers is currently not required if the insurer or HMO modifies prior authorization guidelines. In addition, there is no statutory timeline for processing prior authorizations.

Fail-First Protocols

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

Researchers report that there is mixed evidence on the impact of step therapy policies.[20] A review of the literature found that there is little good empirical evidence for or against cost savings and utilization reduction.[21] Some studies suggest that step therapy policies have been effective at reducing drug costs without increasing the use of other medical services,[22] while other studies have found that step therapy can increase total utilization costs over time because of increased inpatient admissions and emergency department visits.[23]

Statewide Medicaid Managed Care Program

The Florida Medicaid program is a partnership between the federal and state governments. In Florida, the Agency for Health Care Administration (AHCA) oversees the Medicaid program.[24] The Statewide Medicaid Managed Care (SMMC) program is comprised of the Managed Medical Assistance (MMA) program and the Long-Term Care (LTC) managed care program. AHCA contracts with managed care plans to provide services to eligible recipients.[25]

Managed Care Covered Services

The benefits package offered by the MMA plans is comprehensive and covers all Medicaid state plan benefits (with very limited exceptions). This includes all medically necessary services for children. Most Florida Medicaid recipients who are eligible for the full array of benefits are enrolled in an MMA plan. AHCA maintains coverage policies for most Florida Medicaid service which are incorporated into the MMA plan contracts effective June 1, 2017. Florida Medicaid managed care plans cannot be more restrictive than these policies or the Florida Medicaid state plan (which is approved by the federal Centers for Medicare and Medicaid Services) in providing services their enrollees.[26]

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

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[20] Rahul K. Nayak and Steven D. Pearson, *The Ethics Of 'Fail First': Guidelines and Practical Scenarios for Step Therapy Coverage Policies*, Health Affairs 33, No.10 (2014):1779-1785.
[21] Motheral, B.R., *Pharmaceutical Step Therapy Interventions: A Critical Review of the Literature*, Journal of Managed Care Pharmacy 17, no. 2 (2011) 143-55, available at: http://www.jmcp.org/doi/pdf/10.18553/jmcp.2011.17.2.143 (last accessed December 29, 2017).
[22] Supra, FN 20 at pg. 1780.
[23] Id.
[24] Part III of ch. 409, F.S., governs the Medicaid program.
[25] A managed care plan that is eligible to provide services under the SMCC program must have a contract with the agency to provide services under the Medicaid program; be a health insurer, an exclusive provider organization or a HMO authorized under ch. 624, 627, or 641, F.S., respectively, or a provider service network authorized under s. 409.912(2), F.S., or an accountable care organization authorized under federal law. (s.409.962, F.S.)
[26] Agency for Health Care Administration, *Agency Analysis for HB 199*, on file with the House Health Innovation Subcommittee.

prescribers within each therapeutic class. The agency also manages the federally required Medicaid Drug Utilization Board, which meets quarterly, develops, and reviews clinical prior authorization criteria, including step therapy protocols for drugs that are not on the Medicaid PDL.

Medicaid managed care plans serving MMA enrollees are required to provide all prescription drugs listed on the agency's PDL and otherwise covered by Medicaid.[27] As such, the managed care plans have not implemented their own plan-specific formularies or PDL. In addition, the plan's prior authorization criteria and other protocols related to prescribed drugs cannot be more restrictive than the criteria established by the agency.[28]

Prior Authorization Requirements

Medicaid managed care plans may implement service authorization and utilization management requirements for the services they provider under the SMMC program. However, Medicaid managed care plans are required to ensure that service authorization decisions are based on objective evidenced-based criteria; utilization management procedures are applied consistently; and all decisions to deny or limit a requested service are made by health care providers who have the appropriate clinical expertise in treating the enrollee's condition.[29] The Medicaid managed care plans are also required to adopt practice guidelines that are based on valid and reliable clinical evidence or a consensus of health care professionals in a particular field.[30] These practice guidelines must also consider the needs of the enrollees, be adopted in consultation with providers and be reviewed and updated periodically, as appropriate.[31]

Medicaid managed care plans must establish and maintain a utilization management system to monitor utilization of services, including an automated service authorization system for denials, service limitations, and reductions of authorization. Section 627.42392, F.S., requires the use of a standard prior authorization form by health insurers. A health insurer that does not provide an electronic prior authorization process for use by its providers is required to use the prior authorization form adopted by the Financial Services Commission for authorization of procedures, treatments, or prescription drugs. Currently, Medicaid managed care plans are required by contract to have electronic authorization processes and are therefore exempt from this provision.[32]

The SMMC contract requires managed care plans to authorize or deny a standard request for prior authorization for services other than prescribed drugs within 7 days and authorize or deny an expedited request within 48 hours after receiving the request. Within 24 hours after receipt of a request, a managed care plan must respond (deny, approve, or request additional information) to a request for prior authorization for prescription drugs. The timeframe for standard authorization decisions can be extended up to 7 additional days if the enrollee or the provider requests an extension or the managed care plan justifies the need for additional information and describes how the extension is in the enrollee's interest.[33]

Enrollee Materials and Services

Managed care plans are contractually required to notify enrollees via the enrollee handbook of any procedures for obtaining required services and authorization requirements, including any services available without prior authorization. All enrollee communications, including written materials, spoken

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[27] See Agency for Health Care Administration Pharmacy Policy available at http://ahca.myflorida.com/Medicaid/Policy_and_Quality/Policy/pharmacy_policy/index.shtml (last visited January 13, 2018).
[28] Agency for Health Care Administration, *Agency Analysis for HB 199*, on file with the House Health Innovation Subcommittee.
[29] Id at page 3.
[30] These guidelines are consistent with requirements found in federal regulation (See 42 CFR s. 438.236(b)). All service authorization decisions made by the managed care plans must be consistent with the state's Medicaid medical necessity definition. Rule 59G-1.010, F.A.C.
[31] Agency for Health Care Administration, *Agency Analysis for HB 199*, on file with the House Health Innovation Subcommittee.
[32] Id at page 3.
[33] Id at page 3.

scripts, and websites, must be at or near the fourth grade reading level. Managed care plans are required by contract to issue a provider handbook to all providers that includes prior authorization and referral procedures, including required forms. Managed care plans are required to keep all provider handbooks and bulletins up to date and in compliance with state and federal laws. The managed care plans must notify its enrollees in writing of any changes to covered services or service authorization protocols at least 30 days in advance of the change.[34]

The managed care plan must send a written notice of adverse benefit determination to the enrollee to inform the enrollee about a decision to deny, reduce, suspend, or terminate a requested service and provide directions on how the enrollee may ask for a plan appeal to dispute the managed care plan's adverse benefit determination. The enrollee has 60 days after the plan's adverse benefit determination to ask for a plan appeal. For decisions that are appealed, the managed care plan must have a second health care professional who was neither involved in any previous level of review or decision-making, nor a subordinate of any such individual. The managed care plan then has 30 days from the date of the enrollee's request to make a final decision. The managed care plan has 72 hours to respond to the enrollee or his or her authorized representative's request for an expedited plan appeal. The enrollee must complete the plan appeal process before asking for a Medicaid fair hearing.[35]

Florida State Employee Group Insurance Program

Under the authority of s. 110.123, F.S., the Department of Management Services (DMS), through the Division of State Group Insurance, administers the state group insurance program by providing employee benefits such as health, life, dental, and vision insurance products under a cafeteria plan consistent with s. 125, Internal Revenue Code. To administer the state group health insurance program, DMS contracts with third part administrators, HMOs, and a PBM for the state employees' prescription drug program pursuant to s. 110.12315, F.S.

Contractually, health plans and contracted third party administrators area required to review urgent or emergency prior authorization requests within 24 hours after receipt and within 14 calendar days after initial receipt for routine requests. Current industry standards for utilization review change notices to plan participants or enrollees is 30 days.[36]

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.[37] The PPACA requires health insurers to make coverage available to all individuals and employers, without exclusions for preexisting conditions and without basing premiums on any health-related factors. The PPACA also mandates required essential health benefits[38] and other provisions.

The PPACA requires insurers and HMOs that offer qualified health plans (QHPs) to provide ten categories of essential health benefits (EHB), which includes prescription drugs.[39] In Florida, the federal Health Insurance Marketplace must certify such plans of an insurer or HMO as meeting the EHB and other requirements.[40] The federal deadline for insurers and HMOs to submit 2018 annual rates and

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[34] Agency for Health Care Administration, *Agency Analysis for HB 199.* On file with the staff of the Health Innovation Subcommittee.
[35] Id at page 4.
[36] Department of Management Services, *Agency Analysis of HB 199.* On file with staff of the Health Innovation Subcommittee.
[37] The Patient Protection and Affordable Care Act (Pub. L. No. 111-148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010.
[38] 42 U.S.C. s. 18022
[39] See Center for Consumer Information & Insurance Oversight, *Insurance on Essential Health Benefits (EHB) Benchmark Plans* https://www.cms.gov/cciio/resources/data-resources/ehb.html (last viewed on January 13, 2018).
[40] Center for Consumer Information & Insurance Oversight, *Qualified Health Plans,* https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp.html (last viewed January 13, 2018).

forms to the Florida Office of Insurance Regulation was May 3, 2017.[41] Recently, the U.S. Department of Health and Human Services (HHS) proposed federal regulations that included provisions to provide states with additional flexibility in the definition of EHBs for 2019 and 2020 and increase affordability of health insurance for the individual and small group markets.[42]

Prescription Drug Coverage

For purposes of complying with the federal EHB for prescription drugs, plans must include in their formulary drug list the greater of one drug for each U.S. Pharmacopeia (USP) category and class; or the same number of drugs in each USP category and class as the state's EHB benchmark plan. Plans must have a Pharmacy and Therapeutics Committee design formularies using scientific evident that will include consideration of safety and efficacy, cover a range of drugs in a broad distribution of therapeutic categories and classes, and provide access to drugs that are included in broadly accepted treatment guidelines. The PPACA also requires plans to implement an internal appeals and independent external review process if an insured is denied coverage of a drug on the formulary.[43]

Plans are required to publish a current and complete list of all covered drugs on its formulary drug list, including any tiered structure and any restrictions on the way a drug can be obtained, in a manner that is easily accessible to insureds, prospective insureds, the state, and the public.[44] Restrictions include prior authorization, step therapy, quantify limits and access restrictions.[45]

Effect of Proposed Changes

Prior Authorization

HB 199 amends s. 627.42392, F.S., to revise criteria for prior authorization forms, requirements for prior authorization information, restrictions on prior authorization procedures, and timeframes for prior authorization request approval or denial by health insurers or pharmacy benefit managers. The new criteria applies to any medical procedure, course of treatment or prescription drug.

The bill requires health insurers and PBMs to authorize or deny a prior authorization request and notify the patient and the patient's treating health care provider within 3 business days of receiving a completed prior authorization form for non-urgent care situations or 24 hours for urgent care situations. The bill defines an "urgent care situation" as a situation in which the standard timeframe to treat an insured's injury or condition would seriously jeopardize the insured's life, health or ability to regain maximum function, or subject the insured to severe pain that cannot be adequately managed, based on the opinion of the treating health care provider.

The bill requires health insurers and PBMs to provide detailed descriptions of requirements to obtain prior authorization in easily understandable language and prior authorization forms in writing or electronic format, upon request, and made available on a publicly accessible website.

The bill restricts a health insurer or PBM from making changes to or implementing any new requirements for prior authorization. Any changes or restrictions must be available on a publicly accessible website at least 60 days before implementation or provided in writing to policyholders and health care providers affected by the changes. Written notice must be provided electronically or by

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[41] Office of Insurance Regulation, *Guidance to Insurers*, available at http://www.floir.com/sitedocuments/PPACANoticetoIndustry201802032017.pdf (last viewed January 13, 2018).
[42] *See* Proposed Rule, 82 FR 51052 (Nov. 2, 2017) available at https://www.federalregister.gov/documents/2017/11/02/2017-23599/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2019 (last viewed January 13, 2018).
[43] 45 C.F.R. s. 147.136
[44] 45 C.F.R. s. 156.122(d)
[45] According to CMS, this formulary drug list website link should be the same direct formulary drug list link for obtaining information on prescription drug coverage in the Summary of Benefits Coverage, in accordance with 45 CFR s. 147.00(a)(2).

another means agreed to by the insured or health care provider, at least 60 days before the changes are implemented. The bill exempts the expansion of health care services from this requirement.

Finally, the bill deletes a reference to s. 624.603, F.S., which removes disability insurance form the list of insurance types that are subject to the prior authorization requirements of the bill and current law.

Fail-First Protocols

HB 199 creates s. 627.42393, F.S, which requires a health insurer, HMO or managed care plan to publish on its website, and provide in writing, a procedure for an insured and health care provider to request an exception for a fail-first protocol.

The bill requires an insurer to publish on its website and provide in writing to an insured a procedure for an insured and health care provider to request a protocol exception. This procedure must include:

- A description of the manner in which an insured or health care provider may request a protocol exception;
- The manner and timeframe in which the health insurer is required to authorize or deny a protocol exception request or respond to an appeal to a health insurer's authorization or denial; and
- Conditions in which the protocol exception request must be granted.

The bill requires health insurers to authorize or deny a protocol exception request within 3 business days for non-urgent care situations and 24 hours for urgent care situations. The bill requires an authorization to specify the medical procedure, course of treatment, or prescription drug, and for a denial requires a detailed written explanation of the reason for denial, including the rationale supporting the denial, and the appeal procedure.

The bill requires a health insurer to grant a protocol exception request if a preceding prescription drug or medical treatment is:

- Contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured;
- Expected to be ineffective, based on the medical history of the insured and the clinical evidence of the characteristics of the preceding prescription or medical treatment;
- In the same pharmacologic class or has the same mechanism of action to a drug or treatment previously received by the insured that lacked efficacy or effectiveness or adversely affected the insured; or
- Not in the insured's best interest because use of such drug is expected to cause a significant barrier to the insured's adherence or compliance with a plan of care, worsen a medical condition that exists simultaneously but independent of the condition under treatment, or decrease the ability to achieve or maintain his or her ability to perform daily activities.

The bill also authorizes an insurer to request a copy of relevant documentation from the insured's medical record in support of a protocol exception request.

The bill establishes definitions for terms used in the bill:

- "Fail-first protocol" to mean a written protocol that specifies the order in which certain medical procedures, courses of treatment, or prescription drugs must be used to treat an insured's condition.
- "Health insurer" to mean the same as s. 627.42392, F.S., which 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).
- "Preceding prescription drug or medical treatment" to mean a medical procedure, course of treatment, or prescription drug that must be used pursuant to a health insurer's fail-first protocol

as a condition of coverage under a health insurance policy or a health maintenance contract to treat an insured's condition.

- "Protocol exception" to mean a determination by a health insurer that a fail-first protocol is not medically appropriate or indicated for treatment of an insured's condition and the health insurer authorizes the use of another medical procedure, course of treatment, or prescription drug prescribed or recommended by the treating health care provider for the insured's condition.

These changes may add to the administrative burdens of an insurer, but will add consumer protections similar to the prior authorization changes. These changes increase the amount and accessibility of information available to the insured and his or her health care provider, setting timelines for authorization or denial of a protocol exception request, and detailing conditions in which a protocol exception request must be granted. However, they may limit insurer's ability to manage health care costs, which may increase risk and generate higher premiums and cost-sharing for consumers and employers.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 627.42392, F.S, relating to prior authorization.
Section 2: Creates s. 627.42393, F.S., relating to fail-first protocols.
Section 3: Provides an effective date of July 1, 2018.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The bill will have an indeterminate negative fiscal impact on Medicaid managed care plans. The plans would be required to augment their existing clinical authorization processes in order to comply with the requirements of the bill. An increase in administrative and clinical expenses by the Medicaid managed care plans could require an increase in state spending via increases in capitation rates paid to those plans. Additionally, the plans will have to revise their grievance and appeal process to meet the new requirements and timeframes. The current grievance and appeal process allows for resolution of standard appeals in 30 days and expedited appeals in 72 hours. The bill requires resolution within 72 hours and 24 hours respectively. Additional administrative costs would be accounted for in the SMCC capitation rates, which could increase rates.[46]

   The bill would have an indeterminate negative impact on the state group insurance program's fully-insured HMO to implement the 24-hour and 72-hour response times in the bill. The bill would have an indeterminate negative impact on the program's pharmacy benefit management contractor for the implementation of the revised timeframes for review and determination of prior authorization requests.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

[46] Agency for Health Care Administration, *Agency Analysis of HB 199*, on file with the House Innovation Subcommittee.

2. Expenditures:

   The requirements to implement the 24-hour and 72-hour response times for review and determination of prior authorization requests could have a negative impact on local government health plans.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The increased notice, information provision requirements, and timeframe requirements will have an indeterminate negative fiscal impact on health insurers, PBMs, and utilization review entities due to increased administrative costs and workload.

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:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The effective date of the bill may implicate Art. 1, Sec. 10 of the Florida Constitution related to impairment of contracts. This issue may be addressed by amending the bill to make its provisions applicable to contracts executed or renewed after the bill becoming law.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to health insurer authorization; amending s. 627.42392, F.S.; redefining the term "health insurer"; defining the term "urgent care situation"; prohibiting prior authorization forms from requiring certain information; requiring health insurers and pharmacy benefits managers on behalf of health insurers to provide certain information relating to prior authorization by specified means; prohibiting such insurers and pharmacy benefits managers from implementing or making changes to requirements or restrictions to obtain prior authorization except under certain circumstances; providing applicability; requiring such insurers and pharmacy benefits managers to authorize or deny prior authorization requests and provide certain notices within specified timeframes; creating s. 627.42393, F.S.; defining terms; requiring health insurers to publish on their websites and provide to insureds in writing a procedure for insureds and health care providers to request protocol exceptions; specifying requirements for such procedure; requiring health insurers, within specified timeframes, to authorize or deny a protocol exception request or respond to appeals of their authorizations or denials; requiring

authorizations or denials to specify certain information; requiring health insurers to grant protocol exception requests under certain circumstances; authorizing health insurers to request documentation in support of a protocol exception request; providing an effective date.

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

Section 1. Section 627.42392, Florida Statutes, is amended to read:

627.42392 Prior authorization.—

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

(a) "Health insurer" means an authorized insurer offering an individual or group insurance policy that provides major medical or similar comprehensive coverage ~~health insurance as defined in s. 624.603~~, a managed care plan as defined in s. 409.962(10), or a health maintenance organization as defined in s. 641.19(12).

(b) "Urgent care situation" has the same meaning as in s. 627.42393.

(2) Notwithstanding any other provision of law, effective January 1, 2017, or six (6) months after the effective date of the rule adopting the prior authorization form, whichever is later, a health insurer, or a pharmacy benefits manager on

behalf of the health insurer, which does not provide an electronic prior authorization process for use by its contracted providers, shall only use the prior authorization form that has been approved by the Financial Services Commission for granting a prior authorization for a medical procedure, course of treatment, or prescription drug benefit. Such form may not exceed two pages in length, excluding any instructions or guiding documentation, and must include all clinical documentation necessary for the health insurer to make a decision. At a minimum, the form must include: (1) sufficient patient information to identify the member, date of birth, full name, and Health Plan ID number; (2) provider name, address and phone number; (3) the medical procedure, course of treatment, or prescription drug benefit being requested, including the medical reason therefor, and all services tried and failed; (4) any laboratory documentation required; and (5) an attestation that all information provided is true and accurate. The form, whether in electronic or paper format, may not require information that is not necessary for the determination of medical necessity of, or coverage for, the requested medical procedure, course of treatment, or prescription drug.

(3) The Financial Services Commission in consultation with the Agency for Health Care Administration shall adopt by rule guidelines for all prior authorization forms which ensure the general uniformity of such forms.

(4) Electronic prior authorization approvals do not preclude benefit verification or medical review by the insurer under either the medical or pharmacy benefits.

(5) A health insurer or a pharmacy benefits manager on behalf of the health insurer must provide the following information in writing or in an electronic format upon request, and on a publicly accessible Internet website:

(a) Detailed descriptions of requirements and restrictions to obtain prior authorization for coverage of a medical procedure, course of treatment, or prescription drug in clear, easily understandable language. Clinical criteria must be described in language easily understandable by a health care provider.

(b) Prior authorization forms.

(6) A health insurer or a pharmacy benefits manager on behalf of the health insurer may not implement any new requirements or restrictions or make changes to existing requirements or restrictions to obtain prior authorization unless:

(a) The changes have been available on a publicly accessible Internet website at least 60 days before the implementation of the changes.

(b) Policyholders and health care providers who are affected by the new requirements and restrictions or changes to the requirements and restrictions are provided with a written

notice of the changes at least 60 days before the changes are implemented. Such notice may be delivered electronically or by other means as agreed to by the insured or health care provider.

This subsection does not apply to expansion of health care services coverage.

(7) A health insurer or a pharmacy benefits manager on behalf of the health insurer must authorize or deny a prior authorization request and notify the patient and the patient's treating health care provider of the decision within:

(a) Seventy-two hours of obtaining a completed prior authorization form for nonurgent care situations.

(b) Twenty-four hours of obtaining a completed prior authorization form for urgent care situations.

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

627.42393 Fail-first protocols.—

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

(a) "Fail-first protocol" means a written protocol that specifies the order in which a certain medical procedure, course of treatment, or prescription drug must be used to treat an insured's condition.

(b) "Health insurer" has the same meaning as provided in s. 627.42392.

(c) "Preceding prescription drug or medical treatment"

means a medical procedure, course of treatment, or prescription drug that must be used pursuant to a health insurer's fail-first protocol as a condition of coverage under a health insurance policy or a health maintenance contract to treat an insured's condition.

(d) "Protocol exception" means a determination by a health insurer that a fail-first protocol is not medically appropriate or indicated for treatment of an insured's condition and the health insurer authorizes the use of another medical procedure, course of treatment, or prescription drug prescribed or recommended by the treating health care provider for the insured's condition.

(e) "Urgent care situation" means an injury or condition of an insured which, if medical care and treatment are not provided earlier than the time generally considered by the medical profession to be reasonable for a nonurgent situation, in the opinion of the insured's treating physician, would:

1. Seriously jeopardize the insured's life, health, or ability to regain maximum function; or

2. Subject the insured to severe pain that cannot be adequately managed.

(2) A health insurer must publish on its website and provide to an insured in writing a procedure for an insured and health care provider to request a protocol exception. The procedure must include:

(a) A description of the manner in which an insured or health care provider may request a protocol exception.

(b) The manner and timeframe in which the health insurer is required to authorize or deny a protocol exception request or respond to an appeal of a health insurer's authorization or denial of a request.

(c) The conditions under which the protocol exception request must be granted.

(3)(a) The health insurer must authorize or deny a protocol exception request or respond to an appeal of a health insurer's authorization or denial of a request within:

1. Seventy-two hours of obtaining a completed prior authorization form for nonurgent care situations.

2. Twenty-four hours of obtaining a completed prior authorization form for urgent care situations.

(b) An authorization of the request must specify the approved medical procedure, course of treatment, or prescription drug benefits.

(c) A denial of the request must include a detailed, written explanation of the reason for the denial, the clinical rationale that supports the denial, and the procedure to appeal the health insurer's determination.

(4) A health insurer must grant a protocol exception request if:

(a) A preceding prescription drug or medical treatment is

contraindicated or will likely cause an adverse reaction or physical or mental harm to the insured;

(b) A preceding prescription drug is expected to be ineffective, based on the medical history of the insured and the clinical evidence of the characteristics of the preceding prescription drug or medical treatment;

(c) The insured has previously received a preceding prescription drug or medical treatment that is in the same pharmacologic class or has the same mechanism of action, and such drug or treatment lacked efficacy or effectiveness or adversely affected the insured; or

(d) A preceding prescription drug or medical treatment is not in the best interest of the insured because the insured's use of such drug or treatment is expected to:

1. Cause a significant barrier to the insured's adherence to or compliance with the insured's plan of care;

2. Worsen an insured's medical condition that exists simultaneously but independently with the condition under treatment; or

3. Decrease the insured's ability to achieve or maintain his or her ability to perform daily activities.

(5) The health insurer may request a copy of relevant documentation from the insured's medical record in support of a protocol exception request.

Section 3. This act shall take effect July 1, 2018.

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 Harrison offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 627.6476, Florida Statutes, is created to read:

627.6476 Step Therapy protocols.—

(1) As used in this section, the term "step therapy protocol" means a written protocol that specifies the order in which a certain prescription drug must be used to treat an insured's condition.

(2)(a) An insured may not be required to repeat a step therapy protocol with either their current health insurer or a new health insurer for a prescription drug provided that the

drug is appropriately prescribed and is considered safe and effective for the insured's condition.

(b) Nothing in this section shall preclude an insured's new health insurer from imposing a prior authorization requirement for the continued coverage of a drug prescribed pursuant to a step therapy protocol imposed by the former health insurer.

(c) A health insurer is not required to add a drug to its prescription drug formulary, or to cover a prescription drug's use for a purpose not currently covered by the insurer, to comply with the section.

(d) This section applies to contracts entered into or renewed on or after January 1, 2019. This section does not apply to Medicaid managed care plans pursuant to part IV of chapter 409.

Section 2. Section 627.6671, Florida Statutes, is created to read:

627.6671 Step Therapy protocols.—

(1) As used in this section, the term "step therapy protocol" means a written protocol that specifies the order in which a certain prescription drug must be used to treat an insured's condition.

(2)(a) An insured may not be required to repeat a step therapy protocol with either their current health insurer or a new health insurer for a prescription drug provided that the

drug is appropriately prescribed and is considered safe and effective for the insured's condition.

(b) Nothing in this section shall preclude an insured's new health insurer from imposing a prior authorization requirement for the continued coverage of a drug prescribed pursuant to a step therapy protocol imposed by the former health insurer.

(c) A health insurer is not required to add a drug to its prescription drug formulary, or to cover a prescription drug's use for a purpose not currently covered by the insurer, to comply with the section.

(d) This section applies to contracts entered into or renewed on or after January 1, 2019. This section does not apply to Medicaid managed care plans pursuant to part IV of chapter 409.

Section 3. Section 641.317, Florida Statutes, is created to read:

641.317 Step Therapy protocols.-

(1) As used in this section, the term "step therapy protocol" means a written protocol that specifies the order in which a certain prescription drug must be used to treat a subscriber's condition.

(2)(a) A subscriber may not be required to repeat a step therapy protocol with either their current health maintenance organization or a new health maintenance organization for a

prescription drug provided that the drug is appropriately prescribed and is considered safe and effective for the subscriber's condition.

(b) Nothing in this section shall preclude a subscriber's new health maintenance organization from imposing a prior authorization requirement for the continued coverage of a drug prescribed pursuant to a step therapy protocol imposed by the former health maintenance organization.

(c) A health maintenance organization is not required to add a drug to its prescription drug formulary, or to cover a prescription drug's use for a purpose not currently covered by the health maintenance organization, to comply with the section.

(d) This section applies to contracts entered into or renewed on or after January 1, 2019. This section does not apply to Medicaid managed care plans pursuant to part IV of chapter 409.

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

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

Remove everything before the enacting clause and insert: An act relating to step therapy protocols; creating s. 627.6476, F.S.; defining "step therapy"; prohibiting health insurers from requiring insureds to repeat step therapy protocols; providing

applicability; creating s. 627.6671, F.S.; defining "step therapy"; prohibiting health insurers from requiring insureds to repeat step therapy protocols; providing applicability; creating s. 641.317, F.S.; defining "step therapy"; prohibiting health insurers from requiring insureds to repeat step therapy protocols; providing applicability; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 351 Pharmacy Benefits Managers
SPONSOR(S): Santiago
TIED BILLS: **IDEN./SIM. BILLS:**

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

SUMMARY ANALYSIS

Health insurers increasingly rely on pharmacy benefit managers (PBMs) to provide a range of specified services related to the acquisition and distribution of prescription drugs. PBMs negotiate with pharmaceutical manufacturers in an effort to acquire drugs at the lowest possible price. PBMs also negotiate with pharmacies to develop reliable distribution networks for those drugs. These services are provided on behalf of a PBM's client.

HB 351 requires PBMs that conduct business in Florida to register with the Board of Pharmacy within the Department of Health (DOH) by providing identifying organizational information, submitting an application for registration, and submitting an annual registration fee. An expanded definition of the term "pharmacy benefit manager" is included in the bill.

HB 351 also introduces limits on patient cost sharing for specialty drugs, which the bill defines as drugs prescribed for an individual with a complex, chronic or rare medical condition; that cost $600 or more for up to a 30-day supply; that are not typically stocked at retail pharmacies; and require a difficult or unusual process of delivery to the patient in the preparation, handling, storage, inventory, or distribution of the drug; or requires enhanced education, management or support beyond those required for traditional dispensing. The bill limits the copayment or coinsurance a health insurer or health maintenance organization (HMO) may charge an insured to $150 for up to a 30-day supply of a specialty drug. The bill also provides additional parameters for dispensing specialty drugs. The bill requires the Office of Insurance Regulation (OIR) to adjudicate complaints regarding specialty drug determinations.

The bill prohibits Medicaid managed care plans from entering into contracts with PBMs unless the contract prevents the PBM from requiring enrollees use certain retail pharmacies. The contract must also prevent the PBM from providing incentives to enrollees to use a retail pharmacy, mail order pharmacy, specialty drug pharmacy or other pharmacy entity in which the PBM has an ownership interest or in which the pharmacies have an ownership interest in the PBM. The MMA contract must require PBMs to update the maximum allowable cost every 7 calendar days on January 1 of each year to accurately reflect the market price of acquiring the drug.

The bill has a significant, indeterminate, negative impact to DOH, which will be offset by fee revenue. The bill has a significant, indeterminate, negative impact on the Medicaid program and the state employee health prescription drug benefit program. The bill has an indeterminate negative impact on OIR for specialty drug complaint adjudication. The bill may have an indeterminate, negative impact on local government employee health plans.

The bill has an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

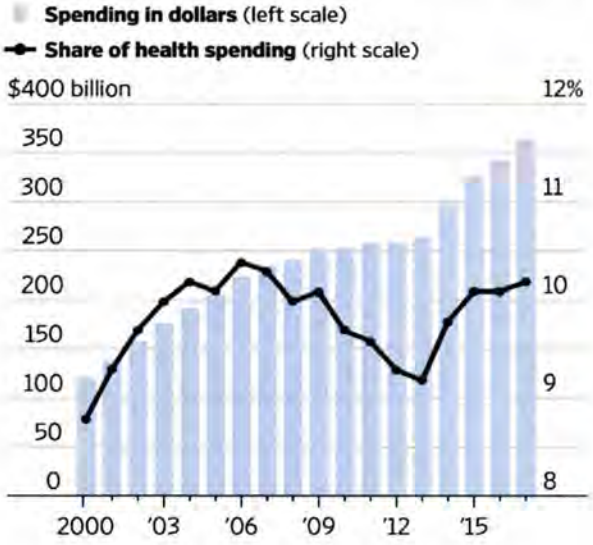
A. EFFECT OF PROPOSED CHANGES:

Background

Prescription Drug Cost and Pricing

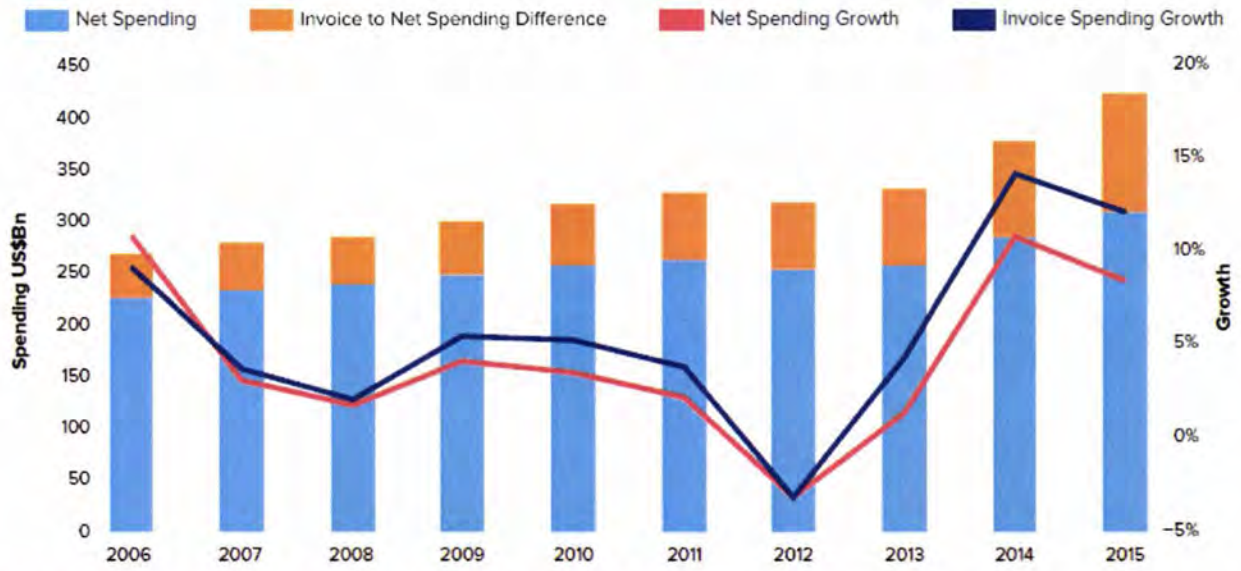
Spending on prescription drugs has risen sharply in the United States over the past few years.[1] From 2013 to 2015, out-of-pocket costs for prescription drugs rose 20 percent,[2] to an average cost of $44 per brand name prescription drug.[3] Additionally, prescription drug prices increased an average 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 as a Share of Health Spending 2000-2017[7]



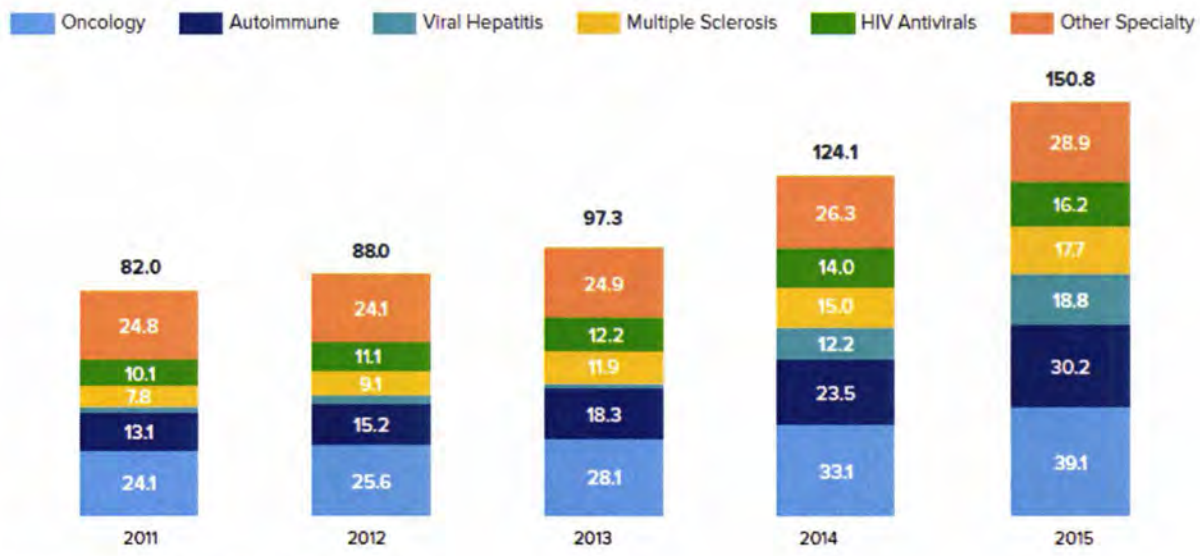
[1] Ameet Sarpatwari, Jerry Avorn, and Aaron S. Kesselheim, *State Initiatives to Control Medication Costs — Can Transparency Legislation Help?*, N. ENGL. J. MED. 2016; 374:2301-2304 Jun. 16, 2016, http://www.nejm.org/doi/full/10.1056/NEJMp1605100#t=article (last visited March 13, 2017).
[2] Troy Parks, *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 March 10, 2017).
[3] 2017 Segal Health Plan Cost Trend Survey, *available at*, https://www.segalco.com/media/2716/me-trend-survey-2017.pdf (last visited March 13, 2017)
[4] TRUVERIS, *Americans faced double digit increases in prescription drug prices in 2014, according to Truveris National Drug Index*, https://truveris.com/press-releases/ndi-americans-faced-double-digit-increases-in-prescription-drug-prices-in-2014/ (last visited March 13, 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] CENTERS FOR MEDICARE AND MEDICAID SERVICES, *National Health Expenditures by Type of Service and Source of Funds: Calendar Years 1960 to 2015*, .zip file available at, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (Last visited March 13, 2017).
[7] 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 March 13, 2017).

Total U.S. Spending on Prescription Drugs, 2015[8]



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

Total U.S. Spending on Specialty Prescription Drugs, 2015[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 March 13, 2017).

[9] Id.

Pharmacy Benefit Managers

Health insurers and HMOs increasingly utilize pharmacy benefit managers (PBMs) to provide a range of specified services related to the acquisition and distribution of prescription drugs.[10] PBMs enter into contracts with both health plans and pharmacies. PBMs negotiate with drug manufacturers, on behalf of health plans, in an effort to purchase drugs at reduced prices or with the promise of additional rebates. This negotiation process often involves the development of drug formularies, which are tiered drug lists that incentivize the use of some drugs over others.[11] PBMs simultaneously negotiate with pharmacies to establish reimbursements for dispensing prescription drugs to patients.

PBMs have become major participants in the pharmaceutical supply chain. These entities first emerged as claims processors in the late-1960s and early 1970s, but began to assume much more complex responsibilities in the 1990s in concert with advancements in information technology.[12] By 2016, PBMs were responsible for managing the pharmacy benefits of about 266 million Americans.[13] Around 60 PBMs are currently operational in the United States, and the three largest – Express Scripts, CVS Caremark, and OptumRx – have a combined market share of more than 60%.[14] PBMs assert that their services result in significant savings for both insurers and patients.[15] Broadly, PBMs generate revenue from the following sources:

(1) Fees from their clients (insurers, self-insured employers, union health plans, and government) for the administration of claims and drug dispensing;
(2) A share of the savings from rebates negotiated from drug companies – in most cases, the rebates are shared between the PBM and the health insurer or plan sponsor; and
(3) A combination of revenues and savings from maintaining pharmacy networks, including per prescription fees[16] from network pharmacies and volume-based contracting.

Each PBM generates revenues from all or some combination of these sources. In theory, the negotiating leverage of PBMs should translate into savings for patients, employers and insurers in the form of reduced drug costs. In addition, health insurers benefit from sharing in the increased manufacturer rebates that PBMs are often able to realize,[17] which may also reduce costs for consumers and employers.

Regulation of PBMs in Florida

PBMs are not regulated by the State of Florida. However, s. 465.1862, F.S., in the Pharmacy Practice Act, does subject contracts between PBMs and pharmacies to certain requirements. Contracts between PBMs and pharmacies must include obligations that the PBM update Maximum Allowable Cost (MAC) pricing at least every seven days and maintain a process that will, in a timely manner, eliminate drugs

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[10] The term "pharmacy benefit manager" is defined in S. 465.1862(b), F.S.
[11] Academy of Managed Care Pharmacy (AMCP). *Formulary Management*. Available at http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=9298 (last accessed December 20, 2017). See also, Pharmaceutical Care Management Association (PCMA). *Pharmacy Contracting & Reimbursement*. Available at https://www.pcmanet.org/policy-issues/pharmacy-contracting-reimbursement/ (last accessed December 20, 2017).
[12] "The ABCs of PBMs: Issue Brief." National Health Policy Forum. October 27, 1999. Available at http://ww.nhpf.org/library/issue-briefs/IB749_ABCsofPBMs_10-27-99.pdf (last accessed December 20, 2017).
[13] Pharmaceutical Care Management Association (PCMA). "That's What PBMs Do." Available at http://thatswhatpbmsdo.com/ (last accessed December 20, 2017).
[14] Fein, Adam J. *2017 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers*. Drug Channels Institute. February 2017. Available at http://drugchannelsinstitute.com/products/industry_report/pharmacy/ (last accessed December 20, 2017).
[15] Visante. *The Return on Investment (ROI) on PBM Services*. November 2016. Available at https://www.pcmanet.org/wp-content/uploads/2016/11/ROI-on-PBM-Services-FINAL.pdf (last accessed December 20, 2017).
[16] "Health Policy Brief: Pharmacy Benefits Managers," *Health Affairs*, September 14, 2017. Pharmacies are generally expected to submit a fee for each prescription to PBMs in order to participate in the PBM's network. DOI: 10.1377/hpb2017.13 (last accessed December 20, 2017).
[17] Id.

from MAC lists or modify drug prices to remain consistent with changes in pricing data used in formulating MAC prices and product availability.[18] MAC price lists set the upper limit amount that a PBM plan will reimburse a contracted pharmacy for generic drugs and some brand-name drugs with generic versions, known as multi-source brands. State Medicaid programs have utilized MAC pricing as a cost-control tool. States with MAC pricing controls typically publish lists of selected generic and multi-source brand drugs along with the maximum price at which Medicaid will reimburse for those drugs. In general, pharmacies will receive payment no higher than the MAC price when billing Medicaid for drugs on a state's MAC list.[19]

The Department of Health (DOH), in conjunction with the Board of Pharmacy, implements chapter 465, F.S., the Pharmacy Protection Act; however, the MAC list requirements of s. 465.1862, F.S., are only enforceable against the pharmacy. DOH and the Board do not have authority to enforce this requirement against PBMs.

Regulation of PBMs in Other States

Florida is not unique in its lack of regulation related to PBMs. Generally, state regulation of PBMs has been aimed at improving the transparency of PBM operations, and can be categorized in two ways:

1) Licensure or registration requirements for PBMs;
2) Patient protections, price transparency requirements, or prohibitions on certain practices by PBMs.[20]

While this categorization is not intended to be a comprehensive accounting of the actions taken by states to regulate PBM practices, it is reflective of a nationwide trend that has emerged in the past several years. States enacting regulations of PBMs are as follows. [21]

Licensure/Registration of PBMs		Patient Protections and Pricing Transparency	Both Licensure and Patient Protections
Iowa (2007)	North Dakota (2005)	Georgia (2017)	Arkansas (2015)
Kansas (2006)	Rhode Island (2004)	Louisiana (2016)	Connecticut (2007, 2017)
Kentucky (2016)	South Dakota (2004)	North Carolina (2017)	Washington (2014)
Maryland (2003)	Wyoming (2016)	Tennessee (2009)	
New Mexico (2016)		Texas (2017)	

Specialty Drugs

In general, specialty pharmaceuticals include a range of drugs that:

- Are designed to treat chronic, serious, or life-threatening health conditions;
- Are complex to manufacture and may require special handling;
- Are of limited distribution; and

[18] S. 465.1862, F.S.
[19] U.S. Department of Health and Human Services. *Medicaid Drug Pricing in State Maximum Allowable Cost Programs*. Report of the Office of Inspector General. August 2013. Available at https://oig.hhs.gov/oei/reports/oei-03-11-00640.pdf (last accessed January 11, 2018).
[20] PBM Watch. "Pharmacy Benefit Manager Legislation". Available at http://www.pbmwatch.com/pbm-legislation.html (last accessed December 21, 2017).
[21] See also Pharmacists United for Truth and Transparency. *State Regulations in Pharmacy Benefit Management*. Available at https://www.marleydrug.com/wp-content/uploads/2016/05/PUTT_State-Regulations_061713a.pdf (last accessed December 21, 2017) and National Association of Community Pharmacists. *State Laws Reforming the Practices of Pharmacy Benefit Managers (PBMs)*. Available at http://www.ncpanet.org/pdf/leg/nov12/pbm_enacted_legislation.pdf (last accessed December 21, 2017).

- Meet certain cost thresholds.[22]

Health conditions treated by specialty drugs are cancer, rheumatoid arthritis, multiple sclerosis, and hepatitis C.[23] However, because these drugs are often very expensive, patients may experience financial hardships accessing specialty medications. One recent survey reported that the *average* annual cost of therapy for a specialty drug was $52,486 in 2015.[24]

Health insurers, whether public or private, generally provide coverage of specialty drugs. However, the costs associated with specialty drugs has led insurers to adopt revised benefit designs to manage utilization of these drugs. For example, specialty drugs are most often placed on an insurer's highest formulary tier – meaning that an insured will likely face significant cost sharing in order to obtain a specialty drug.[25] The trend toward specialty tiers – drug tiers exclusively for specialty drugs – on insurer drug formularies has been particularly noteworthy. In 2017, nearly half of all large employers in the U.S. had adopted formularies with one or more specialty drug tiers.[26] For drugs included on these specialty tiers, the average monthly copayment was $101 and the average coinsurance rate was 27%.[27]

Some states have responded to the emergence of specialty drug tiers and high cost sharing by capping out-of-pocket payments that may be required of insured patients. For example, the Council of the District of Columbia recently passed a law that limits patient cost sharing to $150 for a 30-day supply of a specialty drug.[28] Delaware, Louisiana, and Maryland have likewise established ceilings for the patient cost sharing on specialty drugs.[29] New York has gone a step further by prohibiting the use of specialty drug tiers by insurers.[30] This action effectively limits patient cost sharing for specialty drugs to the same amounts assigned to more conventional prescription drugs and likely increases utilization of such drugs. However, it may have the effect of shifting the costs of these drugs to other forms of cost-sharing, such as premiums.

Effect of Proposed Changes

Regulation of Pharmacy Benefit Managers

HB 351 creates new registration program for PBMs. The DOH Board of Pharmacy would, by rule, create an application form and set an annual registration fee sufficient to cover the cost to administer the registration program. PBMs would register with the Board of Pharmacy by providing identifying information on the organization and submitting an application and fee for registration. The bill expands the current definition of PBM in the pharmacy practice act to include a list of PBM functions: processing claims; managing pharmacy networks; paying pharmacies for drugs or medical supplies; and negotiating for rebates from drug manufacturers. An entity that performs any one of these functions is a PBM and is subject to the bill's registration requirement.

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[22] "Specialty Pharmaceuticals." Health Affairs Health Policy Brief, November 25, 2013. DOI: 10.1377/hpb20131125.510855. Available at https://www.healthaffairs.org/do/10.1377/hpb20131125.510855/full/ (last accessed January 2, 2018).
[23] Id.
[24] AARP Public Policy Institute. *Trends in Retail Prices of Prescription Drugs Widely Used by Older Americans: 2006 to 2015.* December 2017. Available at https://www.aarp.org/content/dam/aarp/ppi/2017/11/trends-in-retail-prices-of-prescription-drugs-widely-used-by-older-americans-december.pdf (last accessed January 2, 2018).
[25] Pew Charitable Trusts. *Specialty Drugs and Health Costs*. Fact Sheet. December 2016. Available at http://www.pewtrusts.org/~/media/assets/2016/12/specialty_drugs_and_health_care_costs.pdf (last accessed January 2, 2018).
[26] Kaiser Family Foundation and Health Research & Educational Trust. *2017 Employer Health Benefits Survey*. Section 9: Prescription Drug Benefits. Available at https://www.kff.org/health-costs/report/2017-employer-health-benefits-survey/ (last accessed January 2, 2018).
[27] Id.
[28] Council of the District of Columbia, Law L21-0248, Effective April 7, 2017. Available at http://lims.dccouncil.us/Legislation/B21-0032?FromSearchResults=true (last accessed January 2, 2018).
[29] "Protecting Patients from Higher Cost Sharing." Celgene Corporation. March 9, 2015. Available at https://www.celgene.com/protecting-patients-higher-cost-sharing/ (last accessed January 2, 2018).
[30] Consolidated Laws of New York. Chapter 536 of 2010.

The bill amends the Pharmacy Act requirements for contracts entered into between health insurers and PBMs. The bill prohibits health insurers from entering into contracts with PBMs, unless those contracts specify that the PBM may not require a member or otherwise incentivize a member to use a retail pharmacy or other pharmacy entity in which the PBM has an ownership interest or which has an ownership interest in the PBM.

Further, the bill prohibits a PBM from placing a drug on a MAC list unless there are at least two therapeutically equivalent multi-source generic drugs, or at least one generic drug available from at least one manufacturer, generally available for purchase by network pharmacies from national or regional wholesalers, and the drug is not obsolete. The bill imposes additional MAC-related requirements for PBMs. PBMs must:

- Provide each network pharmacy at the beginning of a contract term, and upon request thereafter, the sources utilized to determine the MAC price;
- Provide a process for each network pharmacy provider to readily access the maximum allowable price specific to that provider;
- Review and update each applicable MAC list every seven business days to accurately reflect drug acquisition prices and apply the updates to reimbursements by not later than one business day; and
- Ensure that dispensing fees are not included in the calculation of MAC.

Each PBM must also establish a process for network pharmacies with less than 15 retail locations in the state to appeal the reimbursement amount for a drug subject to MAC. Appeals are limited to cases in which the MAC price for the drug is less than the net amount that the network pharmacy paid to the drug manufacturer or wholesaler. The bill establishes a process for adjudicating such appeals. The bill requires the PBM to resolve an appeal within 30 calendar days, or the appeal is deemed denied. If a pharmacy or pharmacist can demonstrate that it is unable to purchase a therapeutically equivalent drug product from a drug manufacturer or wholesaler doing business in the state at the PBM's list price for such drug product then the PBM must uphold the appeal.

If the PBM denies an appeal, it must provide the reason for denial and the national drug code of a drug that has been purchased by other network pharmacies in the state at a price that is equal to or less than the predetermined reimbursement cost for the multisource generic drug.

The bill creates an appeal process for appeals denied by the PBM. If an appeal is denied, or if the pharmacy is unsatisfied with the outcome of the appeal, the pharmacy or pharmacist may dispute the decision and request review by the Board of Pharmacy within 30 calendar days of receiving a decision. The Board may render a binding decision in a dispute between a PBM and a pharmacy of an appeal and, after reviewing all relevant information, may direct the PBM to make an adjustment to the disputed claim, deny the appeal, or take other action deemed fair and equitable. The Board must provide a copy of the final decision to both parties within 7 calendar days; however, if an appeal is upheld, the PBM must make a reasonable adjustment to the price no later than one day after the date of determination.

Cost Sharing for Specialty Drugs

The bill creates s. 465.1869, F.S., which sets new parameters for dispensing specialty drugs. The bill limits the copayment or coinsurance charged by a health insurer or HMO to $150 for up to a 30-day supply of a specialty drug. In other words, $150 would be the maximum monthly patient cost share for a specialty drug. This cost sharing limit would be adjusted on July 1 of each year by a percentage equal to the percentage change from the preceding year in the medical care component of the March Consumer Price Index for all urban consumers (CPI-U), U.S. city average, which is calculated by the U.S. Bureau of Labor Statistics. For example, the annual change in the medical care component of

CPI-U was 1.6% from November 2016 to November 2017.[31] If the $150 limit had been indexed to the CPI-U during that time period, it would increase to just over $152.

A specialty drug is defined in the bill is one which:

- Is prescribed for an individual with a complex or chronic medical condition or a rare medical condition;
- Costs $600 or more for up to a 30-day supply;
- Is not typically stocked at retail pharmacies; and
- Requires a difficult or unusual process of delivery to the patient in the preparation, handling, storage, inventory, or distribution of the drug; or
- Requires enhanced patient education, management, or support, beyond those required for traditional dispensing, before or after administration of the drug.

The bill provides limited discretion to insurers and HMOs regarding the pharmacies and facilities at which specialty drugs may be dispensed. Insurers may require that a specialty drug be obtained from a pharmacy participating in the insurer's network, if the pharmacy:

- Is licensed under chapter 465;
- Meets the insurer's performance standards;
- Has inventory or is readily able to obtain the covered specialty drug; and
- Accepts the insurer's reimbursement rates.

Section 465.1869, F.S., also establishes criteria by which a pharmacy registered under s. 340B of the U.S. Public Health Services Act[32] may apply to be a designated pharmacy for the purpose of allowing patients with HIV, AIDS, or Hepatitis C to receive the $150 maximum cost share at such pharmacies.

Additionally, in cases when an insurer or HMO denies a pharmacy's request to dispense a covered specialty drug, the bill requires that the insurer or HMO provide justification for the denial. The bill charges the Office of Insurance Regulation (OIR) with adjudicating any complaints that are filed by an insured in response to coverage denials for specialty drugs. OIR may seek advice from an independent review organization or medical expert. The insurance carrier that is the subject of the complaint is responsible for paying reasonable expenses incurred by the review organization or medical expert, if utilized.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 409.975, F.S.; introducing certain requirements in contracts between managed care plans and PBMs;
Section 2: Creates s. 465.1863, F.S.; requiring registration of PBMs with the Board of Pharmacy;
Section 3: Creates s. 465.1864, F.S.; providing definitions;
Section 4: Creates s. 465.1865, F.S.; outlining duties of a PBM;
Section 5: Creates s. 465.1866, F.S.; establishing an appeals process for reimbursements by a PBM;

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[31] U.S. Bureau of Labor Statistics. "Consumer Price Index for All Urban Consumers (CPI-U): U. S. city average, by expenditure category." Available at https://www.bls.gov/news.release/cpi.t01.htm (last accessed January 3, 2018).
[32] The 340B drug pricing program limits the prices drug manufacturers may charge for certain outpatient medications sold to specified covered entities. Eligible entities include federally qualified health centers, federally qualified health center look-alikes, native Hawaiian health centers, urban Indian health centers, Ryan White HIV/AIDS program grantees, Children's hospitals, critical access hospitals, disproportionate share hospitals, free-standing cancer hospitals, rural referral centers, sole community hospitals, black lunch clinics, comprehensive hemophilia diagnostic treatment centers, Title X family planning clinics, and tuberculosis clinics. As a condition for participation in the Medicaid program, drug manufacturers enter into pricing agreements with the Department of Health and Human Services (HHS). The Health Resources Services Administration (HRSA) calculates the ceiling or maximum price for each covered drug that a covered entity may pay. See, Titles 42 U.S.C. §256b, 42 U.S.C. §1396r-8.

Section 6: Creates s. 465.1867, F.S.; providing rulemaking authority;
Section 7: Creates s. 465.1868, F.S.; providing penalties;
Section 8: Creates s. 465.1869, F.S., providing definitions, copayment requirements, notice requirements, and authorization for OIR to receive complaints.
Section 9: Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   DOH would experience and increase in revenue in the form of registration fees paid by PBMs. This revenue would be used to cover the costs of the PBM registration program.

2. Expenditures:

   The bill will have an indeterminate impact on the Medicaid managed care program if appeals from small pharmacy chains to PBMs are upheld and plans have to pay the higher reimbursement amount for generic drugs. The Agency for Health Care Administration estimates that for every 1% increase in pharmacy expenditures, there is a $25 million increase in the plan costs. This potential impact may increase the Medicaid managed care plans' capitation rates.[33] However, the amount of appeals and the number of plans paying the higher reimbursement amount is unknown at this time, causing the fiscal impact to be indeterminate.

   DOH will incur an indeterminate increase in expenditures to develop and maintain the PBM registration program, including modifications to its Licensing and Enforcement Information Database System.[34] These impacts will be offset by fees.

   The bill will have a significant negative impact on the state employee prescription drug benefit program within the Department of Management Services (DMS). According to the DMS-contracted PBM (CVS Caremark) the bill would increase costs by approximately $4.1 million annually.[35]

   The bill will have an indeterminate negative impact on the Office of Insurance Regulation for adjudicating consumer complaints regarding specialty drug determinations.[36]

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

The bill may have an indeterminate negative impact on local government health plans.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill will have an indeterminate fiscal impact on health insurers, HMOs, and PBMs. To the extent that insurers and HMOs can no longer employ cost sharing above $150 for up to a 30-day supply of a specialty drug, costs may instead be spread across an insured population in the form of higher premiums.

D. FISCAL COMMENTS:

None.

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[33] Agency for Health Care Administration. *Agency Analysis of HB 351.* On file with staff of the House Health Innovation Subcommittee.
[34] Department of Health, *Agency Analysis for HB 351.* On file with the staff of the House Health Innovation Subcommittee.
[35] Department of Management Services, *Agency Analysis for HB 351.* On file with the staff of the House Health Innovation Subcommittee.
[36] Office of Insurance Regulation, *Agency Analysis for HB 351.* On file with the staff of the House Health Innovation Subcommittee.

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:

   None.

B. RULE-MAKING AUTHORITY:

The bill provides the Board of Pharmacy sufficient rulemaking authority to implement the PBM registration program and the appeals process for drug reimbursement disputes between pharmacies and PBMs. The bill does not provide sufficient rule-making authority to OIR to administer the specialty drug complaint adjudication process.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The effective date of the bill may implicate Art. 1 Sec. 10 of the Florida Constitution related to impairment of contracts. This issue may be addressed by amending the bill to make its provisions applicable to contracts executed or renewed after July 1, 2018 and making the effective date of the bill July 1, 2018.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to pharmacy benefits managers; amending s. 409.975, F.S.; prohibiting a managed care plan from contracting with a pharmacy benefits manager to manage the prescription drug coverage provided under the plan unless certain requirements are met; creating s. 465.1863, F.S.; requiring pharmacy benefits managers to register with the Board of Pharmacy; providing application requirements; requiring renewal; creating s. 465.1864, F.S.; providing definitions; creating s. 465.1865, F.S.; requiring specified duties of pharmacy benefits managers; creating s. 465.1866, F.S.; requiring pharmacy benefits managers to create a process to appeal predetermined reimbursement costs; providing deadlines for the appeals process; creating s. 465.1867, F.S.; providing rulemaking authority; creating s. 465.1868, F.S.; providing penalties; creating s. 465.1869, F.S.; providing definitions; providing applicability; providing copayment requirements; authorizing a pharmacy to dispense specialty drugs under certain conditions; providing requirements; providing notice requirements; providing construction; authorizing specified complaints to be filed with the Commissioner on Insurance Regulation;

providing an effective date.

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

Section 1. Subsection (1) of section 409.975, Florida Statutes, is amended to read:

409.975 Managed care plan accountability.—In addition to the requirements of s. 409.967, plans and providers participating in the managed medical assistance program shall comply with the requirements of this section.

(1) PROVIDER NETWORKS.—Managed care plans must develop and maintain provider networks that meet the medical needs of their enrollees in accordance with standards established pursuant to s. 409.967(2)(c). Except as provided in this section, managed care plans may limit the providers in their networks based on credentials, quality indicators, and price.

(a) A managed care plan may not enter into a contract with a pharmacy benefits manager (PBM) to manage the prescription drug coverage provided under the plan or to control the costs of the prescription drug coverage under such plan unless:

1. The contract prevents the PBM from requiring that a plan enrollee use a retail pharmacy or other pharmacy entity providing pharmacy services in which the PBM has an ownership interest or which has an ownership interest in the PBM, or the contract provides an incentive to a plan enrollee to encourage

the enrollee to use a retail pharmacy, mail order pharmacy, specialty pharmacy, or other pharmacy entity providing pharmacy services in which the PBM has an ownership interest or which has an ownership interest in the PBM, if the incentive is applicable only to such pharmacies; and

2. The contract requires the PBM to update the maximum allowable cost as defined by s. 465.1862(1)(a) every 7 calendar days beginning on January 1 of each year, to accurately reflect the market price of acquiring the drug.

(b) Plans must include all providers in the region which ~~that~~ are classified by the agency as essential Medicaid providers, unless the agency approves, in writing, an alternative arrangement for securing the types of services offered by the essential providers. Providers are essential for serving Medicaid enrollees if they offer services that are not available from any other provider within a reasonable access standard, or if they provided a substantial share of the total units of a particular service used by Medicaid patients within the region during the last 3 years and the combined capacity of other service providers in the region is insufficient to meet the total needs of the Medicaid patients. The agency may not classify physicians and other practitioners as essential providers. The agency, at a minimum, shall determine which providers in the following categories are essential Medicaid providers:

1. Federally qualified health centers.

2. Statutory teaching hospitals as defined in s. 408.07(45).

3. Hospitals that are trauma centers as defined in s. 395.4001(14).

4. Hospitals located at least 25 miles from any other hospital with similar services.

Managed care plans that have not contracted with all essential providers in the region as of the first date of recipient enrollment, or with whom an essential provider has terminated its contract, must negotiate in good faith with such essential providers for 1 year or until an agreement is reached, whichever is first. Payments for services rendered by a nonparticipating essential provider shall be made at the applicable Medicaid rate as of the first day of the contract between the agency and the plan. A rate schedule for all essential providers shall be attached to the contract between the agency and the plan. After 1 year, managed care plans that are unable to contract with essential providers shall notify the agency and propose an alternative arrangement for securing the essential services for Medicaid enrollees. The arrangement must rely on contracts with other participating providers, regardless of whether those providers are located within the same region as the nonparticipating essential service provider. If the alternative

arrangement is approved by the agency, payments to nonparticipating essential providers after the date of the agency's approval shall equal 90 percent of the applicable Medicaid rate. Except for payment for emergency services, if the alternative arrangement is not approved by the agency, payment to nonparticipating essential providers shall equal 110 percent of the applicable Medicaid rate.

(c) ~~(b)~~ Certain providers are statewide resources and essential providers for all managed care plans in all regions. All managed care plans must include these essential providers in their networks. Statewide essential providers include:

1. Faculty plans of Florida medical schools.

2. Regional perinatal intensive care centers as defined in s. 383.16(2).

3. Hospitals licensed as specialty children's hospitals as defined in s. 395.002(28).

4. Accredited and integrated systems serving medically complex children which comprise separately licensed, but commonly owned, health care providers delivering at least the following services: medical group home, in-home and outpatient nursing care and therapies, pharmacy services, durable medical equipment, and Prescribed Pediatric Extended Care.

Managed care plans that have not contracted with all statewide essential providers in all regions as of the first date of

recipient enrollment must continue to negotiate in good faith. Payments to physicians on the faculty of nonparticipating Florida medical schools shall be made at the applicable Medicaid rate. Payments for services rendered by regional perinatal intensive care centers shall be made at the applicable Medicaid rate as of the first day of the contract between the agency and the plan. Except for payments for emergency services, payments to nonparticipating specialty children's hospitals shall equal the highest rate established by contract between that provider and any other Medicaid managed care plan.

(d) ~~(c)~~ After 12 months of active participation in a plan's network, the plan may exclude any essential provider from the network for failure to meet quality or performance criteria. If the plan excludes an essential provider from the plan, the plan must provide written notice to all recipients who have chosen that provider for care. The notice shall be provided at least 30 days before the effective date of the exclusion. For purposes of this paragraph, the term "essential provider" includes providers determined by the agency to be essential Medicaid providers under paragraph (b) ~~(a)~~ and the statewide essential providers specified in paragraph (c) ~~(b)~~.

(e) ~~(d)~~ The applicable Medicaid rates for emergency services paid by a plan under this section to a provider with which the plan does not have an active contract shall be determined according to s. 409.967(2)(b).

(f)~~(e)~~ Each managed care plan must ~~may~~ offer a network contract to each home medical equipment and supplies provider in the region which meets quality and fraud prevention and detection standards established by the plan and which agrees to accept the lowest price previously negotiated between the plan and another such provider.

Section 2. Section 465.1863, Florida Statutes, is created to read:

465.1863 Registration of pharmacy benefits managers required.—

(1) To conduct business in this state, a pharmacy benefits manager must register with the board and maintain annual renewal of his or registration.

(2) A person seeking to register as a pharmacy benefits manager shall submit an application to the board, on a form adopted by rule of the board, which includes the following:

(a) The name, business address, phone number, and contact person for the pharmacy benefits manager.

(b) Where applicable, the federal tax employer identification number for the entity.

(c) A registration fee established by the board by rule.

(3) To annually renew registration, a pharmacy benefits manager shall pay a renewal fee established by the board by rule.

Section 3. Section 465.1864, Florida Statutes, is created

to read:

465.1864 Definitions.—As used in sections 465.1863-465.1869, the term:

(1) "Claim" means a request from a pharmacy or pharmacist to be reimbursed for the cost of filling or refilling a prescription for a drug or for providing a medical supply or service.

(2) "Insurer" means an entity licensed under chapter 624 which offers an individual health insurance policy or a group health insurance policy, a preferred provider organization as defined in s. 627.6471, an exclusive provider organization as defined in s. 627.6472, a health maintenance organization licensed under part I of chapter 641, or a prepaid limited health service organization or discount plan organization licensed under chapter 636.

(3) "List" means the list of drugs for which predetermined reimbursement costs have been established, such as a maximum allowable cost list or any other benchmark price list utilized by the pharmacy benefits manager, and which list includes the basis of the methodology and sources utilized to determine multisource generic drug reimbursement amounts.

(4) "Multiple source drug" means a therapeutically equivalent drug that is available from at least two manufacturers.

(5) "Multisource generic drug" means a covered outpatient

prescription drug for which there is at least one other drug product that is rated as therapeutically equivalent under the United States Food and Drug Administration's most recent publication of its "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book), is pharmaceutically equivalent or bioequivalent as determined by the United States Food and Drug Administration, and is sold or marketed in the state during the period.

(6) "Network pharmacy" means a retail drug establishment licensed as a pharmacy that contracts with a pharmacy benefits manager.

(7) "Pharmacy benefits manager" means a person or entity doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health insurance plan, as defined in former s. 627.6482, to residents of this state and that:

(a) Processes claims for prescription drugs or medical supplies or provides retail network management for pharmacies or pharmacists;

(b) Pays pharmacies or pharmacists for prescription drugs or medical supplies; or

(c) Negotiates rebates with manufacturers for drugs paid for or procured.

(8) Therapeutically equivalent" means a drug product of the identical base or salt as the specific drug product

prescribed with essentially the same efficacy and toxicity when administered to an individual in the same dosage regimen.

Section 4. Section 465.1865, Florida Statutes, is created to read:

465.1865 Duties of a pharmacy benefits manager.—

(1) A pharmacy benefits manager may not place a drug on a list unless there are at least two multiple source drugs, or at least one generic drug available from only one manufacturer, generally available for purchase by a network pharmacy from a national or regional manufacturer or wholesaler.

(2) A pharmacy benefits manager shall:

(a) Ensure that all drugs on a list are readily available for purchase by a pharmacy in the state from a national or regional manufacturer or wholesaler.

(b) Make available to each network pharmacy, at the beginning of the term of a contract with such network pharmacy and upon the renewal of such contract, the sources utilized to determine the predetermined reimbursement costs for multisource generic drugs.

(c) Upon request, make a list available to a network pharmacy in a readily accessible and usable format.

(d) Update each list maintained by the pharmacy benefits manager every seven business days and make such lists, including all changes in the price of drugs, available to a network pharmacy in a readily accessible and usable format.

(e) Ensure that dispensing fees are not included in the calculation of the predetermined reimbursement costs for multisource generic drugs.

Section 5. Section 465.1866, Florida Statutes, is created to read:

465.1866 Appeals process.—A pharmacy benefits manager shall establish a process by which a network pharmacy with fewer than 15 retail locations in the state may appeal a predetermined reimbursement cost for a multisource generic drug if the reimbursement for the drug is less than the net amount that the network pharmacy paid to the drug manufacturer or wholesaler.

(1) An appeal requested under this section must be completed within 30 calendar days of the network pharmacy's submission of its appeal. If, after 30 calendar days, the network pharmacy has not received a decision on its appeal from the pharmacy benefits manager, the appeal is deemed denied.

(2) The pharmacy benefits manager shall uphold an appeal submitted by a network pharmacy if the pharmacy or pharmacist can demonstrate that it is unable to purchase a therapeutically equivalent drug product from a drug manufacturer or wholesaler doing business in the state at the pharmacy benefits manager's list price for such drug product.

(3) As part of the appeals process established under this section, a pharmacy benefits manager must provide:

(a) A telephone number at which a network pharmacy may

contact the pharmacy benefits manager and speak with an individual who is responsible for processing appeals.

(b) If an appeal is denied, the reason for the denial and the national drug code of a drug that has been purchased by other network pharmacies in the state at a price that is equal to or less than the predetermined reimbursement cost for the multisource generic drug.

(4) If an appeal is upheld, the pharmacy benefits manager shall make a reasonable adjustment to the price no later than one day after the date of determination.

(5) If an appeal is denied, or if the network pharmacy is unsatisfied with the outcome of the appeal, the pharmacy or pharmacist may dispute the decision and request review by the board within 30 calendar days of receiving a decision.

(6) The board may render a binding decision in a dispute between a pharmacy benefits manager and a pharmacy arising out of an appeal under this section.

(a) After reviewing all relevant information in the appeal, the board may direct the pharmacy benefits manager to make an adjustment to the disputed claim, deny the appeal, or take other action deemed fair and equitable.

(b) Upon the resolution of the dispute, the board shall provide a copy of the final decision to both parties within 7 calendar days.

(c) The board may authorize the department to resolve

disputes under this subsection.

(7) This section applies only to a network pharmacy with fewer than 15 retail locations in the state.

Section 6. Section 465.1867, Florida Statutes, is created to read:

465.1867 Rulemaking authority.—The board may adopt rules to implement and establish registration and renewal fees sufficient for oversight of ss. 465.1863-465.1869.

Section 7. Section 465.1868, Florida Statutes, is created to read:

465.1868 Penalties.—A pharmacy benefits manager that knowingly and willfully misleads consumers or other businesses or violates s. 465.1863, s. 465.1865, or s. 465.1866 commits an unfair and deceptive trade practice, as prohibited by s. 501.204(1), and is subject to a civil penalty, pursuant to s. 501.2075, in the amount of $10,000 for each violation.

Section 8. Section 465.1869, Florida Statutes, is created to read:

465.1869 Authority to dispense specialty drugs.—

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

(a) "Complex or chronic medical condition" means a physical, behavioral, or developmental condition that may have no known cure, is progressive, or can be debilitating or fatal if left untreated or undertreated. The term includes multiple sclerosis, hepatitis C, and rheumatoid arthritis.

(b) "Managed care system" means a system of cost containment methods that an insurer, a nonprofit health service plan, or a health maintenance organization uses to review and preauthorize drugs prescribed by a health care provider for a covered individual to control utilization, quality, and claims.

(c) "Rare medical condition" means a disease or condition that affects fewer than 200,000 individuals in the United States or approximately 1 in 1,500 individuals worldwide. The term includes cystic fibrosis, hemophilia, and multiple myeloma.

(d) "Specialty drug" means a prescription drug that:

1. Is prescribed for an individual with a complex or chronic medical condition or a rare medical condition;

2. Costs $600 or more for up to a 30-day supply;

3. Is not typically stocked at retail pharmacies; and

4.a. Requires a difficult or unusual process of delivery to the patient in the preparation, handling, storage, inventory, or distribution of the drug; or

b. Requires enhanced patient education, management, or support, beyond those required for traditional dispensing, before or after administration of the drug.

(2) This section applies to:

(a) Insurers and nonprofit health service plans that provide coverage for prescription drugs under individual, group, or blanket health insurance policies or contracts that are issued or delivered in the state; and

(b) Health maintenance organizations that provide coverage for prescription drugs under individual or group contracts that are issued or delivered in the state.

(3)(a) Subject to paragraph (b), an entity subject to this section may not impose a copayment or coinsurance requirement on a covered specialty drug that exceeds $150 for up to a 30-day supply of the specialty drug.

(b) On July 1 of each year, the limit on the copayment or coinsurance requirement on a covered specialty drug shall increase by a percentage equal to the percentage change from the preceding year in the medical care component of the March Consumer Price Index for All Urban Consumers, U.S. City Average, from the U.S. Department of Labor, Bureau of Labor Statistics.

(4)(a) This section does not preclude an entity subject to this section from requiring a covered specialty drug to be obtained through:

1.a. A designated pharmacy or other source authorized under chapter 465 to dispense or administer prescription drugs; or

b. A pharmacy participating in the entity's provider network, if the entity determines that the pharmacy:

(I) Is licensed under the chapter 465;

(II) Meets the entity's performance standards;

(III) Has in inventory or is able to readily obtain the covered specialty drug from the manufacturer; and

(IV) Accepts the entity's network reimbursement rates.

(b) An entity subject to this section shall post its performance standards on the entity's web site.

(5)(a) A pharmacy registered under s. 340B of the Public Health Services Act may apply to be a designated pharmacy under subparagraph (4)(a)1. for the purpose of enabling the pharmacy's patients with HIV, AIDS, or hepatitis C to receive the copayment or coinsurance maximum provided for in subsection (3) if:

1. The pharmacy is owned by a federally qualified health center, as defined in 42 U.S.C. s. 254B;

2. The federally qualified health center provides integrated and coordinated medical and pharmaceutical services to patients with HIV, AIDS, or hepatitis C; and

3. The prescription drugs are covered specialty drugs for the treatment of HIV, AIDS, or hepatitis C.

(b) An entity subject to this section may not unreasonably withhold approval of a pharmacy's application under paragraph (a).

(6)(a) An entity subject to this section that denies a request of a pharmacy participating in the entity's network for authorization to dispense a covered specialty drug shall notify the pharmacy of the reason for the denial.

(b) The notice required under paragraph (a) must be in writing and state the specific reason for the denial.

(7) This subsection does not prohibit a manufacturer from

establishing a limited distribution network for one or more of manufacturer's specialty drugs.

(8) A determination by an entity subject to this section that a prescription drug is not a specialty drug is considered a denial under s. 627.6141.

(9) Complaints may be filed with the Commissioner of Insurance Regulation under this subsection if the entity made its determination that a prescription drug is not a specialty drug on the basis that the prescription drug is not prescribed for an individual with a complex or chronic medical condition or a rare medical condition. For such complaints:

(a) The commissioner may seek advice from an independent review organization or medical expert; and

(b) The expenses for any advice provided by an independent review organization or medical expert shall be paid for as follows:

1. The carrier that is the subject of the complaint is responsible for paying the reasonable expenses of the independent review organization or medical expert selected by the commissioner in accordance with paragraph (a).

2. The independent review organization or medical expert shall:

a. Present to the carrier for payment a detailed account of the expenses incurred by the independent review organization or medical expert; and

b. Provide a copy of the detailed account of expenses to the commissioner.

Section 9. This act shall take effect July 1, 2018.

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 Santiago offered the following:

Amendment (with title amendment)

Remove everything after the enacting clause and insert:

Section 1. Section 465.0244, Florida Statutes, is amended to read:

465.0244 Information disclosure.—

(1) Every pharmacy shall make available on its website a hyperlink to the health information that is disseminated by the Agency for Health Care Administration pursuant to s. 408.05(3) and shall place in the area where customers receive filled prescriptions notice that such information is available electronically and the address of its Internet website.

(2) In addition to the requirements of section 465.025, a pharmacist shall inform customers of a lower cost alternative for their prescription and whether their cost-sharing obligation exceeds the retail price of their prescription in the absence of prescription drug coverage.

Section 2. Section 465.1862, Florida Statutes, is repealed.

Section 3. Section 624.490, Florida Statutes, is created to read:

624.490 Registration of pharmacy benefit managers.—

(1) As used in this section, "pharmacy benefit manager" means a person or entity doing business in this state which contracts to administer prescription drug benefits on behalf of a health insurer or a health maintenance organization.

(2) To conduct business in this state, a pharmacy benefit manager must register with the Office of Insurance Regulation. To register, a pharmacy benefit manager shall submit a fee determined by the office, a copy of the registrant's corporate charter, articles of incorporation, or other charter document, and a form established by the office containing the identity, address, and taxpayer identification number, when applicable, of:

(a) The registrant;

(b) The chief executive officer or a similarly titled person responsible for the executive oversight of the registrant;

(c) The chief financial officer or a similarly titled person responsible for the financial oversight of the registrant;

(d) Each person or entity responsible for the affairs of the registrant, including, but not limited to, the day-to-day operations of the registrant.

(3) The registrant shall report a change in any information required by subsection (2) to the office in writing within 60 days after the change.

(4) Upon receipt of a complete registration form and the registration fee, the office shall issue a registration certificate. The certificate may be in paper or electronic form, and shall clearly indicate the expiration date of the registration. Registration certificates are nontransferable.

(5) The term of registration shall be two years from the date of issuance. The office shall set an initial registration fee and a renewal registration fee, which are nonrefundable. Total fees may not exceed the cost of administering this section.

(6) The office shall adopt rules necessary to implement the provisions of this section.

Section 4. Section 627.64741, Florida Statutes, is created to read:

627.64741 Pharmacy benefit manager contracts.—

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

(a) "Maximum allowable cost" means the per-unit amount that a pharmacy benefit manager reimburses a pharmacist for a prescription drug, excluding dispensing fees, prior to the application of copayments, coinsurance, and other cost-sharing charges, if any.

(b) "Pharmacy benefit manager" means a person or entity doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health insurer to residents of this state.

(2) A contract between a health insurer and a pharmacy benefit manager must include requirements that the pharmacy benefit manager:

(a) Update maximum allowable cost pricing information at least every 7 calendar days; and

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

(3) A contract between a health insurer and a pharmacy benefit manager shall prohibit the pharmacy benefit manager from

limiting a pharmacy's or pharmacist's ability to substitute a less expensive, generically equivalent drug product for a brand name drug, pursuant to section 465.025, or to disclose to a subscriber whether the subscriber's cost-sharing obligation exceeds the retail price for a covered prescription drug, and availability of a more affordable alternative drug, pursuant to s. 465.0244.

(4) A contract between a health insurer and a pharmacy benefit manager shall prohibit the pharmacy benefit manager from requiring an insured to make a payment for a prescription drug at the point of sale in an amount greater than the lesser of:

(a) The applicable cost-sharing amount;

(b) The total submitted charges for the prescription drug;

(c) The retail price of the drug in the absence of prescription drug coverage or programs that otherwise reduce the cost of a drug to the patient.

Section 5. Section 627.6572, Florida Statutes, is created to read:

627.6572 Pharmacy Benefit Manager Contracts.—

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

(a) "Maximum allowable cost" means the per-unit amount that a pharmacy benefit manager reimburses a pharmacist for a prescription drug, excluding dispensing fees, prior to the application of copayments, coinsurance, and other cost-sharing charges, if any.

(b) "Pharmacy benefit manager" means a person or entity doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health insurer to residents of this state.

(2) A contract between a health insurer and a pharmacy benefit manager must include requirements that the pharmacy benefit manager:

(a) Update maximum allowable cost pricing information at least every 7 calendar days; and

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

(3) A contract between a health insurer and a pharmacy benefit manager shall prohibit the pharmacy benefit manager from limiting a pharmacy's or pharmacist's ability to substitute a less expensive, generically equivalent drug product for a brand name drug, pursuant to section 465.025, or to disclose to a subscriber whether the subscriber's cost-sharing obligation exceeds the retail price for a covered prescription drug, and availability of a more affordable alternative drug, pursuant to s. 465.0244.

(4) A contract between a health insurer and a pharmacy benefit manager shall prohibit the pharmacy benefit manager from

requiring an insured to make a payment for a prescription drug at the point of sale in an amount greater than the lesser of:

(a) The applicable cost-sharing amount;

(b) The total submitted charges for the prescription drug;

(c) The retail price of the drug in the absence of prescription drug coverage or programs that otherwise reduce the cost of a drug to the patient.

Section 6. Section 641.314, Florida Statutes, is created to read:

641.314 Pharmacy benefit manager contracts.—

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

(a) "Maximum allowable cost" means the per-unit amount that a pharmacy benefit manager reimburses a pharmacist for a prescription drug, excluding dispensing fees, prior to the application of copayments, coinsurance, and other cost-sharing charges, if any.

(b) "Pharmacy benefit manager" means a person or entity doing business in this state which contracts to administer or manage prescription drug benefits on behalf of a health maintenance organization to residents of this state.

(2) A contract between a health maintenance organization and a pharmacy benefit manager must include requirements that the pharmacy benefit manager:

(a) Update maximum allowable cost pricing information at least every 7 calendar days; and

(b) Maintain a process that will, in a timely manner, eliminate drugs from maximum allowable cost lists or modify drug prices to remain consistent with changes in pricing data used in formulating maximum allowable cost prices and product availability.

(3) A contract between a health maintenance organization and a pharmacy benefit manager shall prohibit the pharmacy benefit manager from limiting a pharmacy's or pharmacist's ability to substitute a less expensive, generically equivalent drug product for a brand name drug, pursuant to section 465.025, or to disclose to a subscriber whether the subscriber's cost-sharing obligation exceeds the retail price for a covered prescription drug, and availability of a more affordable alternative drug, pursuant to section 465.0244.

(4) A contract between a health maintenance organization and a pharmacy benefit manager shall prohibit the pharmacy benefit manager from requiring a subscriber to make a payment for a prescription drug at the point of sale in an amount greater than the lesser of:

(a) The applicable cost-sharing amount;

(b) The total submitted charges for the prescription drug;

(c) The retail price of the drug in the absence of prescription drug coverage or programs that otherwise reduce the cost of a drug to the patient.

Section 7. This act applies to contracts entered into or renewed on or after July 1, 2018.

Section 8. This act shall take effect July 1, 2018.

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

Remove everything before the enacting clause and insert:
An act relating to prescription drug pricing transparency; amending s. 465.0244, F.S.; permitting pharmacists to inform customers about lower cost alternatives for their prescriptions and whether their cost-sharing exceeds the retail price for their prescriptions; repealing s. 465.1862, F.S.; creating s. 624.490, F.S.; requiring registration of pharmacy benefit managers with the Office of Insurance Regulation; creating s. 627.64741, F.S.; requiring certain terms in health insurer contracts with pharmacy benefit managers; creating s. 627.6572, F.S.; requiring certain terms in health insurer contracts with pharmacy benefit managers; creating s. 641.314, F.S.; requiring certain terms in health maintenance organization contracts with pharmacy benefit managers; providing applicability; providing an effective date.

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 443 Nursing Home and Assisted Living Facility Resident Rights
SPONSOR(S): Slosberg
TIED BILLS: **IDEN./SIM. BILLS:**

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

SUMMARY ANALYSIS

Nursing homes are regulated by the Agency for Health Care Administration (AHCA) under the Health Care Licensing Procedures Act (Act) in part II of chapter 408, F.S. Assisted Living Facilities (ALF) are licensed and regulated by AHCA under part I of ch. 429, F.S., and part II of ch. 408, F.S.

Current law requires nursing home facilities provide copies of a resident's records, including any medical records and records concerning the care and treatment of the resident performed at the facility, within 14 working days after receipt of a written request by a current resident or the resident's authorized representative.

Federal regulations require nursing home facilities provide residents with access to personal and medical records within 24 hours, excluding weekends and holidays, of an oral or written request of the resident. Nursing home facilities must allow residents to obtain a copy of the records within 2 working days of the request.

Current law requires ALFs to provide residents with at least 45 days' notice for the relocation of a resident or residency termination. Reasons for relocation must be set forth in writing. In order for a facility to terminate the residency of an individual without notice, the facility must show good cause in a court of competent jurisdiction.

HB 443 requires nursing homes to notify residents and the State Long Term Care Ombudsman with the facility's current contact information, including a functional telephone number, and to notify residents and the State Long Term Care Ombudsman of any change in contact information within 30 days after such change and authorizes AHCA to take disciplinary action against nursing homes that fail to do so.

The bill also aligns Florida law with federal regulations regarding the provision of records to nursing home residents.

The bill requires an ALF that is relocating a resident to provide the reasons for relocation of a resident to the resident or the resident's legal representative. The bill also requires the ALF provide of a copy of the required notice of relocation to the State Long Term Care Ombudsman Program within 7 calendar days after the notice is provided to the resident or the resident's legal representative.

The bill does not have a fiscal impact on state or local government.

The bill has an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Nursing Homes

Licensure

Nursing homes are regulated by AHCA under the Health Care Licensing Procedures Act (Act) in part II of chapter 408, F.S., which contains uniform licensing standards for 29 provider types including nursing homes. In addition, nursing homes must comply with the requirements contained in the individual authorizing statutes of part II of chapter 400, F.S., which includes unique provisions for licensure beyond the uniform criteria. AHCA must electronically provide a list by name and address of all nursing home facilities in this state, including any prior name by which a facility was known during the previous 24-month period.[1]

Access to Records

Section 400.145, F.S. requires nursing home facilities provide copies of a resident's records, including any medical records and records concerning the care and treatment of the resident performed at the facility, within 14 working days after receipt of a written request by a current resident or the resident's authorized representative. The facility must provide the records within 30 days if the request relates to a former resident. If the facility determines that disclosure of the records to the resident would be detrimental the physical or mental health of the resident, the facility may refuse to furnish the records directly to the resident. If the facility refuses to furnish the records directly to the resident, the resident may request the facility provide the records to another medical provider designated by the resident.

Federal regulations require nursing home facilities provide residents with access to personal and medical records within 24 hours, excluding weekends and holidays, of an oral or written request of the resident. Nursing home facilities must allow residents to obtain a copy of the records within 2 working days of the request.[2]

Assisted Living Facilities

Licensure

An ALF is a residential establishment, or part of a residential establishment, that provides housing, meals, and one or more personal services for a period exceeding 24 hours to one or more adults who are not relatives of the owner or administrator.[3] A personal service is direct physical assistance with, or supervision of, the activities of daily living and the self-administration of medication.[4] Activities of daily living include ambulation, bathing, dressing, eating, grooming, toileting, and other similar tasks.[5]

ALFs are licensed and regulated by AHCA under part I of ch. 429, F.S., and part II of ch. 408, F.S.[6] In addition to a standard license, an ALF may have one or more specialty licenses that allow the ALF to

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[1] S. 400.191(2)(a)2, F.S. The list can be obtained at: http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (last visited December 15, 2017).
[2] 42 CFR 483.10
[3] S. 429.02(5), F.S. An ALF does not include an adult family-care home or a non-transient public lodging establishment.
[4] S. 429.02(16), F.S.
[5] S. 429.02(1), F.S.
[6] Under s. 429.04, F.S., the following are exempt from licensure: ALFs operated by an agency of the federal government; facilities licensed under ch. 393, F.S., relating to individuals with developmental disabilities; facilities licensed under ch. 394, F.S., relating to

provide additional care. These specialty licenses include limited nursing services,[7] limited mental health services,[8] and extended congregate care services.[9] The Department of Elder Affairs (DOEA) is responsible for establishing training requirements for ALF administrators and staff.[10]

As of November 20, 2017, there are 3,108 licensed ALFs in Florida with 98,833 beds.[11]

Resident's Rights

When individuals enter assisted living facilities, they gain special "Residents' Rights[12]," which includes the right to receive at least 45 days' notice of relocation or termination of residency from the facility. A notice of at least 45 days is not required if, for medical reasons, the resident is certified by a physician to require an emergency relocation to a facility providing a more skilled level of care or the resident engages in a pattern of conduct that is harmful or offensive to other residents. If a resident has been adjudicated mentally incapacitated, the resident's guardian must be given at least 45 days' notice of a nonemergency relocation or residency termination. Reasons for relocation must be set forth in writing. In order for a facility to terminate the residency of an individual without notice, the facility must show good cause in a court of competent jurisdiction.

State Long-Term Care Ombudsman Program

The State Long-Term Care Ombudsman Program (LTCOP) within the DOEA is a statewide, volunteer-based system of local councils that act as advocates for residents of long-term care facilities.[13] The LTCOP was established by Title VII of the federal Older Americans Act[14] and its operation is governed by state statute.[15] Through 13 districts[16] that together cover the entire state, volunteers identify, investigate, and resolve complaints made by, or on behalf of, residents of nursing homes, assisted living facilities, adult family care homes, and continuing care retirement communities. In addition to investigating and resolving complaints, the LTCOP performs the following services or activities:

- Represent the interests of residents before governmental agencies and seek administrative, legal, and other remedies to protect the health, safety, welfare, and rights of the residents.

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mental health; licensed adult family care homes; a person providing housing, meals, and one or more personal services on a 24-basis in the person's own home to no more than 2 adults; certain facilities that have been incorporated in this state for 50 years or more on or before July 1, 1983; certain continuing care facilities; certain retirement facilities; and residential units located within a community care facility or co-located with a nursing home or ALF in which services are provided on an outpatient basis.

[7] S. 429.07(3)(c), F.S. Limited nursing services include acts that may be performed by a person licensed nurse but are not complex enough to require 24-hour nursing supervision and may include such services as the application and care of routine dressings, and care of casts, braces, and splints (s. 429.02(13), F.S.)

[8] S. 429.075, F.S. A facility that serves one or mental health residents must obtain a licensed mental health license. A limited mental health ALF must assist a mental health patient in carrying out activities identified in the resident's community support living plan. A community support plan is written document that includes information about the supports, services, and special needs of the resident to live in the ALF and a method by which facility staff can recognize and respond to the signs and symptoms particular to that resident which indicate the need for professional services (s. 429.02(7), F.S.)

[9] S. 429.07(3)(b), F.S. Extended congregate care facilities provide services to an individual that would otherwise be ineligible for continued care in an ALF. The primary purpose is to allow a resident the option of remaining in a familiar setting from which they would otherwise be disqualified for continued residency as they become more impaired.

[10] S. 429.52, F.S.

[11] Agency for Health Care Administration, *Facility/Provider Search Results-Assisted Living Facilities*, available at http://www.floridahealthfinder.gov/facilitylocator/ListFacilities.aspx (report generated on November 20, 2017).

[12] S. 429.028, F.S.

[13] For 2015-2016, 292 volunteers worked an estimated 39,292 hours, which resulted in estimated average savings in salaries and administrative costs of $925,719. See Florida's Long-Term Care Ombudsman Program, *2015-2016 Annual Report*, available at http://ombudsman.myflorida.com/publications/ar/LTCOP_2015_2016_Annual_Report.pdf (last visited December 15, 2017).

[14] 42 U.S.C. §§ 3001 et seq. (as amended by Public Law 106-501).

[15] Part I, Ch. 400, F.S.

[16] The 13 districts are: Northwest Florida, Panhandle, North Central Florida, First Coast, West Coast, West Central Florida, East Central Florida, Southwest Florida, Palm Beach County, Broward County, South Dade & the Keys, North Dade, and South Central Florida.

- Monitoring of and commenting on the development and implementation of federal, state, and local laws, regulations, and policies regarding health, safety, and welfare of residents in long-term care facilities.
- Providing information and referrals with regard to long-term care facilities.
- Conducting annual assessments of long-term care facilities.
- Aiding the development of resident and family councils.[17]

An ombudsman "is a specially trained and certified volunteer who has been given authority under federal and state law to identify, investigate and resolve complaints made by, or on behalf of, long-term care facility residents."[18] It is important to note that the LTCOP does not have enforcement or regulatory oversight. Certified ombudsmen in the local councils work as independent advocates for residents to mediate disputes on an informal basis.

Florida law requires that the Office of State Long-Term Care Ombudsman (office) maintain a statewide system for collecting and analyzing data relating to complaints and conditions in long-term care facilities.[19] The office must also publish the information pertaining to the number and types of complaints received by the program on a quarterly basis.[20] Additionally, federal law requires the office to have a statewide data system to collect, analyze, and report data on residents, facilities, and complaints to federal officials as well as the National Ombudsman Resource Center.[21]

Ombudsmen also complete annual assessments of each long-term care facility in the state to ensure the health, safety, and welfare of the residents.[22] No advance warning of the assessment is to be given to the long-term care facility. An ombudsman is not allowed to forcibly enter the facility to complete the assessment; however, the administrator of the facility commits a violation of part I of ch. 400, F.S., if the ombudsman is not allowed to enter the facility, and, in such circumstances, the Agency for Health Care Administration (AHCA) may use appropriate administrative remedies.[23] The AHCA also conducts routine licensure and complaint surveys of nursing homes, assisted living facilities, and adult day care homes. As part of the survey process, the AHCA must complete offsite survey preparation, which includes a review of information about the facility prior to the survey. One of the sources of this information is the State Long-Term Care Ombudsman.

Effect of the Bill

Nursing Homes

HB 443 requires nursing homes to notify residents and the State Long Term Care Ombudsman with the facility's current contact information, including a function telephone number, and to notify residents and the State Long Term Care Ombudsman of any change in contact information within 30 days after such change. The bill requires AHCA take disciplinary action against any facility that fails to comply with the notification requirements.

The bill aligns Florida law with federal law regarding the provision of records to nursing home residents. The bill requires nursing homes provide current residents access to personal and medical records within 24 hours, excluding weekends and holidays, of the request and provide a copy of the records to the resident or resident's authorized representative within 2 working days of the request.

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[17] S. 200.0065, F.S.
[18] Florida's Long-Term Care Ombudsman Program, *Residents and Families*, available at http://ombudsman.myflorida.com/ResidentFam.php (last visited on December 15, 2017).
[19] S. 400.0089, F.S.
[20] Id.
[21] 42 U.S.C. s. 3058g(c) and 42 U.S.C. s. 3058g(h)(1).
[22] S. 400.0074, F.S.; the entire list of responsibilities of an ombudsman can be found at s. 400.0065, F.S.
[23] Id.

The bill allows a facility to refuse to furnish psychiatric records to a resident if a licensed medical professional determines that disclosure to the resident would reasonably be likely to endanger the life or physical safety of the resident or another person. If a facility refuses to furnish the records to a resident, the resident may request in writing that the records be furnished to another licensed medical provider designated by the resident.

Assisted Living Facilities

The bill requires an ALF that is relocating a resident to provide the reasons for relocation of a resident to the resident or the resident's legal representative. The bill also requires the ALF provide of a copy of the required notice of relocation to the State Long Term Care Ombudsman Program within 7 calendar days after the notice is provided to the resident or the resident's legal representative.

B. SECTION DIRECTORY:

Section 1: Amends s. 400.102, F.S., relating to action by agency against licensee: grounds.
Section 2: Amends s. 400.141, F.S., relating to administration and management of nursing home facilities.
Section 3: Amends s. 400.145, F.S., relating to copies of records of care and treatment of resident.
Section 4: Amends s. 429.28, F.S., relating to resident bill or rights.
Section 5: Reenacts s. 400.121, F.S., relating to denial, suspension, revocation of license; administrative fines; procedure; order to increase staffing.
Section 6: Provides an effective date of July 1, 2018.

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:

ALFs may incur additional expenses due to the requirements to provide a copy of the reasons for relocation to the resident or resident's authorized representative and a copy of the relocation notice to the State Long Term Care Ombudsman Program.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   Not Applicable. The bill does not affect local government.

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to nursing home and assisted living facility resident rights; amending s. 400.102, F.S.; providing additional grounds for action by the Agency for Health Care Administration against a licensee; amending s. 400.141, F.S.; requiring a nursing home facility to provide current and updated contact information to the resident and the State Long-Term Care Ombudsman Program; amending s. 400.145, F.S.; requiring nursing home facilities to provide access to or copies of certain resident records under certain conditions and within a specified timeframe; providing an exception for psychiatric records under certain circumstances; amending s. 429.28, F.S.; providing notice requirements regarding relocation or termination of residency from an assisted living facility; requiring the facility to send a copy of the notice to the State Long-Term Care Ombudsman Program within a specified timeframe; reenacting s. 400.121(1) and (2), F.S., relating to imposition of administrative fines by the agency to incorporate the amendment made to s. 400.102, F.S.; providing an effective date.

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

Section 1. Subsection (5) is added to section 400.102, Florida Statutes, to read:

400.102 Action by agency against licensee; grounds.—In addition to the grounds listed in part II of chapter 408, any of the following conditions shall be grounds for action by the agency against a licensee:

(5) Failure to provide residents and the State Long-Term Care Ombudsman Program with a facility's current contact information, including a functional telephone number, and notify residents and the State Long-Term Care Ombudsman Program of any change in contact information within 30 days after a change in such information.

Section 2. Paragraph (v) is added to subsection (1) of section 400.141, Florida Statutes, to read:

400.141 Administration and management of nursing home facilities.—

(1) Every licensed facility shall comply with all applicable standards and rules of the agency and shall:

(v) Provide residents and the State Long-Term Care Ombudsman Program with a facility's current contact information, including a functional telephone number, and notify residents and the State Long-Term Care Ombudsman Program of any change in contact information within 30 days after a change in such information.

Section 3. Subsections (1) and (5) of section 400.145, Florida Statutes, are amended to read:

400.145 Copies of records of care and treatment of resident.—

(1) A resident has the right to access personal and medical records pertaining to him or herself. Upon receipt of a written or oral request that complies with the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and this section, a nursing home facility shall furnish to a competent resident, or to a representative of that resident who is authorized to make requests for the resident's records under HIPAA or subsection (2), copies of the resident's paper and electronic records that are in possession of the facility. Such records must include any personal records, medical records, and records concerning the care and treatment of the resident ~~performed by the facility~~, except for progress notes and consultation report sections of a psychiatric nature. The facility shall provide access to the requested records within 24 hours, excluding weekends and holidays, ~~14 working days~~ after receipt of a request relating to a current resident or within 30 working days after receipt of a request relating to a former resident. The facility shall provide the resident or the authorized representative of that resident with a copy of the requested records or any portion thereof within 2 working days after receipt of such request.

(5) If a licensed medical provider ~~nursing home facility~~ determines that disclosure of psychiatric ~~the~~ records to the resident would reasonably be likely to endanger the life or physical safety of the resident or another person ~~be detrimental to the physical or mental health of the resident~~, the facility may refuse to furnish the record directly to the resident; however, upon such refusal, the resident's records shall, upon written request by the resident, be furnished to any other licensed medical provider designated by the resident.

Section 4. Paragraph (k) of subsection (1) of section 429.28, Florida Statutes, is amended to read:

429.28 Resident bill of rights.—

(1) No resident of a facility shall be deprived of any civil or legal rights, benefits, or privileges guaranteed by law, the Constitution of the State of Florida, or the Constitution of the United States as a resident of a facility. Every resident of a facility shall have the right to:

(k) At least 45 days' notice of relocation or termination of residency from the facility unless, for medical reasons, the resident is certified by a physician to require an emergency relocation to a facility providing a more skilled level of care or the resident engages in a pattern of conduct that is harmful or offensive to other residents. In the case of a resident who has been adjudicated mentally incapacitated, the guardian shall be given at least 45 days' notice of a nonemergency relocation

or residency termination. Reasons for relocation shall be set forth in writing and provided to the resident or the resident's legal representative. The facility shall send a copy of the notice to a representative of the State Long-Term Care Ombudsman Program within 7 calendar days after the notice is provided to the resident or the resident's legal representative. In order for a facility to terminate the residency of an individual without notice as provided herein, the facility shall show good cause in a court of competent jurisdiction.

Section 5. For the purpose of incorporating the amendment made by this act to section 400.102, Florida Statutes, in a reference thereto, subsections (1) and (2) of section 400.121, Florida Statutes, are reenacted to read:

400.121 Denial, suspension, revocation of license; administrative fines; procedure; order to increase staffing.—

(1) The agency may deny an application, revoke or suspend a license, and impose an administrative fine, not to exceed $500 per violation per day for the violation of any provision of this part, part II of chapter 408, or applicable rules, against any applicant or licensee for the following violations by the applicant, licensee, or other controlling interest:

(a) A violation of any provision of this part, part II of chapter 408, or applicable rules; or

(b) An adverse action by a regulatory agency against any other licensed facility that has a common controlling interest

with the licensee or applicant against whom the action under this section is being brought. If the adverse action involves solely the management company, the applicant or licensee shall be given 30 days to remedy before final action is taken. If the adverse action is based solely upon actions by a controlling interest, the applicant or licensee may present factors in mitigation of any proposed penalty based upon a showing that such penalty is inappropriate under the circumstances.

All hearings shall be held within the county in which the licensee or applicant operates or applies for a license to operate a facility as defined herein.

(2) Except as provided in s. 400.23(8), a $500 fine shall be imposed for each violation. Each day a violation of this part or part II of chapter 408 occurs constitutes a separate violation and is subject to a separate fine, but in no event may any fine aggregate more than $5,000. A fine may be levied pursuant to this section in lieu of and notwithstanding the provisions of s. 400.23. Fines paid shall be deposited in the Health Care Trust Fund and expended as provided in s. 400.063.

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

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 443 (2018)

Amendment No. 1

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 Slosberg offered the following:

Amendment

Remove lines 70-75 and insert:

receipt of a request relating to a current resident ~~or within 30 working days after receipt of a request relating to a former resident~~. The facility shall provide the resident or the authorized representative of that resident with a copy of the requested records or any portion thereof within 2 working days after receipt of a request relating to a current resident or within 30 working days after receipt of a request relating to a former resident.

COMMITTEE/SUBCOMMITTEE AMENDMENT

Bill No. HB 443 (2018)

Amendment No. 2

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 Slosberg offered the following:

Amendment (with title amendment)

Remove lines 93-106 and insert:

(k) At least 45 days' written notice of relocation or termination of residency from the facility unless, for medical reasons, the resident is certified by a physician to require an emergency relocation to a facility providing a more skilled level of care or the resident engages in a pattern of conduct that is harmful or offensive to other residents. In the case of a resident who has been adjudicated mentally incapacitated, the guardian shall be given at least 45 days' written notice of a nonemergency relocation or residency termination. Reasons for

relocation shall be set forth in writing and provided to the resident or the resident's legal representative. In order

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

Remove lines 17-19 and insert:

facility; ~~requiring the facility to send a copy of the notice to the State Long-Term Care Ombudsman Program within a specified timeframe;~~ reenacting s. 400.121(1)

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1021 Florida Insurance Code Exemption for Nonprofit Religious Organizations
SPONSOR(S): Altman
TIED BILLS: **IDEN./SIM. BILLS:** SB 660

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

SUMMARY ANALYSIS

A health care sharing ministry is an organization that facilitates the sharing of health care expenses among individuals with similar and sincerely held beliefs. These organizations resemble insurance in that members pay monthly membership fees and submit claims when they incur medical bills. However, these organizations are not health insurers in the traditional sense.

Florida law refers to health care sharing ministries as "nonprofit religious organizations". S. 624.1265, F.S. provides nonprofit religious organizations that meet certain conditions with an explicit exemption from the Florida Insurance Code. This safe harbor has existed since 2008.

The Patient Protection and Affordable Care Act (PPACA) of 2010 established an individual coverage mandate applicable to most Americans. However, the law also provides an exemption from the coverage mandate to participants in health care sharing ministries.

HB 1021 amends S. 624.1265, F.S., to more closely reflect the federal requirements governing operation of health care sharing ministries. The bill allows for participation by individuals "who share a common set of ethical or religious beliefs". This change brings the Florida statute into alignment with PPACA, and also expands the opportunity for participation by removing the requirement that participants adhere to the same religion.

The bill also requires nonprofit religious organizations that provide health care sharing services to specify contribution amounts to prospective participants and to report monthly to participants the amount of qualified needs actually funded in the previous month in accordance with criteria set by the organization. The bill establishes a new audit requirement for these organizations and directs such entities to coordinate an annual audit with an independent accounting firm.

HB 1021 also modifies the standard disclaimer that must be provided by nonprofit religious organizations to prospective participants. The disclaimer indicates that these organizations are not insurers and are exempt from the Florida Insurance Code.

The bill has no fiscal impact to state or local government.

The bill has an effective date of July 1, 2018.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Health Care Sharing Ministries

A health care sharing ministry is an organization that facilitates the sharing of health care expenses among individuals with similar and sincerely held beliefs.[1] These organizations resemble insurance in that members pay monthly membership fees and submit claims when they incur medical bills.[2] However, these organizations are not health insurers in the traditional sense. It is unclear whether they maintain cash reserves and they do not guarantee payment of claims. Some health care sharing ministries act as clearinghouses to allow one or more participants to directly pay the medical expenses of another participant. Other health care sharing ministries receive contributions from members, which are then pooled and held in trust for future reimbursements to eligible participants to pay authorized medical expenses.[3]

The federal Patient Protection and Affordable Care Act (PPACA) of 2010[4] defines a limited form of a non-profit, tax-exempt health care sharing ministry as an organization:

- Members of which share a common set of ethical or religious beliefs and share medical expenses among members in accordance with those beliefs and without regard to the state in which a member resides or is employed;
- Members of which retain membership even after they develop a medical condition;
- Which (or a predecessor of which) has been in existence at all times since December 31, 1999, and medical expenses of its members have been shared continuously and without interruption since at least December 31, 1999; and,
- Which conducts an annual audit performed by an independent certified public accounting firm in accordance with generally accepted accounting principles that is made available to the public upon request.[5]

PPACA grants organizations meeting these criteria special status.[6] PPACA created an individual coverage mandate – meaning that most individuals must obtain health insurance or pay a tax penalty to the federal government.[7] However, individuals participating in a health care sharing ministry are exempt from this penalty and are considered to have met the individual mandate by virtue of their participation.[8]

Nearly half the states in the U.S. have established "safe harbors"[9] that provide these organizations with wholesale exemptions from state insurance laws.[10]

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[1] See, e.g., Alliance of Health Care Sharing Ministries, http://www.healthcaresharing.org/about-us/ (last accessed December 29, 2017).
[2] Timothy Stoltzfus Jost, *Loopholes in the Affordable Care Act: Regulatory Gaps and Border Crossing Techniques and How to Address Them*, 5 St. Louis U. J. Health L. & Pol'y 27 (2011). Available at https://scholarlycommons.law.wlu.edu/cgi/viewcontent.cgi?referer=https://scholar.google.com/&httpsredir=1&article=1265&context=wlufac (last accessed January 12, 2018).
[3] Id.
[4] Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148. On March 30, 2010, PPACA was amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152.
[5] 26 US Code 5000A(d)(2)(B).
[6] *Supra* note 4.
[7] *Supra* note 5.
[8] U.S. Internal Revenue Service, "Individual Shared Responsibility Provision – Exemptions: Claiming or Reporting," Available at https://www.irs.gov/affordable-care-act/individuals-and-families/aca-individual-shared-responsibility-provision-exemptions (last accessed January 15, 2018).
[9] A safe harbor law states that certain types of behavior or activities are not considered violations of law as long as they fall within certain parameters.
[10] Benjamin Boyd, *Health Care Sharing Ministries: Scam or Solution?*, 26 J.L. & Health 219 (2013). Available at http://engagedscholarship.csuohio.edu/jlh/vol26/iss2/4 (last accessed January 13, 2018).

Health Care Sharing Ministry Regulation in Florida

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, HMOs, and other risk-bearing entities under chapters 624, 627, and 641, F.S..[11] The Agency for Health Care Administration (agency) regulates the quality of care by HMOs under part III of ch. 641, F.S. Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from the agency.[12]

All persons who transact insurance in the state must comply with the Code.[13] OIR has the power to collect, propose, publish, and disseminate any information relating to the subject matter of the Code,[14] and may investigate any matter relating to insurance.[15]

Florida has provided a safe harbor to health care sharing ministries since 2008, making such organizations exempt from regulation as insurers by the Office of Insurance Regulation (OIR).[16] Section 624.1265, F.S., outlines criteria that must be met in order for an entity to be defined as a "nonprofit religious organization" for purposes of the exemption.[17] Entities seeking this designation must:

- Meet the qualifications established under Title 26, s. 501 of the Internal Revenue Code;
- Limit its participants to members of the same religion;
- Act as an organizational clearinghouse for information between participants who have financial, physical, or medical needs and participants who have the ability to pay for the benefit of those participants who have financial, physical, or medical needs;
- Provide for the financial or medical needs of a participant through payments directly from one participant to another participant; and,
- Suggest amounts that participants may voluntarily give with no assumption of risk or promise to pay among the participants or between the participants.[18]

In addition to these requirements, the law gives nonprofit religious organizations certain authority to manage membership. These organizations may establish qualifications of participation relating to the health of a prospective participant.[19] For example, nonprofit religious organizations may exclude individuals with pre-existing or complex health conditions from participation. In insurance terminology, this practice is known as medical underwriting.[20] Nonprofit religious organizations also may cancel the membership of a participant when he or she indicates unwillingness to participate by virtue of failing to make a payment to another participant for a period in excess of 60 days.[21]

Lastly, current law directs nonprofit religious organizations to provide each participant with written notice indicating that the organization is not an insurance company and is not subject to the regulatory requirements or consumer protections of the Florida Insurance Code.[22]

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[11] S. 20.121(3)(a), F.S.
[12] S. 641.21(1), F.S.
[13] S. 624.11, F.S.
[14] S. 624.307(4), F.S.
[15] S. 624.307(3), F.S.
[16] S. 624.1265, F.S.
[17] The Florida Insurance Code refers to "nonprofit religious organizations" and not "health care sharing ministries". In practice, the terms are equivalent.
[18] S. 624.1265(1), F.S.
[19] S. 624.1265(2), F.S.
[20] See, for example, Gary Claxton, et al. "Pre-existing Conditions and Medical Underwriting in the Individual Insurance Market Prior to the ACA," Henry J. Kaiser Family Foundation, December 12, 2016. Available at https://www.kff.org/health-reform/issue-brief/pre-existing-conditions-and-medical-underwriting-in-the-individual-insurance-market-prior-to-the-aca/ (last accessed January 13, 2018).
[21] *Supra* note 18.
[22] S. 624.1265(3), F.S.

Effect of Proposed Changes

HB 1021 amends S. 624.1265, F.S., to more closely reflect the federal requirements governing operation of health care sharing ministries. The bill amends the participation requirements associated with nonprofit religious organizations and modifies disclaimers that must be provided to participants.

From a membership perspective, the bill allows for participation by individuals "who share a common set of ethical or religious beliefs". Under current law, participation is limited to individuals "of the same religion," which is a more restrictive standard. This change brings the Florida statute into alignment with PPACA, and also expands the opportunity for participation.

Currently, s. 624.1265, F.S., dictates that the nonprofit religious organizations act as an organizational clearinghouse for information between participants who have financial, physical, or medical needs and participants who have the ability to pay for the benefit of those participants. The bill replaces the term "organizational clearinghouse" with the term "facilitator" to require that the nonprofit religious organization act as a facilitator among participants who have financial or medical needs[23] to assist those with financial or medical needs in accordance with criteria established by the nonprofit religious organization. There does not seem to be a substantive difference between these terms.

The bill also requires that the nonprofit religious organization provide for the financial or medical needs of a participant through pooled contributions from other participants, removing the authority in current law for direct payments from one participant to another. It is unknown whether any existing nonprofit religious organizations use a direct payment method; if so, the bill would require those organizations to change their business model.

The bill requires that nonprofit religious organizations set contribution levels for participants and to report monthly to participants the amount of qualified needs actually funded in the previous month in accordance with criteria set by the organization.

The bill establishes an annual audit requirement for nonprofit religious organizations that does not currently exist in Florida law. It requires a nonprofit religious organization that provides medical cost sharing services to arrange for an annual audit to be performed by an independent certified public accounting firm in accordance with generally accepted accounting principles. The findings of this audit must be made available to the public by providing a copy upon request or by posting on the nonprofit religious organization's website.

Lastly, the bill amends the disclaimer that must be provided to participants, which explicitly reflects the nonprofit religious organization's exemption from the Florida Insurance Code and its consumer protections.

The bill has an effective date of July 1, 2018.

B. SECTION DIRECTORY:

Section 1: Amends s. 624.1265, F.S., relating to nonprofit religious organization exemption.
Section 2: Provides for an effective date of July 1, 2018.

[23] The bill removes the term "physical" from the list of needs that must be addressed by nonprofit religious organizations under the statute. The effects of this change are not entirely clear.

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

2. Other:

   None.

B. RULE-MAKING AUTHORITY:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

A bill to be entitled

An act relating to the Florida Insurance Code exemption for nonprofit religious organizations; amending s. 624.1265, F.S.; revising criteria under which a nonprofit religious organization that facilitates the sharing of contributions among its participants for financial or medical needs is exempt from requirements of the code; revising construction; revising requirements for a notice provided by the organization; providing an effective date.

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

Section 1. Section 624.1265, Florida Statutes, is amended to read:

624.1265 Nonprofit religious organization exemption; authority; notice.—

(1) A nonprofit religious organization is not subject to the requirements of the Florida Insurance Code if the nonprofit religious organization:

(a) Qualifies under Title 26, s. 501 of the Internal Revenue Code of 1986, as amended;

(b) Limits its participants to those members who share a common set of ethical or religious beliefs ~~of the same religion~~;

(c) Acts as a facilitator among ~~an organizational~~

~~clearinghouse for information between~~ participants who have financial~~, physical,~~ or medical needs to assist those with financial or medical needs in accordance with criteria established by the nonprofit religious organization ~~and participants who have the ability to pay for the benefit of those participants who have financial, physical, or medical needs~~;

(d) Provides for the financial or medical needs of a participant through contributions from other participants; ~~payments directly from one participant to another participant; and~~

(e) Provides amounts that participants may contribute, with no assumption of risk and no promise to pay:

1. Among the participants; or

2. By the nonprofit religious organization to the participants;

(f) Provides monthly to the participants the total dollar amount of qualified needs actually shared in the previous month in accordance with criteria established by the nonprofit religious organization; and

(g) Conducts an annual audit that is performed by an independent certified public accounting firm in accordance with generally accepted accounting principles and that is made available to the public by providing a copy upon request or by posting on the nonprofit religious organization's website

~~suggests amounts that participants may voluntarily give with no assumption of risk or promise to pay among the participants or between the participants~~.

(2) This section does not prevent:

(a) The organization described in subsection (1) from acting as a facilitator among participants who have financial or medical needs to assist those with financial or medical needs in accordance with criteria established by the organization; ~~establishing qualifications of participation relating to the health of a prospective participant, does not prevent~~

(b) A participant from limiting the financial or medical needs that may be eligible for payment; or~~, and does not prevent~~

(c) The organization from canceling the membership of a participant when such participant indicates his or her unwillingness to participate by failing to make a payment to another participant for a period in excess of 60 days.

(3) The nonprofit religious organization described in subsection (1) shall provide a written disclaimer on or accompanying all applications and guideline materials distributed by or on behalf of the nonprofit religious organization. The disclaimer must read in substance: "Notice: The organization facilitating the sharing of medical expenses is not an insurance company, and neither its guidelines nor plan of operation is an insurance policy. Whether anyone chooses to assist you with your medical bills will be totally voluntary

because no other participant is compelled by law to contribute toward your medical bills. As such, participation in the organization or a subscription to any of its documents should never be considered to be insurance. Regardless of whether you receive any payments for medical expenses or whether this organization continues to operate, you are always personally responsible for the payment of your own medical bills." ~~each prospective participant in the organizational clearinghouse written notice that the organization is not an insurance company, that membership is not offered through an insurance company, and that the organization is not subject to the regulatory requirements or consumer protections of the Florida Insurance Code.~~

Section 2. This act shall take effect July 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 Altman offered the following:

Amendment

Remove everything after the enacting clause and insert:

Section 1. Section 624.1265, Florida Statutes, is amended to read:

624.1265 Nonprofit religious organization exemption; authority; notice.—

(1) A nonprofit religious organization is not subject to the requirements of the Florida Insurance Code if the nonprofit religious organization:

(a) Qualifies under Title 26, s. 501 of the Internal Revenue Code of 1986, as amended;

(b) Limits its participants to those members who share a

common set of ethical or religious beliefs ~~of the same religion~~;

(c) Acts as a facilitator among ~~an organizational clearinghouse for information between~~ participants who have financial, physical, or medical needs to assist those with financial or medical needs in accordance with criteria established by the nonprofit religious organization ~~and participants who have the ability to pay for the benefit of those participants who have financial, physical, or medical needs~~;

(d) Provides for the financial or medical needs of a participant through contributions from other participants, or through payments directly from one participant to another participant; ~~and~~

(e) Provides amounts that participants may contribute, with no assumption of risk and no promise to pay:

1. Among the participants; or

2. By the nonprofit religious organization to the participants;

(f) Provides monthly to the participants the total dollar amount of qualified needs actually shared in the previous month in accordance with criteria established by the nonprofit religious organization; and

(g) Conducts an annual audit that is performed by an independent certified public accounting firm in accordance with generally accepted accounting principles and that is made

available to the public by providing a copy upon request or by posting on the nonprofit religious organization's website ~~suggests amounts that participants may voluntarily give with no assumption of risk or promise to pay among the participants or between the participants~~.

(2) This section does not prevent:

(a) The organization described in subsection (1) from acting as a facilitator among participants who have financial or medical needs to assist those with financial or medical needs in accordance with criteria established by the organization; ~~establishing qualifications of participation relating to the health of a prospective participant, does not prevent~~

(b) A participant from limiting the financial or medical needs that may be eligible for payment; or~~, and does not prevent~~

(c) The organization from canceling the membership of a participant when such participant indicates his or her unwillingness to participate by failing to meet the conditions of membership ~~make a payment to another participant~~ for a period in excess of 60 days.

(3) The nonprofit religious organization described in subsection (1) shall provide a written disclaimer on or accompanying all applications and guideline materials distributed by or on behalf of the nonprofit religious organization. The disclaimer must read in substance: "Notice: The organization facilitating the sharing of medical expenses is

not an insurance company, and neither its guidelines nor plan of operation is an insurance policy. Membership is not offered through an insurance company, and the organization is not subject to the regulatory requirements or consumer protections of the Florida Insurance Code. Whether anyone chooses to assist you with your medical bills will be totally voluntary because no other participant is compelled by law to contribute toward your medical bills. As such, participation in the organization or a subscription to any of its documents should never be considered to be insurance. Regardless of whether you receive any payments for medical expenses or whether this organization continues to operate, you are always personally responsible for the payment of your own medical bills." ~~each prospective participant in the organizational clearinghouse written notice that the organization is not an insurance company, that membership is not offered through an insurance company, and that the organization is not subject to the regulatory requirements or consumer protections of the Florida Insurance Code.~~

Section 2. This act shall take effect July 1, 2018.