## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 559 Prescription Drug Utilization Management
**SPONSOR(S):** Health Market Reform Subcommittee, Massullo
**TIED BILLS:** **IDEN./SIM. BILLS:**

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR or BUDGET/POLICY CHIEF |
|---|---|---|---|
| 1) Health Market Reform Subcommittee | 14 Y, 0 N, As CS | Grabowski | Crosier |
| 2) Appropriations Committee | | | |
| 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. The last option, in which a health insurance plan requires a covered individual to try a preferred drug before using a nonpreferred drug, is generally known as step therapy.

CS/HB 559 amends s. 627.42392, F.S., which sets parameters on the use of prior authorization by health insurers. The bill defines “prior authorization” as a statement from a health insurer that a certain medical service or treatment is covered under the terms of a policy or contract for a specific period of time. The term was not previously defined in chapter 627, F.S.

The bill requires each health insurers to establish an online platform for the submission of prior authorization requests by January 1, 2020. Contracted health care providers must submit all prior authorization requests using the online platform beginning on that date.

CS/HB 599 creates s. 627.42393 F.S., which defines a “step therapy protocol” as a written protocol that specifies the order in which a certain prescription drug must be used in order to treat an individual’s health condition. The bill prohibits current and future health plans from requiring an insured to repeat a step therapy protocol for a particular drug, provided that the insured has previously been approved to use the drug via a step therapy protocol and is currently using the drug.

In the event that an individual changes health insurance plans, the bill specifies that the new insurer or HMOs is not precluded from imposing a prior authorization requirement for the continued coverage of a drug that was associated with step therapy in the former health plan. The bill also stipulates that a health insurer or an HMO is not required to add a drug to its drug formulary or cover a drug for a purpose not currently covered in order to comply with the step therapy restriction.

The bill applies to policies entered into or renewed on or after January 1, 2020, and does not apply to the Medicaid managed care plans.

The bill has an indeterminate negative fiscal impact on the State Employee Group Insurance Program, and may also have an indeterminate negative fiscal impact on local units of government.

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

## FULL ANALYSIS

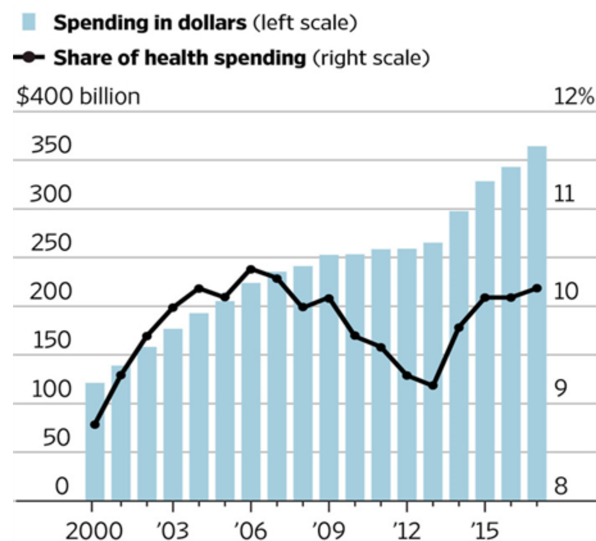
## I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

**Background**

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 14.3 percent in 2019, accounting for 35 percent of the prescription drug spending trend even though they represent a small minority 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, 2019).

[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 13, 2019).

[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, 2019)

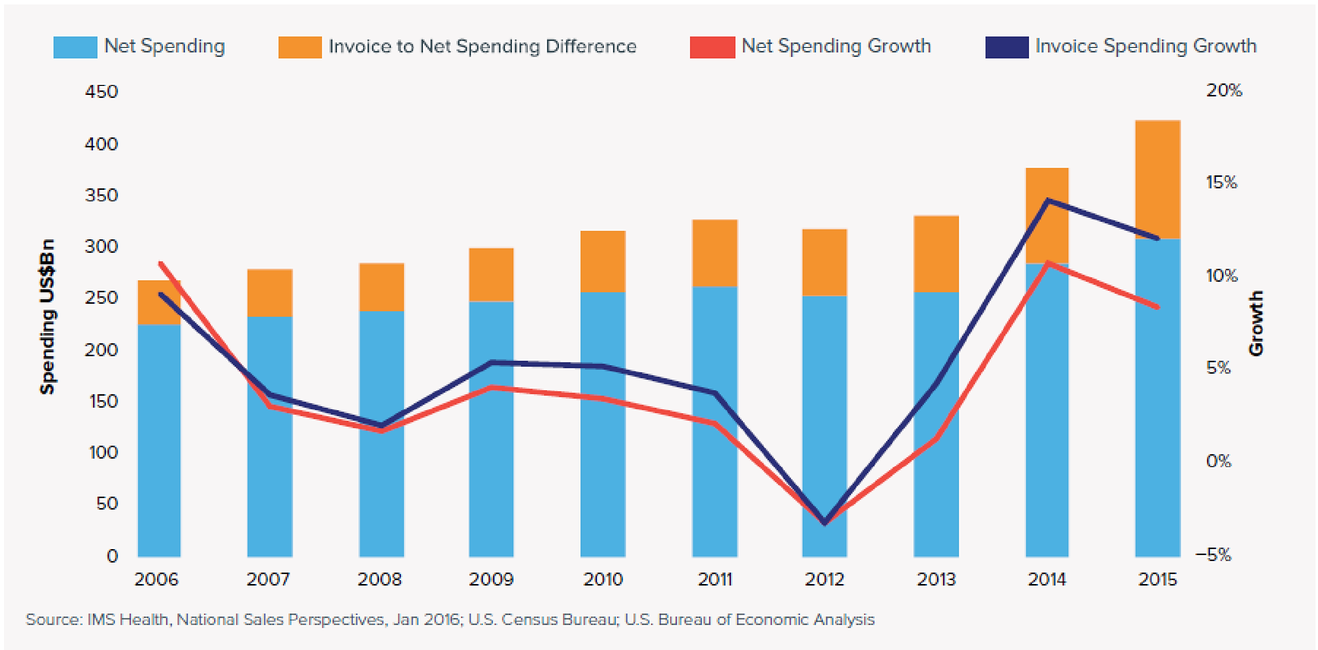
[4] TRUVERIS, *Americans faced double digit increases in prescription drug prices in 2014, according to Truveris National Drug Index*, https://truveris.com/press-releases/ndi-americans-faced-double-digit-increases-in-prescription-drug-prices-in-2014/ (last visited March 13, 2019)

[5] 2019 Segal Health Plan Cost Trend Survey, available at https://www.segalco.com/annual-health-plan-cost-trend-survey/2019/#PublicSector. (last visited March 13, 2019). Specialty drugs are high-cost prescription medications used to treat complex, chronic conditions and often require special handling and administration.

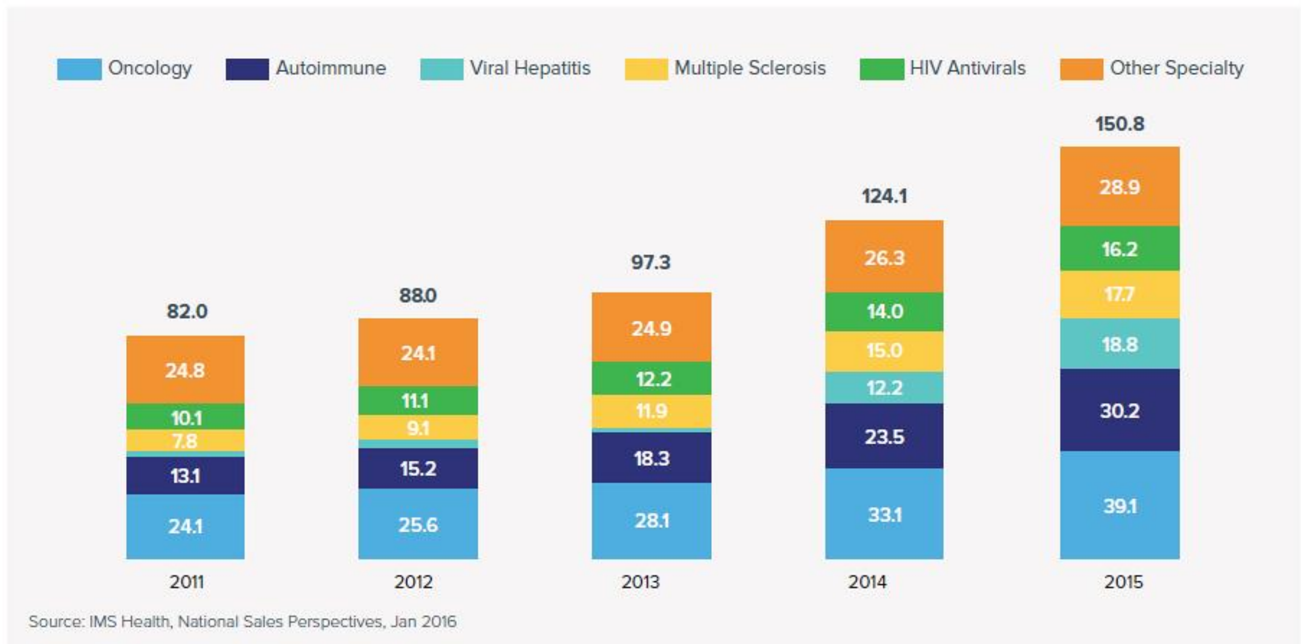
[6] CENTERS FOR MEDICARE AND MEDICAID SERVICES, *National Health Expenditures by Type of Service and Source of Funds: Calendar Years 1960 to 2015*, .zip file available at, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html (Last visited March 13, 2019).

[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, 2019).

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




**Total U.S. Spending on Specialty Prescription Drugs, 2015**[9]

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[8] *Medicines Use and Spending in the U.S. – A Review of 2015 and Outlook to 2020*, QUINTILESIMS, APR. 2016, https://morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf (last visited March 13, 2019).

[9] Id.

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.[10] 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.[11] Managed care systems combine the delivery and financing of health care services by limiting the choice of doctors and hospitals.[12] 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[13] (PPO) and health maintenance organizations[14] (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.[15] 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.[16] 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.[17]

All persons who transact insurance in the state must comply with the Code.[18] OIR has the power to collect, propose, publish, and disseminate any information relating to the subject matter of the Code,[19] and may investigate any matter relating to insurance.[20]

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 (step therapy).

*Pharmacy Benefit Managers*

Advances in pharmaceuticals have transformed health care over the last several decades. Many health care problems are prevented, cured, or managed effectively using prescription drugs. As a result, national expenditures for prescription drugs have grown from $121 billion in 2000 to $324.5 billion in 2016.[21] Health plan sponsors, which include commercial insurers, private employers, and government

[10] S. 624.603, F.S.
[11] 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 March 13, 2019).
[12] Id.
[13] S. 627.6471, F.S.
[14] Part I of chapter 641, F.S.
[15] S. 20.121(3)(a), F.S.
[16] S. 641.21(1), F.S.
[17] S. 641.495, F.S.
[18] S. 624.11, F.S.
[19] S. 624.307(4), F.S.
[20] S. 624.307(3), F.S.
[21] 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 visited March 13, 2019).

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.[22]

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.[23] Payments for the services are established in contracts between health plan sponsors and PBMs.[24] 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[25] for brand-name drugs and maximum allowable cost price for generic drugs, plus a dispensing fee.[26]

*Prior Authorization*

Under prior authorization, a health care provider is required to seek approval from an insurer before a patient may receive specified medical services or 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.

*Step Therapy Protocols*

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

Researchers report that there is mixed evidence on the impact of step therapy policies.[27] A review of the literature found that there is little good empirical evidence for or against cost savings and utilization reduction.[28] Some studies suggest that step therapy policies have been effective at reducing drug costs without increasing the use of other medical services,[29] while other studies have found that step therapy can increase total utilization costs over time because of increased inpatient admissions and emergency department visits.[30]

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

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[22] Id.
[23] 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 March 13, 2019).
[24] Id.
[25] 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.
[26] Supra, FN 21.
[27] 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.
[28] 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 visited March 13, 2019).
[29] Supra, FN 27 at pg. 1780.
[30] Id.

consistent with s. 125, Internal Revenue Code. To administer the state group health insurance program, DMS contracts with third part administrators, HMOs, and a PBM for the state employees' prescription drug program pursuant to s. 110.12315, F.S.

Federal Patient Protection and Affordable Care Act

*Health Insurance Reforms*

The federal Patient Protection and Affordable Care Act (PPACA) was signed into law on March 23, 2010.[31] 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[32] 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.[33] In Florida, the federal Health Insurance Marketplace must certify such plans of an insurer or HMO as meeting the EHB and other requirements.[34] The federal deadline for insurers and HMOs to submit 2018 annual rates and forms to the Florida Office of Insurance Regulation was May 3, 2017.[35] 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.[36]

*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.[37]

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.[38] Restrictions include prior authorization, step therapy, quantify limits and access restrictions.[39]

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[31] 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.
[32] 42 U.S.C. s. 18022
[33] 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 visited March 13, 2019).
[34] Center for Consumer Information & Insurance Oversight, *Qualified Health Plans,* https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/qhp.html (last visited March 13, 2019).
[35] Office of Insurance Regulation, *Guidance to Insurers,* available at http://www.floir.com/sitedocuments/PPACANoticetoIndustry201802032017.pdf (last visited March 13, 2019).
[36] *See* Proposed Rule, 82 FR 51052 (Nov. 2, 2017) available at https://www.federalregister.gov/documents/2017/11/02/2017-23599/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2019 (last visited March 13, 2019).
[37] 45 C.F.R. s. 147.136
[38] 45 C.F.R. s. 156.122(d)
[39] 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).

**Effect of Proposed Changes**

Prior Authorization

CS/HB 559 amends s. 627.42392, F.S., which sets parameters on the use of prior authorization by health insurers. The bill defines "prior authorization" as a statement from a health insurer that a certain medical service or treatment is covered under the terms of a policy or contract for a specific period of time. The term was not previously defined in chapter 627, F.S.

Effective January 1, 2020, the bill requires that each insurer, or pharmacy benefits manager acting on behalf of an insurer, offer a secure, online platform for accepting prior authorization forms from health care providers. All contracted providers must use this platform to submit prior authorization requests on behalf of insured patients. The platform must also allow insurers to request additional information in support of a prior authorization request from a provider.

The bill clarifies that prior authorization requests submitted through a facsimile machine do not constitute electronic requests and do not comply with the requirement that providers submit prior authorization requests electronically.

Step Therapy Protocols

CS/HB 559 creates s. 627.42393 F.S., which prohibits health insurers and HMOs from requiring covered individuals to repeat a step therapy protocol that was imposed previously.

The bill defines a "step therapy protocol" as a written protocol that specifies the order in which a certain prescription drug must be used in order to treat an individual's health condition. The bill prohibits current and future health plans from requiring an insured to repeat a step therapy protocol for a particular drug, provided that the following conditions are met:

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

In the event that an individual changes health insurance plans, the bill specifies that the new insurer or HMOs is not precluded from imposing a prior authorization requirement for the continued coverage of a drug that was associated with step therapy in the former health plan.

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

The bill exempts Medicaid managed care plans from the restriction on step therapy protocols.

The bill applies to policies entered into or renewed on or after January 1, 2020.

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

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 step therapy protocol.
**Section 3:** Provides an effective date of July 1, 2019.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The restriction of the use of step therapy protocols has an indeterminate negative fiscal impact on the Division of State Group Insurance (DSGI).

   The bill's exemption for Medicaid managed care plans prevents any negative fiscal impact to the state Medicaid program.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   The restriction on the use of step therapy protocols may have an indeterminate negative impact on local governments that offer health plans to employees.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health insurers who have not already established an online platform for the submission of prior authorization requests may incur additional costs to comply with the requirements of the bill. Likewise, providers who are not already submitting prior authorization requests electronically may incur some compliance costs.

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

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:

Current law provides the Financial Services Commission and the Agency for Healthcare Administration with sufficient rule-making authority to implement the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

There is an inconsistency in the current draft of the bill. While section 2 of the bill explicitly, “does not apply to Medicaid managed care plans pursuant to part IV of chapter 409,” the section references a definition of the term “health insurer” that includes, “a managed care plan as defined in s. 409.962(10)”. The bill is intended to exclude Medicaid managed care plans from the requirements of section 2.

## IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 19, 2019, the Health Market Reform Subcommittee adopted a strike-all amendment to the bill. The amendment defines the term “prior authorization”, which was not previously defined in statute. The amendment also requires each health insurer to offer an online platform for the submission of prior authorization requests by January 1, 2020. Beginning on that date, all contracted health care providers will be required to submit prior authorization requests using the online platform.

The amendment prohibits an insurer from imposing a step therapy protocol in cases where:

- An insured has been approved to receive a specific drug by a previous insurer; AND,
- An insured is currently taking the drug, as demonstrated by a previous insurer having paid for the drug on the insured’s behalf within the previous 90 days.

This restriction does not apply to Medicaid managed care plans, but does apply to all other insurers and HMOs regulated by the state.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute as passed by the Health Market Reform Subcommittee.