

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 199 Step Therapy Protocols

SPONSOR(S): Insurance & Banking Subcommittee; Health Innovation Subcommittee; Harrison

TIED BILLS: IDEN./SIM. **BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	14 Y, 0 N, As CS	Grabowski	Crosier
2) Insurance & Banking Subcommittee	13 Y, 0 N, As CS	Peterson	Luczynski
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/CS/HB 199 creates ss. 627.6476, 627.6671, and 641.317, F.S., which prohibit health insurers and HMOs from requiring covered individuals to repeat a step therapy protocol that was completed previously. Once an individual completes the required step therapy protocol for a particular drug, he or she may not be required to repeat that protocol. However, the bill does not preclude health insurers or HMOs from imposing a prior authorization requirement on drugs previously subject to a step therapy protocol. The bill applies to an individual's current health insurance plan, and also future plans if he or she switches to another health plan.

The bill specifies 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, 2019, and does not apply to the Medicaid managed care plans.

The bill may have an indeterminate negative fiscal impact on local units of government. The bill would have no impact on state or local government revenues. It would have negative fiscal impacts on the private sector.

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

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

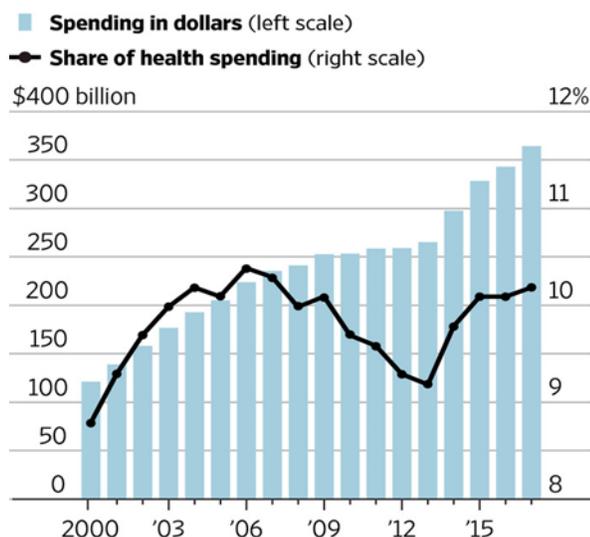
A. EFFECT OF PROPOSED CHANGES:

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 2000-2017⁷



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)

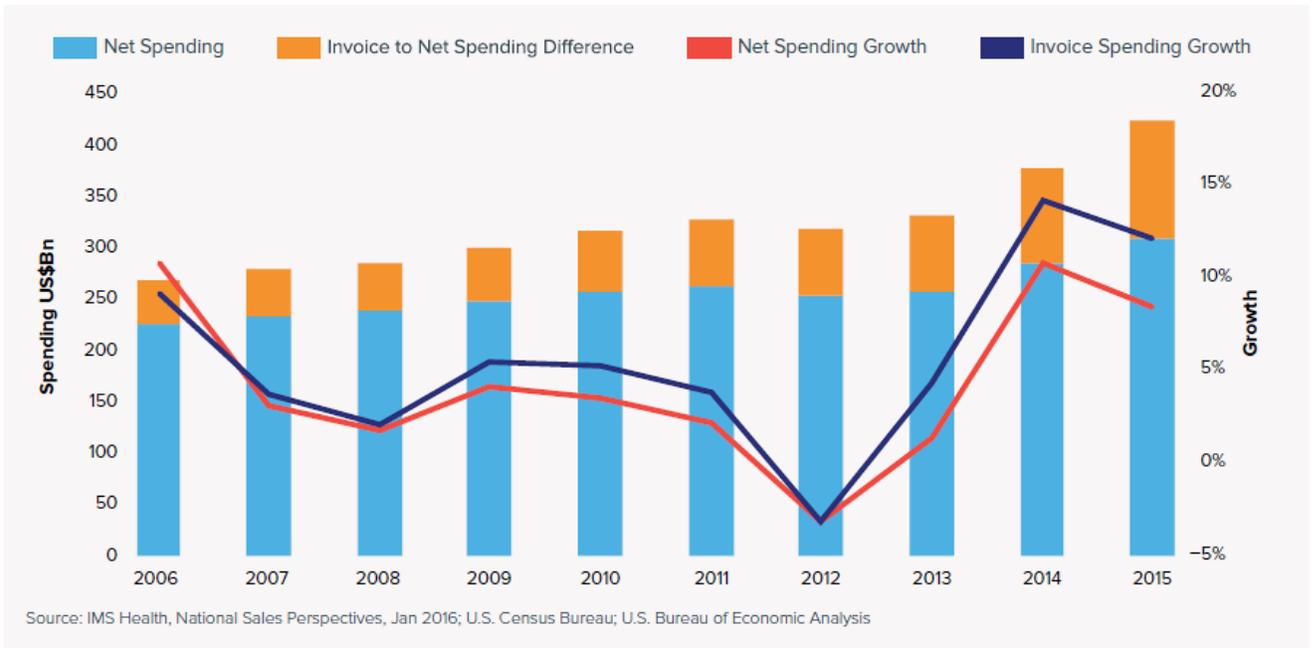
⁴ TRUVERIS, *Americans faced double digit increases in prescription drug prices in 2014, according to Truveris National Drug Index*, <https://truveris.com/press-releases/ndi-americans-faced-double-digit-increases-in-prescription-drug-prices-in-2014/> (last visited March 13, 2017)

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

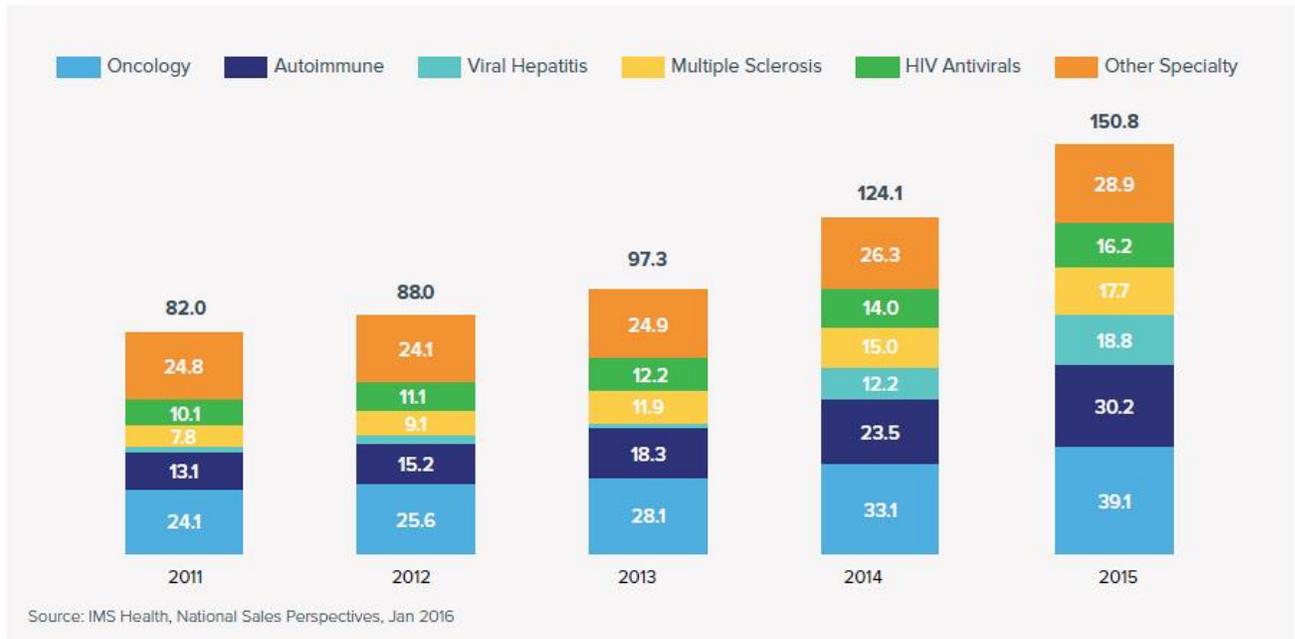
⁶ CENTERS FOR MEDICARE AND MEDICAID SERVICES, *National Health Expenditures by Type of Service and Source of Funds: Calendar Years 1960 to 2015*, .zip file available at, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> (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, 2015⁸



Total U.S. Spending on Specialty Prescription Drugs, 2015⁹



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.

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 organizations¹³ (PPO) and health maintenance organizations¹⁴ (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 Florida Insurance Code (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.²¹ 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

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 December 28, 2017).

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. The Florida Insurance Code is chapters 624-632, 634, 635, 636, 641, 642, 648, and 651, F.S. S. 624.01, F.S.

¹⁹ S. 624.307(4), F.S.

²⁰ S. 624.307(3), F.S.

²¹ There is no definition of "formulary" in the Code. The Florida Pharmacy Act, ch. 465, F.S., defines an "institutional formulary system" as "a method whereby the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations which in the medical staff's clinical judgment are most useful in patient care, and which are available for dispensing by a practicing pharmacist in a Class II institutional pharmacy." S. 465.003(7), F.S.

2016.²² 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.²³

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.²⁴ Payments for the services are established in contracts between health plan sponsors and PBMs.²⁵ 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 price²⁶ for brand-name drugs and maximum allowable cost price for generic drugs, plus a dispensing fee.²⁷

Prior Authorization

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

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 the medical provider 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.²⁸

²² 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).

²³ Id.

²⁴ 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).

²⁵ Id.

²⁶ 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.

²⁷ Supra, FN 21.

²⁸ There is no definition in statute of "step therapy" or "fail-first." "Step therapy" only appears in statute for purposes of the state Medicaid program. Section 409.912(5)(a)16., F.S., provides:

The agency shall implement a step-therapy prior authorization approval process for medications excluded from the preferred drug list. Medications listed on the preferred drug list must be used within the previous 12 months before the alternative medications that are not listed. The step-therapy prior authorization may require the prescriber to use the medications of a similar drug class or for a similar medical indication unless contraindicated in the Food and Drug Administration labeling. The trial period between the specified steps may vary according to the medical indication. The step-therapy approval process shall be developed in accordance with the committee as stated in s. 409.91195(7) and (8). A drug product may be approved without meeting the step-therapy prior authorization criteria if the prescribing physician provides the agency with additional written medical or clinical documentation that the product is medically necessary because:

- a. There is not a drug on the preferred drug list to treat the disease or medical condition which is an acceptable clinical alternative;
- b. The alternatives have been ineffective in the treatment of the beneficiary's disease; or
- c. Based on historic evidence and known characteristics of the patient and the drug, the drug is likely to be ineffective, or the number of doses have been ineffective.

Researchers report that there is mixed evidence on the impact of step therapy policies.²⁹ A review of the literature found that there is little good empirical evidence for or against cost savings and utilization reduction.³⁰ Some studies suggest that step therapy policies have been effective at reducing drug costs without increasing the use of other medical services,³¹ while other studies have found that step therapy can increase total utilization costs over time because of increased inpatient admissions and emergency department visits.³²

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.

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, 2010.³³ 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 benefits³⁴ 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.³⁵ In Florida, the federal Health Insurance Marketplace must certify such plans of an insurer or HMO as meeting the EHB and other requirements.³⁶ The federal deadline for insurers and HMOs to submit 2018 annual rates and forms to the Florida Office of Insurance Regulation was May 3, 2017.³⁷ 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.³⁸

The agency shall work with the physician to determine the best alternative for the patient. The agency may adopt rules waiving the requirements for written clinical documentation for specific drugs in limited clinical situations.

²⁹ 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.

³⁰ 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).

³¹ Supra, FN 27 at pg. 1780.

³² Id.

³³ 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.

³⁴ 42 U.S.C. s. 18022

³⁵ See Center for Consumer Information & Insurance Oversight, *Insurance on Essential Health Benefits (EHB) Benchmark Plans* <https://www.cms.gov/ccio/resources/data-resources/ehb.html> (last viewed on January 13, 2018).

³⁶ Center for Consumer Information & Insurance Oversight, *Qualified Health Plans*, <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/ghp.html> (last viewed January 13, 2018).

³⁷ Office of Insurance Regulation, *Guidance to Insurers*, available at <http://www.floir.com/sitedocuments/PPACANoticeToIndustry201802032017.pdf> (last viewed January 13, 2018).

³⁸ 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).

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 evidence that will include consideration of safety and efficacy, cover a range of drugs in a broad distribution of therapeutic categories and classes, and provide access to drugs that are included in broadly accepted treatment guidelines. 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.³⁹

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.⁴⁰ Restrictions include prior authorization, step therapy, quantity limits and access restrictions.⁴¹

Effect of Proposed Changes

Step Therapy Protocols

CS/CS/HB 199 creates ss. 627.6476, 627.6671, and 641.317, F.S., which prohibit health insurers and HMOs from requiring covered individuals to repeat a step therapy protocol that was completed previously. This language is placed in these three sections of the Code, as each governs operations of certain health insurance plans.⁴²

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 repeated step therapy protocols for a particular drug. Once an individual completes the required step therapy protocol for a particular drug, he or she may not be required to repeat that protocol – even if he or she changes health insurance plans. 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 specifies 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, 2019.

The bill provides an effective date of July 1, 2018

B. SECTION DIRECTORY:

- Section 1:** Creates s. 627.6476, F.S., relating to step therapy protocols.
- Section 2:** Creates s. 627.6671, F.S., relating to step therapy protocols.
- Section 3:** Creates s. 641.317, F.S., relating to step therapy protocols.
- Section 4:** Provides an effective date of July 1, 2018.

³⁹ 45 C.F.R. s. 147.136

⁴⁰ 45 C.F.R. s. 156.122(d)

⁴¹ 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).

⁴² S. 627.6476, F.S., applies to non-group health insurance, S. 627.6671, F.S., applies to group health insurance, and S. 641.317, F.S., applies to health maintenance organizations.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

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:

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:

Not applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill does not specify how a prior step therapy conducted with a former health insurance plan must be documented to the subsequent health insurance plan in order for the beneficiary to benefit from the limitation on repeated step therapy created by the bill.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On January 17, 2018, the Health Innovation Subcommittee adopted a strike-all amendment that prohibits health insurers and HMOs from requiring covered individuals to repeat step therapy protocols that have been completed previously and removed all other provisions of the original bill. The amendment specifies that health insurers and HMOs are not precluded from imposing a prior authorization requirement, nor does it require these entities to add a drug to an existing drug formulary or cover a drug for a purpose not currently covered in order to comply with the step therapy restriction. Lastly, the amendment exempts Medicaid managed care plans from the restriction on step therapy.

On January 30, 2018, the Insurance & Banking Subcommittee considered the bill, adopted one amendment, and reported the bill as a committee substitute. The amendment clarifies that the requirements of the bill extend to health insurance offered in the small group market.

The staff analysis has been updated to reflect the committee substitute as passed by the Insurance & Banking Subcommittee.