HOUSE OF REPRESENTATIVES STAFF FINAL BILL ANALYSIS

BILL #: HB 459 Step-therapy Protocols
SPONSOR(S): Willhite and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 730

FINAL HOUSE FLOOR ACTION: 107 **Y's** 0 **N's** **GOVERNOR'S ACTION:** Approved

SUMMARY ANALYSIS

HB 459 passed the House on February 25, 2022, and subsequently passed the Senate on March 8, 2022.

Insurers and health maintenance organizations (HMOs) use many cost containment strategies to manage 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 or service before using a nonpreferred drug or service, is generally known as step therapy.

The Florida Insurance Code has largely been silent on the use of step therapy by insurers and HMOs. The only current law addressing step therapy relates to repetition of step therapy protocols, in certain circumstances.

The bill defines "step therapy protocol" as a protocol or program that establishes the specific sequence in which prescription drugs, medical procedures, or courses of treatment must be used to treat a health condition. The bill also requires a process to receive a "protocol exemption", which is a determination by an insurer or HMO to exempt an insured patient from an existing step therapy protocol.

The bill requires an insurer or HMO to publish on its website, and provide to an insured in writing, a procedure for an insured patient and health care provider to request a protocol exemption. The procedure must include:

- The manner in which an insured patient or health care provider may request a protocol exemption;
- The manner and timeframe in which the health insurer or HMO is required to authorize or deny a protocol exemption request; and,
- The manner and timeframe in which an insured patient may appeal the denial of a request.

The bill requires an insurer or HMO granting a protocol exemption to specify the prescription drug, medical procedure, or course of treatment approved. Alternatively, an insurer or HMO denying a protocol exemption request must provide a written explanation of the denial, including the clinical rationale supporting the denial. The written explanation must also describe the procedure for appealing the determination by the insurer or HMO.

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

The bill was approved by the Governor on April 6, 2022, ch. 2022-47, L.O.F., and will become effective on July 1, 2022.

I. SUBSTANTIVE INFORMATION

A. EFFECT OF 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 for 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] while the Agency for Health Care Administration (agency) regulates the quality of care by HMOs.[7] Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from the agency.[8] 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.[9]

All persons who transact insurance in the state must comply with the Florida Insurance Code.[10] OIR has the power to collect, propose, publish, and disseminate any information relating to the subject matter of the Code,[11] and may investigate any matter relating to insurance.[12]

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 or service before obtaining an alternate drug or service for a particular medical condition (step therapy).

Pharmacy Benefit Managers

[1] S. 624.603, F.S.
[2] Florida Department of Financial Services, *Health Insurance and Health Maintenance Organizations, A Guide for Consumers,* http://www.myfloridacfo.com/Division/Consumers/understandingCoverage/Guides/documents/HealthGuide.pdf (last visited Mar. 25, 2022).
[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] Part III of chapter 641, F.S.
[8] S. 641.21(1), F.S.
[9] S. 641.495, F.S.
[10] S. 624.11, F.S. Chapters 624-632, 634, 635, 636, 641, 642, 648, and 651 constitute the Florida Insurance Code. S. 624.01, F.S.
[11] S. 624.307(4), F.S.
[12] S. 624.307(3), F.S.

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 $122 billion in 2000 to $369.7 billion in 2019.[13] Health plan sponsors, which include commercial insurers, private employers, and government plans, such as Medicaid and Medicare, spent $312 billion on prescription drugs in 2019, while consumers paid $53.7 billion out-of-pocket for prescription drugs that year.[14]

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.[15] Payments for the services are established in contracts between health plan sponsors and PBMs.[16] 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[17] for brand-name drugs and maximum allowable cost price for generic drugs, plus a dispensing fee.[18]

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 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.

Health plans use step therapy protocols differently for drugs indicated for different diseases. For instance, plans apply protocols in 5 percent of decisions for cancer treatments and 36 percent of decisions for non-cancer indications. They apply step protocols in 13 percent of decisions for drugs treating rare conditions, and 33 percent for drugs used to treat more commonly occurring conditions. One reason may be that drugs used for cancer or rare diseases typically have fewer therapeutic substitutes than drugs indicated for other diseases.[19]

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[13] Centers for Medicare and Medicaid Services, *National Health Expenditure Data, Historical, Highlights,* https://www.cms.gov/files/document/highlights.pdf (last visited Mar. 25, 2022).
[14] Id.
[15] Office of Program Policy Analysis & Government Accountability, *Legislature Could Consider Options to Address Pharmacy Benefit Manager Business Practices*, Report No. 07-08 (Feb. 2007), https://oppaga.fl.gov/Products/ReportDetail?rn=07-08 (last visited Mar. 25, 2022).
[16] Id.
[17] 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.
[18] Supra note 13.
[19] "Variation In The Use Of Step Therapy Protocols Across US Health Plans," *Health Affairs* Blog, September 14, 2018, https://www.healthaffairs.org/do/10.1377/hblog20180912.391231/full/ (last visited Mar. 25, 2022).

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]

Federal Patient Protection and Affordable Care Act – Drug Coverage Exceptions and Appeals

The federal Patient Protection and Affordable Care Act (PPACA)[24] requires insurers and HMOs to make coverage available to all individuals and employers, without preexisting condition exclusions and without basing premiums on any health-related factors. PPACA also mandates essential health benefits (EHB)[25] and other provisions.

PPACA requires insurers and HMOs offering qualified health plans to provide 10 categories of EHB, which includes prescription drugs.[26] For purposes of complying with the federal EHB requirements 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.[27]

Prescription Drug Coverage Denial Exceptions

Federal rules establish a uniform process for insurers and HMOs that allows an insured or subscriber, or their prescribing physician, to request a prescription drug coverage exception and gain access to clinically appropriate drugs that are not included on the formulary drug list of the insurer or HMO.[28] The insurer or HMO must make a timely determination on exception requests. If an insurer or HMOs denies an exception request, the insurer or HMO must have a process for the denial to be reviewed by an independent review organization.

The insurer or HMO must make its determination and notify the insured or subscriber and the prescribing physician of the determination within 72 hours of receiving the request. If the insurer or HMO grants the exception, it must cover the non-formulary drug for the duration of the prescription, including refills.

[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, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0516 (last visited Mar. 25, 2022).
[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, http://www.jmcp.org/doi/pdf/10.18553/jmcp.2011.17.2.143 (last visited Mar. 25, 2022).
[22] Supra note 20 at pg. 1780.
[23] Id.
[24] 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.
[25] 42 U.S.C. s.18022.
[26] See Center for Consumer Information & Insurance Oversight, *Information on Essential Health Benefits (EHB) Benchmark Plans* https://www.cms.gov/cciio/resources/data-resources/ehb.html (last visited Mar. 25, 2022) for Florida's benchmark plan.
[27] 45 C.F.R. s. 156.122(a)
[28] 45 C.F.R. s. 156.122(c). Federal rules also establish parallel requirements for claim denials, generally. 45 C.F.R. s. 147.136. This rule requires insurers and HMOs to provide both internal review and external appeal processes for claim denials. The internal review request must be filed within 180 days of notice of deniat and a written determination is due within 30 days , if the requested service(s) have not yet been received, or 60 days, if the service(s) have already been received. A written request for external review must be filed within four months of the notice of claim denial or final determination of the internal review and must be decided as soon as possible, b ut not more than 45 days, unless there are exigent circumstances, then the review must be decided within 72 hours or less.

If there are exigent circumstances,[29] the insurer or HMO must make its determination and notify the insured, subscriber, or the prescribing physician of its determination within 24 hours of receiving the request. If the insurer or HMO grants the expedited exception it must cover the non-formulary drug for the duration of the exigent circumstance.

When the insured or subscriber requests independent review of an exception denial, the determination by the independent review organization must be made within 72 hours, for non-exigent requests, or within 24 hours, for exigent requests.[30]

Florida Law on Step Therapy

Until recently, the Florida Insurance Code was silent on step therapy protocols, leaving insurers and HMOs free to develop policies they felt appropriate.

In 2019, the Legislature created ss. 627.42393 and 641.31, F.S.,[31] which provide a specific and limited prohibition on the use of step therapy by insurers and HMOs. Under this law, insurers and HMOs may not require a step therapy protocol for covered individuals who:

- Were previously approved to receive a specific drug through completion of a step therapy protocol by a previous health insurance plan; and,
- Can provide documentation from the previous health insurance plan indicating that the specific drug was paid for on the individual's behalf during the past 90 days.[32]

This protects individuals who switch from one health plan to another from having to repeat a step therapy protocol.

Current law does not address exemptions from step-therapy requirements.

Effect of Proposed Changes

The bill regulates the use of step therapy by insurers and HMOs. The bill applies to any protocol or program that establishes the specific sequence in which prescription drugs, medical procedures, or courses of treatment must be used to treat a health condition, called a "step therapy protocol."

The bill requires an insurer or HMO to publish on its website, and provide to an insured in writing, a procedure for an insured patient and health care provider to request a protocol exemption.[33] The procedure must include:

- The manner in which an insured patient or health care provider may request a protocol exemption;
- The manner and timeframe in which the health insurer or HMO is required to authorize or deny a protocol exemption request; and,
- The manner and timeframe in which an insured patient may appeal the denial of a request.

Under the bill, an insurer or HMO granting a protocol exemption must specify the prescription drug, medical procedure, or course of treatment approved. Alternatively, an insurer or HMO denying a protocol exemption request must provide a written explanation of the denial, including the clinical rationale supporting the denial. The written explanation must also describe the procedure for appealing

[29] Exigent circumstances exist when an insured or subscriber is suffering from a health condition that may seriously jeopardize the insured's or subscriber's life, health, or ability to regain maximum function or when an insured or subscriber is undergoing a current course of treatment using a non-formulary drug.
[30] 45 C.F.R. s. 156.122(c)(3).
[31] Ch. 2019-138, L.O.F., ss. 12 and 13.
[32] Ss. 627.42393 and 641.31(46), F.S.
[33] A "protocol exemption" is a determination by an insurer or HMO to exempt an insured patient from an existing step therapy protocol.

the determination by the insurer or HMO. PPACA establishes the time[34] for determining an exception request and duration of coverage for granted exceptions, while the bill specifies the required minimum content of grants and denials of exception requests.

The bill provides an effective date of July 1, 2022.

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.

[34] The bll requires the insurer to act on an exception request "within a reasonable time," while PPACA specifies the time (within 72 hours, for non-exigent requests, and within 24 hours, for exigent requests). The PPACA time for determinations will control, to the extent of any possible conflict between the two laws.