

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 459 Step-therapy Protocols

**SPONSOR(S):** Willhite and others

**TIED BILLS:** **IDEN./SIM. BILLS:** SB 730

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Finance & Facilities Subcommittee	15 Y, 0 N	Lloyd	Lloyd
2) Health & Human Services Committee	19 Y, 0 N	Lloyd	Calamas

### SUMMARY ANALYSIS

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 provides an effective date of July 1, 2022.

# 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.<sup>1</sup> 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.<sup>2</sup> Managed care systems combine the delivery and financing of health care services by limiting the choice of doctors and hospitals.<sup>3</sup> 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<sup>4</sup> (PPO) and health maintenance organizations<sup>5</sup> (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,<sup>6</sup> while the Agency for Health Care Administration (agency) regulates the quality of care by HMOs.<sup>7</sup> Before receiving a certificate of authority from the OIR, an HMO must receive a Health Care Provider Certificate from the agency.<sup>8</sup> 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.<sup>9</sup>

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

#### 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*

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<sup>1</sup> S. 624.603, F.S.

<sup>2</sup> 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 accessed Nov. 23, 2021).

<sup>3</sup> *Id.*

<sup>4</sup> S. 627.6471, F.S.

<sup>5</sup> Part I of chapter 641, F.S.

<sup>6</sup> S. 20.121(3)(a), F.S.

<sup>7</sup> Part III of chapter 641, F.S.

<sup>8</sup> S. 641.21(1), F.S.

<sup>9</sup> S. 641.495, F.S.

<sup>10</sup> 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.

<sup>11</sup> S. 624.307(4), F.S.

<sup>12</sup> 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.<sup>13</sup> 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.<sup>14</sup>

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

### *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.<sup>19</sup>

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<sup>13</sup> Centers for Medicare and Medicaid Services, *National Health Expenditure Data, Historical, Highlights*, <https://www.cms.gov/files/document/highlights.pdf> (last accessed Nov. 23, 2021).

<sup>14</sup> Id.

<sup>15</sup> 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 accessed Nov. 23, 2021).

<sup>16</sup> Id.

<sup>17</sup> 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.

<sup>18</sup> Supra note 13.

<sup>19</sup> "Variation In The Use Of Step Therapy Protocols Across US Health Plans," *Health Affairs Blog*, September 14, 2018, <https://www.healthaffairs.org/doi/10.1377/hblog20180912.391231/full/> (last accessed Nov. 23, 2021).

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

### 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 adopted HB 843,<sup>24</sup> which included 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 a covered individual if they:

- Were previously approved to receive a specific drug through completion of a step therapy protocol by a separate health insurance plan; and,
- Can provide documentation from the separate health insurance plan indicating that the specific drug was paid for on the individual's behalf during the past 90 days.<sup>25</sup>

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

### **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.<sup>26</sup> 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 the determination by the insurer or HMO.

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

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<sup>20</sup> 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 accessed Nov. 28, 2021).

<sup>21</sup> 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 accessed Nov. 23, 2021).

<sup>22</sup> Supra note 20 at pg. 1780.

<sup>23</sup> Id.

<sup>24</sup> Ch. 2019-138, L.O.F.

<sup>25</sup> Ss. 627.42393 and 641.31(46), F.S.

<sup>26</sup> A “protocol exemption” is a determination by an insurer or HMO to exempt an insured patient from an existing step therapy protocol.

B. SECTION DIRECTORY:

**Section 1:** Amends s. 627.42393, F.S.; relating to step-therapy protocol.

**Section 2:** Amends s. 641.31, F.S.; relating to health maintenance contracts.

**Section 3:** 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.

**III. COMMENTS**

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The OIR has sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

**IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES**

