

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 877 Health Insurer Authorization  
**SPONSOR(S):** Health Innovation Subcommittee, Harrison  
**TIED BILLS:** **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	15 Y, 0 N, As CS	Tuszynski	Poche
2) Appropriations Committee			
3) Health & Human Services Committee			

### SUMMARY ANALYSIS

Insurers and health maintenance organizations (HMO) 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 a drug that they will cover over a certain period of time, requiring enrollees to obtain prior authorization from their plan before filling a certain prescription or obtaining a certain treatment (prior authorization), or requiring enrollees to first try a preferred drug to treat a medical condition before obtaining an alternate drug to treat the condition (fail-first or step therapy).

CS/HB 877 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 requirement. The bill establishes timeframes for the authorization or denial of a fail-first protocol exception request in non-urgent care situations and urgent care situations. The bill requires a health insurer or HMO to grant a fail-first protocol exception request when a preceding prescription drug or medical treatment is:

- Contraindicated or will likely cause an adverse reaction;
- Expected to be ineffective; or
- In the same pharmacologic class or same mechanism of action to a drug or treatment previously received by the insured that lacked efficacy or effectiveness.

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

The bill has an effective date of July 1, 2017

## 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 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.<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).

##### *Preferred Provider Organization*

A PPO is a health plan that contracts with providers, such as hospitals and doctors, for an alternative or reduced rate of payment to create a provider network. PPO plan members generally see specialists without prior referral or authorization from the insurer. Generally, the member is only responsible for the policy co-payment, deductible, or co-insurance amounts if covered services are obtained from network providers. However, if a member chooses to obtain services from an out-of-network provider, those out-of-pocket costs likely will be higher. An insurer that offers a PPO plan must make its current list of preferred providers available to its members.

##### *Health Maintenance Organization*

An HMO is an organization that provides a wide range of health care services, including emergency care, inpatient hospital care, physician care, ambulatory diagnostic treatment and preventive health care, pursuant to contractual arrangements with preferred providers in a designated service area. The network is made up of providers who have agreed to supply services to members at pre-negotiated rates. Traditionally, a member must use the HMO's network of health care providers in order for the HMO to pay for covered services. The use of a health care provider outside of the network generally results in the HMO limiting or denying the payment of benefits for such services.<sup>6</sup>

##### *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

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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*, available at: <http://www.myfloridacfo.com/Division/Consumers/understandingCoverage/Guides/documents/HealthGuide.pdf> (last visited March 23, 2017).

<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> Section 641.31(38), F.S., creates an exception to this general rule. It authorizes an HMO to offer a point-of-service benefit. The benefit, offered pursuant to a rider, enables a subscriber to select, at the time of service and without referral, a nonparticipating provider for a covered service. The HMO may require the subscriber to pay a reasonable co-payment for each visit for services provided by a nonparticipating provider.

2016.<sup>7</sup> 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.<sup>8</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>9</sup> Payments for the services are established in contracts between health plan sponsors and PBMs.<sup>10</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>11</sup> for brand-name drugs and maximum allowable cost price for generic drugs, plus a dispensing fee.<sup>12</sup>

### *Office of Insurance Regulation*

The regulatory oversight of insurance companies is generally reserved to the states. In Florida, the Office of Insurance Regulation (OIR), within the Department of Financial Services (DFS), regulates insurers and other risk bearing entities, including licensing, rates, policy forms, market conduct, claims, issuance of certificates of authority, solvency, viatical settlements, premium financing, and administrative supervision, as provided under the Florida Insurance Code (Code).<sup>13</sup>

All persons who transact insurance in the state must comply with the Code.<sup>14</sup> OIR has the power to collect, propose, publish, and disseminate any information relating to the subject matter of the Code,<sup>15</sup> and may investigate any matter relating to insurance.<sup>16</sup>

The Code requires health insurers and HMOs to provide an outline of coverage or other information describing the benefits, coverages, and limitations of a policy or contract. This may include an outline of coverage describing the principal exclusions and limitations of the policy.<sup>17</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 to treat a medical condition before obtaining an alternate drug for that condition (fail-first or step therapy).

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<sup>7</sup> 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 March 23, 2017).

<sup>8</sup> *Id.*

<sup>9</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), available at: <http://www.oppaga.state.fl.us/MonitorDocs/Reports/pdf/0708rpt.pdf> (last visited March 23, 2017).

<sup>10</sup> *Id.*

<sup>11</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>12</sup> *Supra*, FN 9.

<sup>13</sup> S. 20.121(3)(a)1., F.S. The OIR's commissioner is the agency head for purposes of final agency action, and its rulemaking body is the Financial Services Commission, consisting of the Governor and the Cabinet.

<sup>14</sup> S. 624.11, F.S.

<sup>15</sup> S. 624.307(4), F.S.

<sup>16</sup> S. 624.307(3), F.S.

<sup>17</sup> S. 627.642, F.S.

## *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.<sup>18</sup> A review of the literature found that there is little good empirical evidence for or against cost savings and utilization reduction.<sup>19</sup> Some studies suggest that step therapy policies have been effective at reducing drug costs without increasing the use of other medical services,<sup>20</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>21</sup>

In Florida, there is no law or rule regulating fail-first protocols or step therapy.

### **Effect of Proposed Language**

#### Fail-First Protocols

CS/HB 877 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 from a fail-first protocol requirement. The bill defines:

- “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 an authorized insurer offering health insurance as defined in s. 624.603, F.S., or a health maintenance organization as defined in s. 641.19(12), F.S.
- “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.

The procedure that an insurer publishes on its website and provides in writing to an insured or health care provider in order to request a protocol exception must include:

- A description of the manner in which an insured or health care provider may request a protocol exception;

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<sup>18</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.

<sup>19</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, available at: <http://www.jmcp.org/doi/pdf/10.18553/jmcp.2011.17.2.143> (last accessed March 22, 2017).

<sup>20</sup> Supra, FN 18 at pg. 1780.

<sup>21</sup> Id.

- 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 any authorization to specify the medical procedure, course of treatment, or prescription drug and any denial to include 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; or
- In the same pharmacologic class or same mechanism of action to a drug or treatment previously received by the insured that lacked efficacy or effectiveness or adversely affected the insured.

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.

These new requirements will add to the administrative burdens of health insurers, PBMs, and utilization review entities. However, the changes add consumer protections by increasing 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.

Finally, the bill removes "a managed care plan as defined in s. 409.962(9)" from the definition of "health insurer" in s. 627.42392, F.S., as that cross-reference is obsolete.

The bill provides an effective date of July 1, 2017.

## B. SECTION DIRECTORY:

**Section 1:** Creates s. 627.42393, F.S., relating to fail-first protocols.

**Section 2:** Provides an effective date of July 1, 2017.

## 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:

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 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 affect local government.

2. Other:  
None.

B. RULE-MAKING AUTHORITY:

Not Applicable.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

### IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 27, 2017, the Health Innovation Subcommittee adopted a strike-all amendment that:

- Removed the proposed changes to prior authorization procedures.
- Removed the mandate that a health insurer or HMO grant a fail-first protocol exception if a preceding prescription or medical treatment is not in the best interest of the insured, based on whether it is expected to:
  - Cause a significant barrier to compliance with the insured's plan of care,
  - Worsen an independently occurring condition, or

- Decrease the insured's ability to perform daily activities.
- Updated cross-references and made technical changes to bill language and structure for clarity and conciseness.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.