The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Banking and Insurance

BILL:	SB 730
INTRODUCER:	Senators Harrell and Polsky
SUBJECT:	Step-therapy Protocols
DATE:	February 2, 2022
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Johnson	Knudson	BI	**Pre-meeting**
2.			HP	
3.			RC	

I. Summary:

SB 730 establishes standards for processing step-therapy protocol exemptions. A step-therapy protocol is a written protocol used by an insurer or a health maintenance organization (HMO) that specifies the order in which certain medical procedures, treatments, or prescription drugs must be used to treat a condition. A protocol exemption is a determination by an insurer or HMO to authorize the use of an alternate procedure, treatment, or prescription drug to treat a condition of an insured or subscriber rather than the procedure, treatment, or drug indicated by the step-therapy protocol.

SB 730 provides that the insurer or HMO must prescribe the manner, form, and timeframe in which an insured or subscriber may request a protocol exemption. Further, SB 730 requires the insurer or HMO to authorize or deny a protocol exemption in reasonable amount of time. If the insurer or HMO denies the protocol exemption, the insurer or HMO must provide the insured or subscriber with a written response and the procedure for appealing a denial. The bill provides insurers wide discretion in meeting these requirements.

II. Present Situation:

Insurers use many cost containment and utilization review strategies to manage medical and drug spending and patient safety. For example, plans may place utilization management requirements on the use of certain medical treatments or drugs on their formulary. Under prior authorization, a health care provider is required to seek approval from an insurer before a patient may receive a specified diagnostic or therapeutic treatment or specified prescription drugs under a plan.[1] In some cases, plans require an insured or subscriber to use a step therapy protocol for drugs or a medical treatment, which requires the insured or subscriber to try one drug or medical procedure

[1] JAMA Health Forum. 2021;2(5):e210859.doi.

for treatment first to treat the medical condition before the insurer or HMO will authorized coverage for another drug, procedure, or treatment for that condition.[2]

Regulation of Insurers and Health Maintenance Organizations

The Office of Insurance Regulation (OIR) licenses and regulates the activities of insurers, health maintenance organizations (HMOs), and other risk-bearing entities.[3] The Florida Insurance Code (code) requires health insurers and HMOs to provide cost containment measures. Section 627.4234, F.S., requires a health insurance policy or health care services plan, which provides medical, hospital, or surgical expense coverage delivered or issued for delivery in this state to include one or more specified procedures or provisions to contain costs or cost increases.

Prior Authorization

Any "health insurer" (health insurer, HMO, Medicaid managed care plan) or pharmacy benefit manager, on behalf of the health insurer, that does not use an online prior authorization form must use a standardized form adopted by the Financial Services Commission (FSC) to obtain a prior authorization for a medical procedure, course of treatment, or prescription drug benefit.[4] The form must include all clinical documentation necessary for the health insurer to make a decision.

Step Therapy Protocols

The code[5] prohibits insurers or HMOs issuing comprehensive major medical health coverage from requiring completion of a step therapy protocol for insureds or subscribers who demonstrate previous completion of a related step therapy process, if the following conditions are met:

- The insured or subscriber has previously been approved to receive the drug through a step therapy protocol imposed by a health insurer that issued major medical coverage to the insured; and,
- The insured or subscriber documentation that an insurer or HMO made payment for the drug on the insured's behalf within the past 90 days.

However, this provision does not require an insurer or an HMO to add a drug to its drug formulary or cover a drug not currently covered in order to comply with the step therapy restriction.[6]

Federal Patient Protection and Affordable Care Act

[2] HEALTH AFFAIRS 40, No. 11 (2021) 1749-1757.
[3] Section 20.121(3), F.S. the Office of Insurance Regulation is an office within the FSC. The FSC is composed of the Governor, the Attorney General, the Chief Financial Officer, and the Commissioner of Agriculture. The FSC members serve as the agency head for purposes of rulemaking.
[4] Section 627.42392, F.S.
[5] Sections 627.4293 and 641.31(46), F.S.
[6] *Id.*

The federal Patient Protection and Affordable Care Act (PPACA)[7] 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 essential health benefits[8] and other provisions.

The PPACA requires insurers and HMOs that offer qualified health plans (plans) to provide 10 categories of essential health benefits (EHB), which includes prescription drugs.[9]
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.[10]

State and Federal Transparency Provisions Relating to Benefits, Coverage Exceptions, and Appeals for Insureds and Subscribers

Benefits
Health insurers and HMOs are required to provide an outline of coverage or other information describing the benefits, coverages, exclusions, and limitations of a policy or contract. [11] Further, each contract, certificate, or member handbook of an HMO must delineate the services for which a subscriber is entitled and any limitations under the contract.[12]

Access to Formulary Drug List and any Restrictions
Plans are required to publish on their website 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 or subscribers, prospective insureds or subscribers, the state, and the public.[13]

Request for Prescription Drug Exception[14]
Federal rules establish a uniform exceptions process for plans that allows an insured or subscriber, or their prescribing physician, to request and gain access to clinically appropriate drugs not otherwise covered by the insurer or HMO (request for exception).[15] If a plan denies a request for a standard exception or an expedited exception request, the plan must have a process for the insured or subscriber to request the original exception request and subsequent denial of

[7] 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.
[8] 42 U.S.C. s.18022.
[9] 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 viewed Jan. 28, 2022) for Florida's benchmark plan.
[10] 45 C.F.R. 156.122(a)
[11] Section 627.642, F.S.
[12] Section 641.31(4), F.S.
[13] 45 C.F.R. s. 156.122(d).
[14] 45 C.F.R. s. 156.122(c).
[15] The exception process applies to drugs that are not included on the formulary drug list of the plan. The internal and external appeals process prescribed in 45 C.F.R. s. 147.136 applies if an enrollee receives an adverse benefit determination for a drug that is included on the plan's formulary drug list.

such request be reviewed by an independent review organization. A plan must make its determination on the external exception request within 72 hours following receipt of a standard request, and within 24 hours following receipt an expedited exception.

Standard exception request. A plan must have a process for an insured or subscriber or their prescribing physician to request a standard review of a decision that a drug is not covered by the plan. A plan must make their determination on a standard exception and notify the insured or subscriber and the prescribing physician of the coverage determination no later than 72 hours following receipt of the request. A plan that grants a standard exception request must provide coverage of the non-formulary drug for the duration of the prescription, including refills.

Expedited exception request. A plan must have a process for an insured or subscriber, or their prescribing physician to request an expedited review based on exigent circumstances. Exigent circumstances exist when an enrollee is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug. A plan must make its coverage determination on an expedited review request based on exigent circumstances and notify the enrollee or the prescribing physician of its coverage determination no later than 24 hours following receipt of the request. A plan that grants an exception based on exigent circumstances must provide coverage of the non-formulary drug for the duration of the exigency.

Internal Claim Appeals and External Review Program[16]

Plans must implement an internal appeals and independent external review process for claims that are denied. Generally, an insured or subscriber may file an internal appeal with the plan within 180 days of receipt of the notice of a denied claim. [17] If an insured or subscriber requests an internal appeal of a denied claim, the plan must provide a written determination of the decision within the following time:

- Within 30 days, if it is a request for prior authorization.
- Within 60 days, if the services have already been received.
- Within 72 hours or less for urgent care cases.[18]

An insured or subscriber must file a written request for an external review within four months after the date of receipt of the notice or final determination from the plan.[19]

A 2021 report analyzed claims denials and appeals in marketplace plans.[20] Of all denials with reasons reported for 2019, about 18 percent were denied because the claim was for an excluded service; about 9 percent were denied due to prior authorization or lack of referral, and less than 1

[16] 45 C.F.R. s. 147.136. The rules apply to non-grandfathered plans, which include health insurance policies that were first sold or significantly modified in certain ways after March 23, 2010.
[17] *See* Healthcare.gov, Appealing a health plan decision-Internal appeals, available at Internal appeals | HealthCare.gov (last visited Jan. 29, 2022). A claim is a request for coverage.
[18] *Id.*
[19] *See* Healthcare.gov, Appealing a health plan decision-External Review, available at External Review | HealthCare.gov (last visited Jan. 28, 2022).
[20] Kaiser Family Foundation, Claims Denials and Appeals in ACA Marketplace Plans (Jan. 20, 2021) available at Claims Denials and Appeals in ACA Marketplace Plans | KFF (last visited Jan. 28, 2022). The federal government requires HealthCare.gov plans or marketplace plans to report reasons for claims denials at the plan level.

percent were denied based on medical necessity. The remaining plan-reported denials (72 percent) were denied for other reasons.[21]

Florida State 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, the DMS contracts with third party administrators, HMOs, and a PBM for the state employees' prescription drug program pursuant to s. 110.12315, F.S. As a group plan, the program must comply with federal regulations of internal appeal and external review programs for drug exceptions and benefit disputes.

III. Effect of Proposed Changes:

Sections 1 and 2 amends ss. 627.42393 and 641.31, F.S., The sections defines the terms, "protocol exemption," and "step-therapy protocol."

The sections require a health insurer or HMO to publish on its website and provide to an insured or subscriber (or his or her health care provider) written procedures for requesting a protocol exemption or an appeal of an insurer or HMO's denial of a protocol exemption request. At a minimum, the procedure must include:

- The manner in which the insured or subscriber may request a protocol exemption, including a form for making the request.
- The manner and timeframe in which the health insurer or HMO must authorize or deny a protocol exemption request, including the requirement that such response must occur within a "reasonable time."
- The manner and the timeframe in which an insured or subscriber may appeal a denial of an insurer or HMO protocol exemption request.

An authorization of a protocol exemption request must specify the approved drug, procedure, or course of treatment. A denial must include a written explanation of the reason for the denial, and the procedure for appealing the denial. An insurer or HMO may request relevant medical records in support of a protocol exemption request.

Section 3 provides the act takes effect July 1, 2022.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

[21] *Id.*

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Currently, insurers and HMOs must comply with federal regulations that prescribe uniform time, notice, and protocol to process drug exceptions and benefit denials and appeals for insureds and subscribers. The provisions of the bill are not consistent with the provisions of the federal rules, which may cause confusion for treating physicians, insureds, and subscribers.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

The bill requires insurers and HMOs to publish and provide a protocol exempton procedure to insureds and subscribers. The bill provides wide discretion for an insurer or HMO in establishing timeframes and the manner to review, deny, and appeal step therapy exceptions for a procedure, treatments, or prescription drugs. For instance, the bill does not specify:

- The manner in which an insurer must allow the protocol exemption requests to be made, just that the insurer or HMO provide a form for making the request.
- The content of the form used to request a protocol exemption.
- The “reasonable” timeframe in which the health insurer must authorize or deny a protocol exemption request.
- The manner and timeframe for appealing the insurer’s or HMO’s denial of a protocol exemption request.

This lack of specificity is in contrast to current federal rules, which establish a uniform exceptions process – including internal and external appeals – for health plans that allow an insured or subscriber, or their prescribing physician, to request and gain access to clinically appropriate drugs not otherwise covered by the insurer or HMO (request for exception) Existing federal rules also provide an expedited process for requesting and appealing denied covered benefits and drug exceptions that an insurer or HMOs must use when an insured or subscriber is suffering from a health condition that may seriously jeopardize his or her life, health, or ability to regain maximum function.

The federal regulations also provide the process and specific timelines and manner for an insurer or HMO to authorize or deny benefits, as well as an internal appeal process and external review process for an insured or subscriber.

It is unclear whether an insured or HMO must establish an expedited process for the drug exception requests or the internal and external appeals process for covered benefits. Federal regulations may preempt these provisions if an insurer or HMO prescribes a process that does not comply with the minimum federal protections for drug exceptions and benefit determinations. A state may determine that a plan of an insurer or HMO satisfies the requirements of Title 45 s. 156.122(c), relating to drug exception requests, if the plan has a process to allow an enrollee to request and gain access to clinically appropriate drugs not otherwise covered by the plan that is compliant with the state's applicable coverage appeals laws and regulations that are at least as stringent as the requirements of (c) and include:

- An internal review;
- An external review;
- The ability to expedite the reviews; and
- Timeframes that are the same or shorter than the timeframes under (c).[22]

It is unclear how the OIR would enforce the provisions of the bill since the provisions do not expressly require the Office of Insurance Regulation to ensure plans are complying with minimum federal requirements.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends sections 627.42393 and 641.31 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

[22] 45 CFR 156.22(c)(4)

B. Amendments:

None.