SLS 20RS-96 **ORIGINAL**

2020 Regular Session

SENATE BILL NO. 59

BY SENATOR FRED MILLS

PHARMACEUTICALS. Provides relative to coverage of step therapy or fail first protocols. (8/1/20)

AN ACT

To amend and reenact R.S. 22:1053, relative to coverage of step therapy or fail first protocols; to provide for clinical review criteria and use of clinical practice guidelines to be used as minimum standards in developing a step therapy or fail first protocol; to provide for clarification on providers lawfully allowed to prescribe; to provide for an override request process for restricted prescription drugs; to provide for override clinical evidence; to provide for decision-making timelines; to provide for appeal rights; to provide for definitions; to provide for technical changes; and to provide for related matters.

Be it enacted by the Legislature of Louisiana:

Section 1. R.S. 22:1053 is hereby amended and reenacted to read as follows:

§1053. Requirement for coverage of step therapy or fail first protocols

A. Any health coverage plan specified in Subsection ~~H~~ **K** of this Section which includes prescription benefits as part of its policy or contract, which utilizes step therapy or fail first protocols, and which is issued for delivery, delivered, renewed, or otherwise contracted for in this state on or after January 1, ~~2011~~ **2020**, shall comply with the provisions of this Section.

B.**(1) Any step therapy or fail first protocol established by a health coverage plan shall be based on clinical review criteria and clinical practice guidelines that are developed and endorsed by a multidisciplinary panel of experts who manage conflicts of interest among the members of writing and review groups by:**

(**a) Requiring members to disclose any potential conflicts of interest with health coverage plans or pharmaceutical manufacturers and to recuse themselves from voting if they have a conflict of interest.**

(b) Using a methodologist to work with writing groups to provide objectivity in data analysis and ranking of evidence through the preparation of evidence tables and facilitating consensus.

(c) Offering opportunities for public review and comments.

(d) Creating an explicit and transparent decision making process.

(e) Basing decisions on high quality studies, research, peer reviewed publications, and medical practice.

(f) Minimizing biases and conflicts of interest.

(g) Explaining the relationship between treatment options and outcomes.

(h) Rating the quality of the evidence supporting recommendations.

(i) Considering relevant patient subgroups and preferences.

(j) Considering the needs of atypical patient populations and diagnoses when establishing clinical review criteria.

(k) Recommending that the prescription drugs be taken in the specific sequence required by the step therapy protocol.

(l) Continuously updating, through a review of new evidence, research, and newly developed treatments.

(2) This Subsection shall not be construed to require health coverage plans to establish a new entity to develop clinical review criteria used for step therapy or fail first protocols.

C. When medications for the treatment of any medical condition are

restricted for use by ~~an insurer by~~ **any health coverage plan through** a step therapy or fail first protocol, the prescribing ~~physician~~ **practitioner** shall have access to a clear and convenient process to expeditiously request an override of such restriction ~~from the insurer~~. **The override process shall be made easily accessible on the health coverage plan's website.** An override of such restriction shall be expeditiously granted by the ~~insurer under~~ **health coverage plan if the prescribing practitioner, using sound clinical evidence, can demonstrate** any of the following ~~circumstances~~:

(1) ~~The prescribing physician can demonstrate to the health coverage plan, based on sound clinical evidence, that the~~ **The** preferred treatment required under **the** step therapy or fail first protocol has been ineffective in the treatment of the ~~insured's~~ **patient's** disease or medical condition. **The prescribing practitioner shall demonstrate to the health coverage plan that the patient has tried the required prescription drug while under their current or a previous health insurance or health coverage plan, or another prescription drug in the same pharmacologic class or with the same mechanism of action, and such prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.**

(2) ~~The prescribing physician can demonstrate to the health coverage plan, based on sound clinical evidence, that the~~ **The** preferred treatment required under the step therapy or fail first protocol is reasonably expected to be ineffective based on the known relevant physical or mental characteristics and medical history of the ~~insured~~ **patient** and known characteristics of the drug regimen.

(3) ~~The prescribing physician can demonstrate to the health coverage plan, based on sound clinical evidence, that the~~ **The** preferred treatment required under the step therapy or fail first protocol ~~will cause~~ **is contraindicated** or will likely cause an adverse reaction or ~~other~~ physical **or mental** harm to the ~~insured~~ **patient**.

(4) The patient is stable on a prescription drug selected by their healthcare provider for the medical condition under consideration while on a

current or previous health insurance or health coverage plan.

(5) The required prescription drug is not in the best interest of the patient based on medical necessity.

D. Approval of a step therapy or fail first protocol override request, when issued by a health coverage plan, shall include clear authorization of coverage for the prescription drug prescribed by the patient's prescribing practitioner.

E. Denial of a step therapy or fail first protocol override request shall not be considered a final adverse determination and shall be eligible for an appeal of coverage determination pursuant to R.S. 22:2401.

F. A health coverage plan shall approve or deny a step therapy or fail first protocol override request, or an appeal of a step therapy or fail first protocol override request determination made pursuant to R.S. 22:2401, within seventy-two hours of receipt. In cases where exigent circumstances exist, a health coverage plan shall approve or deny a step therapy or fail first protocol override request, or an appeal of a step therapy or fail first protocol override request determination made pursuant to R.S. 22:2401, within twenty-four hours of receipt. If a health coverage plan fails to comply with the timelines provided for in this Subsection, the override request shall be considered approved.

G. In the case of a denial, the health coverage plan shall provide the patient and the prescribing practitioner with the reason for the denial, an alternative covered medication, if applicable, and information regarding the procedure for submitting an appeal to the denial.

~~C.~~**H.** The duration of any step therapy or fail first protocol shall not be longer than the customary period for the medication when such treatment is demonstrated by the prescribing ~~physician~~ **practitioner** to be clinically ineffective. When the health coverage plan can demonstrate, through sound clinical evidence, that the originally prescribed medication is likely to require more than the customary period for such medication to provide any relief or an amelioration to the ~~insured~~ **patient**,

the step therapy or fail first protocol may be extended for an additional period of time no longer than the original customary period for the medication.

~~D.~~ **I.(1)** No health coverage plan shall use step therapy or fail first protocols as the basis to restrict any prescription benefit for the treatment of stage-four advanced, metastatic cancer or associated conditions if at least one of the following criteria is met:

~~(1)~~**(a)** The prescribed drug or drug regimen has the United States Food and Drug Administration approved indication.

~~(2)~~**(b)** The prescribed drug or drug regimen has the National Comprehensive Cancer Network Drugs and Biologics Compendium indication.

~~(3)~~**(c)** The prescribed drug or drug regimen is supported by peer-reviewed, evidenced-based medical literature.

~~E.~~**(2)** The provisions of **this** Subsection ~~D of this Section~~ shall not apply if the preferred drug or drug regimen is considered clinically equivalent for therapy, contains the identical active ingredient or ingredients, and is proven to have the same efficacy. For purposes of this Subsection, different salts proven to have the same efficacy shall not be considered as different active ingredients.

~~F.~~**(3)** For drugs prescribed for associated conditions as defined in this Section, the treating healthcare provider shall inform the health coverage plan that the condition is a condition associated with stage-four advanced, metastatic cancer when requesting authorization.

~~G.~~**J.**(1) If a prescribed drug is denied by a health coverage plan based upon step therapy or fail first protocols, the health coverage plan shall provide the prescriber with a list of the alternative comparable formulary medications in writing and attached to the letter of denial of prescription drug coverage.

(2) It shall be deemed sufficient to meet the requirements of this Subsection if a health coverage plan includes the information required by this Subsection in the denial letter sent by the health coverage plan or its agent. For any request made by providers utilizing electronic health records with capabilities, the notice may be sent

electronically.

(3) Simple notification of the availability and location of the formulary shall not be deemed sufficient to meet the requirements of this Subsection.

K. As used in this Section, the following definitions shall apply:

(1) "Health coverage plan" means:

(a) An individual or group plan or program which is established by contract, certificate, law, plan, policy, subscriber agreement, or by any other method and which is entered into, issued, or offered for the purpose of arranging for, delivering, paying for, providing, or reimbursing any of the costs of health or medical care, including pharmacy services, drugs, or devices.

(b) Any hospital, health, or medical expense insurance policy, hospital or medical service contract, employee welfare benefit plan, contract or agreement with a health maintenance organization or a preferred provider organization, health and accident insurance policy, or any other insurance contract of this type, including a group insurance plan and the Office of Group Benefits programs.

(c) Any plan that is subject to the provisions of this Section which is administered by a pharmacy benefit manager.

~~H.(1)(a) As used in this Section, a "health coverage plan" shall mean any hospital, health, or medical expense insurance policy, hospital or medical service contract, employee welfare benefit plan, contract or agreement with a health maintenance organization or a preferred provider organization, health and accident insurance policy, or any other insurance contract of this type, including a group insurance plan and the Office of Group Benefits programs.~~

~~(b) "Health coverage plan" shall include any plan that is subject to the provisions of this Section which is administered by a pharmacy benefit manager.~~

(2) ~~As used in this Section, "stage-four~~ **"Stage-four** advanced, metastatic cancer" means cancer that has spread from the lymph nodes or other areas or parts of the body~~.~~

~~(3) As used in this Section,~~ **and** "associated conditions" means the symptoms or side effects associated with stage-four advanced, metastatic cancer or its treatment.

The original instrument and the following digest, which constitutes no part of the legislative instrument, were prepared by Christine Arbo Peck.

DIGEST

SB 59 Original 2020 Regular Session Fred Mills

Present law provides certain requirements for implementation of step therapy or fail first protocols utilized by any health coverage plan.

Proposed law retains present law and adds further requirements for the development of the step therapy or fail first protocol to be based on clinical review criteria and clinical practice guidelines that are developed and endorsed by a multidisciplinary panel of experts based on certain identified criteria.

Proposed law does not require the health coverage plan to establish a new entity to develop clinical review criteria.

Present law provides for a step therapy or fail first protocol override process to be utilized by prescribing physicians.

Proposed law retains present law relative to the override process, expands the accessibility of the process to the health coverage plan's website, and changes the designation of the prescriber from a prescribing physician to a prescribing practitioner and changes the designation of the effected individual from insured to patient.

Present law provides opportunity for the prescriber to demonstrate to the health coverage plan that the preferred treatment has been ineffective in treating the disease or mental condition of the insured.

Proposed law retains present law and provides additional criteria in which a prescriber can demonstrate that the patient tried the required prescription drug under a current or prior health coverage plan, or another drug in the same drug class, and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event.

Present law provides the prescriber with an opportunity to demonstrate to the health coverage plan that the preferred treatment will cause or will likely cause an adverse reaction or other physical harm to the patient.

Proposed law retains present law and further allows the prescriber to demonstrate that the preferred treatment is contraindicated or will cause mental harm to the patient, that the patient is stable on a certain prescription drug, or that the preferred drug is not in the best interest of the patient based on medical necessity.

Proposed law provides that a health coverage plan shall approve or deny a step therapy of fail first protocol override request within 72 hours of receipt. Proposed law provides that in exigent circumstances, the health coverage plan shall approve or deny a step therapy or fail first protocol override request within 24 hours of receipt. Proposed law provides that failure by a health coverage plan to comply with the timelines in proposed law shall cause the override request to be considered approved.

Proposed law provides that if a health coverage plan denies an override request, the health

coverage plan shall provide the prescribing practitioner and the patient with a reason for the denial, an alternative covered medication, and information regarding the procedure for submitting an appeal to the denial.

Proposed law provides definitions for health coverage plan and stage-four advanced, metastatic cancer.

Effective August 1, 2020.

(Amends R.S. 22:1053)