

2020 Regular Session

HOUSE BILL NO. 263

BY REPRESENTATIVE HUVAL

DRUGS/PRESCRIPTION: Provides for insurance coverage of step therapy or fail first protocols

1 AN ACT

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

10 Be it enacted by the Legislature of Louisiana:

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

12 §1053. Requirement for coverage of step therapy or fail first protocols

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

18 B.(1) Any step therapy or fail first protocol established by a health coverage  
19 plan shall be based on clinical review criteria and clinical practice guidelines that are  
20 developed and endorsed by a multidisciplinary panel of experts who manage

1 conflicts of interest among the members of writing and review groups by doing all  
2 of the following:

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

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

9 (c) Offering opportunities for public review and comments.

10 (d) Creating an explicit and transparent decisionmaking process.

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

13 (f) Minimizing biases and conflicts of interest.

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

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

16 (i) Considering relevant patient subgroups and preferences.

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

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

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

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

26 C. When medications for the treatment of any medical condition are  
27 restricted for use by ~~an insurer~~ by any health coverage plan through a step therapy  
28 or fail first protocol, the prescribing ~~physician~~ practitioner shall have access to a  
29 clear and convenient process to expeditiously request an override of ~~such~~ the

1       restriction ~~from the insurer~~. The override process shall be made easily accessible on  
2       the health coverage plan's website. An override of ~~such~~ the restriction shall be  
3       expeditiously granted by the ~~insurer under~~ health coverage plan if the prescribing  
4       practitioner, using sound clinical evidence, can demonstrate any of the following  
5       circumstances:

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

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

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

24              (4) The patient is stable on a prescription drug selected by his healthcare  
25       provider for the medical condition under consideration while on a current or previous  
26       health insurance or health coverage plan.

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

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

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

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

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

20          ~~E.~~ H. The duration of any step therapy or fail first protocol shall not be  
21          longer than the customary period for the medication when ~~such~~ the treatment is  
22          demonstrated by the prescribing ~~physician~~ practitioner to be clinically ineffective.  
23          When the health coverage plan can demonstrate, through sound clinical evidence,  
24          that the originally prescribed medication is likely to require more than the customary  
25          period for ~~such~~ the medication to provide any relief or an amelioration to the ~~insured~~  
26          patient, the step therapy or fail first protocol may be extended for an additional  
27          period of time no longer than the original customary period for the medication.

28          ~~D.~~ I.(1) No health coverage plan shall use step therapy or fail first protocols  
29          as the basis to restrict any prescription benefit for the treatment of stage-four

1 advanced, metastatic cancer or associated conditions if at least one of the following  
2 criteria is met:

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

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

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

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

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

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

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

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

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



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 used by prescribing physicians.

Proposed law retains present law but adds the requirement that the override process be accessible on the health coverage plan's website and expands the permitted prescriber class from a physician to a practitioner.

Present law provides for an 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 requires a health coverage plan to approve or deny a step therapy or fail first protocol override request within 72 hours of receipt, except, 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 requires a health coverage plan, if the plan denies an override request, to provide the prescribing practitioner and the patient with the reason for the denial, an alternative covered medication, and information regarding the procedure for submitting an appeal of the denial.

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

(Amends R.S. 22:1053)