**RÉSUMÉ DIGEST**

**ACT 181 (HB 263)** **2020 Regular Session** **Huval**

Existing law establishes certain requirements for implementation of step therapy or fail first protocols used by any health coverage plan.

New law requires the development of a step therapy or fail first protocol to be based on certain identified clinical review criteria and clinical practice guidelines developed and endorsed by a multidisciplinary panel of experts. New law does not require health coverage plans to establish a new entity to develop clinical review criteria and does not prohibit the substitution of an AB-rated generic equivalent or interchangeable biological product as designated by the federal Food and Drug Administration (FDA).

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

New law requires the override process to be accessible on a health coverage plan's website and expands the prescriber class to include practitioners. Further requires a health coverage plan to grant an override restriction if the prescriber, using sound clinical evidence, can demonstrate certain patient outcomes to treatment.

Existing law requires the prescriber to demonstrate to a health coverage plan that the preferred treatment under the step therapy or fail first protocol has been ineffective in treating the disease or mental condition of the insured.

New law requires the prescriber to demonstrate that a patient tried a current or prior health coverage plan's required prescribed drug, 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.

Existing law requires the prescriber to demonstrate to a health coverage plan that the preferred treatment under the step therapy or fail first protocol will likely cause an adverse reaction or other physical harm to the patient.

New law further requires the prescriber to demonstrate that the preferred treatment is contraindicated or will cause mental harm to the patient, that the patient has a positive therapeutic outcome on a certain prescription drug, or that the preferred drug is not in the best interest of the patient based on medical necessity as evidenced by valid documentation submitted by the prescriber.

New law requires a health coverage plan's approval of a step therapy or fail first override request to include clear authorization of coverage for the drug prescribed by the patient's practitioner, provided the drug is covered by the health coverage plan.

New 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 must approve or deny the override request within 24 hours of receipt. Further provides that an override request is considered approved if the health coverage plan fails to comply with the timelines provided in new law.

New law requires a health coverage plan, if the plan denies an override request, to provide the prescribing practitioner and the patient with reason for the denial, an alternative covered medication, and information regarding the procedure for submitting an appeal of the denial.

New law requires a practitioner or healthcare provider, in the case of an appeal, to consider atypical diagnoses and the needs of atypical patient populations when deciding on appeals.

New law modifies the definition of "health coverage plan" and "stage-four advanced, metastatic cancer".

Effective upon signature of governor (June 11, 2020).

(Amends R.S. 22:1053)