

**First Regular Session
Seventy-fourth General Assembly
STATE OF COLORADO**

INTRODUCED

LLS NO. 23-0232.01 Shelby Ross x4510

HOUSE BILL 23-1183

HOUSE SPONSORSHIP

Jodeh and Sirota,

SENATE SPONSORSHIP

(None),

House Committees
Health & Insurance

Senate Committees

A BILL FOR AN ACT

101 **CONCERNING MEDICAID PRIOR AUTHORIZATION REQUESTS FOR A**
102 **STEP-THERAPY EXCEPTION.**

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at <http://leg.colorado.gov>.)

The bill requires the department of health care policy and financing (state department) to grant an exception to step therapy if the prescribing provider submits a prior authorization request with justification and supporting clinical documentation for treatment of a serious or complex medical condition. The bill requires the state department to provide a response to a prior authorization request for a

Shading denotes HOUSE amendment. Double underlining denotes SENATE amendment.
*Capital letters or bold & italic numbers indicate new material to be added to existing law.
Dashes through the words or numbers indicate deletions from existing law.*

step-therapy exception within 24 hours after receipt of the request.

If a prior authorization request for a step-therapy exception is incomplete or if additional clinically relevant information is required, the bill requires the state department to notify the prescribing provider within 24 hours after the submission of the request. If the state department does not receive a response within 72 hours after the state department's request for additional information, the prior authorization is denied. If the prior authorization request is denied, the bill requires the state department to inform the recipient in writing that the recipient has a right to appeal the determination.

If the state department does not make a determination regarding the step-therapy exception request, respond to the appeal of the denial of the request, or request additional clinically relevant information, the step-therapy exception request or the appeal of the denial is deemed granted. The bill requires the state department to authorize coverage for the prescription drug prescribed by the recipient's prescribing provider if the prior authorization request for a step-therapy exception request is granted.

The bill requires the state department to make the prior authorization requirements for coverage of prescription drugs and a description of the step-therapy exemption process available on the state department's website and provide to the recipient, upon written request, all specific clinical review criteria and other clinical information relating to a recipient's particular condition or disease.

1 *Be it enacted by the General Assembly of the State of Colorado:*

2 **SECTION 1.** In Colorado Revised Statutes, **add** 25.5-4-427 as
3 follows:

4 **25.5-4-427. Prior authorization for a step-therapy exception**
5 **- rules - definition.** (1) AS USED IN THIS SECTION, UNLESS THE CONTEXT
6 OTHERWISE REQUIRES, "STEP THERAPY" MEANS A PROTOCOL THAT
7 REQUIRES A RECIPIENT TO USE A PRESCRIPTION DRUG OR SEQUENCE OF
8 PRESCRIPTION DRUGS, OTHER THAN THE DRUG THAT THE RECIPIENT'S
9 HEALTH-CARE PROVIDER RECOMMENDS FOR THE RECIPIENT'S TREATMENT,
10 BEFORE THE STATE DEPARTMENT PROVIDES COVERAGE FOR THE
11 RECOMMENDED PRESCRIPTION DRUG.

1 (2) (a) THE STATE DEPARTMENT SHALL GRANT AN EXCEPTION TO
2 STEP THERAPY IF THE PRESCRIBING PROVIDER SUBMITS A PRIOR
3 AUTHORIZATION REQUEST WITH JUSTIFICATION AND SUPPORTING CLINICAL
4 DOCUMENTATION FOR TREATMENT OF A SERIOUS OR COMPLEX MEDICAL
5 CONDITION, IF REQUIRED, THAT STATES:

6 (I) THE PROVIDER ATTESTS THAT THE REQUIRED PRESCRIPTION
7 DRUG IS CONTRAINDICATED, OR WILL LIKELY CAUSE INTOLERABLE SIDE
8 EFFECTS, A SIGNIFICANT DRUG-DRUG INTERACTION, OR AN ALLERGIC
9 REACTION TO THE RECIPIENT;

10 (II) THE REQUIRED PRESCRIPTION DRUG LACKS EFFICACY BASED ON
11 THE KNOWN CLINICAL CHARACTERISTICS OF THE RECIPIENT AND THE
12 KNOWN CHARACTERISTICS OF THE PRESCRIPTION DRUG REGIMEN;

13 (III) THE RECIPIENT HAS TRIED THE REQUIRED PRESCRIPTION DRUG,
14 AND THE USE OF THE PRESCRIPTION DRUG BY THE RECIPIENT WAS
15 DISCONTINUED DUE TO INTOLERABLE SIDE EFFECTS, A SIGNIFICANT
16 DRUG-DRUG INTERACTION, OR AN ALLERGIC REACTION; OR

17 (IV) THE RECIPIENT IS STABLE ON A PRESCRIPTION DRUG SELECTED
18 BY THE PRESCRIBING PROVIDER FOR THE MEDICAL CONDITION.

19 (b) (I) EXCEPT AS PROVIDED IN SUBSECTION (2)(b)(II) OF THIS
20 SECTION, THE STATE DEPARTMENT SHALL PROVIDE A RESPONSE TO A PRIOR
21 AUTHORIZATION REQUEST FOR A STEP-THERAPY EXCEPTION WITHIN
22 TWENTY-FOUR HOURS AFTER RECEIPT OF THE REQUEST.

23 (II) IF A PRIOR AUTHORIZATION REQUEST FOR A STEP-THERAPY
24 EXCEPTION IS INCOMPLETE OR IF ADDITIONAL CLINICALLY RELEVANT
25 INFORMATION IS REQUIRED, THE STATE DEPARTMENT SHALL NOTIFY THE
26 PRESCRIBING PROVIDER WITHIN TWENTY-FOUR HOURS AFTER THE
27 SUBMISSION OF THE REQUEST THAT THE REQUEST IS INCOMPLETE OR THAT

1 ADDITIONAL CLINICALLY RELEVANT INFORMATION IS REQUIRED. THE
2 STATE DEPARTMENT SHALL SPECIFY THE ADDITIONAL INFORMATION THAT
3 IS REQUIRED IN ORDER TO CONSIDER THE PRIOR AUTHORIZATION REQUEST.
4 IF THE STATE DEPARTMENT DOES NOT RECEIVE A RESPONSE WITHIN
5 SEVENTY-TWO HOURS AFTER THE STATE DEPARTMENT'S REQUEST FOR
6 ADDITIONAL INFORMATION, THE PRIOR AUTHORIZATION REQUEST IS
7 DENIED. IF THE STATE DEPARTMENT RECEIVES A TIMELY RESPONSE FROM
8 THE PROVIDER, THE STATE DEPARTMENT SHALL PROVIDE A RESPONSE
9 WITHIN TWENTY-FOUR HOURS AFTER RECEIVING THE RESPONSE.

10 (c) IF THE PRIOR AUTHORIZATION REQUEST FOR A STEP-THERAPY
11 EXCEPTION IS DENIED, THE STATE DEPARTMENT SHALL INFORM THE
12 RECIPIENT IN WRITING THAT THE RECIPIENT HAS THE RIGHT TO APPEAL THE
13 ADVERSE DETERMINATION PURSUANT TO STATE DEPARTMENT RULES.

14 (d) IF THE STATE DEPARTMENT DOES NOT MAKE A DETERMINATION
15 REGARDING THE STEP-THERAPY EXCEPTION REQUEST, OR DOES NOT
16 RESPOND TO THE APPEAL OF THE DENIAL OF THE REQUEST, OR DOES NOT
17 REQUEST ADDITIONAL CLINICALLY RELEVANT INFORMATION PURSUANT TO
18 SUBSECTION (2)(b)(II) OF THIS SECTION WITHIN THE REQUIRED TIME, THE
19 STEP-THERAPY EXCEPTION REQUEST OR THE APPEAL OF THE DENIAL OF THE
20 REQUEST IS DEEMED GRANTED.

21 (3) IF THE PRIOR AUTHORIZATION REQUEST FOR A STEP-THERAPY
22 EXCEPTION REQUEST IS GRANTED, THE STATE DEPARTMENT SHALL
23 AUTHORIZE COVERAGE FOR THE PRESCRIPTION DRUG PRESCRIBED BY THE
24 RECIPIENT'S PRESCRIBING PROVIDER.

25 (4) THE STATE DEPARTMENT SHALL:

26 (a) MAKE THE PRIOR AUTHORIZATION REQUIREMENTS FOR
27 COVERAGE OF PRESCRIPTION DRUGS AND A DESCRIPTION OF THE

1 STEP-THERAPY EXEMPTION PROCESS AVAILABLE ON THE STATE
2 DEPARTMENT'S WEBSITE; AND

3 (b) UPON WRITTEN REQUEST, PROVIDE ALL SPECIFIC CLINICAL
4 REVIEW CRITERIA AND OTHER CLINICAL INFORMATION RELATING TO A
5 RECIPIENT'S PARTICULAR CONDITION OR DISEASE, INCLUDING PRIOR
6 AUTHORIZATION CRITERIA RELATING TO A STEP-THERAPY EXCEPTION, TO
7 THE RECIPIENT.

8 (5) THIS SECTION DOES NOT PROHIBIT:

9 (a) THE STATE DEPARTMENT FROM REQUIRING A RECIPIENT TO TRY
10 A GENERIC EQUIVALENT OF A BRAND NAME DRUG OR AN
11 INTERCHANGEABLE BIOLOGICAL PRODUCT AS DEFINED IN 42 U.S.C. SEC.
12 262 (i)(3), UNLESS THE RECIPIENT OR RECIPIENT'S PRESCRIBING PROVIDER
13 HAS REQUESTED A STEP-THERAPY EXCEPTION AND A PRIOR
14 AUTHORIZATION HAS BEEN APPROVED FOR THE REQUESTED DRUG
15 PURSUANT TO SUBSECTION (3) OF THIS SECTION;

16 (b) THE STATE DEPARTMENT FROM DENYING A PRIOR
17 AUTHORIZATION REQUEST FOR A STEP-THERAPY EXCEPTION WHEN THE
18 REQUEST DOES NOT MEET ONE OF THE CRITERIA SET FORTH IN SUBSECTION
19 (2)(a) OF THIS SECTION BASED ON THE JUSTIFICATION AND SUPPORTING
20 CLINICAL DOCUMENTATION SUBMITTED BY THE PROVIDER, IF APPLICABLE;
21 OR

22 (c) A PROVIDER FROM PRESCRIBING A DRUG THAT, IN THE
23 PROVIDER'S CLINICAL JUDGMENT, IS DETERMINED TO BE MEDICALLY
24 APPROPRIATE.

25 (6) THE STATE BOARD MAY PROMULGATE RULES TO IMPLEMENT
26 THIS SECTION.

27 **SECTION 2. Safety clause.** The general assembly hereby finds,

- 1 determines, and declares that this act is necessary for the immediate
- 2 preservation of the public peace, health, or safety.