First Regular Session Seventy-fourth General Assembly STATE OF COLORADO

ENGROSSED

This Version Includes All Amendments Adopted on Second Reading in the House of Introduction HOUSE BILL 23-1183

LLS NO. 23-0232.01 Shelby Ross x4510

HOUSE SPONSORSHIP

Jodeh and Sirota,

Winter F.,

SENATE SPONSORSHIP

House Committees Health & Insurance Appropriations

Senate Committees

A BILL FOR AN ACT

101 CONCERNING MEDICAID PRIOR AUTHORIZATION REQUESTS FOR A

102 STEP-THERAPY EXCEPTION AND, IN CONNECTION THEREWITH,

103 MAKING AN APPROPRIATION.

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 <u>http://leg.colorado.gov</u>.)

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

HOUSE Amended 2nd Reading March 17, 2023 department to provide a response to a prior authorization request for a 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 OTHERWISE REQUIRES, "STEP THERAPY" MEANS A PROTOCOL THAT 6 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.

(2) (a) THE STATE DEPARTMENT SHALL REVIEW AND DETERMINE
 IF AN EXCEPTION TO STEP THERAPY IS GRANTED IF THE PRESCRIBING
 PROVIDER SUBMITS A PRIOR AUTHORIZATION REQUEST WITH JUSTIFICATION
 AND SUPPORTING CLINICAL DOCUMENTATION FOR TREATMENT OF A
 SERIOUS OR COMPLEX MEDICAL 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;

(III) THE RECIPIENT HAS TRIED THE REQUIRED PRESCRIPTION DRUG,
AND THE USE OF THE PRESCRIPTION DRUG BY THE RECIPIENT WAS
DISCONTINUED DUE TO INTOLERABLE SIDE EFFECTS, A SIGNIFICANT
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.

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

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

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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.

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

19 (4) THE STATE DEPARTMENT SHALL MAKE THE PRIOR
20 AUTHORIZATION REQUIREMENTS FOR COVERAGE OF PRESCRIPTION DRUGS
21 AND A DESCRIPTION OF THE STEP-THERAPY EXEMPTION PROCESS
22 AVAILABLE ON THE STATE DEPARTMENT'S WEBSITE.

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(5) THIS SECTION DOES NOT PROHIBIT:

(a) THE STATE DEPARTMENT FROM REQUIRING A RECIPIENT TO TRY
A GENERIC EQUIVALENT OF A BRAND NAME DRUG OR AN
INTERCHANGEABLE BIOLOGICAL PRODUCT AS DEFINED IN 42 U.S.C. SEC.

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262 (i)(3), UNLESS THE RECIPIENT OR RECIPIENT'S PRESCRIBING PROVIDER
 HAS REQUESTED A STEP-THERAPY EXCEPTION AND A PRIOR
 AUTHORIZATION HAS BEEN APPROVED FOR THE REQUESTED DRUG
 PURSUANT TO SUBSECTION (3) OF THIS SECTION;

5 (b) THE STATE DEPARTMENT FROM DENYING A PRIOR 6 AUTHORIZATION REQUEST FOR A STEP-THERAPY EXCEPTION WHEN THE 7 REQUEST DOES NOT MEET ONE OF THE CRITERIA SET FORTH IN SUBSECTION 8 (2)(a) OF THIS SECTION BASED ON THE JUSTIFICATION AND SUPPORTING 9 CLINICAL DOCUMENTATION SUBMITTED BY THE PROVIDER, IF APPLICABLE; 10 OR

11 (c) A PROVIDER FROM PRESCRIBING A DRUG THAT, IN THE
12 PROVIDER'S CLINICAL JUDGMENT, IS DETERMINED TO BE MEDICALLY
13 APPROPRIATE.

14 (6) THE STATE BOARD MAY PROMULGATE RULES TO IMPLEMENT15 THIS SECTION.

16 **SECTION 2.** Appropriation. (1) For the 2023-24 state fiscal 17 year, \$56,250 is appropriated to the department of health care policy and 18 financing. This appropriation is from the general fund. To implement this 19 act, the department may use this appropriation for Medicaid management 20 information system maintenance and projects.

(2) For the 2023-24 state fiscal year, the general assembly anticipates that the department of health care policy and financing will receive \$168,750 in federal funds for Medicaid management information system maintenance and projects to implement this act. The appropriation in subsection (1) of this section is based on the assumption that the department will receive this amount of federal funds, which is subject to the "(I)" notation as defined in the annual general appropriation act for the

1 same fiscal year.

SECTION 3. Safety clause. The general assembly hereby finds,
determines, and declares that this act is necessary for the immediate
preservation of the public peace, health, or safety.