

**Second Regular Session
Seventy-second General Assembly
STATE OF COLORADO**

INTRODUCED

LLS NO. 20-0100.01 Kristen Forrestal x4217

HOUSE BILL 20-1061

HOUSE SPONSORSHIP

Valdez A. and Herod,

SENATE SPONSORSHIP

(None),

House Committees

Public Health Care & Human Services

Senate Committees

A BILL FOR AN ACT

101 **CONCERNING PHARMACISTS' ABILITY TO PROVIDE HIV INFECTION**
102 **PREVENTION MEDICATIONS TO PATIENTS.**

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>.)

With regard to coverage under a health benefit plan for HIV infection prevention medications, the bill:

- ! Prevents a health insurance carrier from requiring a covered person to undergo step therapy or to receive prior authorization before receiving HIV infection prevention drugs;

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

- ! Requires carriers to cover HIV infection prevention drugs prescribed or dispensed by a pharmacist and to provide an adequate consultative fee to those pharmacists; and
- ! Allows a pharmacist to prescribe and dispense HIV infection prevention drugs if the pharmacist fulfills specific requirements.

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

2 **SECTION 1.** In Colorado Revised Statutes, 10-16-102, **add**
3 (27.5), (38.5), (50.5), and (50.7) as follows:

4 **10-16-102. Definitions.** As used in this article 16, unless the
5 context otherwise requires:

6 (27.5) "FDA" MEANS THE FOOD AND DRUG ADMINISTRATION IN
7 THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, OR
8 ANY SUCCESSOR ENTITY.

9 (38.5) "HIV INFECTION PREVENTION DRUG" MEANS PREEXPOSURE
10 PROPHYLAXIS, POST-EXPOSURE PROPHYLAXIS, OR OTHER DRUGS APPROVED
11 BY THE FDA FOR THE PREVENTION OF HIV INFECTION.

12 (50.5) "POST-EXPOSURE PROPHYLAXIS" MEANS:

13 (a) TENOFOVIR DISOPROXIL FUMARATE (300 MG) WITH
14 EMTRICITABINE (200 MG), TAKEN ONCE DAILY, IN COMBINATION WITH
15 EITHER RALTEGRAVIR (400 MG), TAKEN TWICE DAILY, OR DOLUTEGRAVIR
16 (50 MG), TAKEN ONCE DAILY;

17 (b) TENOFOVIR DISOPROXIL FUMARATE (300 MG) AND
18 EMTRICITABINE (200 MG), TAKEN ONCE DAILY, IN COMBINATION WITH
19 DARUNAVIR (800 MG) AND RITONAVIR (100 MG), TAKEN ONCE DAILY; OR

20 (c) ANOTHER FDA-APPROVED DRUG OR DRUG COMBINATION
21 DETERMINED BY THE STATE BOARD OF PHARMACY TO MEET THE SAME
22 CLINICAL ELIGIBILITY RECOMMENDATIONS PROVIDED IN CDC GUIDELINES,

1 AS DEFINED IN SECTION 12-280-125.7.

2 (50.7) "PREEXPOSURE PROPHYLAXIS" MEANS A FIXED-DOSE
3 COMBINATION OF TENOFOVIR DISOPROXIL FUMARATE (300 MG) WITH
4 EMTRICITABINE (200 MG), OR ANOTHER DRUG OR DRUG COMBINATION
5 DETERMINED BY THE STATE BOARD OF PHARMACY TO MEET THE SAME
6 CLINICAL ELIGIBILITY RECOMMENDATIONS PROVIDED IN CDC GUIDELINES,
7 AS DEFINED IN SECTION 12-280-125.7.

8 **SECTION 2.** In Colorado Revised Statutes, 10-16-104, **add**
9 (18)(e) as follows:

10 **10-16-104. Mandatory coverage provisions - definitions -**
11 **rules. (18) Preventive health care services. (e) (I) ALL INDIVIDUAL**
12 **AND GROUP HEALTH BENEFIT PLANS MUST PROVIDE COVERAGE FOR HIV**
13 **INFECTION PREVENTION DRUGS THAT ARE PRESCRIBED AND DISPENSED**
14 **PURSUANT TO SECTION 12-280-125.7.**

15 (II) THE CARRIER SHALL PROVIDE A PHARMACIST WHO PRESCRIBES
16 AND DISPENSES HIV INFECTION PREVENTION DRUGS PURSUANT TO
17 SECTION 12-280-125.7 AN ADEQUATE CONSULTATIVE FEE, OR, IF MEDICAL
18 BILLING IS NOT AVAILABLE, AN ADEQUATE DISPENSING FEE, THAT IS
19 EQUIVALENT OR THAT IS PROVIDED TO A PHYSICIAN OR ADVANCED
20 PRACTICE NURSE.

21 **SECTION 3.** In Colorado Revised Statutes, **add** 10-16-152 as
22 follows:

23 **10-16-152. HIV prevention medication - limitations on**
24 **carriers - step therapy - prior authorization.** A CARRIER SHALL NOT
25 REQUIRE A COVERED PERSON TO UNDERGO STEP THERAPY OR TO RECEIVE
26 PRIOR AUTHORIZATION BEFORE A PHARMACIST MAY, PURSUANT TO
27 SECTION 12-280-125.7, PRESCRIBE AND DISPENSE AN HIV INFECTION

1 PREVENTION DRUG.

2 **SECTION 4.** In Colorado Revised Statutes, 12-280-103, **amend**
3 (39)(c)(II)(C) and (39)(d); and **add** (39)(e) as follows:

4 **12-280-103. Definitions - rules.** As used in this article 280, unless
5 the context otherwise requires or the term is otherwise defined in another
6 part of this article 280:

7 (39) "Practice of pharmacy" means:

8 (c) The provision of a therapeutic interchange selection or a
9 therapeutically equivalent selection to a patient if, during the patient's stay
10 at a nursing care facility or a long-term acute care hospital licensed under
11 part 1 of article 3 of title 25, the selection has been approved for the
12 patient:

13 (II) By one of the following health care providers:

14 (C) An advanced practice nurse prescriber licensed as a
15 professional nurse under section 12-255-110, registered as an advanced
16 practice nurse under section 12-255-111, and authorized to prescribe
17 controlled substances or prescription drugs pursuant to section
18 12-255-112, if the advanced practice nurse prescriber has developed an
19 articulated plan to maintain ongoing collaboration with physicians and
20 other health care professionals; ~~and~~

21 (d) The dispensing of chronic maintenance drugs pursuant to
22 section 12-280-125.5 and board rules adopted in accordance with that
23 section; AND

24 (e) THE PRESCRIBING AND DISPENSING OF HIV INFECTION
25 PREVENTION DRUGS, AS DEFINED IN AND PURSUANT TO SECTION
26 12-280-125.7.

27 **SECTION 5.** In Colorado Revised Statutes, **add** 12-280-125.7 as

1 follows:

2 **12-280-125.7. Pharmacists' authority to prescribe and**
3 **dispense HIV infection prevention drugs - definitions - rules. (1) AS**
4 USED IN THIS SECTION:

5 (a) "CDC" MEANS THE FEDERAL CENTERS FOR DISEASE CONTROL
6 AND PREVENTION IN THE UNITED STATES DEPARTMENT OF HEALTH AND
7 HUMAN SERVICES, OR ANY SUCCESSOR ENTITY.

8 (b) "CDC GUIDELINES" MEANS THE CDC GUIDELINES FOR
9 PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION AND
10 THE "UPDATED GUIDELINES FOR ANTIRETROVIRAL POST-EXPOSURE
11 PROPHYLAXIS AFTER SEXUAL, INJECTION DRUG USE, OR OTHER
12 NONOCCUPATIONAL EXPOSURE TO HIV", AND ANY ANALOGOUS
13 SUBSEQUENT GUIDELINES PUBLISHED BY THE CDC.

14 (c) "HIV INFECTION PREVENTION DRUG" MEANS PREEXPOSURE
15 PROPHYLAXIS, POST-EXPOSURE PROPHYLAXIS, OR OTHER DRUGS APPROVED
16 BY THE FDA FOR THE PREVENTION OF HIV INFECTION.

17 (d) "POST-EXPOSURE PROPHYLAXIS" MEANS:

18 (I) TENOFOVIR DISOPROXIL FUMARATE (300 MG) WITH
19 EMTRICITABINE (200 MG), TAKEN ONCE DAILY, IN COMBINATION WITH
20 EITHER RALTEGRAVIR (400 MG), TAKEN TWICE DAILY, OR DOLUTEGRAVIR
21 (50 MG), TAKEN ONCE DAILY;

22 (II) TENOFOVIR DISOPROXIL FUMARATE (300 MG) AND
23 EMTRICITABINE (200 MG), TAKEN ONCE DAILY, IN COMBINATION WITH
24 DARUNAVIR (800 MG) AND RITONAVIR (100 MG), TAKEN ONCE DAILY; OR

25 (III) ANOTHER DRUG OR DRUG COMBINATION DETERMINED BY THE
26 BOARD TO MEET THE SAME CLINICAL ELIGIBILITY RECOMMENDATIONS
27 PROVIDED IN CDC GUIDELINES.

1 (e) "PREEXPOSURE PROPHYLAXIS" MEANS A FIXED-DOSE
2 COMBINATION OF TENOFOVIR DISOPROXIL FUMARATE (300 MG) WITH
3 EMTRICITABINE (200 MG), OR ANOTHER DRUG OR DRUG COMBINATION
4 DETERMINED BY THE BOARD TO MEET THE SAME CLINICAL ELIGIBILITY
5 RECOMMENDATIONS PROVIDED IN CDC GUIDELINES.

6 (2) A PHARMACIST MAY PRESCRIBE AND DISPENSE HIV INFECTION
7 PREVENTION DRUGS IN ACCORDANCE WITH THIS SECTION.

8 (3) (a) BEFORE PRESCRIBING OR DISPENSING HIV INFECTION
9 PREVENTION DRUGS TO A PATIENT, A PHARMACIST MUST COMPLETE A
10 TRAINING PROGRAM APPROVED BY THE BOARD THAT ADDRESSES THE USE
11 OF HIV INFECTION PREVENTION DRUGS. THE BOARD SHALL CONSULT WITH
12 THE COLORADO PHARMACISTS SOCIETY AND THE COLORADO HIV
13 ALLIANCE FOR PREVENTION, CARE AND TREATMENT, OR THEIR
14 SUCCESSOR ORGANIZATIONS, PRIOR TO APPROVING APPROPRIATE TRAINING
15 PROGRAMS.

16 (b) WHEN PRESCRIBING AND DISPENSING PREEXPOSURE
17 PROPHYLAXIS OR OTHER FDA-APPROVED PREEXPOSURE DRUGS, A
18 PHARMACIST SHALL:

19 (I) SCREEN THE PATIENT FOR HIV AND MUST DETERMINE THAT THE
20 PATIENT RECEIVED A NEGATIVE HIV TEST WITHIN THE PREVIOUS SEVEN
21 DAYS;

22 (II) PROVIDE COUNSELING TO THE PATIENT THAT INCLUDES
23 EDUCATION ABOUT SIDE EFFECTS OF THE MEDICATION; THE IMPORTANCE
24 OF ADHERING TO THE DRUG REGIMEN, TESTING, AND TREATMENT, AS
25 APPLICABLE, FOR HIV AND SEXUALLY TRANSMITTED DISEASES;
26 BEHAVIORAL RISK REDUCTION SUPPORT; AND PREGNANCY TESTING;

27 (III) ADVISE THE PATIENT ON CURRENT CDC GUIDELINES AND

1 RECOMMENDATIONS REGARDING ONGOING USE OF THE MEDICATION;

2 (IV) DOCUMENT THE SERVICES PROVIDED BY THE PHARMACIST IN
3 THE RECORD SYSTEM MAINTAINED BY THE PHARMACY FOR THE PATIENT
4 AND:

5 (A) DOCUMENT THE SERVICES PROVIDED IN THE PATIENT'S HEALTH
6 RECORD, IF THE RECORD IS AVAILABLE; OR

7 (B) IF THE PATIENT'S HEALTH RECORD IS NOT AVAILABLE, PROVIDE
8 WRITTEN DOCUMENTATION OF THE SERVICES PROVIDED TO THE PATIENT;
9 AND

10 (V) (A) NOTIFY THE PATIENT'S PRIMARY CARE PROVIDER THAT THE
11 PHARMACIST COMPLETED THE REQUIREMENTS IN THIS SUBSECTION (3)(b);
12 OR

13 (B) IF NO PRIMARY CARE PROVIDER IS INDICATED, PROVIDE THE
14 PATIENT A LIST OF PHYSICIANS AND SURGEONS, CLINICS, OR OTHER HEALTH
15 CARE SERVICE PROVIDERS TO CONTACT FOR HEALTH CARE SERVICES AND
16 PROVIDE THE PATIENT A WRITTEN RECORD OF THE PRESCRIBED AND
17 DISPENSED DRUGS AND ANY APPLICABLE TEST RESULTS.

18 (c) WHEN DISPENSING A COMPLETE COURSE OF POST-EXPOSURE
19 PROPHYLAXIS OR OTHER FDA-APPROVED HIV POST-EXPOSURE DRUGS, A
20 PHARMACIST SHALL:

21 (I) SCREEN THE PATIENT FOR HIV AND MUST DETERMINE THAT THE
22 EXPOSURE MEETS THE CLINICAL CRITERIA FOR USE OF POST-EXPOSURE
23 PROPHYLAXIS CONSISTENT WITH THE MOST RECENT CDC GUIDELINES;

24 (II) PROVIDE HIV TESTING OR DETERMINE THE PATIENT IS WILLING
25 TO RECEIVE AN HIV TEST CONSISTENT WITH THE MOST RECENT CDC
26 GUIDELINES;

27 (III) PROVIDE COUNSELING TO THE PATIENT ON THE USE OF THE

1 MEDICATION CONSISTENT WITH THE MOST RECENT CDC GUIDELINES,
2 INCLUDING EDUCATION ABOUT SIDE EFFECTS OF THE MEDICATION, AND
3 THE IMPORTANCE OF ADHERING TO THE DRUG REGIMEN AND TESTING FOR
4 HIV AND SEXUALLY TRANSMITTED DISEASES; AND

5 (IV) NOTIFY THE PATIENT'S PRIMARY CARE PROVIDER OF THE
6 POST-EXPOSURE PROPHYLAXIS TREATMENT, OR, IF NO PRIMARY CARE
7 PROVIDER IS INDICATED, PROVIDE THE PATIENT A LIST OF PHYSICIANS AND
8 SURGEONS, CLINICS, OR OTHER HEALTH CARE SERVICE PROVIDERS TO
9 CONTACT FOR HEALTH CARE SERVICES.

10 (d) NEITHER A PHARMACIST NOR A PATIENT MAY WAIVE THE
11 REQUIREMENTS IN THIS SUBSECTION (3).

12 (4) A PHARMACIST WHO PROVIDES COUNSELING, ASSESSMENTS, OR
13 TESTS PURSUANT TO THIS SECTION SHALL ENSURE THAT THESE SERVICES
14 ARE PROVIDED IN A PRIVATE AND SANITARY LOCATION, AND THE
15 PHARMACIST SHALL NOT INTERRUPT THE PERFORMANCE OF THESE
16 SERVICES TO PERFORM OTHER DUTIES.

17 (5) THE BOARD MAY PROMULGATE RULES NECESSARY TO
18 IMPLEMENT THIS SECTION.

19 **SECTION 6. Safety clause.** The general assembly hereby finds,
20 determines, and declares that this act is necessary for the immediate
21 preservation of the public peace, health, or safety.