Second Regular Session Seventy-second General Assembly STATE OF COLORADO

REREVISED

This Version Includes All Amendments Adopted in the Second House

LLS NO. 20-0100.01 Kristen Forrestal x4217

HOUSE BILL 20-1061

HOUSE SPONSORSHIP

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House Committees

Public Health Care & Human Services Appropriations

Senate Committees

Health & Human Services Appropriations

A BILL FOR AN ACT

101	CONCERNING PHARMACISTS' ABILITY TO PROVIDE HIV INFECTION
102	PREVENTION MEDICATIONS TO PATIENTS, AND, IN CONNECTION
103	THEREWITH, 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 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

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.

Reading Unamended SENATE

SENATE Amended 2nd Reading June 5, 2020

3rd Reading Unamended March 5, 2020

Amended 2nd Reading

Amended 2nd Reading March 2, 2020 drugs;

- ! 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
- BY THE FDA FOR THE PREVENTION OF HIV INFECTION.
- 12 (50.5) "POST-EXPOSURE PROPHYLAXIS" MEANS A DRUG OR DRUG
- 13 COMBINATION THAT MEETS THE SAME CLINICAL ELIGIBILITY
- 14 RECOMMENDATIONS PROVIDED IN CDC GUIDELINES, AS DEFINED IN
- 15 SECTION 12-280-125.7.
- 16 (50.7) "Preexposure prophylaxis" means a drug or drug
- 17 COMBINATION THAT MEETS THE SAME CLINICAL ELIGIBILITY
- 18 RECOMMENDATIONS PROVIDED IN CDC GUIDELINES, AS DEFINED IN
- 19 SECTION 12-280-125.7.
- SECTION 2. In Colorado Revised Statutes, 10-16-104, add
- 21 (18)(e) as follows:
- 22 10-16-104. Mandatory coverage provisions definitions -

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I	rules. (18) Preventive health care services. (e) (1) A CARRIER SHALL
2	REIMBURSE A PHARMACIST EMPLOYED BY AN IN-NETWORK PHARMACY FOR
3	PRESCRIBING AND DISPENSING HIV INFECTION PREVENTION DRUGS TO A
4	COVERED PERSON. A CARRIER SHALL PROVIDE A PHARMACIST WHO
5	PRESCRIBES AND DISPENSES HIV INFECTION PREVENTION DRUGS $\underline{\text{TO A}}$
6	COVERED PERSON PURSUANT TO SECTION 12-280-125.7 AN ADEQUATE
7	CONSULTATIVE FEE, OR, IF MEDICAL BILLING IS NOT AVAILABLE, AN
8	ENHANCED DISPENSING FEE, THAT IS EQUIVALENT OR THAT IS PROVIDED TO
9	A PHYSICIAN OR ADVANCED PRACTICE NURSE.
10	$\underline{\text{(II)}}$ This subsection (18)(e) does not apply to an integrated
11	HEALTH CARE DELIVERY SYSTEM THAT DISPENSES A MAJORITY OF
12	PRESCRIPTION DRUGS THROUGH INTEGRATED PHARMACIES.
13	SECTION 3. In Colorado Revised Statutes, add 10-16-152 as
14	follows:
15	10-16-152. HIV prevention medication - limitations on
16	carriers - step therapy - prior authorization. A CARRIER SHALL NOT
17	DECLUDE A COLUMN DED DED COLUMN TO LINDER COLUMN TWEN A DIVIDIO DECENTE
	REQUIRE A COVERED PERSON TO UNDERGO STEP THERAPY OR TO RECEIVE
18	PRIOR AUTHORIZATION BEFORE A PHARMACIST MAY, PURSUANT TO
18 19	
	PRIOR AUTHORIZATION BEFORE A PHARMACIST MAY, PURSUANT TO
19	PRIOR AUTHORIZATION BEFORE A PHARMACIST MAY, PURSUANT TO SECTION 12-280-125.7, PRESCRIBE AND DISPENSE AN HIV INFECTION
19 20	PRIOR AUTHORIZATION BEFORE A PHARMACIST MAY, PURSUANT TO SECTION 12-280-125.7, PRESCRIBE AND DISPENSE AN HIV INFECTION PREVENTION DRUG.
19 20 21	PRIOR AUTHORIZATION BEFORE A PHARMACIST MAY, PURSUANT TO SECTION 12-280-125.7, PRESCRIBE AND DISPENSE AN HIV INFECTION PREVENTION DRUG. SECTION 4. In Colorado Revised Statutes, 12-280-103, amend
19 20 21 22	PRIOR AUTHORIZATION BEFORE A PHARMACIST MAY, PURSUANT TO SECTION 12-280-125.7, PRESCRIBE AND DISPENSE AN HIV INFECTION PREVENTION DRUG. SECTION 4. In Colorado Revised Statutes, 12-280-103, amend (39)(c)(II)(C) and (39)(d); and add (39)(e) as follows:
19 20 21 22 23	PRIOR AUTHORIZATION BEFORE A PHARMACIST MAY, PURSUANT TO SECTION 12-280-125.7, PRESCRIBE AND DISPENSE AN HIV INFECTION PREVENTION DRUG. SECTION 4. In Colorado Revised Statutes, 12-280-103, amend (39)(c)(II)(C) and (39)(d); and add (39)(e) as follows: 12-280-103. Definitions - rules. As used in this article 280, unless
19 20 21 22 23 24	PRIOR AUTHORIZATION BEFORE A PHARMACIST MAY, PURSUANT TO SECTION 12-280-125.7, PRESCRIBE AND DISPENSE AN HIV INFECTION PREVENTION DRUG. SECTION 4. In Colorado Revised Statutes, 12-280-103, amend (39)(c)(II)(C) and (39)(d); and add (39)(e) as follows: 12-280-103. Definitions - rules. As used in this article 280, unless the context otherwise requires or the term is otherwise defined in another

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1 therapeutically equivalent selection to a patient if, during the patient's stay 2 at a nursing care facility or a long-term acute care hospital licensed under 3 part 1 of article 3 of title 25, the selection has been approved for the 4 patient: 5 (II) By one of the following health care providers: 6 An advanced practice nurse prescriber licensed as a (C) 7 professional nurse under section 12-255-110, registered as an advanced 8 practice nurse under section 12-255-111, and authorized to prescribe 9 controlled substances or prescription drugs pursuant to section 10 12-255-112, if the advanced practice nurse prescriber has developed an 11 articulated plan to maintain ongoing collaboration with physicians and 12 other health care professionals; and 13 (d) The dispensing of chronic maintenance drugs pursuant to 14 section 12-280-125.5 and board rules adopted in accordance with that 15 section; AND 16 (e) PURSUANT TO A STANDING ORDER OR TO A STATEWIDE DRUG 17 THERAPY PROTOCOL DEVELOPED PURSUANT TO SECTION 12-280-125.7, 18 THE PRESCRIBING AND DISPENSING OF POST-EXPOSURE PROPHYLAXIS, AS 19 DEFINED IN SECTION 12-280-125.7 (1)(d), FOR NONOCCUPATIONAL 20 EXPOSURE TO HIV INFECTION AND PREEXPOSURE PROPHYLAXIS, AS 21 DEFINED IN SECTION 12-280-125.7 (1)(e), AND THE ORDERING OF LAB 22 TESTS IN CONJUNCTION WITH PRESCRIBING OR DISPENSING THE DRUGS. 23 **SECTION 5.** In Colorado Revised Statutes, add 12-280-125.7 as 24 follows: 25 12-280-125.7. Pharmacists' authority to prescribe and 26 dispense HIV infection prevention drugs - definitions - rules. (1) AS

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USED IN THIS SECTION:

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1	(a) CDC MEANS THE FEDERAL CENTERS FOR DISEASE CONTROL
2	AND PREVENTION IN THE UNITED STATES DEPARTMENT OF HEALTH AND
3	HUMAN SERVICES, OR ANY SUCCESSOR ENTITY.
4	(b) "CDC GUIDELINES" MEANS THE CDC GUIDELINES FOR
5	PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION AND
6	THE "UPDATED GUIDELINES FOR ANTIRETROVIRAL POST-EXPOSURE
7	PROPHYLAXIS AFTER SEXUAL, INJECTION DRUG USE, OR OTHER
8	NONOCCUPATIONAL EXPOSURE TO HIV", AND ANY ANALOGOUS
9	SUBSEQUENT GUIDELINES PUBLISHED BY THE CDC.
10	(c) "HIV INFECTION PREVENTION DRUG" MEANS PREEXPOSURE
11	PROPHYLAXIS, POST-EXPOSURE PROPHYLAXIS, OR OTHER DRUGS APPROVED
12	BY THE FDA FOR THE PREVENTION OF HIV INFECTION.
13	(d) "POST-EXPOSURE PROPHYLAXIS" MEANS A DRUG OR DRUG
14	COMBINATION THAT MEETS THE SAME CLINICAL ELIGIBILITY
15	RECOMMENDATIONS PROVIDED IN CDC GUIDELINES.
16	(e) "PREEXPOSURE PROPHYLAXIS" MEANS A DRUG OR DRUG
17	COMBINATION THAT MEETS THE SAME CLINICAL ELIGIBILITY
18	RECOMMENDATIONS PROVIDED IN CDC GUIDELINES.
19	(f) "PRESCRIBER" MEANS:
20	(I) A PHYSICIAN OR PHYSICIAN ASSISTANT LICENSED PURSUANT TO
21	ARTICLE 240 OF THIS TITLE 12; OR
22	(II) AN ADVANCED PRACTICE NURSE, AS DEFINED IN SECTION
23	12-255-104 (1), WITH PRESCRIPTIVE AUTHORITY PURSUANT TO SECTION
24	12-255-112.
25	(g) "STANDING ORDER" MEANS A PRESCRIPTION ORDER WRITTEN
26	BY A PRESCRIBER THAT IS NOT SPECIFIC TO AND DOES NOT IDENTIFY A
27	PARTICULAR PATIENT.

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1	(2) A PHARMACIST MAY PRESCRIBE AND DISPENSE HIV INFECTION
2	PREVENTION DRUGS IN ACCORDANCE WITH A STANDING ORDER PURSUANT
3	TO SECTION 25-1-130 OR A STATEWIDE DRUG THERAPY PROTOCOL
4	DEVELOPED PURSUANT TO SUBSECTION (5) OF THIS SECTION.
5	(3) BEFORE PRESCRIBING OR DISPENSING HIV INFECTION
6	PREVENTION DRUGS TO A PATIENT, A PHARMACIST MUST:
7	(a) HOLD A CURRENT LICENSE TO PRACTICE IN COLORADO;
8	(b) BE ENGAGED IN THE PRACTICE OF PHARMACY;
9	(c) HAVE EARNED A DOCTORATE OF PHARMACY DEGREE OR
10	COMPLETED AT LEAST FIVE YEARS OF EXPERIENCE AS A LICENSED
11	PHARMACIST;
12	(d) CARRY ADEQUATE PROFESSIONAL LIABILITY INSURANCE AS
13	DETERMINED BY THE BOARD; AND
14	(e) COMPLETE A TRAINING PROGRAM ACCREDITED BY THE
15	ACCREDITATION COUNCIL FOR PHARMACY EDUCATION, OR ITS SUCCESSOR
16	ENTITY, PURSUANT TO THE PROTOCOL DEVELOPED BY THE BOARD.
17	(4) THE BOARD SHALL PROMULGATE RULES NECESSARY TO
18	IMPLEMENT THIS SECTION, INCLUDING RULES THAT ESTABLISH PROTOCOLS
19	FOR PRESCRIBING AND DISPENSING PREEXPOSURE PROPHYLAXIS AND
20	POST-EXPOSURE PROPHYLAXIS.
21	(5) (a) ON OR BEFORE SIX MONTHS AFTER THE EFFECTIVE DATE OF
22	THIS SECTION, THE STATE BOARD OF PHARMACY, THE COLORADO MEDICAL
23	BOARD, AND THE STATE BOARD OF NURSING SHALL, IN COLLABORATION
24	WITH THE DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT, AND AS
25	DESCRIBED IN SECTION 12-280-601 (1)(b), DEVELOP STATEWIDE DRUG
26	THERAPY PROTOCOLS FOR PHARMACISTS TO PRESCRIBE AND DISPENSE HIV
2.7	INFECTION PREVENTION DRUGS

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1	(b) IF THE STATE BOARD OF PHARMACY, THE COLORADO MEDICAL
2	BOARD, AND THE STATE BOARD OF NURSING ARE NOT ABLE TO AGREE IN
3	THE TIME PERIOD REQUIRED BY SUBSECTION (5)(a) OF THIS SECTION TO
4	STATEWIDE DRUG THERAPY PROTOCOLS FOR PHARMACISTS TO PRESCRIBE
5	AND DISPENSE HIV INFECTION PREVENTION DRUGS, THE STATE BOARD OF
6	PHARMACY SHALL COLLABORATE WITH THE DEPARTMENT OF PUBLIC
7	HEALTH AND ENVIRONMENT TO DEVELOP AND IMPLEMENT STATEWIDE
8	DRUG THERAPY PROTOCOLS BY JANUARY 1, 2021.
9	(c) IN DEVELOPING THE STATEWIDE DRUG THERAPY PROTOCOLS,
10	THE APPLICABLE BOARDS AND THE DEPARTMENT OF PUBLIC HEALTH AND
11	ENVIRONMENT SHALL CONSIDER PHYSICIAN REFERRALS; LAB TESTING,
12	INCLUDING PREEXPOSURE AND POST-EXPOSURE PRESCRIBING TESTS, AND
13	APPROPRIATE REFERRALS PURSUANT TO CDC GUIDELINES; COUNSELING
14	PURSUANT TO CDC GUIDELINES; AND PATIENT FOLLOW-UP CARE AND
15	COUNSELING.
16	SECTION 6. In Colorado Revised Statutes, add 25-1-130 as
17	follows:
18	25-1-130. Standing order - post-exposure prophylaxis -
19	definition. (1) On or before <u>August</u> 1, 2020, and until a statewide
20	DRUG THERAPY PROTOCOL IS IMPLEMENTED PURSUANT TO SECTION
21	12-280-125.7, THE DEPARTMENT SHALL IMPLEMENT AND MAINTAIN A
22	STANDING ORDER FOR POST-EXPOSURE PROPHYLAXIS SO THAT
23	PHARMACISTS MAY PRESCRIBE AND DISPENSE POST-EXPOSURE
24	PROPHYLAXIS PURSUANT TO SECTION 12-280-125.7.
25	(2) AS USED IN THIS SECTION "POST-EXPOSURE PROPHYLAXIS" HAS
26	THE SAME MEANING AS SET FORTH IN SECTION 12-280-125.7.
27	SECTION 7. Appropriation. For the 2020-21 state fiscal year,

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\$13,347 is appropriated to the department of regulatory agencies for use 1 by the division of insurance. This appropriation is from the division of 2 3 insurance cash fund created in section 10-1-103 (3), C.R.S., and is based 4 on an assumption that the division will require an additional 0.2 FTE. To 5 implement this act, the division may use this appropriation for personal 6 services. **SECTION 8.** Safety clause. The general assembly hereby finds, 7 8 determines, and declares that this act is necessary for the immediate

preservation of the public peace, health, or safety.

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