A BILL FOR AN ACT

CONCERNING PHARMACISTS' ABILITY TO PROVIDE HIV INFECTION 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;
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.

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

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

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

(27.5) "FDA" means the Food and Drug Administration in the United States Department of Health and Human Services, or any successor entity.

(38.5) "HIV infection prevention drug" means preexposure prophylaxis, post-exposure prophylaxis, or other drugs approved by the FDA for the prevention of HIV infection.

(50.5) "Post-exposure prophylaxis" means:

(a) Tenofovir disoproxil fumarate (300 mg) with emtricitabine (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily;

(b) Tenofovir disoproxil fumarate (300 mg) and emtricitabine (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily; or

(c) Another FDA-approved drug or drug combination determined by the State Board of Pharmacy to meet the same clinical eligibility recommendations provided in CDC guidelines,
AS DEFINED IN SECTION 12-280-125.7.

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

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

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

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

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

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

(39) "Practice of pharmacy" means:

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

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

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

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

(e) The prescribing and dispensing of HIV infection prevention drugs, as defined in and pursuant to section 12-280-125.7.

SECTION 5. In Colorado Revised Statutes, add 12-280-125.7 as
follows:

12-280-125.7. Pharmacists' authority to prescribe and dispense HIV infection prevention drugs - definitions - rules. (1) As used in this section:

(a) "CDC" means the Federal Centers for Disease Control and Prevention in the United States Department of Health and Human Services, or any successor entity.

(b) "CDC Guidelines" means the CDC Guidelines for Preexposure Prophylaxis for the Prevention of HIV Infection and the "Updated Guidelines for Antiretroviral Post-exposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV", and any analogous subsequent guidelines published by the CDC.

(c) "HIV Infection Prevention Drug" means Preexposure Prophylaxis, Post-exposure Prophylaxis, or other drugs approved by the FDA for the prevention of HIV Infection.

(d) "Post-exposure Prophylaxis" means:

(I) Tenofovir Disoproxil Fumarate (300 mg) with Emtricitabine (200 mg), taken once daily, in combination with either Raltegravir (400 mg), taken twice daily, or Dolutegravir (50 mg), taken once daily;

(II) Tenofovir Disoproxil Fumarate (300 mg) and Emtricitabine (200 mg), taken once daily, in combination with Darunavir (800 mg) and Ritonavir (100 mg), taken once daily; or

(III) Another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC Guidelines.
(e) "Preexposure prophylaxis" means a fixed-dose combination of tenofovir disoproxil fumarate (300 mg) with emtricitabine (200 mg), or another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

(2) A pharmacist may prescribe and dispense HIV infection prevention drugs in accordance with this section.

(3) (a) Before prescribing or dispensing HIV infection prevention drugs to a patient, a pharmacist must complete a training program approved by the board that addresses the use of HIV infection prevention drugs. The board shall consult with the Colorado Pharmacists Society and the Colorado HIV Alliance for Prevention, Care and Treatment, or their successor organizations, prior to approving appropriate training programs.

(b) When prescribing and dispensing preexposure prophylaxis or other FDA-approved preexposure drugs, a pharmacist shall:

(I) Screen the patient for HIV and must determine that the patient received a negative HIV test within the previous seven days;

(II) Provide counseling to the patient that includes education about side effects of the medication; the importance of adhering to the drug regimen, testing, and treatment, as applicable, for HIV and sexually transmitted diseases; behavioral risk reduction support; and pregnancy testing;

(III) Advise the patient on current CDC guidelines and
RECOMMENDATIONS REGARDING ONGOING USE OF THE MEDICATION;

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

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

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

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

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

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

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

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

(III) PROVIDE COUNSELING TO THE PATIENT ON THE USE OF THE
MEDICATION CONSISTENT WITH THE MOST RECENT CDC GUIDELINES,
INCLUDING EDUCATION ABOUT SIDE EFFECTS OF THE MEDICATION, AND
THE IMPORTANCE OF ADHERING TO THE DRUG REGIMEN AND TESTING FOR
HIV AND SEXUALLY TRANSMITTED DISEASES; AND

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

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

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

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

SECTION 6. 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.