A BILL FOR AN ACT

CONCERNING PHARMACISTS' ABILITY TO PROVIDE HIV INFECTION PREVENTION MEDICATIONS TO PATIENTS, AND, IN CONNECTION 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
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 DRUG OR DRUG COMBINATION THAT MEETS THE SAME CLINICAL ELIGIBILITY RECOMMENDATIONS PROVIDED IN CDC GUIDELINES, AS DEFINED IN SECTION 12-280-125.7.

(50.7) "PREEXPOSURE PROPHYLAXIS" MEANS A DRUG OR DRUG COMBINATION THAT MEETS 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) A CARRIER SHALL REIMBURSE A PHARMACIST EMPLOYED BY AN IN-NETWORK PHARMACY FOR PRESCRIBING AND DISPENSING HIV INFECTION PREVENTION DRUGS TO A COVERED PERSON. A CARRIER SHALL PROVIDE A PHARMACIST WHO PRESCRIBES AND DISPENSES HIV INFECTION PREVENTION DRUGS TO A COVERED PERSON PURSUANT TO SECTION 12-280-125.7 AN ADEQUATE CONSULTATIVE FEE, OR, IF MEDICAL BILLING IS NOT AVAILABLE, AN ENHANCED DISPENSING FEE, THAT IS EQUIVALENT OR THAT IS PROVIDED TO A PHYSICIAN OR ADVANCED PRACTICE NURSE.

(II) THIS SUBSECTION (18)(e) DOES NOT APPLY TO AN INTEGRATED HEALTH CARE DELIVERY SYSTEM THAT DISPENSES A MAJORITY OF PRESCRIPTION DRUGS THROUGH INTEGRATED PHARMACIES.

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 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 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) Pursuant to a standing order or to a statewide drug
therapy protocol developed pursuant to section 12-280-125.7,
the prescribing and dispensing of post-exposure prophylaxis, as
defined in section 12-280-125.7 (1)(d), for nonoccupational
exposure to HIV infection and preexposure prophylaxis, as
defined in section 12-280-125.7 (1)(e), and the ordering of lab
tests in conjunction with prescribing or dispensing the drugs.

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 a drug or drug combination that meets the same clinical eligibility recommendations provided in CDC guidelines.

(e) "Preexposure Prophylaxis" means a drug or drug combination that meets the same clinical eligibility recommendations provided in CDC guidelines.

(f) "Prescriber" means:

(I) A physician or physician assistant licensed pursuant to Article 240 of this Title 12; or

(II) An advanced practice nurse, as defined in Section 12-255-104 (1), with prescriptive authority pursuant to Section 12-255-112.

(g) "Standing Order" means a prescription order written by a prescriber that is not specific to and does not identify a particular patient.
(2) A pharmacist may prescribe and dispense HIV infection prevention drugs in accordance with a standing order pursuant to section 25-1-130 or a statewide drug therapy protocol developed pursuant to subsection (5) of this section.

(3) Before prescribing or dispensing HIV infection prevention drugs to a patient, a pharmacist must:

(a) hold a current license to practice in Colorado;

(b) be engaged in the practice of pharmacy;

(c) have earned a doctorate of pharmacy degree or completed at least five years of experience as a licensed pharmacist;

(d) carry adequate professional liability insurance as determined by the board; and

(e) complete a training program accredited by the Accreditation Council for Pharmacy Education, or its successor entity, pursuant to the protocol developed by the board.

(4) The board shall promulgate rules necessary to implement this section, including rules that establish protocols for prescribing and dispensing preexposure prophylaxis and post-exposure prophylaxis.

(5) (a) on or before six months after the effective date of this section, the state board of pharmacy, the Colorado medical board, and the state board of nursing shall, in collaboration with the department of public health and environment, and as described in section 12-280-601 (1)(b), develop statewide drug therapy protocols for pharmacists to prescribe and dispense HIV infection prevention drugs.
(b) If the State Board of Pharmacy, the Colorado Medical Board, and the State Board of Nursing are not able to agree in the time period required by subsection (5)(a) of this section to state wide drug therapy protocols for pharmacists to prescribe and dispense HIV infection prevention drugs, the State Board of Pharmacy shall collaborate with the Department of Public Health and Environment to develop and implement state wide drug therapy protocols by January 1, 2021.

(c) In developing the state wide drug therapy protocols, the applicable boards and the Department of Public Health and Environment shall consider physician referrals; lab testing, including preexposure and post-exposure prescribing tests, and appropriate referrals pursuant to CDC guidelines; counseling pursuant to CDC guidelines; and patient follow-up care and counseling.

SECTION 6. In Colorado Revised Statutes, add 25-1-130 as follows:

25-1-130. Standing order - post-exposure prophylaxis - definition. (1) On or before August 1, 2020, and until a state wide drug therapy protocol is implemented pursuant to section 12-280-125.7, the Department shall implement and maintain a standing order for post-exposure prophylaxis so that pharmacists may prescribe and dispense post-exposure prophylaxis pursuant to section 12-280-125.7.

(2) As used in this section "post-exposure prophylaxis" has the same meaning as set forth in section 12-280-125.7.

SECTION 7. Appropriation. For the 2020-21 state fiscal year,
$13,347 is appropriated to the department of regulatory agencies for use by the division of insurance. This appropriation is from the division of insurance cash fund created in section 10-1-103 (3), C.R.S., and is based on an assumption that the division will require an additional 0.2 FTE. To implement this act, the division may use this appropriation for personal services.

**SECTION 8. 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.