

CHAPTER 162

INSURANCE

HOUSE BILL 23-1225

BY REPRESENTATIVE(S) deGruy Kennedy and Dickson, Amabile, Bacon, Bird, Brown, Duran, English, Epps, Froelich, Garcia, Gonzales-Gutierrez, Hamrick, Herod, Jodeh, Joseph, Kipp, Lieder, Lindsay, Lindstedt, Lukens, Mabrey, Mauro, McCormick, McLachlan, Michaelson Jenet, Ortiz, Ricks, Sharbini, Sirota, Snyder, Story, Titone, Velasco, Vigil, Weissman, Woodrow, Young, McCluskie;
also SENATOR(S) Jaquez Lewis and Buckner, Coleman, Cutter, Priola.

AN ACT

CONCERNING THE PRESCRIPTION DRUG AFFORDABILITY BOARD, AND, IN CONNECTION THEREWITH, MODIFYING THE AFFORDABILITY REVIEW PROCESS, ALLOWING THE BOARD TO ESTABLISH UPPER PAYMENT LIMITS FOR AN ADDITIONAL NUMBER OF PRESCRIPTION DRUGS, CLARIFYING WHICH BOARD FUNCTIONS ARE SUBJECT TO JUDICIAL REVIEW, AUTHORIZING AN INDIVIDUAL TO REQUEST AN INDEPENDENT EXTERNAL REVIEW OF A DENIAL OF A REQUEST FOR BENEFITS FOR A PRESCRIPTION DRUG THAT HAS BEEN WITHDRAWN FROM SALE OR DISTRIBUTION IN THE STATE, AND EXTENDING THE REPEAL DATE OF THE BOARD.

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

SECTION 1. In Colorado Revised Statutes, 10-16-1401, **add** (7.5) as follows:

10-16-1401. Definitions. As used in this part 14, unless the context otherwise requires:

(7.5) "BOARD ACTIVITY" MEANS:

(a) SELECTING PRESCRIPTION DRUGS FOR AN AFFORDABILITY REVIEW PURSUANT TO SECTION 10-16-1406 (2);

(b) DETERMINING WHETHER A PRESCRIPTION DRUG IS UNAFFORDABLE PURSUANT TO SECTION 10-16-1406 (3);

(c) SELECTING PRESCRIPTION DRUGS FOR WHICH THE BOARD ESTABLISHES AN UPPER PAYMENT LIMIT PURSUANT TO SECTION 10-16-1407; AND

Capital letters or bold & italic numbers indicate new material added to existing law; dashes through words or numbers indicate deletions from existing law and such material is not part of the act.

(d) ESTABLISHING AN UPPER PAYMENT LIMIT FOR A PRESCRIPTION DRUG PURSUANT TO SECTION 10-16-1407.

SECTION 2. In Colorado Revised Statutes, 10-16-1402, **amend** (3)(c) as follows:

10-16-1402. Colorado prescription drug affordability review board - created - membership - terms - conflicts of interest. (3) (c) (I) Board members ~~staff members, and contractors of the division, on behalf of the board,~~ shall recuse themselves from any board activity OR VOTE in any case in which they have a conflict of interest.

(II) STAFF MEMBERS AND CONTRACTORS OF THE DIVISION, ON BEHALF OF THE BOARD, SHALL DISCLOSE ANY CONFLICT OF INTEREST RELATED TO A PRESCRIPTION DRUG FOR WHICH THE BOARD IS CONDUCTING AN AFFORDABILITY REVIEW OR ESTABLISHING AN UPPER PAYMENT LIMIT.

(III) NOTWITHSTANDING SUBSECTION (3)(d) OF THIS SECTION AND THE REPORTING REQUIREMENTS SET FORTH IN SECTION 10-16-1414 (1)(f), A CONFLICT OF INTEREST DISCLOSED BY A STAFF MEMBER OR BY A CONTRACTOR OF THE DIVISION, WHICH DISCLOSURE PERTAINS TO A PERSONAL ASSOCIATION, MUST REMAIN CONFIDENTIAL. THE BOARD, UPON REVIEW OF SUCH A DISCLOSURE, MAY DIRECT THE STAFF MEMBER OR CONTRACTOR TO RECUSE THEMSELVES BASED ON THE CONFLICT OF INTEREST.

SECTION 3. In Colorado Revised Statutes, 10-16-1404, **amend** (1) as follows:

10-16-1404. Colorado prescription drug affordability review board meetings - required to be public - exceptions. (1) The board shall hold its first meeting within six weeks after all of the board members are appointed and shall meet at least every six weeks thereafter to review prescription drugs; except that the chair may cancel or postpone a meeting if the board has no prescription drugs to review OR FOR GOOD CAUSE.

SECTION 4. In Colorado Revised Statutes, 10-16-1406, **amend** (1) introductory portion, (1)(a), (1)(b), and (2) introductory portion; **repeal** (1)(c); and **add** (8) as follows:

10-16-1406. Colorado prescription drug affordability review board - affordability reviews of prescription drugs. (1) The board may conduct affordability reviews of prescription drugs in accordance with this section. The board shall identify, for purposes of determining whether to conduct an affordability review: ~~any prescription drug that is:~~

(a) ~~A brand-name drug or biological product that, as adjusted annually for inflation, has~~ ANY PRESCRIPTION DRUG THAT HAS:

(I) ~~An initial~~ A wholesale acquisition cost of ~~thirty~~ THREE thousand dollars or more; ~~for a twelve-month supply or for a course of treatment that is less than twelve months in duration; or~~

(I.5) AN INCREASE OF THREE HUNDRED DOLLARS OR MORE ABOVE THE

WHOLESALE ACQUISITION COST FOR THE PRESCRIPTION DRUG IN THE PRECEDING TWELVE MONTHS;

~~(II) An increase in the wholesale acquisition cost of ten percent or more during AN INCREASE OF TWO HUNDRED PERCENT OR MORE ABOVE THE WHOLESALE ACQUISITION COST FOR THE PRESCRIPTION DRUG IN THE immediately preceding twelve months; for a twelve-month supply or for a course of treatment that is less than twelve months in duration; OR~~

~~(III) A CURRENT WHOLESALE ACQUISITION COST FOR AN AVERAGE COURSE OF TREATMENT PER PERSON PER YEAR OF THIRTY THOUSAND DOLLARS OR MORE; AND~~

~~(b) ANY biosimilar drug that has an initial wholesale acquisition cost that is not at least fifteen percent lower than THE WHOLESALE ACQUISITION COST OF the corresponding biological product. or~~

~~(c) A generic drug:~~

~~(i) That, as adjusted annually for inflation, has a wholesale acquisition cost of one hundred dollars or more for:~~

~~(A) A thirty-day supply based on the recommended dosage approved for labeling by the FDA;~~

~~(B) A supply that lasts less than thirty days based on the recommended dosage approved for labeling by the FDA; or~~

~~(C) One dose of the generic drug if the labeling approved by the FDA does not recommend a finite dosage; and~~

~~(H) For which the wholesale acquisition cost increased by two hundred percent or more during the immediately preceding twelve months, as determined by comparing the current wholesale acquisition cost to the average wholesale acquisition cost reported during the immediately preceding twelve months.~~

(2) After identifying prescription drugs as described in subsection (1) of this section, the board shall determine whether to conduct an affordability review for each AN identified prescription drug by:

(8) THE BOARD SHALL ISSUE A REPORT SUMMARIZING, TO THE EXTENT PERMITTED BY SECTION 10-16-1404 (3), THE DATA THAT THE BOARD CONSIDERED IN MAKING THE BOARD'S DETERMINATION AS TO WHETHER A PRESCRIPTION DRUG IS UNAFFORDABLE. THE BOARD SHALL MAKE THE REPORT AVAILABLE ON ITS PUBLIC WEB PAGE.

SECTION 5. In Colorado Revised Statutes, 10-16-1407, **amend** (1) and (5) as follows:

10-16-1407. Colorado prescription drug affordability review board - upper payment limits for certain prescription drugs - rules - severability. (1) (a) The board may establish an upper payment limit for any prescription drug for which the

board has performed an affordability review pursuant to section 10-16-1406 and determined that the use of the prescription drug is unaffordable for Colorado consumers; except that:

(I) The board may not establish an upper payment limit for more than twelve prescription drugs in each calendar year for three years beginning April 1, 2022, UNLESS THE BOARD DETERMINES THAT THERE IS A NEED TO ESTABLISH UPPER PAYMENT LIMITS FOR MORE THAN TWELVE PRESCRIPTION DRUGS, IN WHICH CASE THE BOARD MAY ESTABLISH AN UPPER PAYMENT LIMIT FOR UP TO EIGHTEEN PRESCRIPTION DRUGS SO LONG AS THE BOARD HAS SUFFICIENT STAFF SUPPORT TO DO SO; AND

(II) FOR EACH PRESCRIPTION DRUG FOR WHICH THE BOARD ESTABLISHES AN UPPER PAYMENT LIMIT, THE BOARD MAY INCLUDE MULTIPLE NATIONAL DRUG CODES, AS DESCRIBED IN 21 CFR 207.33, THAT ARE INDICATED FOR THE PRESCRIPTION DRUG.

(b) The failure of an entity to provide information to the board pursuant to section 10-16-1406 (7)(b) does not affect the authority of the board to establish an upper payment limit for ~~the~~ A prescription drug.

(5) An upper payment limit applies to all purchases of and payer reimbursements for a prescription drug that is dispensed or administered to individuals in the state in person, by mail, or by other means and for which an upper payment limit is established. The board shall promulgate rules that establish UPPER PAYMENT LIMITS AND the effective date of any upper payment limit established by the board, which effective date is at least six months after the adoption of the upper payment limit by the board and applies only to purchases, contracts, and plans that are issued on or renewed after the effective date.

SECTION 6. In Colorado Revised Statutes, 10-16-1408, **amend** (1) and (2); and **repeal** (3) as follows:

10-16-1408. Colorado prescription drug affordability review board - judicial review. ~~(1) A person aggrieved by a decision of the board may appeal the decision within sixty days after the decision is made. The board shall consider the appeal and issue a final decision concerning the appeal within sixty days after the board receives the appeal.~~ THE FOLLOWING BOARD FUNCTIONS ARE NOT FINAL AGENCY ACTIONS SUBJECT TO JUDICIAL REVIEW UNDER THE "STATE ADMINISTRATIVE PROCEDURE ACT", ARTICLE 4 OF TITLE 24:

(a) IDENTIFICATION OF ELIGIBLE PRESCRIPTION DRUGS PURSUANT TO SECTION 10-16-1406 (1);

(b) SELECTION OF A PRESCRIPTION DRUG PURSUANT TO SECTION 10-16-1406 (2);
AND

(c) DETERMINATION THAT A PRESCRIPTION DRUG IS UNAFFORDABLE PURSUANT TO SECTION 10-16-1406 (3).

~~(2) Not later than March 31, 2022, the board shall promulgate rules establishing a process and timeline for the consideration by the board of any appeal that is~~

~~submitted to the board pursuant to subsection (1) of this section. The process and timeline must comport with the "State Administrative Procedure Act", article 4 of title 24. A RULE OF THE BOARD ESTABLISHING AN UPPER PAYMENT LIMIT IS A FINAL AGENCY ACTION SUBJECT TO JUDICIAL REVIEW UNDER THE "STATE ADMINISTRATIVE PROCEDURE ACT", ARTICLE 4 OF TITLE 24. A PARTY SEEKING JUDICIAL REVIEW OF A RULE ESTABLISHING AN UPPER PAYMENT LIMIT MAY SEEK REVIEW OF WHETHER THE PRESCRIPTION DRUG SATISFIES THE NECESSARY CRITERIA IN SECTION 10-16-1406 TO BE ELIGIBLE FOR AN UPPER PAYMENT LIMIT.~~

~~(3) In the absence of an appeal, a decision of the board becomes final and ripe for judicial review after sixty days. Any person aggrieved by a final decision of the board may petition for judicial review pursuant to section 24-4-106.~~

SECTION 7. In Colorado Revised Statutes, 10-16-1414, **amend** (1) introductory portion, (1)(b), and (1)(e) as follows:

10-16-1414. Reports. (1) Notwithstanding section 24-1-136 (11)(a), on or before July 1, 2023, and on or before July 1 each year thereafter, the board shall submit a report to the governor, the health and insurance committee of the house of representatives, and the health and human services committee of the senate, or to any successor committees, summarizing the ~~activities~~ WORK of the board during the preceding calendar year. At a minimum, the report must include:

(b) The number of prescription drugs that were subjected to an affordability review by the board pursuant to section 10-16-1406, including the results of each affordability review; ~~and the number and disposition of any appeals or judicial reviews of the board's decisions;~~

(e) A summary of any ~~appeals~~ JUDICIAL REVIEWS of board decisions, ~~that were considered by the board pursuant to section 10-16-1408;~~ including an indication of the outcome of any ~~such appeal~~ JUDICIAL REVIEW;

SECTION 8. In Colorado Revised Statutes, **amend** 10-16-1416 as follows:

10-16-1416. Repeal of part. This part 14 is repealed, effective ~~September 1, 2026~~ SEPTEMBER 1, 2031. Before the repeal, the functions of the board are scheduled for review in accordance with section 24-34-104.

SECTION 9. In Colorado Revised Statutes, 24-34-104, **repeal** (27)(a)(XIX); and **add** (32)(a)(X) as follows:

24-34-104. General assembly review of regulatory agencies and functions for repeal, continuation, or reestablishment - legislative declaration - repeal. (27) (a) The following agencies, functions, or both, are scheduled for repeal on September 1, 2026:

(XIX) ~~The Colorado prescription drug affordability review board created in section 10-16-1402.~~

(32) (a) The following agencies, functions, or both, are scheduled for repeal on September 1, 2031:

(X) THE COLORADO PRESCRIPTION DRUG AFFORDABILITY REVIEW BOARD CREATED IN SECTION 10-16-1402.

SECTION 10. In Colorado Revised Statutes, 10-16-113.5, **amend** (2)(a)(III) and (2)(a)(IV); and **add** (2)(a)(V) as follows:

10-16-113.5. Independent external review of adverse determinations - legislative declaration - definitions - rules. (2) As used in this section, unless the context otherwise requires:

(a) "Adverse determination" means a denial of:

(III) A request for benefits on the grounds that the treatment or services are experimental or investigational; ~~or~~

(IV) A benefit as described in section 10-16-113 (1)(c); OR

(V) A REQUEST FOR BENEFITS FOR A PRESCRIPTION DRUG THAT IS UNAVAILABLE IN THE STATE BECAUSE A MANUFACTURER HAS WITHDRAWN THE PRESCRIPTION DRUG FROM SALE OR DISTRIBUTION WITHIN THE STATE UNDER SECTION 10-16-1412.

SECTION 11. Act subject to petition - effective date. Section 4 of this act takes effect January 1, 2025, and the remainder of this act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly; except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part will not take effect unless approved by the people at the general election to be held in November 2024 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor; except that section 4 of this act takes effect January 1, 2026.

Approved: May 10, 2023