

CHAPTER 437

PROFESSIONS AND OCCUPATIONS

HOUSE BILL 21-1307

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also SENATOR(S) Donovan and Jaquez Lewis, Bridges, Danielson, Gonzales, Kolker, Pettersen, Story, Garcia.

AN ACT**CONCERNING MEASURES TO INCREASE ACCESS TO PRESCRIPTION INSULIN FOR PERSONS WITH DIABETES.**

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

SECTION 1. Legislative declaration. (1) The general assembly hereby finds and declares that:

(a) Approximately 300,000 Coloradans live with type 1 or type 2 diabetes, with as many as 110,000 additional undiagnosed diabetes patients. Around 73,800 Coloradans rely on insulin to manage their diabetes.

(b) Access to this critical life-saving drug is cost-prohibitive for many Coloradans, as the average dosage unit cost of all insulin types increased roughly 280% between 2010 and 2018;

(c) The inability to afford insulin has resulted in individuals attempting to ration or underdose their insulin supply. In one study of 354 eligible patients at the Yale Diabetes Center in Connecticut, 25.5% of patients reported cost-related insulin underuse.

(d) Rationing or underdosing insulin is dangerous for a person with diabetes and can result in the deadly condition of diabetic ketoacidosis;

(e) It is necessary to protect the public health, safety, and welfare of Colorado citizens by providing affordable and emergency life-sustaining insulin to those who

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.

need it; and

(f) This act does not require the state to physically appropriate insulin for its own use; rather, this act governs the reimbursement of insulin provided through the programs created in this act.

SECTION 2. In Colorado Revised Statutes, 10-16-151, **amend** (2) as follows:

10-16-151. Cost sharing in prescription insulin drugs - limits - definition - rules. (2) A carrier that provides coverage for prescription insulin drugs pursuant to the terms of a health coverage plan the carrier offers shall cap the total amount that a covered person is required to pay for ~~a~~ ALL covered prescription insulin ~~drug~~ DRUGS at an amount not to exceed one hundred dollars ~~per~~ FOR THE COVERED PERSON'S ENTIRE thirty-day supply of insulin, regardless of the amount or type of insulin needed to fill the covered person's prescription OR THE NUMBER OF PRESCRIPTIONS.

SECTION 3. In Colorado Revised Statutes, **add** 12-280-139 and 12-280-140 as follows:

12-280-139. Insulin affordability program - record keeping - reimbursement - definitions. (1) AS USED IN THIS SECTION AND SECTION 12-280-140, UNLESS THE CONTEXT OTHERWISE REQUIRES:

(a) "CONSUMER PRICE INDEX" MEANS THE UNITED STATES DEPARTMENT OF LABOR'S BUREAU OF LABOR STATISTICS CONSUMER PRICE INDEX FOR DENVER-AURORA-LAKEWOOD FOR ALL ITEMS PAID BY ALL URBAN CONSUMERS, OR ITS APPLICABLE PREDECESSOR OR SUCCESSOR INDEX.

(b) "DIVISION OF INSURANCE" MEANS THE DIVISION OF INSURANCE IN THE DEPARTMENT OF REGULATORY AGENCIES, CREATED IN SECTION 10-1-103.

(c) "MANUFACTURER" MEANS A PERSON:

(I) ENGAGED IN THE MANUFACTURING OF INSULIN THAT IS SELF-ADMINISTERED ON AN OUTPATIENT BASIS AND IS AVAILABLE FOR PURCHASE BY RESIDENTS OF THIS STATE; AND

(II) THAT HAS ANNUAL GROSS REVENUE OF MORE THAN TWO MILLION DOLLARS FROM THE SALE OF INSULIN IN THIS STATE.

(d) "PHARMACY" MEANS A PHARMACY OUTLET REGISTERED PURSUANT TO THIS ARTICLE 280 WHERE PRESCRIPTIONS ARE COMPOUNDED AND DISPENSED.

(e) "PROGRAM" MEANS THE INSULIN AFFORDABILITY PROGRAM CREATED IN SUBSECTION (2) OF THIS SECTION.

(f) (I) "WHOLESALE ACQUISITION COST" MEANS A MANUFACTURER'S LIST PRICE FOR INSULIN TO WHOLESALERS OR DIRECT PURCHASERS IN THE UNITED STATES FOR THE MOST RECENT MONTH FOR WHICH THE INFORMATION IS REPORTED IN WHOLESALE PRICE GUIDES OR OTHER PUBLICATIONS OF DRUG OR BIOLOGICAL

PRICING DATA.

(II) "WHOLESALE ACQUISITION COST" DOES NOT INCLUDE PROMPT PAY OR OTHER DISCOUNTS, REBATES, OR REDUCTIONS IN PRICE.

(2) EFFECTIVE JANUARY 1, 2022, THE INSULIN AFFORDABILITY PROGRAM IS HEREBY CREATED TO PROVIDE LOW-COST INSULIN TO ELIGIBLE INDIVIDUALS. BY JANUARY 1, 2022, EACH MANUFACTURER SHALL ESTABLISH PROCEDURES TO MAKE INSULIN AVAILABLE IN ACCORDANCE WITH THIS SECTION TO ELIGIBLE INDIVIDUALS WHO NEED ACCESS TO AN AFFORDABLE INSULIN SUPPLY.

(3) TO BE ELIGIBLE TO RECEIVE INSULIN UNDER THE PROGRAM, AN INDIVIDUAL MUST:

(a) BE A RESIDENT OF COLORADO;

(b) NOT BE ELIGIBLE FOR OR ENROLLED IN ASSISTANCE PROVIDED THROUGH THE "COLORADO MEDICAL ASSISTANCE ACT", ARTICLES 4 TO 6 OF TITLE 25.5, OR THE FEDERAL "HEALTH INSURANCE FOR THE AGED ACT", TITLE XVIII OF THE FEDERAL "SOCIAL SECURITY ACT", 42 U.S.C. SEC. 1395 ET SEQ., AS AMENDED;

(c) HAVE A VALID INSULIN PRESCRIPTION OR BE ELIGIBLE FOR AN EMERGENCY SUPPLY AS PROVIDED IN SECTION 12-280-125.5; AND

(d) NOT BE ENROLLED IN PRESCRIPTION DRUG COVERAGE THAT LIMITS THE TOTAL AMOUNT OF COST SHARING THAT THE ENROLLEE IS REQUIRED TO PAY FOR A THIRTY-DAY SUPPLY OF INSULIN TO ONE HUNDRED DOLLARS AS DESCRIBED IN SECTION 10-16-151.

(4) (a) THE DIVISION OF INSURANCE SHALL DEVELOP AN APPLICATION FORM TO BE USED BY AN INDIVIDUAL WHO IS SEEKING INSULIN UNDER THE PROGRAM. THE APPLICATION FORM MUST REQUIRE THE INDIVIDUAL TO SHOW PROOF THAT THE INDIVIDUAL MEETS THE REQUIREMENTS OF SUBSECTION (3) OF THIS SECTION.

(b) THE DIVISION OF INSURANCE AND THE DEPARTMENT OF HEALTH CARE POLICY AND FINANCING SHALL MAKE THE APPLICATION FORM AVAILABLE ON EACH AGENCY'S WEBSITE. THE DIVISION OF INSURANCE SHALL ALSO MAKE THE APPLICATION FORM AVAILABLE TO PHARMACIES, HEALTH-CARE PROVIDERS, AND HEALTH FACILITIES THAT PRESCRIBE OR DISPENSE INSULIN.

(5) TO ACCESS INSULIN THROUGH THE PROGRAM, AN INDIVIDUAL MUST PRESENT, AT A PHARMACY, A COMPLETED, SIGNED, AND DATED APPLICATION FORM WITH PROOF OF THE INDIVIDUAL'S COLORADO RESIDENCY. IF THE INDIVIDUAL IS UNDER EIGHTEEN YEARS OF AGE, THE INDIVIDUAL'S PARENT OR LEGAL GUARDIAN MAY PROVIDE THE PHARMACIST WITH PROOF OF RESIDENCY.

(6) (a) UPON RECEIPT OF AN INDIVIDUAL'S COMPLETED, SIGNED, AND DATED APPLICATION FORM DEMONSTRATING THAT THE INDIVIDUAL IS ELIGIBLE PURSUANT TO SUBSECTION (3) OF THIS SECTION AND THE INDIVIDUAL'S PROOF OF RESIDENCY, A PHARMACIST SHALL DISPENSE THE PRESCRIBED INSULIN IN AN AMOUNT THAT WILL PROVIDE THE INDIVIDUAL WITH A THIRTY-DAY SUPPLY. AN INDIVIDUAL WHO IS

ELIGIBLE TO RECEIVE INSULIN PURSUANT TO THIS SECTION MAY RECEIVE THE INSULIN FOR TWELVE MONTHS.

(b) THE PHARMACIST IS ENCOURAGED TO INFORM THE INDIVIDUAL THAT THEY MAY BE ELIGIBLE FOR THE "COLORADO MEDICAL ASSISTANCE ACT", ARTICLES 4 TO 6 OF TITLE 25.5, OR AN AFFORDABLE INSURANCE PRODUCT ON THE STATE-BASED MARKETPLACE.

(c) THE PHARMACIST IS ENCOURAGED TO NOTIFY THE INDIVIDUAL OF ANY MANUFACTURER-SPONSORED PROGRAMS THAT ASSIST INDIVIDUALS WHO CANNOT AFFORD THEIR PRESCRIPTION INSULIN.

(d) THE PHARMACIST SHALL RETAIN A COPY OF THE APPLICATION FORM SUBMITTED BY THE INDIVIDUAL FOR TWO YEARS AFTER THE DATE THE INSULIN WAS INITIALLY DISPENSED.

(7) A PHARMACY THAT DISPENSES INSULIN PURSUANT TO SUBSECTION (6)(a) OF THIS SECTION MAY COLLECT A COPAYMENT FROM THE INDIVIDUAL TO COVER THE PHARMACY'S COSTS OF PROCESSING AND DISPENSING THE INSULIN IN AN AMOUNT NOT TO EXCEED FIFTY DOLLARS FOR EACH THIRTY-DAY SUPPLY OF INSULIN DISPENSED.

(8)(a) EXCEPT AS PROVIDED IN SUBSECTION (8)(d) OF THIS SECTION, UNLESS THE MANUFACTURER AGREES TO SEND TO THE PHARMACY A REPLACEMENT SUPPLY OF THE SAME INSULIN DISPENSED IN THE AMOUNT DISPENSED THROUGH THE PROGRAM, THE PHARMACY MAY SUBMIT TO THE MANUFACTURER OF THE DISPENSED INSULIN, DIRECTLY OR THROUGH THE MANUFACTURER'S DELEGATED REPRESENTATIVE, SUBCONTRACTOR, OR OTHER VENDOR, AN ELECTRONIC CLAIM FOR PAYMENT THAT IS MADE IN ACCORDANCE WITH THE NATIONAL COUNCIL FOR PRESCRIPTION DRUG PROGRAMS' STANDARDS FOR ELECTRONIC CLAIMS PROCESSING.

(b) BY JANUARY 1, 2022, EACH MANUFACTURER SHALL DEVELOP A PROCESS FOR A PHARMACY TO SUBMIT AN ELECTRONIC CLAIM FOR REIMBURSEMENT AS PROVIDED IN SUBSECTION (8)(a) OF THIS SECTION.

(c) IF THE PHARMACY SUBMITS AN ELECTRONIC CLAIM TO THE MANUFACTURER PURSUANT TO SUBSECTION (8)(a) OF THIS SECTION, THE MANUFACTURER OR THE MANUFACTURER'S DELEGATED REPRESENTATIVE, SUBCONTRACTOR, OR OTHER VENDOR SHALL, WITHIN THIRTY DAYS AFTER RECEIPT OF THE CLAIM, EITHER:

(I) REIMBURSE THE PHARMACY IN AN AMOUNT THAT COVERS THE DIFFERENCE BETWEEN THE PHARMACY'S WHOLESALE ACQUISITION COST FOR THE INSULIN DISPENSED THROUGH THE PROGRAM AND THE AMOUNT THE INDIVIDUAL PAID FOR THE INSULIN PURSUANT TO SUBSECTION (7) OF THIS SECTION; OR

(II) SEND THE PHARMACY A REPLACEMENT SUPPLY OF THE SAME INSULIN IN AN AMOUNT EQUAL TO OR GREATER THAN THE AMOUNT THAT COVERS THE DIFFERENCE BETWEEN THE PHARMACY'S WHOLESALE ACQUISITION COST FOR THE INSULIN DISPENSED THROUGH THE PROGRAM AND THE AMOUNT THE INDIVIDUAL PAID FOR THE INSULIN PURSUANT TO SUBSECTION (7) OF THIS SECTION.

(d) A PHARMACY SHALL NOT SUBMIT A CLAIM FOR PAYMENT FOR INSULIN WITH A WHOLESALE ACQUISITION COST OF EIGHT DOLLARS OR LESS PER MILLILITER, ADJUSTED ANNUALLY BASED ON THE ANNUAL PERCENTAGE CHANGE IN THE CONSUMER PRICE INDEX.

(9) THE DIVISION OF INSURANCE AND THE DEPARTMENT OF HEALTH CARE POLICY AND FINANCING SHALL PROMOTE THE AVAILABILITY OF THE PROGRAM TO COLORADANS. THE PROMOTIONAL MATERIAL MUST INCLUDE INFORMATION ABOUT EACH MANUFACTURER'S CONSUMER INSULIN PROGRAMS. EACH AGENCY MAY SEEK AND ACCEPT GIFTS, GRANTS, AND DONATIONS TO FULFILL THE REQUIREMENTS OF THIS SUBSECTION (9).

(10) A MANUFACTURER'S REIMBURSEMENT PURSUANT TO SUBSECTION (8)(b) OF THIS SECTION IS NOT A KICKBACK.

(11) A MANUFACTURER THAT FAILS TO COMPLY WITH THE REQUIREMENTS OF THIS SECTION IS SUBJECT TO A FINE OF TEN THOUSAND DOLLARS FOR EACH MONTH OF NONCOMPLIANCE.

12-280-140. Emergency prescription insulin supply - eligibility - record keeping - definition. (1) (a) EFFECTIVE JANUARY 1, 2022, AN INDIVIDUAL WHO MEETS THE REQUIREMENTS OF SUBSECTION (2) OF THIS SECTION MAY RECEIVE ONE EMERGENCY THIRTY-DAY SUPPLY OF PRESCRIPTION INSULIN WITHIN A TWELVE-MONTH PERIOD. THE PHARMACY MAY CHARGE THE INDIVIDUAL AN AMOUNT NOT TO EXCEED THIRTY-FIVE DOLLARS FOR THE THIRTY-DAY SUPPLY.

(b) BY JANUARY 1, 2022, EACH MANUFACTURER SHALL ESTABLISH PROCEDURES TO MAKE INSULIN AVAILABLE IN ACCORDANCE WITH THIS SECTION TO ELIGIBLE INDIVIDUALS WHO NEED ACCESS TO AN EMERGENCY PRESCRIPTION INSULIN SUPPLY.

(2) TO BE ELIGIBLE FOR AN EMERGENCY PRESCRIPTION INSULIN SUPPLY, AN INDIVIDUAL MUST:

(a) HAVE A VALID PRESCRIPTION FOR INSULIN OR BE ELIGIBLE FOR AN EMERGENCY SUPPLY AS PROVIDED IN SECTION 12-280-125.5;

(b) HAVE LESS THAN A SEVEN-DAY SUPPLY OF INSULIN AVAILABLE;

(c) BE REQUIRED TO PAY MORE THAN ONE HUNDRED DOLLARS OUT OF POCKET EACH MONTH FOR THE INDIVIDUAL'S INSULIN; AND

(d) BE A RESIDENT OF COLORADO.

(3)(a) THE DIVISION OF INSURANCE SHALL CREATE AND MAKE AVAILABLE TO THE PUBLIC AN APPLICATION FORM FOR INDIVIDUALS SEEKING AN EMERGENCY PRESCRIPTION INSULIN SUPPLY PURSUANT TO THIS SECTION.

(b) AT A MINIMUM, THE APPLICATION FORM MUST REQUIRE THE INDIVIDUAL TO SHOW PROOF THAT THE INDIVIDUAL MEETS THE REQUIREMENTS OF SUBSECTION (2) OF THIS SECTION.

(c) EACH PHARMACY IN THE STATE SHALL MAKE THE APPLICATION FORM AVAILABLE AT THE PHARMACY.

(4) (a) UPON RECEIPT OF AN INDIVIDUAL'S COMPLETED APPLICATION FORM DEMONSTRATING THAT THE INDIVIDUAL IS ELIGIBLE PURSUANT TO SUBSECTION (2) OF THIS SECTION AND THE INDIVIDUAL'S PROOF OF RESIDENCY, A PHARMACIST SHALL DISPENSE THE PRESCRIBED INSULIN IN AN AMOUNT THAT WILL PROVIDE THE INDIVIDUAL WITH A THIRTY-DAY SUPPLY.

(b) IF THE INDIVIDUAL IS UNDER EIGHTEEN YEARS OF AGE, THE INDIVIDUAL'S PARENT OR LEGAL GUARDIAN MAY PROVIDE THE PHARMACIST WITH PROOF OF RESIDENCY.

(5) EACH PHARMACY SHALL KEEP THE APPLICATION FORM FOR EACH INDIVIDUAL WHO RECEIVES AN EMERGENCY PRESCRIPTION INSULIN SUPPLY PURSUANT TO THIS SECTION FOR TWO YEARS FOLLOWING THE DATE ON WHICH THE INSULIN WAS DISPENSED.

(6) (a) EXCEPT AS PROVIDED IN SUBSECTION (6)(d) OF THIS SECTION, UNLESS THE MANUFACTURER AGREES TO SEND TO THE PHARMACY A REPLACEMENT SUPPLY OF THE SAME INSULIN DISPENSED IN THE AMOUNT DISPENSED THROUGH THE PROGRAM, THE PHARMACY MAY SUBMIT TO THE MANUFACTURER OF THE DISPENSED INSULIN, DIRECTLY OR THROUGH THE MANUFACTURER'S DELEGATED REPRESENTATIVE, SUBCONTRACTOR, OR OTHER VENDOR, AN ELECTRONIC CLAIM FOR PAYMENT THAT IS MADE IN ACCORDANCE WITH THE NATIONAL COUNCIL FOR PRESCRIPTION DRUG PROGRAMS' STANDARDS FOR ELECTRONIC CLAIMS PROCESSING.

(b) BY JANUARY 1, 2022, EACH MANUFACTURER SHALL DEVELOP A PROCESS FOR A PHARMACY TO SUBMIT AN ELECTRONIC CLAIM FOR REIMBURSEMENT AS PROVIDED IN SUBSECTION (6)(a) OF THIS SECTION.

(c) IF THE PHARMACY SUBMITS AN ELECTRONIC CLAIM TO THE MANUFACTURER PURSUANT TO SUBSECTION (6)(a) OF THIS SECTION, THE MANUFACTURER OR THE MANUFACTURER'S DELEGATED REPRESENTATIVE, SUBCONTRACTOR, OR OTHER VENDOR SHALL, WITHIN THIRTY DAYS AFTER RECEIPT OF THE CLAIM, EITHER:

(I) REIMBURSE THE PHARMACY IN AN AMOUNT THAT COVERS THE PHARMACY'S WHOLESALE ACQUISITION COST FOR THE INSULIN DISPENSED PURSUANT TO THIS SECTION; OR

(II) SEND THE PHARMACY A REPLACEMENT SUPPLY OF THE SAME INSULIN IN AN AMOUNT EQUAL TO OR GREATER THAN THE AMOUNT THAT COVERS THE PHARMACY'S WHOLESALE ACQUISITION COST FOR THE INSULIN DISPENSED PURSUANT TO THIS SECTION.

(d) A PHARMACY SHALL NOT SUBMIT A CLAIM FOR PAYMENT FOR INSULIN WITH A WHOLESALE ACQUISITION COST OF EIGHT DOLLARS OR LESS PER MILLILITER, ADJUSTED ANNUALLY BASED ON THE ANNUAL PERCENTAGE CHANGE IN THE CONSUMER PRICE INDEX.

(7) THE DIVISION OF INSURANCE AND THE DEPARTMENT OF HEALTH CARE POLICY

AND FINANCING SHALL PROMOTE THE AVAILABILITY OF THE EMERGENCY PRESCRIPTION INSULIN SUPPLY TO COLORADANS. THE PROMOTIONAL MATERIAL MUST INCLUDE INFORMATION ABOUT EACH MANUFACTURER'S CONSUMER INSULIN PROGRAMS. EACH AGENCY MAY SEEK AND ACCEPT GIFTS, GRANTS, AND DONATIONS TO FULFILL THE REQUIREMENTS OF THIS SUBSECTION (7).

(8) A MANUFACTURER'S REIMBURSEMENT PURSUANT TO SUBSECTION (6)(b) OF THIS SECTION IS NOT A KICKBACK.

(9) A MANUFACTURER THAT FAILS TO COMPLY WITH THE REQUIREMENTS OF THIS SECTION IS SUBJECT TO A FINE OF TEN THOUSAND DOLLARS FOR EACH MONTH OF NONCOMPLIANCE.

SECTION 4. Act subject to petition - effective date. 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 2022 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.

Approved: July 6, 2021