REFERENCE TITLE: essential drugs; price increases; limits

State of Arizona
House of Representatives
Fifty-seventh Legislature
First Regular Session
2025

HB 2757

Introduced by
Representatives Mathis: Cavero, Crews, De Los Santos, Gutierrez, Villegas

AN ACT

AMENDING TITLE 36, ARIZONA REVISED STATUTES, BY ADDING CHAPTER 42; RELATING TO PRESCRIPTION DRUGS.

(TEXT OF BILL BEGINS ON NEXT PAGE)

Be it enacted by the Legislature of the State of Arizona:

Section 1. Title 36, Arizona Revised Statutes, is amended by adding chapter 42, to read:

CHAPTER 42

PRESCRIPTION DRUGS

ARTICLE 1. PRICING

36-4201. Definitions

IN THIS ARTICLE, UNLESS THE CONTEXT OTHERWISE REQUIRES:

1. "ESSENTIAL OFF-PATENT OR GENERIC DRUG":

(a) MEANS ANY PRESCRIPTION DRUG THAT MEETS ALL OF THE FOLLOWING:

(i) ALL EXCLUSIVE MARKETING RIGHTS, IF ANY, GRANTED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, SECTION 351 OF THE FEDERAL PUBLIC HEALTH SERVICE ACT, AND FEDERAL PATENT LAW HAVE EXPIRED.

(ii) EITHER APPEARS ON THE MODEL LIST OF ESSENTIAL MEDICINES MOST RECENTLY ADOPTED BY THE WORLD HEALTH ORGANIZATION OR HAS BEEN DESIGNATED BY THE SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AS AN ESSENTIAL MEDICINE DUE TO ITS EFFICACY IN TREATING A LIFE-THREATENING HEALTH CONDITION OR A CHRONIC HEALTH CONDITION THAT SUBSTANTIALLY IMPAIRS AN INDIVIDUAL'S ABILITY TO ENGAGE IN ACTIVITIES OF DAILY LIVING.

(iii) IS ACTIVELY MANUFACTURED AND MARKETED FOR SALE IN THE UNITED STATES BY THREE OR FEWER MANUFACTURERS.

(iv) IS MADE AVAILABLE FOR SALE IN THIS STATE.

(b) INCLUDES ANY DRUG-DEVICE COMBINATION PRODUCT USED TO DELIVER A DRUG FOR WHICH ALL EXCLUSIVE MARKETING RIGHTS, IF ANY, GRANTED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, SECTION 351 OF THE FEDERAL PUBLIC HEALTH SERVICE ACT, AND FEDERAL PATENT LAW HAVE EXPIRED.

2. "PRICE GOUGING" MEANS AN UNCONSCIONABLE INCREASE IN THE PRICE OF A PRESCRIPTION DRUG.

3. "STATE MEDICAL ASSISTANCE PROGRAM" MEANS THE ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM ESTABLISHED BY CHAPTER 29 OF THIS TITLE.

4. "UNCONSCIONABLE INCREASE" MEANS AN INCREASE IN THE PRICE OF A PRESCRIPTION DRUG THAT BOTH:

(a) IS EXCESSIVE AND NOT JUSTIFIED BY THE COST OF PRODUCING THE DRUG OR THE COST OF APPROPRIATE EXPANSION OF ACCESS TO THE DRUG TO PROMOTE PUBLIC HEALTH.

(b) RESULTS IN CONSUMERS FOR WHOM THE DRUG HAS BEEN PRESCRIBED HAVING NO MEANINGFUL CHOICE ABOUT WHETHER TO PURCHASE THE DRUG AT AN EXCESSIVE PRICE BECAUSE OF THE IMPORTANCE OF THE DRUG TO THE CONSUMER'S HEALTH AND INSUFFICIENT COMPETITION IN THE MARKET FOR THE DRUG.

5. "WHOLESALE ACQUISITION COST" HAS THE SAME MEANING PRESCRIBED IN 42 UNITED STATES CODE SECTION 1395w-3a.

36-4202. Manufacturers; wholesale distributors; price gouging prohibited

A. A MANUFACTURER OR WHOLESALE DISTRIBUTOR MAY NOT ENGAGE IN PRICE GOUGING IN THE SALE OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG.

B. IT IS NOT A VIOLATION OF SUBSECTION A OF THIS SECTION FOR A WHOLESALE DISTRIBUTOR TO INCREASE THE PRICE OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG IF THE PRICE INCREASE IS DIRECTLY ATTRIBUTABLE TO ADDITIONAL COSTS FOR THE ESSENTIAL OFF-PATENT OR GENERIC DRUG IMPOSED ON THE WHOLESALE DISTRIBUTOR BY THE MANUFACTURER OF THE ESSENTIAL OFF-PATENT OR GENERIC DRUG.

36-4203. Attorney general; information required; enforcement actions; civil penalty; confidentiality

A. THE STATE MEDICAL ASSISTANCE PROGRAM MAY NOTIFY THE ATTORNEY GENERAL OF ANY INCREASE IN THE PRICE OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG IF BOTH OF THE FOLLOWING APPLY:

1. THE PRICE INCREASE, BY ITSELF OR IN COMBINATION WITH OTHER PRICE INCREASES, WOULD RESULT IN AN INCREASE OF AT LEAST FIFTY PERCENT IN EITHER:

(a) THE WHOLESALE ACQUISITION COST OF THE ESSENTIAL OFF-PATENT OR GENERIC DRUG WITHIN THE PRECEDING ONE-YEAR PERIOD.

(b) THE PRICE PAID BY THE STATE MEDICAL ASSISTANCE PROGRAM FOR THE ESSENTIAL OFF-PATENT OR GENERIC DRUG WITHIN THE PRECEDING ONE-YEAR PERIOD.

2. ONE OF THE FOLLOWING APPLIES:

(a) A THIRTY-DAY SUPPLY OF THE MAXIMUM RECOMMENDED DOSAGE OF THE ESSENTIAL OFF-PATENT OR GENERIC DRUG FOR ANY INDICATION, ACCORDING TO THE LABEL FOR THE ESSENTIAL OFF-PATENT OR GENERIC DRUG APPROVED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, WOULD COST MORE THAN $80 AT THE ESSENTIAL OFF-PATENT OR GENERIC DRUG'S WHOLESALE ACQUISITION COST.

(b) A FULL COURSE OF TREATMENT WITH THE ESSENTIAL OFF-PATENT OR GENERIC DRUG, ACCORDING TO THE LABEL FOR THE ESSENTIAL OFF-PATENT OR GENERIC DRUG APPROVED UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, WOULD COST MORE THAN $80 AT THE ESSENTIAL OFF-PATENT OR GENERIC DRUG'S WHOLESALE ACQUISITION COST.

(c) THE ESSENTIAL OFF-PATENT OR GENERIC DRUG IS MADE AVAILABLE TO CONSUMERS ONLY IN QUANTITIES THAT DO NOT CORRESPOND TO A THIRTY-DAY SUPPLY, A FULL COURSE OF TREATMENT OR A SINGLE DOSE AND WOULD COST MORE THAN $80 AT THE ESSENTIAL OFF-PATENT OR GENERIC DRUG'S WHOLESALE ACQUISITION COST TO OBTAIN A THIRTY-DAY SUPPLY OR A FULL COURSE OF TREATMENT.

B. ON REQUEST OF THE ATTORNEY GENERAL, THE MANUFACTURER OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG IDENTIFIED IN A NOTICE UNDER SUBSECTION A OF THIS SECTION, WITHIN FORTY-FIVE DAYS AFTER THE REQUEST, SHALL SUBMIT A STATEMENT TO THE ATTORNEY GENERAL THAT DOES ALL OF THE FOLLOWING:

1. ITEMIZES THE COMPONENTS OF THE COST OF PRODUCING THE ESSENTIAL OFF-PATENT OR GENERIC DRUG AND IDENTIFIES THE CIRCUMSTANCES AND TIMING OF ANY INCREASE IN MATERIALS OR MANUFACTURING COSTS THAT CAUSED ANY INCREASE IN THE PRICE OF THE ESSENTIAL OFF-PATENT OR GENERIC DRUG WITHIN THE ONE-YEAR PERIOD PRECEDING THE DATE OF THE PRICE INCREASE.

2. IDENTIFIES THE CIRCUMSTANCES AND TIMING OF ANY EXPENDITURES MADE BY THE MANUFACTURER TO EXPAND ACCESS TO THE ESSENTIAL OFF-PATENT OR GENERIC DRUG AND EXPLAINS ANY IMPROVEMENT IN PUBLIC HEALTH ASSOCIATED WITH THOSE EXPENDITURES.

3. PROVIDES ANY OTHER INFORMATION THAT THE MANUFACTURER BELIEVES TO BE RELEVANT TO DETERMINING WHETHER A VIOLATION OF THIS ARTICLE HAS OCCURRED.

C. THE ATTORNEY GENERAL MAY REQUIRE A MANUFACTURER OR A WHOLESALE DISTRIBUTOR OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG TO PRODUCE ANY RECORDS OR OTHER DOCUMENTS THAT MAY BE RELEVANT TO A DETERMINATION OF WHETHER A VIOLATION OF THIS ARTICLE HAS OCCURRED.

D. ON PETITION OF THE ATTORNEY GENERAL AND SUBJECT TO SUBSECTION E OF THIS SECTION, A SUPERIOR COURT MAY ISSUE AN ORDER:

1. COMPELLING A MANUFACTURER OR A WHOLESALE DISTRIBUTOR OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG TO PROVIDE THE STATEMENT REQUIRED UNDER SUBSECTION B OF THIS SECTION AND TO PRODUCE SPECIFIC RECORDS OR OTHER DOCUMENTS REQUESTED BY THE ATTORNEY GENERAL UNDER SUBSECTION C OF THIS SECTION THAT MAY BE RELEVANT TO DETERMINING WHETHER A VIOLATION OF THIS ARTICLE HAS OCCURRED.

2. RESTRAINING OR ENJOINING A VIOLATION OF THIS ARTICLE.

3. RESTORING TO ANY CONSUMER, INCLUDING A THIRD-PARTY PAYOR, ANY MONIES ACQUIRED AS A RESULT OF A PRICE INCREASE THAT VIOLATES THIS ARTICLE.

4. REQUIRING A MANUFACTURER THAT HAS ENGAGED IN PRICE GOUGING IN THE SALE OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG TO MAKE THE ESSENTIAL OFF-PATENT OR GENERIC DRUG AVAILABLE TO PARTICIPANTS IN THE STATE MEDICAL ASSISTANCE PROGRAM FOR A PERIOD OF UP TO ONE YEAR AT THE PRICE AT WHICH THE ESSENTIAL OFF-PATENT OR GENERIC DRUG WAS MADE AVAILABLE TO PARTICIPANTS IMMEDIATELY BEFORE THE MANUFACTURER'S VIOLATION OF THIS ARTICLE.

5. IMPOSING A CIVIL PENALTY OF UP TO $10,000 FOR EACH VIOLATION OF THIS ARTICLE.

E. THE ATTORNEY GENERAL MAY NOT BRING AN ACTION FOR A REMEDY UNDER SUBSECTION D, PARAGRAPH 2, 3, 4 OR 5 OF THIS SECTION UNLESS THE ATTORNEY GENERAL HAS PROVIDED THE MANUFACTURER OR WHOLESALE DISTRIBUTOR OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG WITH AN OPPORTUNITY TO MEET WITH THE ATTORNEY GENERAL TO OFFER A JUSTIFICATION FOR THE INCREASE IN THE PRICE OF THE ESSENTIAL OFF-PATENT OR GENERIC DRUG.

F. ANY INFORMATION PROVIDED BY A MANUFACTURER OR A WHOLESALE DISTRIBUTOR OF AN ESSENTIAL OFF-PATENT OR GENERIC DRUG TO THE ATTORNEY GENERAL UNDER SUBSECTIONS B AND C OF THIS SECTION IS CONSIDERED CONFIDENTIAL COMMERCIAL INFORMATION UNLESS THE CONFIDENTIALITY OF THE INFORMATION IS WAIVED BY THE MANUFACTURER OR WHOLESALE DISTRIBUTOR.

G. IN ANY ACTION BROUGHT BY THE ATTORNEY GENERAL UNDER SUBSECTION D OF THIS SECTION, A PERSON WHO IS ALLEGED TO HAVE VIOLATED A REQUIREMENT OF THIS ARTICLE MAY NOT ASSERT AS A DEFENSE THAT THE PERSON DID NOT DEAL DIRECTLY WITH A CONSUMER RESIDING IN THIS STATE.