

REFERENCE TITLE: essential drugs; price increases; limits

State of Arizona
House of Representatives
Fifty-sixth Legislature
Second Regular Session
2024

HB 2558

Introduced by

Representatives Schwiebert: Aguilar, Crews, De Los Santos, Gutierrez,
Hernandez A, Hernandez L, Longdon, Mathis, Ortiz, Peshlakai, Quiñonez,
Sandoval, Seaman, Stahl Hamilton, Terech, Villegas; Senators Hatathlie,
Sundareshan

AN ACT

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

(TEXT OF BILL BEGINS ON NEXT PAGE)

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

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

4 CHAPTER 42

5 PRESCRIPTION DRUGS

6 ARTICLE 1. GENERAL PROVISIONS

7 36-4201. Definitions

8 IN THIS ARTICLE, UNLESS THE CONTEXT OTHERWISE REQUIRES:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 2. RESTRAINING OR ENJOINING A VIOLATION OF THIS ARTICLE.

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

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

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

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

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

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