

REFERENCE TITLE: prescription drugs; importation program

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

HB 2659

Introduced by
Representatives Shah: Biasiucci, Carbone, Pingerelli; Senators Shamp,
Shope

AN ACT

AMENDING TITLE 36, ARIZONA REVISED STATUTES, BY ADDING CHAPTER 33;
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 33, to read:

4 CHAPTER 33

5 WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM

6 ARTICLE 1. GENERAL PROVISIONS

7 36-3301. Definitions

8 IN THIS ARTICLE, UNLESS THE CONTEXT OTHERWISE REQUIRES:

9 1. "DEPARTMENT" MEANS THE DEPARTMENT OF HEALTH SERVICES.

10 2. "PROGRAM" MEANS THE WHOLESALE PRESCRIPTION DRUG IMPORTATION
11 PROGRAM.

12 3. "340B COVERED ENTITY" AND "340B DRUG PRICING PROGRAM" HAVE THE
13 SAME MEANINGS PRESCRIBED IN SECTION 36-2930.03.

14 36-3302. Importation of prescription drugs; program design;
15 funding design; submittal

16 A. THE DEPARTMENT, IN CONSULTATION WITH INTERESTED STAKEHOLDERS AND
17 APPROPRIATE FEDERAL OFFICIALS, SHALL DESIGN A WHOLESALE PRESCRIPTION DRUG
18 IMPORTATION PROGRAM THAT COMPLIES WITH THE APPLICABLE REQUIREMENTS OF
19 21 UNITED STATES CODE SECTION 384, INCLUDING THE REQUIREMENTS REGARDING
20 SAFETY AND COST SAVINGS. THE PROGRAM DESIGN SHALL:

21 1. REQUIRE THE DEPARTMENT TO EITHER BECOME A LICENSED DRUG
22 WHOLESALER OR CONTRACT WITH A LICENSED DRUG WHOLESALER IN ORDER TO SEEK
23 FEDERAL CERTIFICATION AND APPROVAL TO IMPORT SAFE PRESCRIPTION DRUGS AND
24 PROVIDE SIGNIFICANT PRESCRIPTION DRUG COST SAVINGS TO CONSUMERS.

25 2. USE CANADIAN PRESCRIPTION DRUG SUPPLIERS THAT ARE REGULATED
26 UNDER THE LAWS OF CANADA OR ONE OR MORE CANADIAN PROVINCES, OR BOTH.

27 3. ENSURE THAT ONLY PRESCRIPTION DRUGS MEETING THE UNITED STATES
28 FOOD AND DRUG ADMINISTRATION'S SAFETY, EFFECTIVENESS AND OTHER STANDARDS
29 ARE IMPORTED BY OR ON BEHALF OF THIS STATE.

30 4. IMPORT ONLY THOSE PRESCRIPTION DRUGS THAT ARE EXPECTED TO
31 GENERATE SUBSTANTIAL SAVINGS FOR CONSUMERS IN THIS STATE.

32 5. ENSURE THAT THE PROGRAM COMPLIES WITH THE TRACKING AND TRACING
33 REQUIREMENTS OF 21 UNITED STATES CODE SECTIONS 360eee AND 360eee-1 TO THE
34 EXTENT FEASIBLE AND PRACTICABLE BEFORE IMPORTED DRUGS COME INTO THE
35 POSSESSION OF THIS STATE'S WHOLESALER AND THAT THE PROGRAM FULLY COMPLIES
36 WITH THESE REQUIREMENTS AFTER IMPORTED DRUGS ARE IN THE POSSESSION OF THIS
37 STATE'S WHOLESALER.

38 6. PROHIBIT THE DISTRIBUTION, DISPENSING OR SALE OF IMPORTED DRUGS
39 OUTSIDE OF THIS STATE.

40 7. RECOMMEND A CHARGE PER PRESCRIPTION OR ANOTHER METHOD OF SUPPORT
41 TO ENSURE THAT THE PROGRAM IS ADEQUATELY FUNDED IN A MANNER THAT DOES NOT
42 JEOPARDIZE SIGNIFICANT CONSUMER SAVINGS.

43 8. INCLUDE A ROBUST AUDIT PROTOCOL.

1 B. THE DEPARTMENT SHALL RECOMMEND A FUNDING DESIGN FOR THE PROGRAM
2 AND SUBMIT THE FUNDING DESIGN AND THE PROGRAM DESIGN TO THE GOVERNOR, THE
3 PRESIDENT OF THE SENATE AND THE SPEAKER OF THE HOUSE OF REPRESENTATIVES.

4 36-3303. Attorney general consultation; certification
5 request; federal approval; limit on implementation

6 THE DEPARTMENT SHALL:

7 1. CONSULT WITH THE ATTORNEY GENERAL'S OFFICE TO IDENTIFY THE
8 POTENTIAL FOR AND TO MONITOR ANTICOMPETITIVE BEHAVIOR IN INDUSTRIES THAT
9 WOULD BE AFFECTED BY A WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM IN
10 THIS STATE.

11 2. SUBMIT A FORMAL REQUEST TO THE SECRETARY OF THE UNITED STATES
12 DEPARTMENT OF HEALTH AND HUMAN SERVICES FOR CERTIFICATION OF THIS STATE'S
13 WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM.

14 3. SEEK THE APPROPRIATE FEDERAL APPROVALS, WAIVERS, EXEMPTIONS OR
15 AGREEMENTS AS NEEDED TO ENABLE 340B COVERED ENTITIES THAT ARE ENROLLED IN
16 OR ELIGIBLE FOR THE FEDERAL 340B DRUG PRICING PROGRAM TO PARTICIPATE IN
17 THIS STATE'S WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM TO THE
18 FULLEST EXTENT POSSIBLE WITHOUT JEOPARDIZING THEIR ELIGIBILITY FOR THE
19 340B DRUG PRICING PROGRAM.

20 4. NOT IMPLEMENT THE WHOLESALE PRESCRIPTION DRUG IMPORTATION
21 PROGRAM UNTIL THE LEGISLATURE ENACTS LEGISLATION THAT ESTABLISHES EITHER A
22 CHARGE PER PRESCRIPTION OR ANOTHER SOURCE OF PROGRAM FUNDING.

23 36-3304. Program implementation

24 THE DEPARTMENT SHALL BEGIN IMPLEMENTING AND OPERATING THE PROGRAM
25 WITHIN SIX MONTHS AFTER THE LATER OF EITHER THE LEGISLATURE ENACTING A
26 METHOD OF PROGRAM FUNDING PURSUANT TO SECTION 36-3303, PARAGRAPH 4 OR THE
27 PROGRAM RECEIVING CERTIFICATION AND APPROVAL BY THE SECRETARY OF THE
28 UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES PURSUANT TO SECTION
29 36-3303, PARAGRAPH 2. AS PART OF THE IMPLEMENTATION PROCESS, THE
30 DEPARTMENT, IN ACCORDANCE WITH STATE PROCUREMENT AND CONTRACT LAWS, RULES
31 AND PROCEDURES, SHALL:

32 1. BECOME LICENSED AS A WHOLESALER OR ENTER INTO A CONTRACT WITH A
33 STATE-LICENSED WHOLESALER.

34 2. CONTRACT WITH ONE OR MORE STATE-LICENSED DISTRIBUTORS.

35 3. CONTRACT WITH ONE OR MORE LICENSED AND REGULATED CANADIAN
36 SUPPLIERS.

37 4. ENGAGE WITH HEALTH INSURANCE PLANS, EMPLOYERS, PHARMACIES,
38 HEALTH CARE PROVIDERS AND CONSUMERS.

39 5. DEVELOP A REGISTRATION PROCESS FOR HEALTH INSURANCE PLANS,
40 PHARMACIES AND PRESCRIPTION DRUG-ADMINISTERING HEALTH CARE PROVIDERS THAT
41 ARE WILLING TO PARTICIPATE IN THE PROGRAM.

42 6. CREATE A PUBLICLY AVAILABLE SOURCE FOR LISTING THE PRICES OF
43 IMPORTED PRESCRIPTION DRUG PRODUCTS THAT IS AVAILABLE TO ALL PARTICIPATING
44 ENTITIES AND CONSUMERS.

1 7. ESTABLISH AN OUTREACH AND MARKETING PLAN TO GENERATE PROGRAM
2 AWARENESS.

3 8. ESTABLISH AND STAFF A HOTLINE TO ANSWER QUESTIONS AND ADDRESS
4 THE NEEDS OF CONSUMERS, EMPLOYERS, HEALTH INSURANCE PLANS AND PHARMACIES.

5 9. ESTABLISH THE AUDIT FUNCTION AND A TWO-YEAR AUDIT WORK-PLAN
6 CYCLE.

7 10. CONDUCT ANY OTHER ACTIVITIES THAT THE DEPARTMENT DETERMINES TO
8 BE IMPORTANT TO SUCCESSFULLY IMPLEMENT THE PROGRAM.

9 36-3305. Annual report

10 THE DEPARTMENT SHALL ANNUALLY REPORT TO THE GOVERNOR, THE PRESIDENT
11 OF THE SENATE AND THE SPEAKER OF THE HOUSE OF REPRESENTATIVES AND PROVIDE
12 A COPY OF THE REPORT TO THE SECRETARY OF STATE REGARDING THE OPERATION OF
13 THE WHOLESALE PRESCRIPTION DRUG IMPORTATION PROGRAM DURING THE PREVIOUS
14 CALENDAR YEAR. THE REPORT SHALL INCLUDE INFORMATION REGARDING ALL OF THE
15 FOLLOWING:

16 1. WHICH PRESCRIPTION DRUGS WERE INCLUDED IN THE PROGRAM.

17 2. THE NUMBER OF PARTICIPATING PHARMACIES, HEALTH CARE PROVIDERS
18 AND HEALTH INSURANCE PLANS.

19 3. THE NUMBER OF PRESCRIPTIONS DISPENSED THROUGH THE PROGRAM.

20 4. THE ESTIMATED SAVINGS TO CONSUMERS, HEALTH PLANS, EMPLOYERS AND
21 THIS STATE DURING THE PREVIOUS CALENDAR YEAR AND TO DATE.

22 5. THE IMPLEMENTATION OF THE AUDIT PLAN AND AUDIT FINDINGS.

23 6. ANY OTHER INFORMATION THE DEPARTMENT DEEMS RELEVANT.

24 Sec. 2. Short title

25 This act may be known as the "Safe, Low-cost Prescription Drugs
26 Program Act".