REFERENCE TITLE: generic prescription drugs; manufacturing

State of Arizona
House of Representatives
Fifty-sixth Legislature
First Regular Session
2023

HB 2245

Introduced by
Representatives De Los Santos: Aguilar, Mathis, Ortiz, Sandoval, Stahl
Hamilton, Terech, Travers

AN ACT

AMENDING TITLE 36, ARIZONA REVISED STATUTES, BY ADDING CHAPTER 42; RELATING TO DRUG MANUFACTURING.

(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

ARIZONA AFFORDABLE DRUG MANUFACTURING

ARTICLE 1. GENERAL PROVISIONS

36-4201. Definitions

IN THIS CHAPTER, UNLESS THE CONTEXT OTHERWISE REQUIRES:

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

2. "GENERIC PRESCRIPTION DRUG" MEANS A DRUG THAT IS APPROVED PURSUANT TO SECTION 355, SUBSECTION (j) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT OR A BIOSIMILAR, AS DEFINED UNDER THE PUBLIC HEALTH SERVICE ACT (42 UNITED STATES CODE SECTION 262).

3. "PARTNERSHIP" INCLUDES AGREEMENTS TO PROCURE GENERIC PRESCRIPTION DRUGS BY WAY OF CONTRACTS OR PURCHASING BY A PAYOR, STATE GOVERNMENTAL AGENCY, GROUP PURCHASING ORGANIZATION, NONPROFIT ORGANIZATION OR OTHER ENTITY.

4. "PROVIDER" MEANS A HOSPITAL, A SKILLED NURSING FACILITY, AN OUTPATIENT REHABILITATION FACILITY, A HOME HEALTH AGENCY, A HOSPICE OR A CLINIC.

5. "SUPPLIER":

(a) MEANS A PHYSICIAN, SURGEON OR OTHER HEALTH CARE PROVIDER.

(b) INCLUDES AN ENTITY THAT FURNISHES HEALTH CARE SERVICES OTHER THAN A HEALTH CARE PROVIDER.

36-4202. Partnerships; prescription drugs; project management

A. THE DEPARTMENT SHALL ENTER INTO PARTNERSHIPS, CONSISTENT WITH SECTION 36-4203 IN CONSULTATION WITH OTHER STATE DEPARTMENTS AS NECESSARY, TO INCREASE COMPETITION, LOWER PRICES AND ADDRESS SHORTAGES IN THE MARKET FOR GENERIC PRESCRIPTION DRUGS, TO REDUCE THE COST OF PRESCRIPTION DRUGS FOR PUBLIC AND PRIVATE PURCHASERS, TAXPAYERS AND CONSUMERS AND TO INCREASE PATIENT ACCESS TO AFFORDABLE DRUGS.

B. THE DEPARTMENT MAY HIRE STAFF TO OVERSEE AND PROJECT-MANAGE THE PARTNERSHIPS FOR MANUFACTURING OR DISTRIBUTING GENERIC PRESCRIPTION DRUGS, CONTINGENT ON A LEGISLATIVE APPROPRIATION FOR THIS PURPOSE.

36-4203. Partnerships; generic prescription drugs; priority; consultation

A. THE DEPARTMENT SHALL ENTER INTO PARTNERSHIPS RESULTING IN THE PRODUCTION OR DISTRIBUTION OF GENERIC PRESCRIPTION DRUGS, WITH THE INTENT THAT THESE DRUGS BE MADE WIDELY AVAILABLE TO PUBLIC AND PRIVATE PURCHASERS, PROVIDERS AND SUPPLIERS AND PHARMACIES, AS APPROPRIATE. THE GENERIC PRESCRIPTION DRUGS SHALL BE PRODUCED OR DISTRIBUTED BY A DRUG COMPANY OR GENERIC DRUG MANUFACTURER THAT IS REGISTERED WITH THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

B. THE DEPARTMENT MAY ENTER INTO PARTNERSHIPS PURSUANT TO SUBSECTION A OF THIS SECTION ONLY TO PRODUCE A GENERIC PRESCRIPTION DRUG

AT A PRICE THAT RESULTS IN SAVINGS, TARGETS FAILURES IN THE MARKET FOR GENERIC PRESCRIPTION DRUGS AND IMPROVES PATIENT ACCESS TO AFFORDABLE MEDICATIONS. FOR TOP DRUGS PRIORITIZED PURSUANT TO SUBSECTION D OF THIS SECTION, THE DEPARTMENT SHALL DETERMINE WHETHER VIABLE PATHWAYS EXIST FOR PARTNERSHIPS TO MANUFACTURE OR DISTRIBUTE GENERIC PRESCRIPTION DRUGS BY EXAMINING THE RELEVANT LEGAL, MARKET, POLICY AND REGULATORY FACTORS.

C. THE DEPARTMENT SHALL CONSIDER THE FOLLOWING, IF APPLICABLE, WHEN SETTING THE PRICE OF THE GENERIC PRESCRIPTION DRUG:

1. UNITED STATES FOOD AND DRUG ADMINISTRATION USER FEES.

2. ABBREVIATED NEW DRUG APPLICATION ACQUISITION COSTS AMORTIZED OVER A FIVE-YEAR PERIOD.

3. MANDATORY REBATES.

4. TOTAL CONTRACTING AND PRODUCTION COSTS FOR THE DRUG, INCLUDING A REASONABLE AMOUNT FOR ADMINISTRATIVE, OPERATING AND RATE-OF-RETURN EXPENSES OF THE DRUG COMPANY OR GENERIC DRUG MANUFACTURER.

5. RESEARCH AND DEVELOPMENT COSTS ATTRIBUTED TO THE DRUG OVER A FIVE-YEAR PERIOD.

6. OTHER INITIAL START-UP COSTS AMORTIZED OVER A FIVE-YEAR PERIOD.

D. EACH DRUG SHALL BE MADE AVAILABLE TO HEALTH CARE PROVIDERS, PATIENTS AND PURCHASERS AT A TRANSPARENT PRICE AND WITHOUT REBATES, OTHER THAN FEDERALLY REQUIRED REBATES. THE DEPARTMENT SHALL PRIORITIZE THE SELECTION OF GENERIC PRESCRIPTION DRUGS THAT HAVE THE GREATEST IMPACT ON LOWERING DRUG COSTS TO PATIENTS, INCREASING COMPETITION AND ADDRESSING SHORTAGES IN THE PRESCRIPTION DRUG MARKET, IMPROVING PUBLIC HEALTH OR REDUCING THE COST OF PRESCRIPTION DRUGS TO PUBLIC AND PRIVATE PURCHASERS.

E. IN IDENTIFYING GENERIC PRESCRIPTION DRUGS TO BE PRODUCED, THE DEPARTMENT SHALL CONSIDER PHARMACY SPENDING DATA FROM THE ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM AND OTHER ENTITIES FOR WHICH THE STATE PAYS THE COST OF GENERIC PRESCRIPTION DRUGS.

F. THE PARTNERSHIPS ENTERED INTO PURSUANT TO SUBSECTION A OF THIS SECTION SHALL INCLUDE THE PRODUCTION OF AT LEAST ONE FORM OF INSULIN IF A VIABLE PATHWAY FOR MANUFACTURING A MORE AFFORDABLE FORM OF INSULIN EXISTS. THE DEPARTMENT SHALL PRIORITIZE DRUGS FOR CHRONIC AND HIGH-COST CONDITIONS AND SHALL CONSIDER PRIORITIZING THOSE THAT CAN BE DELIVERED THROUGH MAIL ORDER.

G. THE DEPARTMENT SHALL CONSULT WITH ALL OF THE FOLLOWING PUBLIC AND PRIVATE PURCHASERS TO ASSIST IN DEVELOPING A LIST OF GENERIC PRESCRIPTION DRUGS TO BE MANUFACTURED OR DISTRIBUTED THROUGH PARTNERSHIPS AND TO DETERMINE THE VOLUME OF EACH GENERIC PRESCRIPTION DRUG THAT CAN BE PROCURED OVER A MULTIYEAR PERIOD TO SUPPORT A MARKET FOR LOWER-COST GENERIC PRESCRIPTION DRUGS:

1. THE ARIZONA HEALTH CARE COST CONTAINMENT ADMINISTRATION, THE ARIZONA STATE RETIREMENT SYSTEM, THE DEPARTMENT OF ADMINISTRATION AND THE STATE DEPARTMENT OF CORRECTIONS, OR THE ENTITIES ACTING ON BEHALF OF EACH OF THOSE STATE PURCHASERS.

2. HEALTH INSURERS.
3. HOSPITALS.
4. PHARMACY BENEFIT MANAGERS.

H. BEFORE ENTERING INTO A PARTNERSHIP PURSUANT TO THIS SECTION, THE DEPARTMENT SHALL DETERMINE MINIMUM THRESHOLDS FOR PROCURING AN ENTITY'S EXPECTED VOLUME OF A TARGETED DRUG FROM THE COMPANY OR MANUFACTURER OVER A MULTIYEAR PERIOD.

I. THE ENTITIES LISTED IN SUBSECTION G, PARAGRAPHS 2, 3 AND 4 OF THIS SECTION ARE NOT REQUIRED TO PURCHASE PRESCRIPTION DRUGS FROM THE DEPARTMENT OR ENTITIES THAT CONTRACT OR PARTNER WITH THE DEPARTMENT PURSUANT TO THIS CHAPTER. THE DEPARTMENT IS NOT REQUIRED TO CONSULT WITH EACH OF THE ENTITIES LISTED IN SUBSECTION G, PARAGRAPHS 2, 3 AND 4 OF THIS SECTION IF THE PURCHASER ENGAGEMENT INCLUDES A REASONABLE REPRESENTATION FROM THESE GROUPS.

36-4204. Reports

A. FOR THE PURPOSES OF THIS CHAPTER, SUBJECT TO LEGISLATIVE APPROPRIATIONS:

1. ON OR BEFORE JULY 1, 2025, THE DEPARTMENT SHALL SUBMIT A REPORT TO THE GOVERNOR, THE SPEAKER OF THE HOUSE OF REPRESENTATIVES AND THE PRESIDENT OF THE SENATE ON BOTH OF THE FOLLOWING:

(a) A DESCRIPTION OF THE STATUS OF ALL DRUGS TARGETED UNDER THIS CHAPTER.

(b) AN ANALYSIS OF HOW THE ACTIVITIES OF THE DEPARTMENT MAY IMPACT COMPETITION, ACCESS TO TARGETED DRUGS, THE COSTS OF THOSE DRUGS AND THE COSTS OF GENERIC PRESCRIPTION DRUGS TO PUBLIC AND PRIVATE PURCHASERS.

2. ON OR BEFORE JULY 1, 2026, THE DEPARTMENT SHALL SUBMIT A REPORT TO THE GOVERNOR, THE SPEAKER OF THE HOUSE OF REPRESENTATIVES AND THE PRESIDENT OF THE SENATE THAT ASSESSES THE FEASIBILITY OF DIRECTLY MANUFACTURING GENERIC PRESCRIPTION DRUGS AND SELLING GENERIC PRESCRIPTION DRUGS AT A FAIR PRICE. THE REPORT SHALL INCLUDE AN ANALYSIS OF GOVERNANCE STRUCTURE OPTIONS FOR MANUFACTURING FUNCTIONS, INCLUDING CHARTERING A PRIVATE ORGANIZATION, A PUBLIC-PRIVATE PARTNERSHIP OR A PUBLIC BOARD OF DIRECTORS.

B. A COPY OF EACH OF THE REPORTS SUBMITTED PURSUANT SUBSECTION A OF THIS SECTION SHALL BE SENT TO THE SECRETARY OF STATE.

36-4205. Confidential information; public records exemption

IN ORDER TO PROTECT PROPRIETARY, CONFIDENTIAL INFORMATION REGARDING MANUFACTURER OR DISTRIBUTION COSTS AND DRUG PRICING, UTILIZATION AND REBATES, IT IS NECESSARY THAT THIS ACT LIMIT THE PUBLIC'S RIGHT OF ACCESS TO THAT INFORMATION. NOTWITHSTANDING ANY OTHER PROVISION OF LAW, ALL NONPUBLIC INFORMATION AND DOCUMENTS OBTAINED PURSUANT TO THIS CHAPTER ARE CONFIDENTIAL AND ARE NOT PUBLIC RECORDS AND ARE NOT SUBJECT TO TITLE 39, CHAPTER 1, ARTICLE 2.