REFERENCE TITLE: prescription drugs; upper payment limit

State of Arizona
Senate
Fifty-fifth Legislature
Second Regular Session
2022

SB 1680

Introduced by
Senator Gonzales

AN ACT

AMENDING TITLE 36, ARIZONA REVISED STATUTES, BY ADDING CHAPTER 40; APPROPRIATING MONIES; 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 40, to read:

CHAPTER 40

PRESCRIPTION DRUG AFFORDABILITY BOARD

ARTICLE 1. GENERAL PROVISIONS

36-4001. Definitions

IN THIS ARTICLE, UNLESS THE CONTEXT OTHERWISE REQUIRES:

1. "BIOLOGIC" MEANS A DRUG THAT IS PRODUCED OR DISTRIBUTED IN ACCORDANCE WITH A BIOLOGICS LICENSE APPLICATION APPROVED PURSUANT TO 42 CODE OF FEDERAL REGULATIONS SECTION 447.502.

2. "BIOSIMILAR" MEANS A DRUG THAT IS PRODUCED OR DISTRIBUTED IN ACCORDANCE WITH A BIOLOGICS LICENSE APPLICATION APPROVED PURSUANT TO 42 UNITED STATES CODE SECTION 262(k)(3).

3. "BOARD" MEANS THE PRESCRIPTION DRUG AFFORDABILITY BOARD.

4. "BRAND-NAME DRUG":

(a) MEANS A DRUG THAT IS PRODUCED OR DISTRIBUTED IN ACCORDANCE WITH AN ORIGINAL NEW DRUG APPLICATION APPROVED PURSUANT TO 21 UNITED STATES CODE SECTION 355(c).

(b) DOES NOT INCLUDE AN AUTHORIZED GENERIC DRUG AS DEFINED IN 42 CODE OF FEDERAL REGULATIONS SECTION 447.502.

5. "GENERIC DRUG" MEANS ANY OF THE FOLLOWING:

(a) A RETAIL DRUG THAT IS MARKETED OR DISTRIBUTED IN ACCORDANCE WITH AN ABBREVIATED NEW DRUG APPLICATION APPROVED PURSUANT TO 21 UNITED STATES CODE SECTION 355(j).

(b) AN AUTHORIZED GENERIC DRUG AS DEFINED IN 42 CODE OF FEDERAL REGULATIONS SECTION 447.502.

(c) A DRUG THAT ENTERED THE MARKET BEFORE 1962 AND THAT WAS NOT ORIGINALLY MARKETED UNDER A NEW DRUG APPLICATION.

6. "MANUFACTURER" MEANS AN ENTITY THAT DOES ONE OF THE FOLLOWING:

(a) ENGAGES IN THE MANUFACTURE OF A PRESCRIPTION DRUG PRODUCT.

(b) ENTERS INTO A LEASE WITH ANOTHER MANUFACTURER TO MARKET AND DISTRIBUTE A PRESCRIPTION DRUG PRODUCT UNDER THE ENTITY'S OWN NAME.

(c) SETS OR CHANGES THE WHOLESALE ACQUISITION COST OF THE PRESCRIPTION DRUG PRODUCT THE ENTITY MANUFACTURES OR MARKETS.

7. "PRESCRIPTION DRUG PRODUCT" MEANS A BRAND-NAME DRUG, A GENERIC DRUG, A BIOLOGIC OR A BIOSIMILAR.

8. "STAKEHOLDER COUNCIL" MEANS THE PRESCRIPTION DRUG AFFORDABILITY STAKEHOLDER COUNCIL.

36-4002. Prescription drug affordability board; membership; appointment; conflict of interest prohibited; definition

A. THE PRESCRIPTION DRUG AFFORDABILITY BOARD IS ESTABLISHED TO PROTECT STATE RESIDENTS, STATE AND LOCAL GOVERNMENTS, COMMERCIAL HEALTH PLANS, HEALTH CARE PROVIDERS, PHARMACIES AND OTHER STAKEHOLDERS WITHIN THE HEALTH CARE SYSTEM IN THIS STATE FROM THE HIGH COSTS OF PRESCRIPTION DRUG

PRODUCTS. THE BOARD IS A BODY POLITIC AND AN INDEPENDENT UNIT OF STATE GOVERNMENT. THE EXERCISE BY THE BOARD OF ITS AUTHORITY UNDER THIS ARTICLE IS AN ESSENTIAL STATE FUNCTION.

B. THE BOARD CONSISTS OF FIVE MEMBERS AND THREE ALTERNATES WHO ARE APPOINTED BY THE GOVERNOR PURSUANT TO SECTION 38-211. EACH MEMBER OR ALTERNATE MEMBER OF THE BOARD SHALL SERVE A TERM OF FIVE YEARS. BOARD MEMBERS MUST HAVE EXPERTISE IN HEALTH CARE ECONOMICS AND CLINICAL MEDICINE AND MAY NOT BE AN EMPLOYEE OF, A BOARD MEMBER OF OR A CONSULTANT TO A MANUFACTURER OR TRADE ASSOCIATION FOR MANUFACTURERS. BOARD MEMBERS SHALL ELECT A CHAIRPERSON FROM AMONG THEIR MEMBERS.

C. ANY CONFLICT OF INTEREST, INCLUDING WHETHER THE INDIVIDUAL HAS AN ASSOCIATION, INCLUDING A FINANCIAL OR PERSONAL ASSOCIATION, THAT HAS THE POTENTIAL TO BIAS OR HAS THE APPEARANCE OF BIASING THE INDIVIDUAL'S DECISION IN MATTERS RELATED TO THE BOARD OR THE CONDUCT OF THE BOARD'S ACTIVITIES, SHALL BE CONSIDERED AND DISCLOSED WHEN THE GOVERNOR APPOINTS MEMBERS AND ALTERNATE MEMBERS TO THE BOARD.

D. THE BOARD SHALL HIRE:

1. AN EXECUTIVE DIRECTOR, WHO SHALL HIRE STAFF FOR THE BOARD. STAFF OF THE BOARD SHALL RECEIVE A SALARY AS PROVIDED IN THE BUDGET OF THE BOARD.

2. A GENERAL COUNSEL.

E. BOARD MEMBERS MAY RECEIVE COMPENSATION AS PRESCRIBED IN SECTION 38-611 AND ARE ENTITLED TO REIMBURSEMENT FOR EXPENSES NECESSARILY INCURRED IN ATTENDING BOARD MEETINGS.

F. A MAJORITY OF THE MEMBERS OF THE BOARD CONSTITUTES A QUORUM FOR THE PURPOSES OF CONDUCTING THE BUSINESS OF THE BOARD. THE BOARD SHALL MEET IN OPEN SESSION AT LEAST ONCE EVERY SIX WEEKS TO REVIEW PRESCRIPTION DRUG PRODUCT INFORMATION. THE CHAIRPERSON MAY CANCEL OR POSTPONE A MEETING IF THERE ARE NO PRESCRIPTION DRUG PRODUCTS TO REVIEW. THE BOARD SHALL PROVIDE PUBLIC NOTICE OF EACH BOARD MEETING AT LEAST TWO WEEKS BEFORE THE MEETING. MATERIALS FOR EACH BOARD MEETING SHALL BE MADE AVAILABLE TO THE PUBLIC AT LEAST ONE WEEK BEFORE THE MEETING. THE BOARD SHALL PROVIDE AN OPPORTUNITY FOR PUBLIC COMMENT AT EACH OPEN MEETING OF THE BOARD AND SHALL PROVIDE THE PUBLIC WITH THE OPPORTUNITY TO PROVIDE WRITTEN COMMENTS ON PENDING DECISIONS OF THE BOARD. THE BOARD MAY ALLOW EXPERT TESTIMONY AT BOARD MEETINGS, INCLUDING WHEN THE BOARD MEETS IN CLOSED SESSION. THE BOARD MAY MEET IN CLOSED SESSION TO DISCUSS PROPRIETARY DATA AND INFORMATION REGARDING A PRESCRIPTION DRUG PRODUCT. THE FOLLOWING ACTIONS BY THE BOARD SHALL BE MADE IN OPEN SESSION:

1. DELIBERATIONS ON WHETHER TO SUBJECT A PRESCRIPTION DRUG PRODUCT TO A COST REVIEW PURSUANT TO THIS ARTICLE.

2. ANY VOTE ON WHETHER TO IMPOSE AN UPPER-PAYMENT LIMIT ON PURCHASES AND PAYOR REIMBURSEMENTS OF PRESCRIPTION DRUG PRODUCTS IN THIS STATE.

3. ANY DECISION BY THE BOARD.

G. MEMBERS OF THE BOARD SHALL RECUSE THEMSELVES FROM DECISIONS RELATED TO A PRESCRIPTION DRUG PRODUCT IF THE MEMBER, OR AN IMMEDIATE FAMILY MEMBER OF THE MEMBER, HAS RECEIVED OR COULD RECEIVE EITHER OF THE FOLLOWING:

1. A DIRECT FINANCIAL BENEFIT OF ANY AMOUNT DERIVING FROM THE RESULT OR FINDING OF A STUDY OR DETERMINATION BY OR FOR THE BOARD.

2. A FINANCIAL BENEFIT FROM ANY PERSON THAT OWNS, MANUFACTURES OR PROVIDES PRESCRIPTION DRUG PRODUCTS, SERVICES OR ITEMS TO BE STUDIED BY THE BOARD THAT IN THE AGGREGATE EXCEEDS $5,000 PER YEAR.

H. A CONFLICT OF INTEREST SHALL BE DISCLOSED:

1. BY THE FOLLOWING:

(a) THE BOARD WHEN HIRING BOARD STAFF.

(b) THE APPOINTING AUTHORITY WHEN APPOINTING MEMBERS AND ALTERNATE MEMBERS TO THE BOARD AND MEMBERS TO THE STAKEHOLDER COUNCIL.

(c) THE BOARD WHEN A MEMBER OF THE BOARD IS RECUSED IN ANY FINAL DECISION RESULTING FROM A REVIEW OF A PRESCRIPTION DRUG PRODUCT.

2. EITHER:

(a) BEFORE THE FIRST OPEN MEETING AFTER THE CONFLICT IS IDENTIFIED.

(b) WITHIN FIVE DAYS AFTER THE CONFLICT IS IDENTIFIED.

I. A CONFLICT OF INTEREST DISCLOSED UNDER THIS SECTION SHALL BE POSTED ON THE WEBSITE OF THE BOARD UNLESS THE CHAIRPERSON OF THE BOARD RECUSES THE MEMBER FROM ANY FINAL DECISION RESULTING FROM A REVIEW OF A PRESCRIPTION DRUG PRODUCT. IF THE CONFLICT IS RELATED TO A FINANCIAL INTEREST SPECIFIED IN SUBSECTION G OF THIS SECTION, THE POSTING SHALL INCLUDE THE TYPE, NATURE AND MAGNITUDE OF THE INTERESTS OF THE MEMBER INVOLVED.

J. MEMBERS AND ALTERNATE MEMBERS OF THE BOARD, BOARD STAFF AND THIRD-PARTY CONTRACTORS MAY NOT ACCEPT ANY GIFT OR DONATION OF SERVICES OR PROPERTY THAT INDICATES A POTENTIAL CONFLICT OF INTEREST OR HAS THE APPEARANCE OF BIASING THE WORK OF THE BOARD.

K. FOR THE PURPOSES OF THIS SECTION, "FINANCIAL BENEFIT" INCLUDES HONORARIA, FEES, STOCK, THE VALUE OF THE MEMBER'S OR IMMEDIATE FAMILY MEMBER'S STOCK HOLDINGS AND ANY DIRECT FINANCIAL BENEFIT DERIVING FROM THE FINDING OF A REVIEW CONDUCTED UNDER THIS ARTICLE.

36-4003. Powers and duties of the board

A. TO THE EXTENT PRACTICABLE, THE BOARD SHALL ACCESS PRICING INFORMATION FOR PRESCRIPTION DRUG PRODUCTS BY:

1. ENTERING INTO A MEMORANDUM OF UNDERSTANDING WITH ANOTHER STATE TO WHICH MANUFACTURERS ALREADY REPORT PRICING INFORMATION.

2. ACCESSING OTHER AVAILABLE PRICING INFORMATION.

B. IN ADDITION TO ANY OTHER POWERS PRESCRIBED IN THIS ARTICLE, THE BOARD MAY:

1. ADOPT RULES TO IMPLEMENT THIS ARTICLE.

2. ENTER INTO A CONTRACT WITH A QUALIFIED, INDEPENDENT THIRD-PARTY CONTRACTOR FOR ANY SERVICE NECESSARY TO CARRY OUT THE POWERS AND DUTIES OF THE BOARD.

C. UNLESS PERMISSION IS GRANTED BY THE BOARD, A THIRD-PARTY CONTRACTOR HIRED BY THE BOARD MAY NOT RELEASE, PUBLISH OR OTHERWISE USE ANY INFORMATION TO WHICH THE THIRD PARTY HAS ACCESS UNDER ITS CONTRACT WITH THE BOARD.

36-4004. Prescription drug affordability stakeholder council; membership

A. THE PRESCRIPTION DRUG AFFORDABILITY STAKEHOLDER COUNCIL IS ESTABLISHED TO PROVIDE STAKEHOLDER INPUT TO ASSIST THE BOARD IN MAKING DECISIONS AS REQUIRED UNDER THIS ARTICLE. THE STAKEHOLDER COUNCIL CONSISTS OF THE FOLLOWING MEMBERS WHO ARE APPOINTED AS FOLLOWS:

1. ONE REPRESENTATIVE OF A STATEWIDE HEALTH CARE ADVOCACY COALITION WHO IS APPOINTED BY THE SPEAKER OF THE HOUSE OF REPRESENTATIVES.

2. ONE REPRESENTATIVE OF A STATEWIDE ADVOCACY ORGANIZATION FOR SENIORS WHO IS APPOINTED BY THE SPEAKER OF THE HOUSE OF REPRESENTATIVES.

3. ONE REPRESENTATIVE OF A STATEWIDE ORGANIZATION FOR DIVERSE COMMUNITIES WHO IS APPOINTED BY THE SPEAKER OF THE HOUSE OF REPRESENTATIVES.

4. ONE REPRESENTATIVE OF A LABOR UNION WHO IS APPOINTED BY THE SPEAKER OF THE HOUSE OF REPRESENTATIVES.

5. TWO HEALTH SERVICES RESEARCHERS SPECIALIZING IN PRESCRIPTION DRUG PRODUCTS WHO ARE APPOINTED BY THE SPEAKER OF THE HOUSE OF REPRESENTATIVES.

6. ONE PUBLIC MEMBER WHO IS APPOINTED BY THE SPEAKER OF THE HOUSE OF REPRESENTATIVES.

7. ONE REPRESENTATIVE OF A STATEWIDE ASSOCIATION ADVOCATING FOR DOCTORS WHO IS APPOINTED BY THE PRESIDENT OF THE SENATE.

8. ONE REPRESENTATIVE OF A STATEWIDE ASSOCIATION ADVOCATING FOR NURSES WHO IS APPOINTED BY THE PRESIDENT OF THE SENATE.

9. ONE REPRESENTATIVE OF HOSPITALS IN THIS STATE WHO IS APPOINTED BY THE PRESIDENT OF THE SENATE.

10. ONE REPRESENTATIVE OF HEALTH INSURERS IN THIS STATE WHO IS APPOINTED BY THE PRESIDENT OF THE SENATE.

11. ONE REPRESENTATIVE OF THE DEPARTMENT OF ADMINISTRATION WHO IS APPOINTED BY THE PRESIDENT OF THE SENATE.

12. ONE CLINICAL RESEARCHER WHO IS APPOINTED BY THE PRESIDENT OF THE SENATE.

13. ONE PUBLIC MEMBER WHO IS APPOINTED BY THE PRESIDENT OF THE SENATE.

14. ONE REPRESENTATIVE OF A BRAND-NAME DRUG CORPORATION WHO IS APPOINTED BY THE GOVERNOR.

15. ONE REPRESENTATIVE OF A GENERIC DRUG CORPORATION WHO IS APPOINTED BY THE GOVERNOR.

16. ONE REPRESENTATIVE OF EMPLOYERS IN THIS STATE WHO IS APPOINTED BY THE GOVERNOR.

17. ONE REPRESENTATIVE OF PHARMACY BENEFITS MANAGERS WHO IS APPOINTED BY THE GOVERNOR.

18. ONE REPRESENTATIVE OF PHARMACISTS IN THIS STATE WHO IS APPOINTED BY THE GOVERNOR.

19. ONE PHARMACOLOGIST WHO IS APPOINTED BY THE GOVERNOR.

20. ONE PUBLIC MEMBER WHO IS APPOINTED BY THE GOVERNOR.

B. THE MEMBERS OF THE STAKEHOLDER COUNCIL MUST HAVE KNOWLEDGE IN AT LEAST ONE OF THE FOLLOWING AREAS:

1. THE PHARMACEUTICAL BUSINESS MODEL.

2. SUPPLY CHAIN BUSINESS MODELS.

3. THE PRACTICE OF MEDICINE OR CLINICAL TRAINING.

4. CONSUMER OR PATIENT PERSPECTIVES.

5. HEALTH CARE COSTS TRENDS AND DRIVERS.

6. CLINICAL AND HEALTH SERVICES RESEARCH.

7. THIS STATE'S HEALTH CARE MARKETPLACE.

C. THE CHAIRPERSON OF THE BOARD SHALL APPOINT TWO MEMBERS OF THE STAKEHOLDER COUNCIL TO BE COCHAIRPERSONS OF THE STAKEHOLDER COUNCIL. THE TERM OF EACH STAKEHOLDER COUNCIL MEMBER IS THREE YEARS.

D. MEMBERS OF THE STAKEHOLDER COUNCIL MAY NOT RECEIVE COMPENSATION BUT MAY RECEIVE REIMBURSEMENT FOR EXPENSES NECESSARILY INCURRED IN ATTENDING STAKEHOLDER COUNCIL MEETINGS.

36-4005. Prescription drug products; identification; cost affordability review; upper-payment limits

A. THE BOARD SHALL IDENTIFY PRESCRIPTION DRUG PRODUCTS THAT ARE:

1. BRAND-NAME DRUGS OR BIOLOGICS THAT, AS ADJUSTED ANNUALLY FOR INFLATION IN ACCORDANCE WITH THE CONSUMER PRICE INDEX, HAVE EITHER:

(a) A LAUNCH WHOLESALE ACQUISITION COST OF $30,000 OR MORE PER YEAR OR COURSE OF TREATMENT.

(b) A WHOLESALE ACQUISITION COST INCREASE OF $3,000 OR MORE IN ANY TWELVE-MONTH PERIOD OR COURSE OF TREATMENT IF LESS THAN TWELVE MONTHS.

2. BIOSIMILAR DRUGS THAT HAVE A LAUNCH WHOLESALE ACQUISITION COST THAT IS NOT AT LEAST FIFTEEN PERCENT LOWER THAN THE REFERENCED BRAND BIOLOGIC AT THE TIME THE BIOSIMILARS ARE LAUNCHED.

3. GENERIC DRUGS THAT, AS ADJUSTED ANNUALLY FOR INFLATION IN ACCORDANCE WITH THE CONSUMER PRICE INDEX, HAVE A WHOLESALE ACQUISITION COST THAT EITHER:

(a) IS $100 OR MORE FOR ONE OF THE FOLLOWING:

(i) A THIRTY-DAY SUPPLY LASTING A PATIENT FOR A PERIOD OF THIRTY CONSECUTIVE DAYS BASED ON THE RECOMMENDED DOSAGE APPROVED FOR LABELING BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

(ii) A SUPPLY LASTING A PATIENT FOR FEWER THAN THIRTY DAYS BASED ON THE RECOMMENDED DOSAGE APPROVED FOR LABELING BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

(iii) ONE UNIT OF THE DRUG IF THE LABELING APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION DOES NOT RECOMMEND A FINITE DOSAGE.

(b) INCREASED BY TWO HUNDRED PERCENT OR MORE DURING THE IMMEDIATELY PRECEDING TWELVE-MONTH PERIOD, AS DETERMINED BY THE DIFFERENCE BETWEEN THE RESULTING WHOLESALE ACQUISITION COST AND THE AVERAGE OF THE WHOLESALE ACQUISITION COST REPORTED OVER THE IMMEDIATELY PRECEDING TWELVE MONTHS.

4. OTHER PRESCRIPTION DRUG PRODUCTS THAT MAY CREATE AFFORDABILITY CHALLENGES FOR THE STATE HEALTH CARE SYSTEM AND PATIENTS, IN CONSULTATION WITH THE STAKEHOLDER COUNCIL.

B. AFTER IDENTIFYING PRESCRIPTION DRUG PRODUCTS AS REQUIRED BY SUBSECTION A OF THIS SECTION, THE BOARD SHALL DETERMINE WHETHER TO CONDUCT A COST AFFORDABILITY REVIEW FOR EACH IDENTIFIED PRESCRIPTION DRUG PRODUCT BY SEEKING STAKEHOLDER COUNCIL INPUT ABOUT THE PRESCRIPTION DRUG PRODUCT AND CONSIDERING THE AVERAGE PATIENT COST SHARE OF THE PRESCRIPTION DRUG PRODUCT.

C. THE INFORMATION TO CONDUCT A COST AFFORDABILITY REVIEW MAY INCLUDE ANY DOCUMENT AND RESEARCH RELATED TO THE MANUFACTURER'S SELECTION OF THE INTRODUCTORY PRICE OR PRICE INCREASE OF THE PRESCRIPTION DRUG PRODUCT, INCLUDING LIFE-CYCLE MANAGEMENT, NET AVERAGE PRICE IN THIS STATE, MARKET COMPETITION AND CONTEXT, PROJECTED REVENUE AND THE ESTIMATED VALUE OR COST-EFFECTIVENESS OF THE PRESCRIPTION DRUG PRODUCT.

D. FAILURE OF A MANUFACTURER TO PROVIDE THE BOARD WITH THE INFORMATION FOR A COST AFFORDABILITY REVIEW DOES NOT AFFECT THE AUTHORITY OF THE BOARD TO CONDUCT SUCH A REVIEW.

E. IF THE BOARD CONDUCTS A COST AFFORDABILITY REVIEW OF A PRESCRIPTION DRUG PRODUCT, THE REVIEW SHALL DETERMINE WHETHER USE OF THE PRESCRIPTION DRUG PRODUCT THAT IS FULLY CONSISTENT WITH THE LABELING APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR STANDARD MEDICAL PRACTICE HAS LED OR WILL LEAD TO AFFORDABILITY CHALLENGES FOR THE STATE HEALTH CARE SYSTEM OR HIGH OUT-OF-POCKET COSTS FOR PATIENTS. TO THE EXTENT PRACTICABLE, IN DETERMINING WHETHER A PRESCRIPTION DRUG PRODUCT HAS LED OR WILL LEAD TO AN AFFORDABILITY CHALLENGE, THE BOARD SHALL CONSIDER THE FOLLOWING FACTORS:

1. THE WHOLESALE ACQUISITION COST FOR THE PRESCRIPTION DRUG PRODUCT SOLD IN THIS STATE.

2. THE AVERAGE MONETARY PRICE CONCESSION, DISCOUNT OR REBATE THE MANUFACTURER PROVIDES TO HEALTH PLANS IN THIS STATE OR IS EXPECTED TO PROVIDE TO HEALTH PLANS IN THIS STATE AS REPORTED BY MANUFACTURERS AND HEALTH PLANS, EXPRESSED AS A PERCENTAGE OF THE WHOLESALE ACQUISITION COST FOR THE PRESCRIPTION DRUG PRODUCT UNDER REVIEW.

3. THE TOTAL AMOUNT OF THE PRICE CONCESSION, DISCOUNT OR REBATE THE MANUFACTURER PROVIDES TO EACH PHARMACY BENEFITS MANAGER OPERATING IN THIS STATE FOR THE PRESCRIPTION DRUG PRODUCT UNDER REVIEW, AS REPORTED BY MANUFACTURERS AND PHARMACY BENEFITS MANAGERS, EXPRESSED AS A PERCENTAGE OF THE WHOLESALE ACQUISITION COSTS.

4. THE PRICE AT WHICH THERAPEUTIC ALTERNATIVES HAVE BEEN SOLD IN THIS STATE.

5. THE AVERAGE MONETARY CONCESSION, DISCOUNT OR REBATE THE MANUFACTURER PROVIDES OR IS EXPECTED TO PROVIDE TO HEALTH PLAN PAYORS AND PHARMACY BENEFITS MANAGERS IN THIS STATE FOR THERAPEUTIC ALTERNATIVES.

6. THE COSTS TO HEALTH PLANS BASED ON PATIENT ACCESS CONSISTENT WITH UNITED STATES FOOD AND DRUG ADMINISTRATION-LABELED INDICATIONS AND RECOGNIZED STANDARD MEDICAL PRACTICE.

7. THE IMPACT ON PATIENT ACCESS RESULTING FROM THE COST OF THE PRESCRIPTION DRUG PRODUCT RELATIVE TO INSURANCE BENEFIT DESIGN.

8. THE CURRENT OR EXPECTED DOLLAR VALUE OF DRUG-SPECIFIC PATIENT ACCESS PROGRAMS THAT ARE SUPPORTED BY THE MANUFACTURER.

9. THE RELATIVE FINANCIAL IMPACTS TO HEALTH, MEDICAL OR SOCIAL SERVICES COSTS AS CAN BE QUANTIFIED AND COMPARED TO BASELINE EFFECTS OF EXISTING THERAPEUTIC ALTERNATIVES.

10. THE AVERAGE PATIENT COPAYMENT OR OTHER COST-SHARING AMOUNT FOR THE PRESCRIPTION DRUG PRODUCT IN THE STATE.

11. ANY INFORMATION A MANUFACTURER CHOOSES TO PROVIDE.

12. ANY OTHER FACTORS AS DETERMINED BY THE BOARD IN RULES ADOPTED BY THE BOARD.

F. IF THE BOARD FINDS THAT THE COST OF A PRESCRIPTION DRUG PRODUCT REVIEWED UNDER THIS SECTION HAS LED OR WILL LEAD TO AN AFFORDABILITY CHALLENGE, THE BOARD SHALL ESTABLISH AN UPPER-PAYMENT LIMIT AFTER CONSIDERING ALL OF THE FOLLOWING:

1. THE COST OF ADMINISTERING THE PRESCRIPTION DRUG PRODUCT.

2. THE COST OF DELIVERING THE PRESCRIPTION DRUG PRODUCT TO CONSUMERS.

3. OTHER RELEVANT ADMINISTRATIVE COSTS RELATED TO THE PRESCRIPTION DRUG PRODUCT.

G. THE UPPER-PAYMENT LIMIT APPLIES TO ALL PURCHASES AND PAYOR REIMBURSEMENTS OF THE PRESCRIPTION DRUG PRODUCT DISPENSED OR ADMINISTERED TO INDIVIDUALS IN THIS STATE IN PERSON, BY MAIL OR BY ANY OTHER MEANS.

H. ANY INFORMATION SUBMITTED TO THE BOARD PURSUANT TO THIS SECTION IS A PUBLIC RECORD.

I. THIS SECTION DOES NOT PREVENT A MANUFACTURER FROM MARKETING A PRESCRIPTION DRUG PRODUCT APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION WHILE THE PRODUCT IS UNDER AN AFFORDABILITY REVIEW BY THE BOARD.

36-4006. Remedies

THE ATTORNEY GENERAL MAY PURSUE ANY AVAILABLE REMEDY UNDER STATE LAW WHEN ENFORCING THIS ARTICLE.

36-4007. Appeals

A. A PERSON WHO IS AGGRIEVED BY A DECISION OF THE BOARD MAY REQUEST AN APPEAL OF THE DECISION WITHIN THIRTY DAYS AFTER THE FINDING OF THE BOARD.

B. THE BOARD SHALL HEAR THE APPEAL AND MAKE A FINAL DECISION WITHIN SIXTY DAYS AFTER THE APPEAL IS REQUESTED.

C. A FINAL DECISION OF THE BOARD IS SUBJECT TO JUDICIAL REVIEW PURSUANT TO TITLE 12, CHAPTER 7, ARTICLE 6.

36-4008. Prescription drug affordability fund; manufacturer assessments; purpose

A. THE PRESCRIPTION DRUG AFFORDABILITY FUND IS ESTABLISHED CONSISTING OF ASSESSMENTS ON ALL MANUFACTURERS. THE BOARD SHALL ADMINISTER THE PRESCRIPTION DRUG AFFORDABILITY FUND, AND THE FUND IS CONTINUOUSLY APPROPRIATED. FUND MONIES SHALL BE INVESTED AND REINVESTED IN THE SAME MANNER AS OTHER STATE MONIES. ANY INVESTMENT EARNINGS SHALL BE CREDITED TO THE FUND. THIS SECTION DOES NOT PROHIBIT THE FUND FROM RECEIVING MONIES FROM ANY OTHER SOURCE.

B. THE BOARD SHALL ANNUALLY ASSESS EACH MANUFACTURER BASED ON THE MANUFACTURER'S RELATIVE SHARE OF GROSS REVENUES FROM DRUG SALES IN THIS STATE. A MANUFACTURER ASSESSED UNDER THIS SECTION SHALL ANNUALLY PAY A FEE TO THE BOARD AS PRESCRIBED BY THE BOARD IN RULE. THE BOARD SHALL DEPOSIT, PURSUANT TO SECTIONS 35-146 AND 35-147, ALL MONIES COLLECTED FROM THE ASSESSMENT INTO THE PRESCRIPTION DRUG AFFORDABILITY FUND.

C. THE MONIES IN THE FUND MAY BE USED ONLY FOR THE FOLLOWING PURPOSES:

1. BY THE BOARD FOR THE PURPOSES AUTHORIZED BY THIS ARTICLE, INCLUDING ANY COSTS SPENT BY ANY STATE AGENCY TO IMPLEMENT THIS ARTICLE.

2. TO REPAY ANY STATE GENERAL FUND APPROPRIATION MADE TO ESTABLISH AND FUND THE WORK OF THE BOARD IN ITS FIRST YEAR.

36-4009. Annual report; study

A. BEGINNING ON OR BEFORE DECEMBER 31, 2023 AND EACH YEAR THEREAFTER, THE BOARD SHALL SUBMIT TO THE MEMBERS OF THE HEALTH AND HUMAN SERVICES COMMITTEES OF THE SENATE AND THE HOUSE OF REPRESENTATIVES, OR THEIR SUCCESSOR COMMITTEES, A REPORT THAT INCLUDES:

1. PRICE TRENDS FOR PRESCRIPTION DRUG PRODUCTS.

2. THE NUMBER OF PRESCRIPTION DRUG PRODUCTS THAT WERE SUBJECT TO BOARD REVIEW, INCLUDING THE RESULTS OF THE REVIEW AND THE NUMBER AND DISPOSITION OF APPEALS AND JUDICIAL REVIEWS OF BOARD DECISIONS, IF ANY.

3. ANY RECOMMENDATIONS THE BOARD MAY HAVE ON FURTHER LEGISLATION NEEDED TO MAKE PRESCRIPTION DRUG PRODUCTS MORE AFFORDABLE IN THIS STATE.

B. ON OR BEFORE JUNE 1, 2023, THE BOARD SHALL:

1. CONDUCT A STUDY OF THE OPERATION OF THE GENERIC DRUG MARKET IN THE UNITED STATES THAT INCLUDES A REVIEW OF PHYSICIAN-ADMINISTERED DRUGS AND CONSIDERS ALL OF THE FOLLOWING:

(a) THE PRICES OF GENERIC DRUGS ON A YEAR-OVER-YEAR BASIS.

(b) THE DEGREE TO WHICH GENERIC DRUG PRICES AFFECT YEARLY INSURANCE PREMIUM CHANGES.

(c) ANNUAL CHANGES IN INSURANCE COST-SHARING FOR GENERIC DRUGS.

(d) THE POTENTIAL FOR AND HISTORY OF DRUG SHORTAGES.

(e) THE DEGREE TO WHICH GENERIC DRUG PRICES AFFECT YEARLY STATE MEDICAID SPENDING.

(f) ANY OTHER RELEVANT STUDY QUESTIONS.

2. REPORT ITS FINDINGS TO THE GOVERNOR, THE PRESIDENT OF THE SENATE AND THE SPEAKER OF THE HOUSE OF REPRESENTATIVES AND PROVIDE A COPY OF THE REPORT TO THE SECRETARY OF STATE.

36-4010. Applicability

A. THIS ARTICLE REQUIRES STATE-SPONSORED AND STATE-REGULATED HEALTH PLANS AND HEALTH PROGRAMS TO LIMIT DRUG REIMBURSEMENTS AND DRUG PAYMENTS TO NOT MORE THAN THE BOARD-ESTABLISHED UPPER-PAYMENT LIMIT. HEALTH CARE PROVIDERS WHO DISPENSE AND ADMINISTER DRUGS TO INDIVIDUALS IN THIS STATE MAY NOT BILL MORE THAN THE UPPER-PAYMENT LIMIT TO THE PATIENT OR THE THIRD-PARTY PAYOR WITHOUT REGARD TO WHETHER THE HEALTH PLAN CHOOSES TO REIMBURSE THE PROVIDER ABOVE THE UPPER-PAYMENT LIMIT.

B. THIS ARTICLE DOES NOT APPLY TO ANY HEALTH PLAN THAT IS NOT REGULATED BY THIS STATE.

Sec. 2. Initial terms of prescription drug affordability board and stakeholder council members

A. Notwithstanding section 36-4002, Arizona Revised Statutes, as added by this act, the initial terms of the members and alternate members of the prescription drug affordability board expire as follows:

1. One member and one alternate member in 2025.

2. Two members and one alternate member in 2026.

3. Two members, including the chairperson of the board, and one alternate member in 2027.

B. Notwithstanding section 36-4004, Arizona Revised Statutes, as added by this act, the initial terms of the members of the prescription drug affordability stakeholder council expire as follows:

1. Seven members in 2025.

2. Seven members in 2026.

3. Seven members in 2027.

C. All subsequent appointments shall be made as prescribed by statute.

Sec. 3. Prescription drug affordability fund; appropriation

The sum of $_____ is appropriated from the state general fund in fiscal year 2022-2023 to the prescription drug affordability fund established by section 36-4008, Arizona Revised Statutes, as added by this act, for the purposes of this act.

Sec. 4. Effective date

This act is effective from and after December 31, 2022.

Sec. 5. Severability

If a provision of this act or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to this end the provisions of this act are severable.