REFERENCE TITLE: bulk drug substances; prohibitions

State of Arizona
House of Representatives
Fifty-seventh Legislature
Second Regular Session
2026

HB 4036

Introduced by
Representative Peña

AN ACT

AMENDING TITLE 32, CHAPTER 18, ARTICLE 3, ARIZONA REVISED STATUTES, BY ADDING SECTION 32-1971.01; RELATING TO THE ARIZONA STATE BOARD OF PHARMACY.

(TEXT OF BILL BEGINS ON NEXT PAGE)

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

Section 1. Title 32, chapter 18, article 3, Arizona Revised Statutes, is amended by adding section 32-1971.01, to read:

32-1971.01. Compounded medications; records; inspections; bulk drug substances; prohibitions; deceptive advertising; penalties; rules; definitions

A. IT IS UNLAWFUL FOR ANY PERSON OR ENTITY TO ENGAGE IN THE SALE, TRANSFER OR DISTRIBUTION OF A DRUG COMPOUNDED UNDER SECTION 503A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (21 UNITED STATES CODE SECTION 353a) USING A DRUG SUBSTANCE THAT IS A GLUCOSE-DEPENDENT INSULINOTROPIC POLYPEPTIDE RECEPTOR OR GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONIST USED FOR OBESITY OR WEIGHT MANAGEMENT OR A DRUG SUBSTANCE THAT IS A COMPONENT OF A SIMILAR DRUG APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION FOR OBESITY OR WEIGHT MANAGEMENT UNLESS THE COMPOUNDER OF THE DRUG:

1. USES BULK DRUG SUBSTANCES THAT COMPLY WITH THE STANDARDS OF AN APPLICABLE UNITED STATES PHARMACOPOEIA OR NATIONAL FORMULARY MONOGRAPH, IF A MONOGRAPH EXISTS, AND THE UNITED STATES PHARMACOPOEIA CHAPTER ON PHARMACY COMPOUNDING OR, IF A NATIONAL FORMULARY MONOGRAPH DOES NOT EXIST, THE BULK DRUG SUBSTANCES EITHER:

(a) ARE DRUG SUBSTANCES THAT ARE COMPONENTS OF DRUGS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

(b) APPEAR ON THE LIST DEVELOPED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION PURSUANT TO 21 UNITED STATES CODE SECTION 353a(b)(1)(A)(i)(III).

2. IF THE LABELING OF A DRUG APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION SPECIFIES A PROCESS FOR MANUFACTURING THE BULK DRUG SUBSTANCE, CONFIRMS THAT ANY BULK DRUG SUBSTANCE USED WAS MANUFACTURED ACCORDING TO THE PROCESS PRESCRIBED BY FEDERAL LAW.

3. ENSURES THAT THE BULK DRUG SUBSTANCE IS A PHARMACEUTICAL GRADE PRODUCT.

4. VERIFIES THAT THE BULK DRUG SUBSTANCE IS ACCOMPANIED BY A VALID CERTIFICATE OF ANALYSIS.

5. CONDUCTS AND DOCUMENTS QUALITY CONTROL TESTING OF ANY BULK DRUG SUBSTANCE BEFORE ITS USE IN A COMPOUNDED DRUG TO CONFIRM THE IDENTITY AND CONTENT OF THE BULK DRUG SUBSTANCE AND THE NAME AND QUANTITY OF EACH IMPURITY PRESENT IN THE BULK DRUG SUBSTANCE IN AN AMOUNT THAT EXCEEDS ONE-TENTH OF ONE PERCENT.

6. CONDUCTS AND DOCUMENTS QUALITY CONTROL TESTING OF THE FINISHED DRUG PRODUCT COMPOUNDED IN BATCHES BEFORE RELEASE AND AT EXPIRY FOR ANY IMPURITIES DERIVED FROM THE USE OF THE BULK DRUG SUBSTANCE, INCLUDING THE CHEMICAL NAME AND QUANTITIES OF ANY SUCH IMPURITIES.

7. OBTAINS PROOF THAT THE MANUFACTURE OF THE BULK DRUG SUBSTANCE TOOK PLACE IN AN ESTABLISHMENT THAT MEETS ALL OF THE FOLLOWING:

(a) IS DULY REGISTERED WITH THE UNITED STATES FOOD AND DRUG ADMINISTRATION PURSUANT TO 21 UNITED STATES CODE SECTION 360.

(b) HAS UNDERGONE AN INSPECTION BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION AS A HUMAN DRUG ESTABLISHMENT WITHIN THE LAST TWO YEARS.

(c) IS NOT SUBJECT TO AN IMPORT ALERT BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

8. COMPLIES WITH THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

B. IT IS UNLAWFUL FOR ANY MANUFACTURER OR WHOLESALER TO SELL, TRANSFER OR DISTRIBUTE A BULK DRUG SUBSTANCE IN THIS STATE FOR USE IN COMPOUNDING WITHOUT PROVIDING TO THE PURCHASER:

1. WRITTEN VERIFICATION THAT THE BULK DRUG SUBSTANCE IS PHARMACEUTICAL GRADE AND MEETS THE SOURCING REQUIREMENTS.

2. DOCUMENTATION OF ANY QUALITY CONTROL TESTING AND THE VALID CERTIFICATE OF ANALYSIS AS REQUIRED BY SUBSECTION A, PARAGRAPH 4 OF THIS SECTION.

C. ANY PERSON OR ENTITY ENGAGING IN THE SALE, TRANSFER OR DISTRIBUTION OF COMPOUNDED DRUGS PURSUANT TO SUBSECTION A OF THIS SECTION SHALL MAINTAIN ALL RECORDS RELATED TO THE ACQUISITION, EXAMINATION AND TESTING OF THE BULK DRUG SUBSTANCE FOR AT LEAST TWO YEARS AFTER THE EXPIRATION DATE OF THE LAST LOT OF DRUG CONTAINING THE BULK DRUG SUBSTANCE AND, ON REQUEST BY THE BOARD, SHALL FURNISH THE RECORDS TO THE BOARD WITHIN ONE BUSINESS DAY AFTER RECEIVING THE REQUEST OR WITHIN A REASONABLE TIME AS DETERMINED BY THE BOARD BASED ON THE CIRCUMSTANCES OF THE REQUEST.

D. THE BOARD OR THE BOARD'S AUTHORIZED AGENT HAS THE AUTHORITY TO INSPECT ANY PERSON OR ENTITY THAT ENGAGES IN COMPOUNDING DRUGS, AS WELL ANY DOMESTIC SUPPLIER, WHOLESALER, REPACKAGER OR OTHER PROVIDER OF THE BULK DRUG SUBSTANCE FOR COMPOUNDING, FOR COMPLIANCE WITH THE REQUIREMENTS PRESCRIBED IN SUBSECTION A OF THIS SECTION. REFUSAL TO ALLOW THE BOARD OR THE BOARD'S AUTHORIZED AGENT ACCESS TO CONDUCT AN INSPECTION CONSTITUTES A VIOLATION OF THIS SECTION.

E. IT IS UNLAWFUL FOR ANY PERSON TO ADVERTISE OR OTHERWISE PROMOTE COMPOUNDED MEDICATIONS UNLESS THE ADVERTISEMENT IS TRUTHFUL AND NOT MISLEADING. AN ADVERTISEMENT IS NOT TRUTHFUL AND IS MISLEADING IF IT INCLUDES ANY UNSUBSTANTIATED CLAIM WITH RESPECT TO THE PRODUCT. AN ADVERTISEMENT IS MISLEADING UNLESS IT CONTAINS ALL OF THE FOLLOWING:

1. A DISCLOSURE OF THE POTENTIAL SIDE EFFECTS, ADVERSE REACTIONS, CONTRAINDICATIONS, PRECAUTIONS AND WARNINGS ASSOCIATED WITH ACTIVE INGREDIENTS IN THE MEDICATION, INCLUDING ANY NOTED FROM CLINICAL TRIALS, RESEARCH AND OTHER APPROPRIATE INFORMATION SOURCES.

2. A SUMMARY OF THE SPECIFIED RISK INFORMATION IN THE LABELING OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION-APPROVED DRUG, IF APPLICABLE, IF THE COMPOUNDED DRUG CONTAINS AN ACTIVE INGREDIENT THAT IS NAMED AS AN ACTIVE INGREDIENT IN A UNITED STATES FOOD AND DRUG ADMINISTRATION-APPROVED DRUG.

3. IF APPLICABLE, A CLEAR, CONSPICUOUS STATEMENT THAT THE PRODUCT IS A COMPOUNDED MEDICATION, HAS NOT BEEN APPROVED BY THE UNITED STATES

FOOD AND DRUG ADMINISTRATION AND HAS NOT BEEN EVALUATED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION FOR SAFETY OR EFFICACY.

F. IN ADDITION TO ANY OTHER PENALTIES PRESCRIBED IN THIS CHAPTER, A PERSON OR ENTITY THAT VIOLATES THIS SECTION MAY BE SUBJECT TO:

1. A CIVIL PENALTY OF $1,000 PER DOSE OF THE ILLEGALLY COMPOUNDED DRUG SOLD, TRANSFERRED OR DISTRIBUTED.

2. A SUSPENSION OR REVOCATION OF THE LICENSEE'S OR PERMITTEE'S LICENSE OR PERMIT, AS APPLICABLE.

G. THE BOARD SHALL ADOPT RULES AS NECESSARY TO IMPLEMENT THIS SECTION.

H. FOR THE PURPOSES OF THIS SECTION:

1. "BULK DRUG SUBSTANCE":

(a) MEANS ANY SUBSTANCE THAT IS INTENDED FOR INCORPORATION INTO A FINISHED DRUG PRODUCT AND THAT IS INTENDED TO FURNISH PHARMACOLOGICAL ACTIVITY OR ANOTHER DIRECT EFFECT IN THE DIAGNOSIS, CURE, MITIGATION, TREATMENT OR PREVENTION OF A DISEASE, OR TO AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY.

(b) DOES NOT INCLUDE INTERMEDIATES USED IN THE SYNTHESIS OF THE SUBSTANCE.

2. "PERSON" MEANS ANY INDIVIDUAL, PARTNERSHIP, FIRM, CORPORATION OR OTHER LEGAL ENTITY.

3. "UNSUBSTANTIATED CLAIM" MEANS ANY STATEMENT, REPRESENTATION OR ASSERTION CONCERNING THE SAFETY, EFFICACY OR OTHER ATTRIBUTES OF A DRUG THAT IS NOT SUPPORTED BY COMPETENT AND RELIABLE SCIENTIFIC EVIDENCE.

Sec. 2. Legislative findings

The legislature finds the following:

1. The safety and integrity of compounded medications are paramount for the health and well-being of residents of this state.

2. The United States food and drug administration sets internationally recognized standards for drug approval and regulatory oversight. However, there have been increasing attempts by unscrupulous actors to circumvent these regulations, undermining public trust and patient safety.

3. Foreign entities, including those from countries such as China, have exploited regulatory gaps to introduce inferior or contaminated active pharmaceutical ingredients into the supply chain for medications intended for compounding.

4. Recent cases, such as those involving medications for weight loss, have demonstrated that high demand can lead to the proliferation of use of illicit, substandard and potentially harmful active pharmaceutical ingredients, also known as bulk drug substances, jeopardizing patient health and safety.

5. While the United States food and drug administration bears responsibility for enforcing federal laws to protect citizens from

misbranded and adulterated pharmaceutical ingredients, enforcement has proven insufficient to curtail the influx of these substances.

6. Even after the United States food and drug administration took some action to curb imports of active pharmaceutical ingredients for weight loss medications from entities that are not compliant with current good manufacturing practice requirements, patients in this state remain at risk of receiving compounded medications containing active pharmaceutical ingredients produced by entities that the United States food and drug administration found to not be compliant with those requirements, including active pharmaceutical ingredients imported into the United States before the United States food and drug administration took action.

7. Therefore, it is necessary for this state to take action to protect its residents by ensuring that all active pharmaceutical ingredients used in compounding are sourced from reputable, registered and inspected establishments, and that only pharmaceutical grade, safe and pure ingredients are used in medications for weight loss.