State of Arizona
Senate
Fifty-seventh Legislature
First Regular Session
2025

CHAPTER 139

SENATE BILL 1377

AN ACT

AMENDING SECTION 32-1909, ARIZONA REVISED STATUTES; 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. Section 32-1909, Arizona Revised Statutes, is amended to read:

32-1909. Donated medicine; donors; authorized recipients; requirements; immunity; definitions

A. A donor may donate medicine to an authorized recipient, and an authorized recipient may receive donated medicine from donors. Before a donor may make its first donation to an authorized recipient, the authorized recipient must verify and record all the following:

1. That the donor is legally authorized to possess the medicine.

2. The donor's name, address and telephone number and permit or license number, if applicable.

3. That the donor will remove or redact any patient names and prescription numbers on donated medicine or will otherwise maintain patient confidentiality by executing a confidentiality agreement with the authorized recipient.

B. Notwithstanding any other law, an authorized recipient may transfer donated medicine to another authorized recipient or to an entity participating in a drug donation program operated by another state. Medicine transferred pursuant to this section may be transferred only once.

C. An authorized recipient may accept into inventory only donated medicine that meets all of the following:

1. Is in unopened, tamper-evident packaging or that has been repackaged under this section.

2. Is not adulterated or misbranded.

3. Has been maintained in accordance and in compliance with the United States food and drug administration risk evaluation and mitigation strategies pursuant to 21 United States Code section 355-1, if applicable.

4. Is accompanied by an attestation from the donor stating that the medicine being donated has been kept in a temperature-controlled environment and has not been adulterated.

D. An authorized recipient may accept into inventory a donated biologic only if the donated biologic meets the requirements of subsection C of this section and is donated by a health care professional or an entity legally authorized to ~~posses~~ POSSESS the biologic.

E. Donated medicine that does not meet the requirements of subsection C of this section must be disposed of by returning it to the donor, destroying it in an incinerator, medical waste hauler or other lawful method or transferring it to a returns processor. A record of disposed medicine shall contain a description of the disposal method, the date of disposal and the name, strength and quantity of each medicine disposed of. No other record of disposal is required.

F. A drug manufacturer, repackager, dispenser or wholesaler, other than a returns processor, that participates in this program shall comply

with the requirements of 21 United States Code sections 360eee-1 through 360eee-4 relating to drug supply chain security.

G. All donated medicine received by an authorized recipient but not yet accepted into inventory shall be kept in a separate designated area. Before or when accepting a donation or transfer into inventory, the authorized recipient shall maintain a written or electronic inventory of the donation consisting of the name, strength and quantity of each accepted medicine and the name, address and telephone number of the donor. This record is not required if the donor and authorized recipient are under common ownership or common control. No other record of donation is required.

H. An authorized recipient must store and maintain donated medicine physically or electronically separated from other inventory and in a secure and temperature-controlled environment that meets the drug manufacturers' recommendations and United States pharmacopeia standards.

I. Repackaged medicine shall be labeled with the drug's name, strength and expiration date and shall be kept in a separate designated area until inspected and initialed by a health care professional. If multiple packaged donated medicines with varied expiration dates are repackaged together, the earliest expiration date shall be used.

J. An authorized recipient may administer or dispense only donated medicine that meets all of the following:

1. ~~Meets~~ The requirements of subsection C of this section based on an inspection by a health care professional.

2. If dispensed to an eligible patient, is repackaged into a new container or has all previous patient information on the donated container redacted or removed.

3. Is properly labeled in accordance with board rules.

4. Has an expiration or beyond-use date brought forward from the donated medicine that will not expire before the medicine is completely used by the eligible patient based on the prescribing practitioner's directions for use or, for over-the-counter medicine, on the package's label.

K. An authorized recipient may dispense or administer donated medicine to an eligible patient only if otherwise allowed by law. Donated medicine may be dispensed or administered only to eligible patients pursuant to a valid prescription order and must have patient-specific written or electronic records maintained in accordance with board rules.

L. Donated medicine may not be dispensed or administered to an eligible patient if the prescriber writes or clearly displays on the face of the prescription form "DAW", "dispense as written" or any other language that indicates a substitution is not allowed.

M. The donation, transfer, receipt or facilitation of donated medicine pursuant to this section is not considered wholesale distribution and does not require licensing as a wholesale distributor.

N. Medicine donated under this section may not be resold and is considered nonsaleable. Charging a handling, dispensing or administrative fee under this section is not reselling a donated medicine. The board shall prescribe in rule the limits on the fees that an authorized recipient may charge under this section considering the medicine's retail cost for a monthly supply.

O. When performing any action under this section or otherwise processing donated medicine for tax, manufacturer or other credit, an authorized recipient is considered to be acting as a returns processor and shall comply with all recordkeeping requirements for nonsaleable returns under federal law.

P. An authorized recipient shall retain all records required by this section in a physical or electronic format for a period of at least seven years. A donor and authorized recipient may contract with each other or a third party to create or maintain records on each other's behalf. An identifier, such as a serial number or barcode, may be used in place of any information required to be in a record or on a label pursuant to this section if the identifier allows for such information to be readily retrievable. On request by the board, the identifier used for requested records shall be replaced with the original information. An identifier may not be used on patient labels when dispensing or administering a donated medicine.

Q. A donation or other transfer of possession or control is not a change of ownership unless it is specified as such by the authorized recipient. If a record of the donation's transaction information or history is required, the history must begin with the donor of the medicine and include all prior donations and, if the medicine was previously dispensed, must include only drug information required to be on the patient label in accordance with board rules.

R. A donor or authorized recipient shall make all records available for audit by the board within five business days after the request.

S. The following are not subject to civil liability, criminal liability or professional disciplinary action if acting in good faith under this section:

1. A person involved in the supply chain of donated medicine, including a donor, authorized recipient, manufacturer, repackager, wholesaler or pharmacy.

2. A person, including any employee, officer, volunteer, owner, partner, member, director, contractor or other person or entity associated with the person, that in compliance with this section prescribes, donates, receives, dispenses, administers, transfers, replenishes or repackages medicine, or facilitates any of the above pursuant to this section.

T. This section does not prohibit otherwise legal activities related to nonprescription drugs.

U. EACH OF THE FOLLOWING ENTITIES MAY POST ON THE ENTITY'S PUBLIC WEBSITE INFORMATION REGARDING WHERE AND HOW DONORS MAY DONATE MEDICINE, WHO QUALIFIES AS AN ELIGIBLE PATIENT AND HOW AN ELIGIBLE PATIENT MAY ACCESS DONATED MEDICINE:

1. AUTHORIZED RECIPIENTS.

2. THE DEPARTMENT OF HEALTH SERVICES.

3. THE ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM.

4. HEALTH PROFESSION REGULATORY BOARDS AS DEFINED IN SECTION 32-3201.

~~U.~~ V. For the purposes of this section:

1. "Authorized recipient" means any entity that has a license or permit in good standing in this state and that is legally authorized to possess medicine, including a wholesaler, distributor, reverse distributor, repackager, hospital, pharmacy or health care institution.

2. "Donor":

(a) Means any person, any individual member of the public or any entity legally authorized to possess medicine, including a manufacturer, wholesaler, distributor, third-party logistic provider, pharmacy, dispenser, clinic, surgical center, health center, detention and rehabilitation center, laboratory, medical school, pharmacy school, health care professional or health care facility.

(b) Includes government agencies and entities that are federally authorized to possess medicine, including drug manufacturers, repackagers, relabelers, outsourcing facilities, prisons and importers authorized by the United States food and drug administration.

3. "Eligible patient" means an individual who is indigent, uninsured, underinsured or enrolled in a public health benefits program.

4. "Health care professional" means a health care provider who is licensed or certified pursuant to this title and authorized to dispense or administer prescription drugs.

5. "Medicine" means both prescription and nonprescription drugs, including drugs approved by the United States food and drug administration and labeled for investigational use.

6. "Returns processor" has the same meaning prescribed in 21 United States Code section 360eee and includes a reverse distributor.

7. "Unopened, tamper-evident packaging" has the same meaning as United States pharmacopeia packaging and storage requirements, including unopened unit-dose, multiple-dose and immediate, secondary and tertiary packaging.

APPROVED BY THE GOVERNOR MAY 7, 2025.

FILED IN THE OFFICE OF THE SECRETARY OF STATE MAY 7, 2025.