

Senate Engrossed

donated medicine; requirements

State of Arizona
Senate
Fifty-fifth Legislature
First Regular Session
2021

CHAPTER 137

SENATE BILL 1219

AN ACT

REPEALING SECTION 32-1909, ARIZONA REVISED STATUTES; AMENDING TITLE 32, CHAPTER 18, ARTICLE 1, ARIZONA REVISED STATUTES, BY ADDING A NEW SECTION 32-1909; RELATING TO THE ARIZONA STATE BOARD OF PHARMACY.

(TEXT OF BILL BEGINS ON NEXT PAGE)

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

2 Section 1. Repeal

3 Section 32-1909, Arizona Revised Statutes, is repealed.

4 Sec. 2. Title 32, chapter 18, article 1, Arizona Revised Statutes,
5 is amended by adding a new section 32-1909, to read:

6 32-1909. Donated medicine; donors; authorized recipients;
7 requirements; immunity; definitions

8 A. A DONOR MAY DONATE MEDICINE TO AN AUTHORIZED RECIPIENT, AND AN
9 AUTHORIZED RECIPIENT MAY RECEIVE DONATED MEDICINE FROM DONORS. BEFORE A
10 DONOR MAY MAKE ITS FIRST DONATION TO AN AUTHORIZED RECIPIENT, THE
11 AUTHORIZED RECIPIENT MUST VERIFY AND RECORD ALL THE FOLLOWING:

12 1. THAT THE DONOR IS LEGALLY AUTHORIZED TO POSSESS THE MEDICINE.

13 2. THE DONOR'S NAME, ADDRESS AND TELEPHONE NUMBER AND PERMIT OR
14 LICENSE NUMBER, IF APPLICABLE.

15 3. THAT THE DONOR WILL REMOVE OR REDACT ANY PATIENT NAMES AND
16 PRESCRIPTION NUMBERS ON DONATED MEDICINE OR WILL OTHERWISE MAINTAIN
17 PATIENT CONFIDENTIALITY BY EXECUTING A CONFIDENTIALITY AGREEMENT WITH THE
18 AUTHORIZED RECIPIENT.

19 B. NOTWITHSTANDING ANY OTHER LAW, AN AUTHORIZED RECIPIENT MAY
20 TRANSFER DONATED MEDICINE TO ANOTHER AUTHORIZED RECIPIENT OR TO AN ENTITY
21 PARTICIPATING IN A DRUG DONATION PROGRAM OPERATED BY ANOTHER STATE.
22 MEDICINE TRANSFERRED PURSUANT TO THIS SECTION MAY BE TRANSFERRED ONLY
23 ONCE.

24 C. AN AUTHORIZED RECIPIENT MAY ACCEPT INTO INVENTORY ONLY DONATED
25 MEDICINE THAT MEETS ALL OF THE FOLLOWING:

26 1. IS IN UNOPENED, TAMPER-EVIDENT PACKAGING OR THAT HAS BEEN
27 REPACKAGED UNDER THIS SECTION.

28 2. IS NOT ADULTERATED OR MISBRANDED.

29 3. HAS BEEN MAINTAINED IN ACCORDANCE AND IN COMPLIANCE WITH THE
30 UNITED STATES FOOD AND DRUG ADMINISTRATION RISK EVALUATION AND MITIGATION
31 STRATEGIES PURSUANT TO 21 UNITED STATES CODE SECTION 355-1, IF APPLICABLE.

32 4. IS ACCOMPANIED BY AN ATTESTATION FROM THE DONOR STATING THAT THE
33 MEDICINE BEING DONATED HAS BEEN KEPT IN A TEMPERATURE-CONTROLLED
34 ENVIRONMENT AND HAS NOT BEEN ADULTERATED.

35 D. AN AUTHORIZED RECIPIENT MAY ACCEPT INTO INVENTORY A DONATED
36 BIOLOGIC ONLY IF THE DONATED BIOLOGIC MEETS THE REQUIREMENTS OF SUBSECTION
37 C OF THIS SECTION AND IS DONATED BY A HEALTH CARE PROFESSIONAL OR AN
38 ENTITY LEGALLY AUTHORIZED TO POSSES THE BIOLOGIC.

39 E. DONATED MEDICINE THAT DOES NOT MEET THE REQUIREMENTS OF
40 SUBSECTION C OF THIS SECTION MUST BE DISPOSED OF BY RETURNING IT TO THE
41 DONOR, DESTROYING IT IN AN INCINERATOR, MEDICAL WASTE HAULER OR OTHER
42 LAWFUL METHOD OR TRANSFERRING IT TO A RETURNS PROCESSOR. A RECORD OF
43 DISPOSED MEDICINE SHALL CONTAIN A DESCRIPTION OF THE DISPOSAL METHOD, THE
44 DATE OF DISPOSAL AND THE NAME, STRENGTH AND QUANTITY OF EACH MEDICINE
45 DISPOSED OF. NO OTHER RECORD OF DISPOSAL IS REQUIRED.

1 F. A DRUG MANUFACTURER, REPACKAGER, DISPENSER OR WHOLESALER, OTHER
2 THAN A RETURNS PROCESSOR, THAT PARTICIPATES IN THIS PROGRAM SHALL COMPLY
3 WITH THE REQUIREMENTS OF 21 UNITED STATES CODE SECTIONS 360eee-1 THROUGH
4 360eee-4 RELATING TO DRUG SUPPLY CHAIN SECURITY.

5 G. ALL DONATED MEDICINE RECEIVED BY AN AUTHORIZED RECIPIENT BUT NOT
6 YET ACCEPTED INTO INVENTORY SHALL BE KEPT IN A SEPARATE DESIGNATED AREA.
7 BEFORE OR WHEN ACCEPTING A DONATION OR TRANSFER INTO INVENTORY, THE
8 AUTHORIZED RECIPIENT SHALL MAINTAIN A WRITTEN OR ELECTRONIC INVENTORY OF
9 THE DONATION CONSISTING OF THE NAME, STRENGTH AND QUANTITY OF EACH
10 ACCEPTED MEDICINE AND THE NAME, ADDRESS AND TELEPHONE NUMBER OF THE DONOR.
11 THIS RECORD IS NOT REQUIRED IF THE DONOR AND AUTHORIZED RECIPIENT ARE
12 UNDER COMMON OWNERSHIP OR COMMON CONTROL. NO OTHER RECORD OF DONATION IS
13 REQUIRED.

14 H. AN AUTHORIZED RECIPIENT MUST STORE AND MAINTAIN DONATED MEDICINE
15 PHYSICALLY OR ELECTRONICALLY SEPARATED FROM OTHER INVENTORY AND IN A
16 SECURE AND TEMPERATURE-CONTROLLED ENVIRONMENT THAT MEETS THE DRUG
17 MANUFACTURERS' RECOMMENDATIONS AND UNITED STATES PHARMACOPEIA STANDARDS.

18 I. REPACKAGED MEDICINE SHALL BE LABELED WITH THE DRUG'S NAME,
19 STRENGTH AND EXPIRATION DATE AND SHALL BE KEPT IN A SEPARATE DESIGNATED
20 AREA UNTIL INSPECTED AND INITIALED BY A HEALTH CARE PROFESSIONAL. IF
21 MULTIPLE PACKAGED DONATED MEDICINES WITH VARIED EXPIRATION DATES ARE
22 REPACKAGED TOGETHER, THE EARLIEST EXPIRATION DATE SHALL BE USED.

23 J. AN AUTHORIZED RECIPIENT MAY ADMINISTER OR DISPENSE ONLY DONATED
24 MEDICINE THAT MEETS ALL OF THE FOLLOWING:

25 1. MEETS THE REQUIREMENTS OF SUBSECTION C OF THIS SECTION BASED ON
26 AN INSPECTION BY A HEALTH CARE PROFESSIONAL.

27 2. IF DISPENSED TO AN ELIGIBLE PATIENT, IS REPACKAGED INTO A NEW
28 CONTAINER OR HAS ALL PREVIOUS PATIENT INFORMATION ON THE DONATED CONTAINER
29 REDACTED OR REMOVED.

30 3. IS PROPERLY LABELED IN ACCORDANCE WITH BOARD RULES.

31 4. HAS AN EXPIRATION OR BEYOND-USE DATE BROUGHT FORWARD FROM THE
32 DONATED MEDICINE THAT WILL NOT EXPIRE BEFORE THE MEDICINE IS COMPLETELY
33 USED BY THE ELIGIBLE PATIENT BASED ON THE PRESCRIBING PRACTITIONER'S
34 DIRECTIONS FOR USE OR, FOR OVER-THE-COUNTER MEDICINE, ON THE PACKAGE'S
35 LABEL.

36 K. AN AUTHORIZED RECIPIENT MAY DISPENSE OR ADMINISTER DONATED
37 MEDICINE TO AN ELIGIBLE PATIENT ONLY IF OTHERWISE ALLOWED BY LAW. DONATED
38 MEDICINE MAY BE DISPENSED OR ADMINISTERED ONLY TO ELIGIBLE PATIENTS
39 PURSUANT TO A VALID PRESCRIPTION ORDER AND MUST HAVE PATIENT-SPECIFIC
40 WRITTEN OR ELECTRONIC RECORDS MAINTAINED IN ACCORDANCE WITH BOARD RULES.

41 L. DONATED MEDICINE MAY NOT BE DISPENSED OR ADMINISTERED TO AN
42 ELIGIBLE PATIENT IF THE PRESCRIBER WRITES OR CLEARLY DISPLAYS ON THE FACE
43 OF THE PRESCRIPTION FORM "DAW", "DISPENSE AS WRITTEN" OR ANY OTHER
44 LANGUAGE THAT INDICATES A SUBSTITUTION IS NOT ALLOWED.

1 M. THE DONATION, TRANSFER, RECEIPT OR FACILITATION OF DONATED
2 MEDICINE PURSUANT TO THIS SECTION IS NOT CONSIDERED WHOLESALE DISTRIBUTION
3 AND DOES NOT REQUIRE LICENSING AS A WHOLESALE DISTRIBUTOR.

4 N. MEDICINE DONATED UNDER THIS SECTION MAY NOT BE RESOLD AND IS
5 CONSIDERED NONSALEABLE. CHARGING A HANDLING, DISPENSING OR ADMINISTRATIVE
6 FEE UNDER THIS SECTION IS NOT RESELLING A DONATED MEDICINE. THE BOARD
7 SHALL PRESCRIBE IN RULE THE LIMITS ON THE FEES THAT AN AUTHORIZED
8 RECIPIENT MAY CHARGE UNDER THIS SECTION CONSIDERING THE MEDICINE'S RETAIL
9 COST FOR A MONTHLY SUPPLY.

10 O. WHEN PERFORMING ANY ACTION UNDER THIS SECTION OR OTHERWISE
11 PROCESSING DONATED MEDICINE FOR TAX, MANUFACTURER OR OTHER CREDIT, AN
12 AUTHORIZED RECIPIENT IS CONSIDERED TO BE ACTING AS A RETURNS PROCESSOR AND
13 SHALL COMPLY WITH ALL RECORDKEEPING REQUIREMENTS FOR NONSALEABLE RETURNS
14 UNDER FEDERAL LAW.

15 P. AN AUTHORIZED RECIPIENT SHALL RETAIN ALL RECORDS REQUIRED BY
16 THIS SECTION IN A PHYSICAL OR ELECTRONIC FORMAT FOR A PERIOD OF AT LEAST
17 SEVEN YEARS. A DONOR AND AUTHORIZED RECIPIENT MAY CONTRACT WITH EACH
18 OTHER OR A THIRD PARTY TO CREATE OR MAINTAIN RECORDS ON EACH OTHER'S
19 BEHALF. AN IDENTIFIER, SUCH AS A SERIAL NUMBER OR BARCODE, MAY BE USED IN
20 PLACE OF ANY INFORMATION REQUIRED TO BE IN A RECORD OR ON A LABEL PURSUANT
21 TO THIS SECTION IF THE IDENTIFIER ALLOWS FOR SUCH INFORMATION TO BE
22 READILY RETRIEVABLE. ON REQUEST BY THE BOARD, THE IDENTIFIER USED FOR
23 REQUESTED RECORDS SHALL BE REPLACED WITH THE ORIGINAL INFORMATION. AN
24 IDENTIFIER MAY NOT BE USED ON PATIENT LABELS WHEN DISPENSING OR
25 ADMINISTERING A DONATED MEDICINE.

26 Q. A DONATION OR OTHER TRANSFER OF POSSESSION OR CONTROL IS NOT A
27 CHANGE OF OWNERSHIP UNLESS IT IS SPECIFIED AS SUCH BY THE AUTHORIZED
28 RECIPIENT. IF A RECORD OF THE DONATION'S TRANSACTION INFORMATION OR
29 HISTORY IS REQUIRED, THE HISTORY MUST BEGIN WITH THE DONOR OF THE MEDICINE
30 AND INCLUDE ALL PRIOR DONATIONS AND, IF THE MEDICINE WAS PREVIOUSLY
31 DISPENSED, MUST INCLUDE ONLY DRUG INFORMATION REQUIRED TO BE ON THE
32 PATIENT LABEL IN ACCORDANCE WITH BOARD RULES.

33 R. A DONOR OR AUTHORIZED RECIPIENT SHALL MAKE ALL RECORDS AVAILABLE
34 FOR AUDIT BY THE BOARD WITHIN FIVE BUSINESS DAYS AFTER THE REQUEST.

35 S. THE FOLLOWING ARE NOT SUBJECT TO CIVIL LIABILITY, CRIMINAL
36 LIABILITY OR PROFESSIONAL DISCIPLINARY ACTION IF ACTING IN GOOD FAITH
37 UNDER THIS SECTION:

38 1. A PERSON INVOLVED IN THE SUPPLY CHAIN OF DONATED MEDICINE,
39 INCLUDING A DONOR, AUTHORIZED RECIPIENT, MANUFACTURER, REPACKAGER,
40 WHOLESALE OR PHARMACY.

41 2. A PERSON, INCLUDING ANY EMPLOYEE, OFFICER, VOLUNTEER, OWNER,
42 PARTNER, MEMBER, DIRECTOR, CONTRACTOR OR OTHER PERSON OR ENTITY ASSOCIATED
43 WITH THE PERSON, THAT IN COMPLIANCE WITH THIS SECTION PRESCRIBES, DONATES,
44 RECEIVES, DISPENSES, ADMINISTERS, TRANSFERS, REPLENISHES OR REPACKAGES
45 MEDICINE, OR FACILITATES ANY OF THE ABOVE PURSUANT TO THIS SECTION.

1 T. THIS SECTION DOES NOT PROHIBIT OTHERWISE LEGAL ACTIVITIES
2 RELATED TO NONPRESCRIPTION DRUGS.

3 U. FOR THE PURPOSES OF THIS SECTION:

4 1. "AUTHORIZED RECIPIENT" MEANS ANY ENTITY THAT HAS A LICENSE OR
5 PERMIT IN GOOD STANDING IN THIS STATE AND THAT IS LEGALLY AUTHORIZED TO
6 POSSESS MEDICINE, INCLUDING A WHOLESALER, DISTRIBUTOR, REVERSE
7 DISTRIBUTOR, REPACKAGER, HOSPITAL, PHARMACY OR HEALTH CARE INSTITUTION.

8 2. "DONOR":

9 (a) MEANS ANY PERSON, ANY INDIVIDUAL MEMBER OF THE PUBLIC OR ANY
10 ENTITY LEGALLY AUTHORIZED TO POSSESS MEDICINE, INCLUDING A MANUFACTURER,
11 WHOLESALER, DISTRIBUTOR, THIRD-PARTY LOGISTIC PROVIDER, PHARMACY,
12 DISPENSER, CLINIC, SURGICAL CENTER, HEALTH CENTER, DETENTION AND
13 REHABILITATION CENTER, LABORATORY, MEDICAL SCHOOL, PHARMACY SCHOOL, HEALTH
14 CARE PROFESSIONAL OR HEALTH CARE FACILITY.

15 (b) INCLUDES GOVERNMENT AGENCIES AND ENTITIES THAT ARE FEDERALLY
16 AUTHORIZED TO POSSESS MEDICINE, INCLUDING DRUG MANUFACTURERS, REPACKAGERS,
17 RELABELERS, OUTSOURCING FACILITIES, PRISONS AND IMPORTERS AUTHORIZED BY
18 THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

19 3. "ELIGIBLE PATIENT" MEANS AN INDIVIDUAL WHO IS INDIGENT,
20 UNINSURED, UNDERINSURED OR ENROLLED IN A PUBLIC HEALTH BENEFITS PROGRAM.

21 4. "HEALTH CARE PROFESSIONAL" MEANS A HEALTH CARE PROVIDER WHO IS
22 LICENSED OR CERTIFIED PURSUANT TO THIS TITLE AND AUTHORIZED TO DISPENSE OR
23 ADMINISTER PRESCRIPTION DRUGS.

24 5. "MEDICINE" MEANS BOTH PRESCRIPTION AND NONPRESCRIPTION DRUGS,
25 INCLUDING DRUGS APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION
26 AND LABELED FOR INVESTIGATIONAL USE.

27 6. "RETURNS PROCESSOR" HAS THE SAME MEANING PRESCRIBED IN 21 UNITED
28 STATES CODE SECTION 360eee AND INCLUDES A REVERSE DISTRIBUTOR.

29 7. "UNOPENED, TAMPER-EVIDENT PACKAGING" HAS THE SAME MEANING AS
30 UNITED STATES PHARMACOPEIA PACKAGING AND STORAGE REQUIREMENTS, INCLUDING
31 UNOPENED UNIT-DOSE, MULTIPLE-DOSE AND IMMEDIATE, SECONDARY AND TERTIARY
32 PACKAGING.

APPROVED BY THE GOVERNOR MARCH 26, 2021.

FILED IN THE OFFICE OF THE SECRETARY OF STATE MARCH 26, 2021.