

House Engrossed Senate Bill

~~anti-rabies vaccination; rabies titer~~
(now: terminally ill patients; compounding; pharmacy)

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

CHAPTER 271
SENATE BILL 1353

AN ACT

AMENDING TITLE 32, CHAPTER 18, ARTICLE 3, ARIZONA REVISED STATUTES, BY
ADDING SECTION 32-1971; RELATING TO REGULATION OF PHARMACIES.

(TEXT OF BILL BEGINS ON NEXT PAGE)

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

2 Section 1. Title 32, chapter 18, article 3, Arizona Revised
3 Statutes, is amended by adding section 32-1971, to read:

4 32-1971. Compounding pharmacies; certain medications;
5 requirements; definitions

6 A. CHRONICALLY ILL PATIENTS AND TERMINALLY ILL PATIENTS HAVE THE
7 RIGHT TO DETERMINE, WITH THE ASSISTANCE AND GUIDANCE OF THEIR HEALTH CARE
8 PROVIDERS, INDIVIDUAL COURSES OF TREATMENT THROUGH THE USE OF MEDICATIONS
9 AND TREATMENTS OBTAINED FROM A COMPOUNDING PHARMACY.

10 B. COMPOUNDING PHARMACIES THAT ARE LICENSED IN THIS STATE SHALL
11 HAVE ACCESS TO ACTIVE PHARMACEUTICAL INGREDIENTS FOR USE IN COMPOUNDING
12 THAT MEET UNITED STATES PHARMACOPEIA MONOGRAPHS, IF THE ACTIVE
13 PHARMACEUTICAL INGREDIENT IS PREPARED FOR USE BY A UNITED STATES FOOD AND
14 DRUG ADMINISTRATION-REGISTERED ACTIVE PHARMACEUTICAL INGREDIENT
15 MANUFACTURER OR PACKAGER, IS SHIPPED INTO THIS STATE IN COMPLIANCE WITH
16 STATE LAW AND ARRIVES WITH A CERTIFICATE OF ANALYSIS DETAILING QUALITY
17 SPECIFICATIONS, INCLUDING ANY MEDICATIONS, DIETARY SUPPLEMENTS AND AMINO
18 ACIDS THAT ARE ALREADY IN USE BY COMPOUNDING PHARMACIES IN THIS STATE, IN
19 ORDER TO PROVIDE CHRONICALLY ILL PATIENTS AND TERMINALLY ILL PATIENTS WITH
20 THE PRESCRIBED INDIVIDUAL COURSE OF TREATMENT.

21 C. SUBSECTION B OF THIS SECTION DOES NOT APPLY IF THE ACTIVE
22 PHARMACEUTICAL INGREDIENT IS DEEMED UNSAFE FOR COMPOUNDING BY THE FEDERAL
23 FOOD AND DRUG ADMINISTRATION OR IS PLACED ON THE INTERIM 503A CATEGORY II
24 BULK DRUG SUBSTANCE LIST. COMPOUNDING PHARMACIES MAY USE SUBSTANCES
25 PLACED ON THE INTERIM 503A CATEGORY III BULK DRUG SUBSTANCE LIST ONLY IF
26 THE SUBSTANCE MEETS THE REQUIREMENTS OF THIS SECTION.

27 D. THIS SECTION DOES NOT ALLOW ANY TREATMENT OR USE OF MEDICATION
28 THAT IS INTENDED TO CAUSE THE DEATH OF THE PATIENT.

29 E. FOR THE PURPOSES OF THIS SECTION:

30 1. "CHRONICALLY ILL PATIENT" MEANS A PATIENT WHOSE PHYSICIAN HAS
31 DIAGNOSED THE PATIENT AS HAVING A LONG-TERM DISEASE OR CONDITION THAT IF
32 LEFT UNTREATED MAY CAUSE MAJOR IRREVERSIBLE MORBIDITY AND WHO MIGHT
33 BENEFIT FROM INDIVIDUALIZED OR SPECIALIZED MEDICATION THAT IS NOT
34 COMMERCIALY AVAILABLE.

35 2. "COMPOUNDING PHARMACY" MEANS A PHARMACY THAT IS CLASSIFIED AS A
36 503A PHARMACY BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

37 3. "MONOGRAPHS" MEANS QUALITY STANDARDS FOR PRESCRIPTION MEDICINES
38 AND DIETARY SUPPLEMENTS THAT ARTICULATE THE QUALITY EXPECTATIONS FOR A
39 MEDICINE OR DIETARY SUPPLEMENT, INCLUDING ITS IDENTITY, STRENGTH, PURITY
40 AND PERFORMANCE.

41 4. "TERMINALLY ILL PATIENT" MEANS A PATIENT WHOSE PHYSICIAN HAS
42 DIAGNOSED THE PATIENT WITH A DISEASE THAT, TAKING INTO ACCOUNT THE
43 PATIENT'S MEDICAL CIRCUMSTANCES, WILL CAUSE THE PATIENT'S DEATH IN A
44 REASONABLY FORESEEABLE TIME.

S.B. 1353

APPROVED BY THE GOVERNOR APRIL 20, 2021.

FILED IN THE OFFICE OF THE SECRETARY OF STATE APRIL 20, 2021.