

individualized investigational treatment; availability; prohibitions

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

CHAPTER 189
SENATE BILL 1163

AN ACT

AMENDING TITLE 36, ARIZONA REVISED STATUTES, BY ADDING CHAPTER 11.3;
RELATING TO HEALTH CARE.

(TEXT OF BILL BEGINS ON NEXT PAGE)

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

2 Section 1. Title 36, Arizona Revised Statutes, is amended by adding
3 chapter 11.3, to read:

4 CHAPTER 11.3

5 INDIVIDUALIZED INVESTIGATIONAL TREATMENT

6 ARTICLE 1. GENERAL PROVISIONS

7 36-1331. Definitions

8 IN THIS CHAPTER, UNLESS THE CONTEXT OTHERWISE REQUIRES:

9 1. "ELIGIBLE FACILITY" MEANS A HEALTH CARE INSTITUTION THAT
10 OPERATES UNDER A FEDERALWIDE ASSURANCE FOR THE PROTECTION OF HUMAN
11 SUBJECTS PURSUANT TO 45 CODE OF FEDERAL REGULATIONS PART 46 AND THAT IS
12 SUBJECT TO THE FEDERAL FEDERALWIDE ASSURANCE REGULATIONS, POLICIES AND
13 GUIDELINES, INCLUDING RENEWALS OR UPDATES.

14 2. "ELIGIBLE PATIENT" MEANS A PATIENT WHO MEETS ALL OF THE
15 FOLLOWING CONDITIONS:

16 (a) HAS A LIFE-THREATENING DISEASE OR CONDITION OR A SEVERELY
17 DEBILITATING ILLNESS, ATTESTED TO BY THE PATIENT'S PHYSICIAN.

18 (b) HAS CONSIDERED ALL OTHER TREATMENT OPTIONS CURRENTLY APPROVED
19 BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.

20 (c) HAS RECEIVED A RECOMMENDATION FROM THE PATIENT'S PHYSICIAN FOR
21 AN INDIVIDUALIZED INVESTIGATIONAL TREATMENT BASED ON AN ANALYSIS OF THE
22 PATIENT'S GENOMIC SEQUENCE, HUMAN CHROMOSOMES, DEOXYRIBONUCLEIC ACID,
23 RIBONUCLEIC ACID, GENES, GENE PRODUCTS, SUCH AS ENZYMES AND OTHER TYPES OF
24 PROTEINS, OR METABOLITES.

25 (d) HAS GIVEN WRITTEN INFORMED CONSENT FOR THE USE OF THE
26 INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE.

27 (e) HAS DOCUMENTATION FROM THE PATIENT'S PHYSICIAN THAT THE PATIENT
28 MEETS THE REQUIREMENTS OF THIS PARAGRAPH.

29 3. "INDIVIDUALIZED INVESTIGATIONAL TREATMENT":

30 (a) MEANS A DRUG, BIOLOGICAL PRODUCT OR DEVICE THAT IS UNIQUE TO
31 AND PRODUCED EXCLUSIVELY FOR USE BY AN INDIVIDUAL PATIENT BASED ON THE
32 PATIENT'S OWN GENETIC PROFILE.

33 (b) INCLUDES INDIVIDUALIZED GENE THERAPY, ANTISENSE
34 OLIGONUCLEOTIDES AND INDIVIDUALIZED NEOANTIGEN VACCINES.

35 4. "LIFE-THREATENING DISEASE OR CONDITION" MEANS A DISEASE OR
36 CONDITION THAT BOTH:

37 (a) HAS A HIGH LIKELIHOOD OF DEATH UNLESS THE COURSE OF THE DISEASE
38 OR CONDITION IS INTERRUPTED.

39 (b) HAS A POTENTIALLY FATAL OUTCOME AND FOR WHICH THE END POINT OF
40 CLINICAL TRIAL ANALYSIS IS SURVIVAL.

41 5. "SEVERELY DEBILITATING ILLNESS" MEANS A DISEASE OR CONDITION
42 THAT CAUSES MAJOR IRREVERSIBLE MORBIDITY.

43 6. "WRITTEN INFORMED CONSENT" MEANS A WRITTEN DOCUMENT THAT IS
44 SIGNED BY A PATIENT, THE PATIENT'S PARENT IF THE PATIENT IS A MINOR, THE
45 PATIENT'S LEGAL GUARDIAN OR THE PATIENT'S ADVOCATE DESIGNATED BY THE

1 PATIENT, THAT IS ATTESTED TO BY THE PATIENT'S PHYSICIAN AND A WITNESS AND
2 THAT, AT A MINIMUM, INCLUDES ALL OF THE FOLLOWING:

3 (a) AN EXPLANATION OF THE CURRENTLY APPROVED PRODUCTS AND
4 TREATMENTS FOR THE DISEASE OR CONDITION FROM WHICH THE PATIENT SUFFERS.

5 (b) AN ATTESTATION THAT THE PATIENT CONCURS WITH THE PATIENT'S
6 PHYSICIAN IN BELIEVING THAT ALL CURRENTLY APPROVED AND CONVENTIONALLY
7 RECOGNIZED TREATMENTS ARE UNLIKELY TO PROLONG THE PATIENT'S LIFE.

8 (c) CLEAR IDENTIFICATION OF THE SPECIFIC PROPOSED INDIVIDUALIZED
9 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE THAT THE PATIENT IS
10 SEEKING TO USE.

11 (d) A DESCRIPTION OF THE POTENTIALLY BEST AND WORST OUTCOMES OF
12 USING THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR
13 DEVICE AND A REALISTIC DESCRIPTION OF THE MOST LIKELY OUTCOME, INCLUDING
14 THE POSSIBILITY THAT NEW, UNANTICIPATED, DIFFERENT OR WORSE SYMPTOMS MIGHT
15 RESULT AND THAT DEATH COULD BE HASTENED BY THE PROPOSED TREATMENT. THE
16 DESCRIPTION SHALL BE BASED ON THE PHYSICIAN'S KNOWLEDGE OF THE PROPOSED
17 TREATMENT IN CONJUNCTION WITH AN AWARENESS OF THE PATIENT'S CONDITION.

18 (e) A STATEMENT THAT THE PATIENT'S HEALTH PLAN OR A THIRD-PARTY
19 ADMINISTRATOR AND PROVIDER ARE NOT OBLIGATED TO PAY FOR ANY CARE OR
20 TREATMENT CONSEQUENT TO THE USE OF THE INDIVIDUALIZED INVESTIGATIONAL
21 DRUG, BIOLOGICAL PRODUCT OR DEVICE UNLESS SPECIFICALLY REQUIRED TO DO SO
22 BY LAW OR CONTRACT.

23 (f) A STATEMENT THAT THE PATIENT'S ELIGIBILITY FOR HOSPICE CARE MAY
24 BE WITHDRAWN IF THE PATIENT BEGINS CURATIVE TREATMENT WITH THE
25 INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE AND THAT
26 CARE MAY BE REINSTATED IF THIS TREATMENT ENDS AND THE PATIENT MEETS
27 HOSPICE ELIGIBILITY REQUIREMENTS.

28 (g) A STATEMENT THAT THE PATIENT UNDERSTANDS THAT THE PATIENT IS
29 LIABLE FOR ALL EXPENSES CONSEQUENT TO THE USE OF THE INDIVIDUALIZED
30 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE AND THAT THIS LIABILITY
31 EXTENDS TO THE PATIENT'S ESTATE UNLESS A CONTRACT BETWEEN THE PATIENT AND
32 THE MANUFACTURER OF THE DRUG, BIOLOGICAL PRODUCT OR DEVICE STATES
33 OTHERWISE.

34 36-1332. Individualized investigational treatment;
35 availability

36 A. A MANUFACTURER OPERATING WITHIN AN ELIGIBLE FACILITY AND
37 PURSUANT TO ALL APPLICABLE FEDERALWIDE ASSURANCE REGULATIONS MAY MAKE
38 AVAILABLE TO AN ELIGIBLE PATIENT AN INDIVIDUALIZED INVESTIGATIONAL
39 TREATMENT. AN ELIGIBLE PATIENT'S PHYSICIAN MAY REQUEST AN INDIVIDUALIZED
40 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE FROM AN ELIGIBLE
41 FACILITY OR MANUFACTURER OPERATING WITHIN THE ELIGIBLE FACILITY. THIS
42 ARTICLE DOES NOT REQUIRE THAT A MANUFACTURER MAKE AVAILABLE AN
43 INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE TO AN
44 ELIGIBLE PATIENT.

1 B. AN ELIGIBLE FACILITY OR MANUFACTURER OPERATING WITHIN AN
2 ELIGIBLE FACILITY MAY DO BOTH OF THE FOLLOWING:

3 1. PROVIDE AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL
4 PRODUCT OR DEVICE TO AN ELIGIBLE PATIENT WITHOUT RECEIVING COMPENSATION.

5 2. REQUIRE AN ELIGIBLE PATIENT TO PAY THE COSTS OF, OR THE COSTS
6 ASSOCIATED WITH, THE MANUFACTURE OF THE INDIVIDUALIZED INVESTIGATIONAL
7 DRUG, BIOLOGICAL PRODUCT OR DEVICE.

8 36-1333. Insurance providers; third-party payors; coverage or
9 payment not required

10 A. A HEALTH PLAN, THIRD-PARTY ADMINISTRATOR OR OTHER THIRD-PARTY
11 PAYOR MAY, BUT IS NOT REQUIRED TO, PROVIDE COVERAGE FOR THE COST OF AN
12 INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE OR THE
13 COST OF SERVICES RELATED TO THE USE OF AN INDIVIDUALIZED INVESTIGATIONAL
14 DRUG, BIOLOGICAL PRODUCT OR DEVICE UNDER THIS ARTICLE.

15 B. THIS ARTICLE DOES NOT REQUIRE A HOSPITAL OR OTHER HEALTH CARE
16 INSTITUTION THAT IS LICENSED PURSUANT TO CHAPTER 4 OF THIS TITLE TO
17 PROVIDE NEW OR ADDITIONAL SERVICES UNLESS APPROVED BY THE HOSPITAL OR
18 HEALTH CARE INSTITUTION.

19 36-1334. Heirs; no debt liability related to treatment

20 NOTWITHSTANDING ANY OTHER LAW, IF A PATIENT DIES WHILE BEING TREATED
21 WITH AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE,
22 THE PATIENT'S HEIRS ARE NOT LIABLE FOR ANY OUTSTANDING DEBT RELATED TO THE
23 TREATMENT.

24 36-1335. Eligible patient's access; blocking by state
25 prohibited

26 AN OFFICIAL, EMPLOYEE OR AGENT OF THIS STATE MAY NOT BLOCK OR
27 ATTEMPT TO BLOCK AN ELIGIBLE PATIENT'S ACCESS TO AN INDIVIDUALIZED
28 INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE. COUNSELING, ADVICE OR
29 A RECOMMENDATION CONSISTENT WITH MEDICAL STANDARDS OF CARE FROM A LICENSED
30 PHYSICIAN IS NOT A VIOLATION OF THIS SECTION.

31 36-1336. No private cause of action

32 THIS ARTICLE DOES NOT CREATE A PRIVATE CAUSE OF ACTION AGAINST A
33 MANUFACTURER OF AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT
34 OR DEVICE OR AGAINST ANY OTHER PERSON OR ENTITY INVOLVED IN THE CARE OF AN
35 ELIGIBLE PATIENT USING THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL
36 PRODUCT OR DEVICE FOR ANY HARM DONE TO THE ELIGIBLE PATIENT RESULTING FROM
37 THE INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE IF
38 THE MANUFACTURER OR OTHER PERSON OR ENTITY IS COMPLYING IN GOOD FAITH WITH
39 THE TERMS OF THIS ARTICLE AND HAS EXERCISED REASONABLE CARE.

APPROVED BY THE GOVERNOR APRIL 25, 2022.

FILED IN THE OFFICE OF THE SECRETARY OF STATE APRIL 25, 2022.