REFERENCE TITLE: individualized investigational treatment; availability; prohibitions

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

SB 1163

Introduced by
Senators Barto: Gowan, Kerr, Livingston, Petersen, Townsend;
Representative Bolick

AN ACT

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

(TEXT OF BILL BEGINS ON NEXT PAGE)

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

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

CHAPTER 11.3

INDIVIDUALIZED INVESTIGATIONAL TREATMENT

ARTICLE 1. GENERAL PROVISIONS

36-1331. Definitions

IN THIS CHAPTER, UNLESS THE CONTEXT OTHERWISE REQUIRES:

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

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

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

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

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

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

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

3. "INDIVIDUALIZED INVESTIGATIONAL TREATMENT":

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

36-1332. Individualized investigational treatment; availability

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

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

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

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

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

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

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

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

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

36-1335. Regulatory boards; prohibitions

A HEALTH PROFESSION REGULATORY BOARD MAY NOT REVOKE, FAIL TO RENEW, SUSPEND OR TAKE ANY ACTION AGAINST A PHYSICIAN'S LICENSE ISSUED PURSUANT TO TITLE 32 BASED SOLELY ON THE PHYSICIAN'S RECOMMENDATIONS TO AN ELIGIBLE PATIENT REGARDING ACCESS TO OR TREATMENT WITH AN INDIVIDUALIZED INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT OR DEVICE.

36-1336. Eligible patient's access; blocking by state prohibited

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

36-1337. No private cause of action

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