

State of Arizona
House of Representatives
Fifty-second Legislature
Second Regular Session
2016

CHAPTER 292
HOUSE BILL 2307

AN ACT

AMENDING SECTIONS 36-414 AND 36-841, ARIZONA REVISED STATUTES; AMENDING TITLE 36, CHAPTER 7, ARTICLE 3, ARIZONA REVISED STATUTES, BY ADDING SECTIONS 36-851.01, 36-851.02 AND 36-851.03; RELATING TO THE REVISED UNIFORM ANATOMICAL GIFT ACT.

(TEXT OF BILL BEGINS ON NEXT PAGE)

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

2 Section 1. Section 36-414, Arizona Revised Statutes, is amended to
3 read:

4 36-414. Health services licensing fund; exemption

5 A. The health services licensing fund is established consisting of
6 monies deposited pursuant to sections 36-405, 36-851.01, 36-882, 36-897.01
7 and 36-1903. The department of health services shall administer the fund.

8 B. Monies in the fund are subject to legislative appropriation.

9 C. Monies in the fund are exempt from the provisions of section 35-190
10 relating to lapsing of appropriations.

11 Sec. 2. Section 36-841, Arizona Revised Statutes, is amended to read:

12 36-841. Definitions

13 In this article, unless the context otherwise requires:

14 1. "Adult" means an individual who is at least eighteen years of age.

15 2. "Agent" means an individual who is either:

16 (a) Authorized to make health care decisions on the principal's behalf
17 pursuant to a health care power of attorney.

18 (b) Expressly authorized to make an anatomical gift on the principal's
19 behalf pursuant to any other record signed by the principal.

20 3. "Anatomical gift" means a donation of all or part of a human body
21 to take effect after the donor's death for the purpose of transplantation,
22 therapy, research or education.

23 4. "Decedent" means a deceased individual whose body or part is or may
24 be the source of an anatomical gift. Decedent includes a stillborn infant
25 and, subject to restrictions imposed by any other law, a fetus.

26 5. "Disinterested witness" means a witness other than the spouse,
27 child, parent, sibling, grandchild, grandparent or guardian of the individual
28 who makes, amends, revokes or refuses to make an anatomical gift, or another
29 adult who exhibited special care and concern for the individual.
30 Disinterested witness does not include a person to which an anatomical gift
31 could pass pursuant to section 36-850.

32 6. "Document of gift" means a donor card or other record **THAT IS** used
33 to make an anatomical gift. Document of gift includes a statement or symbol
34 on a driver license, identification card or donor registry.

35 7. "Donor" means an individual whose body or part is the subject of an
36 anatomical gift.

37 8. "Donor registry" means a database that contains records of
38 anatomical gifts.

39 9. "Driver license" means a license or permit **THAT IS** issued pursuant
40 to title 28 to operate a vehicle, whether or not conditions are attached to
41 the license or permit.

42 10. "Eye bank" means a person that is licensed or regulated under
43 federal or state law or is accredited by a nationally recognized accrediting
44 agency to engage in the recovery, screening, testing, processing, storage or
45 distribution of human eyes or portions of human eyes.

- 1 11. "Guardian" means a person who is appointed by a court to make
2 decisions regarding the support, care, education, health or welfare of an
3 individual. Guardian does not include a guardian ad litem.
- 4 12. "Hospital" means a facility that is licensed as a hospital under
5 the laws of any state or that is operated as a hospital by the United States,
6 a state or a subdivision of a state.
- 7 13. "Identification card" means ~~an~~ A NONOPERATING identification ~~card~~
8 LICENSE THAT IS issued by the motor vehicle division of the department of
9 transportation.
- 10 14. "Know" means to have actual knowledge.
- 11 15. "Minor" means an individual who is under eighteen years of age.
- 12 16. "Organ procurement organization" means a person THAT IS designated
13 by the secretary of the United States department of health and human services
14 as an organ procurement organization.
- 15 17. "Parent" means a parent whose parental rights have not been
16 terminated.
- 17 18. "Part" means an organ, eye or tissue of a human being. Part does
18 not include the whole body.
- 19 19. "Person" means an individual, corporation, business trust, estate,
20 trust, partnership, limited liability company, association, joint venture,
21 public corporation, government or governmental subdivision, agency or
22 instrumentality, or any other legal or commercial entity.
- 23 20. "Physician" means an individual WHO IS licensed as a physician
24 pursuant to title 32, chapter 13 or 17.
- 25 21. "Principal" means a person who is the subject of a health care
26 power of attorney.
- 27 22. "Procurement organization" means ANY OF THE FOLLOWING:
28 (a) An organ procurement organization.
29 (b) A tissue bank.
30 (c) An eye bank.
31 (d) A storage facility that is licensed, accredited or approved under
32 federal law or the laws of any state to engage in the recovery, screening,
33 testing, processing, ~~OR~~ storage ~~or distribution~~ of human bodies or parts.
- 34 23. "Prospective donor" means an individual who is dead or near death
35 and who has been determined by a procurement organization to have a part that
36 could be medically suitable for transplantation, therapy, research or
37 education. Prospective donor does not include an individual who has made a
38 refusal.
- 39 24. "Reasonably available" means able to be contacted by a procurement
40 organization without undue effort and willing and able to act in a timely
41 manner consistent with existing medical criteria necessary for the making of
42 an anatomical gift.
- 43 25. "Recipient" means an individual into whose body a decedent's part
44 has been or is intended to be transplanted.

1 C. A LICENSE UNDER THIS SECTION IS VALID FOR TWO YEARS AND MUST BE
2 RENEWED EVERY TWO YEARS. A PERSON SHALL FILE AN APPLICATION FOR RENEWAL AT
3 LEAST THIRTY DAYS BEFORE THE EXPIRATION OF THE CURRENT LICENSE.

4 D. EACH PROCUREMENT ORGANIZATION APPLYING FOR LICENSURE OR LICENSE
5 RENEWAL UNDER THIS SECTION SHALL PAY ALL APPLICABLE FEES AS PRESCRIBED BY THE
6 DIRECTOR. ALL FEES COLLECTED PURSUANT TO THIS SECTION FOR THE LICENSURE AND
7 LICENSE RENEWAL OF PROCUREMENT ORGANIZATIONS SHALL BE DEPOSITED IN THE HEALTH
8 SERVICES LICENSING FUND ESTABLISHED BY SECTION 36-414.

9 E. THE DIRECTOR MAY SANCTION, IMPOSE CIVIL PENALTIES ON OR, PURSUANT
10 TO TITLE 41, CHAPTER 6, ARTICLE 10, SUSPEND OR REVOKE, IN WHOLE OR IN PART,
11 THE LICENSE OF ANY PROCUREMENT ORGANIZATION IF ANY PERSON WHO IS AN OWNER,
12 OFFICER, AGENT OR EMPLOYEE OF THE PROCUREMENT ORGANIZATION IS IN OR CONTINUES
13 TO BE IN VIOLATION OF THIS ARTICLE OR THE RULES OF THE DEPARTMENT OF HEALTH
14 SERVICES ADOPTED PURSUANT TO THIS ARTICLE.

15 F. THIS SECTION DOES NOT APPLY TO ANY OF THE FOLLOWING:

16 1. AN ORGAN PROCUREMENT ORGANIZATION AS DESCRIBED BY 42 UNITED STATES
17 CODE SECTION 273 THAT IS DESIGNATED FOR THIS STATE BY THE SECRETARY OF THE
18 UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES PURSUANT TO 42 UNITED
19 STATES CODE SECTION 1320b-8.

20 2. A PROCUREMENT ORGANIZATION THAT IS REGULATED BY THE UNITED STATES
21 FOOD AND DRUG ADMINISTRATION IN CONNECTION WITH THE RECOVERY OF HUMAN TISSUE
22 INTENDED FOR TRANSPLANTATION PURSUANT TO 21 CODE OF FEDERAL REGULATIONS PART
23 1270.

24 3. A PROCUREMENT ORGANIZATION AS DEFINED IN SECTION 36-841, PARAGRAPH
25 22, SUBDIVISION (d).

26 4. A PROCUREMENT ORGANIZATION THAT IS AFFILIATED WITH AN ACCREDITED
27 EDUCATIONAL INSTITUTION IN CONNECTION WITH THE EDUCATION OF STUDENTS ENROLLED
28 IN A DEGREE-GRANTING PROGRAM FOR HEALTH PROFESSIONALS.

29 5. A PROCUREMENT ORGANIZATION THAT IS AFFILIATED WITH AN ACCREDITED
30 HOSPITAL AS DEFINED IN SECTION 36-401 FOR THE RECOVERY OF ANATOMICAL GIFTS
31 FOR RESEARCH, EDUCATION, QUALITY IMPROVEMENT OR QUALITY ASSURANCE.

32 36-851.02. Procurement organizations: deemed status:
33 requirements: inspection

34 A PROCUREMENT ORGANIZATION THAT IS LICENSED PURSUANT TO SECTION
35 36-851.01 BY VIRTUE OF ITS ACCREDITATION STATUS:

36 1. IS DEEMED TO MEET HEALTH AND SAFETY REQUIREMENTS THAT ARE
37 EQUIVALENT TO THOSE SET FORTH IN SECTION 36-851.03 AND IS NOT REQUIRED TO
38 MEET THE REQUIREMENTS PRESCRIBED IN SECTION 36-851.03 EXCEPT AS SPECIFIED IN
39 PARAGRAPH 2 OF THIS SECTION IF THE PROCUREMENT ORGANIZATION MAINTAINS ITS
40 ACCREDITED STATUS WITH THE ACCREDITING AGENCY.

41 2. SHALL COMPLY WITH ALL OF THE FOLLOWING AS ADOPTED IN RULE BY THE
42 DEPARTMENT OF HEALTH SERVICES:

43 (a) THE PROPER USE AND MAINTENANCE OF DONOR CONSENT FORMS.

44 (b) THE IMPLEMENTATION AND MAINTENANCE OF PROPER IDENTIFICATION
45 SYSTEMS FOR BODIES AND DISARTICULATED ITEMS.

- 1 (c) THE IMPLEMENTATION AND MAINTENANCE OF PROTOCOLS AND MATERIALS FOR
2 PROCEDURES USED BY THE PROCUREMENT ORGANIZATION TO PROPERLY SCREEN END USERS.
- 3 (d) THE PROPER DOCUMENTATION AND DISCLOSURE OF THE DISEASE STATUS OF
4 TISSUE SPECIMENS TO END USERS.
- 5 (e) LABELING, PACKAGING, TRANSPORT AND DISTRIBUTION POLICIES AND
6 PROCEDURES.
- 7 (f) FINAL DISPOSITION PROCEDURES.
- 8 3. SHALL PROVIDE A DESIGNATED AREA FOR TISSUE RECOVERY THAT DOES NOT
9 OPERATE IN A FUNERAL ESTABLISHMENT FOR THE RECOVERY OF WHOLE BODIES FOR
10 MEDICAL RESEARCH AND EDUCATION.
- 11 4. IS SUBJECT TO INSPECTION BY THE DEPARTMENT OF HEALTH SERVICES AT
12 ANY TIME WITH RESPECT TO COMPLIANCE WITH THE REQUIREMENTS OF PARAGRAPH 2 OF
13 THIS SECTION.
- 14 36-851.03. Procurement organizations; requirements;
15 records; rules; inspection
- 16 A. EXCEPT AS PROVIDED IN SECTION 36-851.02, EACH PROCUREMENT
17 ORGANIZATION THAT IS REQUIRED TO BE LICENSED PURSUANT TO SECTION 36-851.01
18 SHALL DO ALL OF THE FOLLOWING:
- 19 1. DESIGNATE A MEDICAL DIRECTOR WHO IS A PHYSICIAN LICENSED PURSUANT
20 TO TITLE 32, CHAPTER 13 OR 17 AND WHO PROVIDES MEDICAL GUIDANCE TO DETERMINE
21 DONOR ELIGIBILITY.
- 22 2. EMPLOY A DIRECTOR WHO HOLDS AT LEAST A BACHELOR'S DEGREE IN A
23 RELATED SCIENCE FROM AN ACCREDITED UNIVERSITY AND WHO IS RESPONSIBLE FOR ALL
24 LICENSED ACTIVITIES OF THE ORGANIZATION.
- 25 3. COMPLY WITH ALL OF THE FOLLOWING AS ADOPTED IN RULE BY THE
26 DEPARTMENT OF HEALTH SERVICES:
- 27 (a) THE PROPER USE AND MAINTENANCE OF DONOR CONSENT FORMS.
- 28 (b) THE IMPLEMENTATION AND MAINTENANCE OF PROPER IDENTIFICATION
29 SYSTEMS FOR BODIES AND DISARTICULATED ITEMS.
- 30 (c) THE IMPLEMENTATION AND MAINTENANCE OF PROTOCOLS AND MATERIALS FOR
31 PROCEDURES USED BY THE PROCUREMENT ORGANIZATION TO PROPERLY SCREEN END USERS.
- 32 (d) THE PROPER DOCUMENTATION AND DISCLOSURE OF THE DISEASE STATUS OF
33 TISSUE SPECIMENS TO END USERS.
- 34 (e) LABELING, PACKAGING, TRANSPORT AND DISTRIBUTION POLICIES AND
35 PROCEDURES.
- 36 (f) FINAL DISPOSITION PROCEDURES.
- 37 4. IMPLEMENT AND MAINTAIN ALL OF THE FOLLOWING:
- 38 (a) STANDARD OPERATING PROCEDURES FOR ALL LICENSED FUNCTIONS OF THE
39 ORGANIZATION.
- 40 (b) A SAFETY AWARENESS AND BLOOD-BORNE PATHOGEN TRAINING PROGRAM THAT
41 COMPLIES WITH STATE AND FEDERAL LAW.
- 42 (c) A CLEANING PROGRAM THAT MITIGATES POTENTIAL CROSS-CONTAMINATION
43 BETWEEN DONORS.
- 44 5. PROVIDE A DESIGNATED AREA FOR TISSUE RECOVERY THAT:
- 45 (a) IS OPEN TO INSPECTION BY THE DEPARTMENT OF HEALTH SERVICES WITH OR
46 WITHOUT NOTICE.

1 (b) DOES NOT OPERATE IN A FUNERAL ESTABLISHMENT FOR THE RECOVERY OF
2 WHOLE BODIES FOR MEDICAL RESEARCH AND EDUCATION.

3 6. PROPERLY TRACK DONORS AND LABEL TISSUE BY DOING BOTH OF THE
4 FOLLOWING:

5 (a) ASSIGNING A UNIQUE IDENTIFYING NUMBER TO EACH DONOR AND USING THIS
6 NUMBER FOR ALL TISSUE FROM THAT DONOR THAT IS RECOVERED AND DISTRIBUTED.

7 (b) AFFIXING LABELS WITH THE FOLLOWING INFORMATION ON ALL
8 NONTRANSPLANT TISSUE SPECIMENS:

9 (i) A STATEMENT THAT UNIVERSAL PRECAUTIONS WILL BE USED.

10 (ii) A STATEMENT THAT THE SPECIMEN IS NOT FOR TRANSPLANT OR CLINICAL
11 USE.

12 (iii) ANY CONDITION OR LIMITATION REGARDING THE USE OF THE SPECIMEN.

13 (iv) CONTACT INFORMATION FOR THE PROCUREMENT ORGANIZATION.

14 7. MAINTAIN THE FOLLOWING RECORDS FOR TEN YEARS AFTER THE LAST DATE OF
15 TISSUE DISTRIBUTION:

16 (a) A COPY OR RECORDED CONSENT OF THE DONATION AUTHORIZATION.

17 (b) A COPY OF THE DONOR'S DEATH CERTIFICATE AND TRANSIT PERMIT ISSUED
18 BY THE STATE WHERE THE DEATH OCCURRED.

19 (c) A COPY OF THE DONOR'S PHYSICAL ASSESSMENT AND RISK ASSESSMENT
20 QUESTIONNAIRE.

21 (d) A COPY OF THE DONOR'S SEROLOGICAL RESULTS, WHEN APPLICABLE.

22 (e) A COPY OF ALL DOCUMENTATION RELATING TO TISSUE RECOVERY, STORAGE
23 AND DISTRIBUTION ACTIVITIES.

24 B. THE DEPARTMENT OF HEALTH SERVICES SHALL ADOPT RULES THAT FOLLOW, AS
25 NEARLY AS PRACTICABLE, THE REQUIREMENTS ON EQUIVALENT SUBJECTS SPECIFIED IN
26 SUBSECTION A OF THIS SECTION THAT ARE SET FORTH IN THE ACCREDITATION
27 REQUIREMENTS OF A NATIONALLY RECOGNIZED ACCREDITING AGENCY THAT IS APPROVED
28 BY THE DEPARTMENT.

29 C. A PROCUREMENT ORGANIZATION THAT IS SUBJECT TO THE REQUIREMENTS OF
30 THIS SECTION IS SUBJECT TO INSPECTION BY THE DEPARTMENT OF HEALTH SERVICES AT
31 ANY TIME TO EVALUATE THE COMPLIANCE BY THE PROCUREMENT ORGANIZATION WITH THE
32 REQUIREMENTS OF THIS ARTICLE AND THE RULES ADOPTED BY THE DEPARTMENT.

33 Sec. 4. Department of health services; rulemaking exemption

34 For the purposes of implementing this act, the department of health
35 services shall adopt rules relating to the licensure of procurement
36 organizations and enforcement of those provisions. The department is exempt
37 from the rulemaking requirements of title 41, chapter 6, Arizona Revised
38 Statutes, for one year after the effective date of this act.

APPROVED BY THE GOVERNOR MAY 17, 2016.

FILED IN THE OFFICE OF THE SECRETARY OF STATE MAY 17, 2016.