

PROPOSED
HOUSE OF REPRESENTATIVES AMENDMENTS TO S.B. 1214
(Reference to Senate engrossed bill)

Amendment instruction key:
[GREEN UNDERLINING IN BRACKETS] indicates text added to statute or previously enacted session law.
[Green underlining in brackets] indicates text added to new session law or text restoring existing law.
[GREEN STRIKEOUT IN BRACKETS] indicates new text removed from statute or previously enacted session law.
[Green strikeout in brackets] indicates text removed from existing statute, previously enacted session law or new session law.
<<Green carets>> indicate a section added to the bill.
<<Green strikeout in carets>> indicates a section removed from the bill.

1 The bill as proposed to be amended is reprinted as follows:

2 Section 1. Title 32, chapter 32, Arizona Revised Statutes, is
3 amended by adding article 2.1, to read:

4 ARTICLE 2.1. STEM CELL AND REGENERATIVE THERAPY

5 32-3235. Definitions

6 IN THIS ARTICLE, UNLESS THE CONTEXT OTHERWISE REQUIRES:

7 1. "PROVIDER" MEANS ANY HEALTH PROFESSIONAL WHO IS LICENSED
8 PURSUANT TO THIS TITLE AND WHOSE SCOPE OF PRACTICE INCLUDES STEM CELL OR
9 REGENERATIVE THERAPY.

10 2. "STEM CELL OR REGENERATIVE THERAPY" MEANS A TREATMENT THAT
11 INVOLVES THE USE OF AFTERBIRTH, INCLUDING PLACENTAL PERINATAL CELLS OR
12 OTHER CELLS OR TISSUES OR AMNIOTIC FLUID, THAT MAY BE AUTOLOGOUS OR
13 ALLOGENEIC OR CULTURE EXPANDED AND THAT COMPLIES WITH THE REQUIREMENTS
14 PRESCRIBED IN THIS ARTICLE.

15 32-3236. Stem cell therapy; regenerative therapy; ethical
16 requirements; informed consent; records;
17 advertising; unprofessional conduct; civil action

18 A. A PROVIDER MAY PERFORM STEM CELL OR REGENERATIVE THERAPY THAT IS
19 NOT APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION IF ALL OF
20 THE FOLLOWING APPLY:

21 1. THE STEM CELL OR REGENERATIVE THERAPY IS WITHIN THE PROVIDER'S
22 LAWFUL SCOPE OF PRACTICE.

23 2. THE PROVIDER HAS COMPLETED A NATIONALLY RECOGNIZED, ACCREDITED
24 OR BOARD-RECOGNIZED CONTINUING EDUCATION TRAINING IN STEM CELL OR
25 REGENERATIVE THERAPY.

26 3. THE STEM CELL OR REGENERATIVE THERAPY COMPLIES WITH THE SOURCING
27 REQUIREMENTS PRESCRIBED IN SUBSECTION B OF THIS SECTION.

1 4. THE PROVIDER OBTAINS WRITTEN INFORMED CONSENT PURSUANT TO
2 SUBSECTION H OF THIS SECTION BEFORE PERFORMING ANY STEM CELL OR
3 REGENERATIVE THERAPY.

4 B. ANY CELLS, EXOSOMES OR BIOLOGIC MATERIALS USED FOR THERAPEUTIC
5 PURPOSES UNDER THIS SECTION MUST BE SOURCED EXCLUSIVELY FROM A FACILITY
6 THAT IS REGISTERED, CERTIFIED OR ACCREDITED AND INSPECTED IN COMPLIANCE
7 WITH SUBSECTION C OF THIS SECTION AND THAT OPERATES IN COMPLIANCE WITH
8 CURRENT GOOD MANUFACTURING PRACTICE STANDARDS.

9 C. TO ENSURE THAT THE RETRIEVAL, MANUFACTURE, STORAGE AND USE OF
10 STEM CELL AND REGENERATIVE MEDICINES USED FOR THERAPIES CONDUCTED PURSUANT
11 TO THIS SECTION MEET THE HIGHEST STANDARDS, THE STEM CELLS OR REGENERATIVE
12 MEDICINES BEING USED MUST MEET THE FOLLOWING REQUIREMENTS:

13 1. BE RETRIEVED, MANUFACTURED AND STORED IN A FACILITY THAT IS
14 EITHER REGISTERED, REGULATED AND INSPECTED BY THE UNITED STATES FOOD AND
15 DRUG ADMINISTRATION OR CERTIFIED OR ACCREDITED BY ANY OF THE FOLLOWING:

16 ~~[(a)] THE NATIONAL MARROW DONOR PROGRAM.~~

17 ~~[(b)]~~ [(a)] THE WORLD MARROW DONOR ASSOCIATION.

18 ~~[(c)]~~ [(b)] THE ASSOCIATION FOR THE ADVANCEMENT OF BLOOD AND
19 BIOTHERAPIES.

20 ~~[(d)]~~ [(c)] THE AMERICAN ASSOCIATION OF TISSUE BANKS.

21 ~~[(e)]~~ [(d)] THE AMERICAN ACADEMY OF STEM CELL MEDICINE.

22 2. BE SUPPLIED BY THE MANUFACTURER WITH APPROPRIATE VALIDATION OF
23 ISOLATION TECHNIQUES, INCLUDING CELL VIABILITY AND SURFACE MARKER REPORTS
24 FOR CELLULAR PRODUCTS, A VISCOSITY REPORT FOR WHARTON'S JELLY AND EXOSOME
25 COUNTS FOR EXOSOME-BASED REGENERATIVE PRODUCTS. LOT-SPECIFIC STERILITY
26 REPORTS AND CERTIFICATES OF ANALYSIS MUST BE PROVIDED WITH EACH PRODUCT
27 BEFORE USE WITH THE PROVIDER'S PATIENT.

28 D. A PROVIDER WHO PERFORMS STEM CELL OR REGENERATIVE THERAPY MAY
29 NOT OBTAIN STEM CELLS OR REGENERATIVE MEDICINES FROM ANY FACILITY THAT
30 DOES NOT HAVE A VALID CERTIFICATION OR ACCREDITATION AS REQUIRED BY
31 SUBSECTION C OF THIS SECTION. ANY CONTRACT OR AGREEMENT BY WHICH A
32 PROVIDER OBTAINS STEM CELLS OR REGENERATIVE MEDICINES FOR THERAPIES FROM A
33 CERTIFIED OR ACCREDITED MANUFACTURING FACILITY MUST INCLUDE THE FOLLOWING
34 INFORMATION:

35 1. THE NAME AND ADDRESS OF THE MANUFACTURING FACILITY.

36 2. THE MANUFACTURING FACILITY'S CERTIFYING OR ACCREDITING
37 ORGANIZATION.

38 3. PROOF OF CERTIFICATION OR ACCREDITATION.

39 4. PROOF OF SITE INSPECTION BY THE UNITED STATES FOOD AND DRUG
40 ADMINISTRATION OR THE CERTIFYING OR ACCREDITING ORGANIZATION NAMED IN
41 PARAGRAPH 2 OF THIS SUBSECTION.

42 5. THE TYPE AND SCOPE OF CERTIFICATION OR ACCREDITATION.

43 6. THE EFFECTIVE DATE AND EXPIRATION DATE OF THE CERTIFICATION OR
44 ACCREDITATION.

45 7. ANY LIMITS OR CONDITIONS IMPOSED BY THE CERTIFYING OR
46 ACCREDITING ORGANIZATION ON THE MANUFACTURING FACILITY.

1 8. A STATEMENT INDICATING, WITH SPECIFICITY, HOW, WHEN AND WHERE
2 THE STEM CELLS WERE OBTAINED, SUCH AS ADULT STEM CELLS, UMBILICAL CORD
3 BLOOD OR AMNIOTIC FLUID.

4 E. ANY MANUFACTURING FACILITY THAT PROVIDES STEM CELLS OR
5 REGENERATIVE MEDICINE TO A PROVIDER FOR STEM CELL OR REGENERATIVE THERAPY
6 MUST NOTIFY THE PROVIDER TO WHOM THE MANUFACTURING FACILITY IS PROVIDING
7 STEM CELLS OR REGENERATIVE MEDICINE WITHIN THIRTY DAYS AFTER ANY CHANGE IN
8 CERTIFICATION OR ACCREDITATION STATUS, INCLUDING SUSPENSION, REVOCATION,
9 RENEWAL OR EXPIRATION.

10 F. A PROVIDER SHALL ENSURE THAT ALL PRODUCTS USED IN STEM CELL OR
11 REGENERATIVE THERAPY ARE OBTAINED FROM A MANUFACTURING FACILITY THAT
12 COMPLIES WITH CURRENT GOOD MANUFACTURING PRACTICES IN ACCORDANCE WITH THE
13 FEDERAL FOOD, DRUG, AND COSMETIC ACT (52 STAT. 1040; 21 UNITED STATES CODE
14 SECTION 301) AND 21 CODE OF FEDERAL REGULATIONS PART 1271.

15 G. ANY PROVIDER ADVERTISING STEM CELL OR REGENERATIVE THERAPY MUST
16 INCLUDE THE FOLLOWING DISCLOSURE IN ANY FORM OF ADVERTISEMENT, IN A TYPE
17 SIZE OF AT LEAST THE LARGEST TYPE USED ELSEWHERE IN THE ADVERTISEMENT:

18 THIS NOTICE IS REQUIRED BY ARIZONA LAW. THIS PROVIDER OFFERS
19 ONE OR MORE STEM CELL OR REGENERATIVE THERAPIES THAT ARE NOT
20 APPROVED BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION.
21 YOU ARE ENCOURAGED TO CONSULT WITH YOUR PRIMARY CARE PROVIDER
22 BEFORE UNDERGOING ANY STEM CELL OR REGENERATIVE THERAPY.

23 H. BEFORE PERFORMING ANY STEM CELL OR REGENERATIVE THERAPY, THE
24 PROVIDER SHALL OBTAIN A SIGNED INFORMED CONSENT FORM FROM THE PATIENT OR,
25 IF THE PATIENT IS NOT LEGALLY COMPETENT, FROM THE PATIENT'S AUTHORIZED
26 REPRESENTATIVE THAT CLEARLY STATES:

27 1. THE NATURE AND CHARACTER OF THE PROPOSED TREATMENT.

28 2. THAT THE TREATMENT HAS NOT BEEN APPROVED BY THE UNITED STATES
29 FOOD AND DRUG ADMINISTRATION.

30 3. THE ANTICIPATED RESULTS OF THE PROPOSED TREATMENT.

31 4. THE RECOGNIZED SERIOUS POSSIBLE RISKS AND COMPLICATIONS OF THE
32 TREATMENT, THE ANTICIPATED BENEFITS OF THE TREATMENT AND ANY ALTERNATIVES
33 TO THE TREATMENT, INCLUDING THE OPTION OF NOT UNDERGOING TREATMENT.

34 5. THAT THE PATIENT IS ENCOURAGED TO CONSULT WITH THE PATIENT'S
35 PRIMARY CARE PROVIDER BEFORE PROCEEDING WITH THE TREATMENT.

36 I. A PROVIDER ADMINISTERING A STEM CELL OR REGENERATIVE THERAPY
37 SHALL MAINTAIN ACCURATE TREATMENT RECORDS, DOCUMENT CLINICAL OUTCOMES AND
38 ANY ADVERSE EVENTS AND REPORT AS FOLLOWS:

39 1. THE PROVIDER SHALL REPORT ANY SERIOUS ADVERSE EVENT THAT IS
40 REASONABLY SUSPECTED TO BE LINKED TO THE THERAPY TO THE PROVIDER'S
41 RESPECTIVE HEALTH PROFESSION REGULATORY BOARD WITHIN FIFTEEN CALENDAR DAYS
42 AFTER THE PROVIDER BECOMES AWARE OF THE SERIOUS ADVERSE EVENT.

43 2. THE PROVIDER SHALL REPORT ANY SERIOUS ADVERSE EVENT TO THE
44 SUPPLIER OF THE STEM CELL OR REGENERATIVE THERAPY.

45 J. A PROVIDER MAY VOLUNTARILY SUBMIT DE-IDENTIFIED PATIENT DATA TO
46 PROFESSIONAL CLINICAL REGISTRIES.

1 K. A PROVIDER WHO:

2 1. VIOLATES THIS SECTION COMMITS AN ACT OF UNPROFESSIONAL CONDUCT
3 PURSUANT TO THE CHAPTER OF THIS TITLE UNDER WHICH THE PROVIDER IS
4 LICENSED.

5 2. ACTS IN GOOD FAITH AND IN COMPLIANCE WITH THIS SECTION IS NOT
6 SUBJECT TO PROFESSIONAL DISCIPLINARY ACTION OR LICENSE REVOCATION SOLELY
7 FOR THE ACT OF ADMINISTERING A STEM CELL OR REGENERATIVE THERAPY. THIS
8 PARAGRAPH DOES NOT APPLY TO CASES INVOLVING GROSS NEGLIGENCE, MEDICAL
9 FRAUD OR INTENTIONAL MISCONDUCT.

10 L. ANY INDIVIDUAL WHO RECEIVES A STEM CELL OR REGENERATIVE THERAPY
11 TREATMENT THAT VIOLATES THIS SECTION MAY BRING A CIVIL ACTION TO RECOVER
12 STATUTORY DAMAGES IN AN AMOUNT OF \$10,000 PER VIOLATION, PLUS ATTORNEY
13 FEES AND COSTS.

14 Sec. 2. Legislative intent

15 The purpose of this act is to authorize qualified providers in this
16 state to administer specific stem cell and regenerative therapies under
17 clearly defined safety conditions, to ensure comprehensive informed
18 consent and advertising transparency and to protect patient safety by
19 ensuring compliance with biological sourcing standards.

20 Sec. 3. Short title

21 This act may be cited as the "Arizona Stem Cell and Regenerative
22 Therapy Act."

23 Enroll and engross to conform

24 Amend title to conform

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