House Engrossed Senate Bill

~~stem cells; birth tissue; therapy~~
(now: stem cells; regenerative therapy)

State of Arizona
Senate
Fifty-seventh Legislature
Second Regular Session
2026

SENATE BILL 1214

AN ACT

AMENDING TITLE 32, CHAPTER 32, ARIZONA REVISED STATUTES, BY ADDING ARTICLE 2.1; RELATING TO THE PRACTICE OF MEDICINE.

(TEXT OF BILL BEGINS ON NEXT PAGE)

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

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

ARTICLE 2.1. STEM CELL AND REGENERATIVE THERAPY

32-3235. Definitions

IN THIS ARTICLE, UNLESS THE CONTEXT OTHERWISE REQUIRES:

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

2. "STEM CELL OR REGENERATIVE THERAPY" MEANS A TREATMENT THAT INVOLVES THE USE OF CELLS, TISSUES OR BIOLOGIC MATERIALS THAT ARE DERIVED EXCLUSIVELY FROM ADULT DONORS OR FROM AFTERBIRTH, INCLUDING PLACENTAL CELLS, PERINATAL CELLS, AMNIOTIC FLUID OR UMBILICAL CORD BLOOD, THAT MAY BE AUTOLOGOUS OR ALLOGENEIC OR CULTURE EXPANDED AND THAT COMPLIES WITH THE REQUIREMENTS PRESCRIBED IN THIS ARTICLE.

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

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

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

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

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

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

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

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

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

(a) THE WORLD MARROW DONOR ASSOCIATION.

(b) THE ASSOCIATION FOR THE ADVANCEMENT OF BLOOD AND BIOTHERAPIES.
(c) THE AMERICAN ASSOCIATION OF TISSUE BANKS.
(d) THE AMERICAN ACADEMY OF STEM CELL MEDICINE.

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

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

1. THE NAME AND ADDRESS OF THE MANUFACTURING FACILITY.
2. THE MANUFACTURING FACILITY'S CERTIFYING OR ACCREDITING ORGANIZATION.
3. PROOF OF CERTIFICATION OR ACCREDITATION.
4. PROOF OF SITE INSPECTION BY THE UNITED STATES FOOD AND DRUG ADMINISTRATION OR THE CERTIFYING OR ACCREDITING ORGANIZATION NAMED IN PARAGRAPH 2 OF THIS SUBSECTION.
5. THE TYPE AND SCOPE OF CERTIFICATION OR ACCREDITATION.
6. THE EFFECTIVE DATE AND EXPIRATION DATE OF THE CERTIFICATION OR ACCREDITATION.
7. ANY LIMITS OR CONDITIONS IMPOSED BY THE CERTIFYING OR ACCREDITING ORGANIZATION ON THE MANUFACTURING FACILITY.
8. A STATEMENT INDICATING, WITH SPECIFICITY, HOW, WHEN AND WHERE THE STEM CELLS WERE OBTAINED, SUCH AS ADULT STEM CELLS, UMBILICAL CORD BLOOD OR AMNIOTIC FLUID.

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

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

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

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

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

1. THE NATURE AND CHARACTER OF THE PROPOSED TREATMENT.

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

3. THE ANTICIPATED RESULTS OF THE PROPOSED TREATMENT.

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

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

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

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

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

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

K. A PROVIDER WHO:

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

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

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

Sec. 2. Legislative intent

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

Sec. 3. Short title

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