FINAL BILL REPORT
ESHB 2356

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Synopsis as Enacted

Brief Description: Concerning stem cell therapies not approved by the United States food and drug administration.

Sponsors: House Committee on Health Care & Wellness (originally sponsored by Representatives Cody, Johnson, McBride, Jinkins, Ryu and Ormsby).

House Committee on Health Care & Wellness
Senate Committee on Health & Long Term Care

Background:

Stem Cell Therapies.

A stem-cell is a type of cell in a living organism that has the potential to split into a variety of different types of cells. Sometimes referred to as "master cells," stem cells can give rise to specialized cells such as blood, brain, or nerve cells, while themselves remaining stem cells.

The only stem cell-based products that are approved by the United States Food and Drug Administration (FDA) for use in the United States consist of blood-forming stem cells (hematopoietic progenitor cells) derived from cord blood. These products are approved for limited use in patients with disorders affecting the body's blood production systems.

Food and Drug Administration Regulation and Exceptions.

The FDA regulates the use of human cells, tissues, and cellular or tissue-based products (HCT/Ps), a category that includes, among other things, bone, skin, heart valves, semen, and stem cells. The FDA takes a tiered, risk-based approach to HCT/P regulation, with different requirements adhering to different sorts of HCT/Ps. As a general rule, HCT/P products are regulated as drugs, and are therefore subject to pre-market FDA clearance and approval and other requirements. However, the regulations provide for two exceptions to the pre-market approval (and in some cases, other) requirements:

Exception 1: The "Same Surgical Procedure" Exception.

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The FDA excludes from regulation (including pre-market approval and clearance requirements) a number of categories of HCT/P users including:

- storage facilities for HCT/Ps;
- certain reproductive establishments that immediately transfer HCT/Ps to a sexually intimate partner of the donor;
- establishments that exclusively use HCT/Ps for nonclinical scientific or educational purposes; and
- establishments that remove HCT/Ps from an individual and implant such HCT/Ps into the same individual during the same surgical procedure.

Exception 2: The "Minimally Manipulated" Exception.

The FDA excludes from the pre-market approval and clearance requirement, but imposes other, less stringent requirements on HCT/P users when:

- the HCT/P is minimally manipulated;
- the HCT/P is intended for homologous use only (meaning the cells perform the same basic function or functions in the recipient as in the donor), as reflected by the labeling, advertising, or other indications by the manufacturer; and
- the manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent; and either:
  - the HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or
  - the HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:
    - is for autologous use (cells are transferred back into the same person from which they were retrieved);
    - is for allogeneic use in a first-degree or second-degree blood relative (cells are transferred into a close relative of the donor); or
    - is for reproductive use.

Food and Drug Administration Guidance and Enforcement Timeline.

The FDA has recently communicated its intention to pursue enforcement actions against providers of stem cell therapies that it views as abusing the above-listed exceptions. In November 2017 the FDA issued two guidance documents discussing the FDA's interpretation of terms within these exceptions.

In order to allow manufacturers of products time to comply with these requirements, until November 2020, the FDA intends to pursue enforcement action only against those noncompliant HCT/P procedures that raise reported or potential significant safety concerns.

Uniform Disciplinary Act.

Credentialed health care providers are subject to professional discipline under the Uniform Disciplinary Act (UDA). Under the UDA, the disciplining authority may take action against a provider for a variety of reasons, including unprofessional conduct, unlicensed practice, and the mental or physical inability to practice skillfully or safely. The Department of Health

is the disciplining authority for many providers, and various boards and commissions are the disciplining authority for the remainder.

Upon a finding of unprofessional conduct, the disciplining authority may order sanctions such as revocation of the license, fines, compliance with probation conditions, or restriction or limitation of the practice.

Summary:

A credentialed health care provider who performs a therapy using HCT/Ps not approved by the FDA must satisfy notice and written informed consent requirements prior to performing the therapy.

The notice must read as follows:

> THIS NOTICE MUST BE PROVIDED TO YOU UNDER WASHINGTON LAW. This health care practitioner performs one or more stem cell therapies that have not yet been approved by the United States Food and Drug Administration. You are encouraged to consult with your primary care provider prior to undergoing a stem cell therapy.

The notice must be provided:

- to the patient prior to therapy, in a written notice in a size of at least eight and one-half inches by eleven inches and in no less than 40 point type;
- in the license holder's office, both in the entrance and in an area visible to patients; and
- in all advertisements for the therapy, in the following manner:
  - in print advertisements, the notice must be no smaller than the largest font size used in the advertisement; and
  - in all other advertisements, the notice must be either printed in a font no smaller than the largest font size used in the advertisement or clearly spoken.

Written Consent.
The credentialed health care provider is also required to obtain a signed consent form before performing the therapy. The consent form must be signed by the patient, or, if the patient is legally not competent, the patient's representative, and must state, in language the patient could reasonably be expected to understand:

- the nature and character of the proposed treatment, including the treatment's FDA approval status;
- the anticipated results of the proposed treatment;
- the recognized possible alternative forms of treatment; and
- the recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including nontreatment.

Violation of these requirements constitutes unprofessional conduct under the UDA.

Notice and consent requirements do not apply to:

- a license holder who has obtained approval for an investigational new drug or device from the FDA; or
- a license holder who performs stem cell therapies on behalf of an institution that has obtained certification by the foundation for the accreditation of cellular therapy, the national institutes of health blood and marrow transplant clinical trials network, or AABB.

Votes on Final Passage:

House	97	0
Senate	48	0

Effective: June 7, 2018