SENATE BILL REPORT
ESHB 2356

As Reported by Senate Committee On:
Health & Long Term Care, February 22, 2018

Title: An act relating to stem cell therapies not approved by the United States food and drug administration.

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).

Brief History: Passed House: 2/12/18, 97-0.
Committee Activity: Health & Long Term Care: 2/20/18, 2/22/18 [DP].

Brief Summary of Bill

- Requires licensed health care professionals to notify patients when the stem cell therapy they provide has not been approved by the Food and Drug Administration (FDA).

SENATE COMMITTEE ON HEALTH & LONG TERM CARE

Majority Report: Do pass.
Signed by Senators Cleveland, Chair; Kuderer, Vice Chair; Rivers, Ranking Member; Bailey, Becker, Conway, Fain, Keiser, Mullet and Van De Wege.

Staff: LeighBeth Merrick (786-7445)

Background: 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 and be used to restore or regenerate cells in a therapeutic manner. The FDA regulates stem cell therapy and conducts an approval process to determine the safety and efficacy of the product. This includes investigating the product's manufacturing process and data from clinical studies. The only FDA approved stem cell therapies are blood-forming stem cells that are derived from cord blood. These products are approved for limited use in patients with disorders affecting the body's blood production systems.

This analysis was prepared by non-partisan legislative staff for the use of legislative members in their deliberations. This analysis is not a part of the legislation nor does it constitute a statement of legislative intent.

Under the Uniform Disciplinary Act (UDA), the Department of Health or professional board or commission may take disciplinary action against licensed health care providers for unprofessional conduct. Disciplining actions include fines, license revocations, and restrictions on practice.

Summary of Bill: Before performing a stem cell therapy that is not approved by the FDA, a licensed health care provider must provide the patient with a written notice and receive the patient's signed consent.

The notice must state: "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 prominently displayed in the entrance and in an area visible to patients in the license holder's office, and be sized at no less than 8.5 inches by 11 inches and in 40 point type or greater. The notice must be used in all advertisements for the therapy. In print advertisements, the notice must be no smaller than the largest font size used in the advertisement. For all other advertisements, the notice must be in a font size no smaller than the largest font size used in the advertisement or clearly spoken.

The written consent form must be provided in a language the patient could reasonably understand and state:

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

Violation of these requirements constitutes unprofessional conduct under the UDA.

The requirements do not apply to licensed health care providers who have FDA investigational new drug or device approval and to licensed health care providers who perform stem cell therapies for institutions that are certified by The Foundation for the Accreditation of Cellular Therapy, The National Institutes of Health Blood and Marrow Transplant Clinical Trials Network, or the American Association of Blood Banks.

Appropriation: None.

Fiscal Note: Available.

Creates Committee/Commission/Task Force that includes Legislative members: No.

Effective Date: Ninety days after adjournment of session in which bill is passed.

Staff Summary of Public Testimony: PRO: These non-FDA approved stem cell therapy clinics are popping all over the state and consumers are not aware or informed that the treatments these clinics are providing is not approved by the FDA. This is a consumer protection bill that ensures patients are given the information they need upfront to make an informed decision. California has passed a similar bill.

Persons Testifying: PRO: Representative Eileen Cody, Prime Sponsor; Ian Goodhew, UW Medicine.

Persons Signed In To Testify But Not Testifying: No one.