CERTIFICATION OF ENROLLMENT

**ENGROSSED SUBSTITUTE HOUSE BILL 2356**

Chapter 216, Laws of 2018

65th Legislature

2018 Regular Session

STEM CELL THERAPIES--INFORMED CONSENT

EFFECTIVE DATE: June 7, 2018

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| Passed by the House February 12, 2018  Yeas 97 Nays 0  FRANK CHOPP  **Speaker of the House of Representatives**  Passed by the Senate March 2, 2018  Yeas 48 Nays 0  KAREN KEISER  **President of the Senate** | CERTIFICATE  I, Bernard Dean, Chief Clerk of the House of Representatives of the State of Washington, do hereby certify that the attached is **ENGROSSED SUBSTITUTE HOUSE BILL 2356** as passed by House of Representatives and the Senate on the dates hereon set forth.  BERNARD DEAN  Chief Clerk |
| Approved March 22, 2018 3:55 PM | March 26, 2018 |
| JAY INSLEE  **Governor of the State of Washington** | **Secretary of State**  **State of Washington** |

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**ENGROSSED SUBSTITUTE HOUSE BILL 2356**

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Passed Legislature - 2018 Regular Session

**State of Washington 65th Legislature 2018 Regular Session**

**By** House Health Care & Wellness (originally sponsored by Representatives Cody, Johnson, McBride, Jinkins, Ryu, and Ormsby)

AN ACT Relating to stem cell therapies not approved by the United States food and drug administration; amending RCW 18.130.180; and adding a new section to chapter 18.130 RCW.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec.**  A new section is added to chapter 18.130 RCW to read as follows:

(1) A license holder subject to this chapter who performs a stem cell therapy that is not approved by the United States food and drug administration, shall provide the patient with the following written notice prior to performing the therapy:

"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."

(2) The written notice required by subsection (1) of this section must be at least eight and one-half inches by eleven inches and written in no less than forty point type. The license holder must also prominently display the written notice in the entrance and in an area visible to patients in the license holder's office.

(3) A license holder who is required to provide written notice under subsection (1) of this section must also 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:

(a) The nature and character of the proposed treatment, including the treatment's food and drug administration approval status;

(b) The anticipated results of the proposed treatment;

(c) The recognized possible alternative forms of treatment; and

(d) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment and in the recognized possible alternative forms of treatment, including nontreatment.

(4) The license holder must include the notice set forth in subsection (1) of this section in any advertisements for the therapy. In print advertisements, the notice must be clearly legible, in a font size no smaller than the largest font size used in the advertisement. In all other forms of advertisements, the notice must be either clearly legible in a font size no smaller than the largest font size used in the advertisement or clearly spoken.

(5) This section does not apply to the following:

(a) A license holder who has obtained approval for an investigational new drug or device from the United States food and drug administration for the use of human cells, tissues, or cellular or tissue-based products.

(b) A license holder who performs a stem cell therapy pursuant to an employment or other contract to perform the therapy on behalf of or under the auspices of an institution certified by the foundation for the accreditation of cellular therapy, the national institutes of health blood and marrow transplant clinical trials network, or AABB.

(6) Violations of this section constitute unprofessional conduct under this chapter.

(7) For purposes of this section:

(a) "Human cells, tissues, or cellular or tissue-based products" has the same meaning as in 21 C.F.R. Sec. 1271.3 as it exists on the effective date of this section.

(b) "Stem cell therapy" means a therapy involving the use of human cells, tissues, or cellular or tissue-based products.

**Sec.**  RCW 18.130.180 and 2010 c 9 s 5 are each amended to read as follows:

The following conduct, acts, or conditions constitute unprofessional conduct for any license holder under the jurisdiction of this chapter:

(1) The commission of any act involving moral turpitude, dishonesty, or corruption relating to the practice of the person's profession, whether the act constitutes a crime or not. If the act constitutes a crime, conviction in a criminal proceeding is not a condition precedent to disciplinary action. Upon such a conviction, however, the judgment and sentence is conclusive evidence at the ensuing disciplinary hearing of the guilt of the license holder of the crime described in the indictment or information, and of the person's violation of the statute on which it is based. For the purposes of this section, conviction includes all instances in which a plea of guilty or nolo contendere is the basis for the conviction and all proceedings in which the sentence has been deferred or suspended. Nothing in this section abrogates rights guaranteed under chapter 9.96A RCW;

(2) Misrepresentation or concealment of a material fact in obtaining a license or in reinstatement thereof;

(3) All advertising which is false, fraudulent, or misleading;

(4) Incompetence, negligence, or malpractice which results in injury to a patient or which creates an unreasonable risk that a patient may be harmed. The use of a nontraditional treatment by itself shall not constitute unprofessional conduct, provided that it does not result in injury to a patient or create an unreasonable risk that a patient may be harmed;

(5) Suspension, revocation, or restriction of the individual's license to practice any health care profession by competent authority in any state, federal, or foreign jurisdiction, a certified copy of the order, stipulation, or agreement being conclusive evidence of the revocation, suspension, or restriction;

(6) Except when authorized by RCW 18.130.345, the possession, use, prescription for use, or distribution of controlled substances or legend drugs in any way other than for legitimate or therapeutic purposes, diversion of controlled substances or legend drugs, the violation of any drug law, or prescribing controlled substances for oneself;

(7) Violation of any state or federal statute or administrative rule regulating the profession in question, including any statute or rule defining or establishing standards of patient care or professional conduct or practice;

(8) Failure to cooperate with the disciplining authority by:

(a) Not furnishing any papers, documents, records, or other items;

(b) Not furnishing in writing a full and complete explanation covering the matter contained in the complaint filed with the disciplining authority;

(c) Not responding to subpoenas issued by the disciplining authority, whether or not the recipient of the subpoena is the accused in the proceeding; or

(d) Not providing reasonable and timely access for authorized representatives of the disciplining authority seeking to perform practice reviews at facilities utilized by the license holder;

(9) Failure to comply with an order issued by the disciplining authority or a stipulation for informal disposition entered into with the disciplining authority;

(10) Aiding or abetting an unlicensed person to practice when a license is required;

(11) Violations of rules established by any health agency;

(12) Practice beyond the scope of practice as defined by law or rule;

(13) Misrepresentation or fraud in any aspect of the conduct of the business or profession;

(14) Failure to adequately supervise auxiliary staff to the extent that the consumer's health or safety is at risk;

(15) Engaging in a profession involving contact with the public while suffering from a contagious or infectious disease involving serious risk to public health;

(16) Promotion for personal gain of any unnecessary or inefficacious drug, device, treatment, procedure, or service;

(17) Conviction of any gross misdemeanor or felony relating to the practice of the person's profession. For the purposes of this subsection, conviction includes all instances in which a plea of guilty or nolo contendere is the basis for conviction and all proceedings in which the sentence has been deferred or suspended. Nothing in this section abrogates rights guaranteed under chapter 9.96A RCW;

(18) The procuring, or aiding or abetting in procuring, a criminal abortion;

(19) The offering, undertaking, or agreeing to cure or treat disease by a secret method, procedure, treatment, or medicine, or the treating, operating, or prescribing for any health condition by a method, means, or procedure which the licensee refuses to divulge upon demand of the disciplining authority;

(20) The willful betrayal of a practitioner-patient privilege as recognized by law;

(21) Violation of chapter 19.68 RCW;

(22) Interference with an investigation or disciplinary proceeding by willful misrepresentation of facts before the disciplining authority or its authorized representative, or by the use of threats or harassment against any patient or witness to prevent them from providing evidence in a disciplinary proceeding or any other legal action, or by the use of financial inducements to any patient or witness to prevent or attempt to prevent him or her from providing evidence in a disciplinary proceeding;

(23) Current misuse of:

(a) Alcohol;

(b) Controlled substances; or

(c) Legend drugs;

(24) Abuse of a client or patient or sexual contact with a client or patient;

(25) Acceptance of more than a nominal gratuity, hospitality, or subsidy offered by a representative or vendor of medical or health-related products or services intended for patients, in contemplation of a sale or for use in research publishable in professional journals, where a conflict of interest is presented, as defined by rules of the disciplining authority, in consultation with the department, based on recognized professional ethical standards;

(26) Violation of section 1 of this act.

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Passed by the House February 12, 2018.

Passed by the Senate March 2, 2018.

Approved by the Governor March 22, 2018.

Filed in Office of Secretary of State March 26, 2018.