8

9 10

11

12 13

14

15 16

HOUSE BILL 2356

State of Washington 65th Legislature 2018 Regular Session

By Representatives Cody, Johnson, McBride, Jinkins, Ryu, and Ormsby Prefiled 01/03/18. Read first time 01/08/18. Referred to Committee on Health Care & Wellness.

- AN ACT Relating to stem cell therapies not approved by the United 1 2 States food and drug administration; amending RCW 18.130.180; and
- adding a new section to chapter 18.130 RCW. 3
- 4 BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:
- 5 NEW SECTION. **Sec. 1.** A new section is added to chapter 18.130 6 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."
- 17 (2) The written notice required by this section must be at least eight and one-half inches by eleven inches and written in no less 18 than forty point type. The license holder must also prominently 19 20 display the written notice in the entrance and in an area visible to 21 patients in the license holder's office.

HB 2356 p. 1

- 1 (3) The license holder must include the notice in any 2 advertisements for the therapy. The notice may be no smaller than the 3 largest font size used in the advertisement.
- 4 (4) This section does not apply to a license holder who has 5 obtained approval for an investigational new drug or device from the 6 United States food and drug administration for the use of human 7 cells, tissues, or cellular or tissue-based products.
- 8 (5) Violations of this section constitute unprofessional conduct 9 under this chapter.
 - (6) For purposes of this section:

21

22

2324

25

2627

28

29

30

31

32

3334

37

- 11 (a) "Human cells, tissues, or cellular or tissue-based products" 12 has the same meaning as in 21 C.F.R. Sec. 1271.3 as it exists on the 13 effective date of this section.
- 14 (b) "Stem cell therapy" means a therapy involving the use of 15 human cells, tissues, or cellular or tissue-based products.
- 16 **Sec. 2.** RCW 18.130.180 and 2010 c 9 s 5 are each amended to read 17 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;
- 35 (2) Misrepresentation or concealment of a material fact in 36 obtaining a license or in reinstatement thereof;
 - (3) All advertising which is false, fraudulent, or misleading;
- 38 (4) Incompetence, negligence, or malpractice which results in 39 injury to a patient or which creates an unreasonable risk that a

p. 2 HB 2356

- 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 (5) Suspension, revocation, or restriction of the individual's 6 license to practice any health care profession by competent authority 7 in any state, federal, or foreign jurisdiction, a certified copy of 8 the order, stipulation, or agreement being conclusive evidence of the 9 revocation, suspension, or restriction;

12

13

14 15

16

17

18

19

20

2324

25

26

27

28 29

30 31

32

33

34

37

- (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:
- 21 (a) Not furnishing any papers, documents, records, or other 22 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;
- 35 (10) Aiding or abetting an unlicensed person to practice when a 36 license is required;
 - (11) Violations of rules established by any health agency;
- 38 (12) Practice beyond the scope of practice as defined by law or 39 rule;

p. 3 HB 2356

- 1 (13) Misrepresentation or fraud in any aspect of the conduct of 2 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;
- 8 (16) Promotion for personal gain of any unnecessary or 9 inefficacious drug, device, treatment, procedure, or service;
- 10 (17) Conviction of any gross misdemeanor or felony relating to 11 the practice of the person's profession. For the purposes of this 12 subsection, conviction includes all instances in which a plea of 13 guilty or nolo contendere is the basis for conviction and all 14 proceedings in which the sentence has been deferred or suspended. 15 Nothing in this section abrogates rights guaranteed under chapter 16 9.96A RCW;
- 17 (18) The procuring, or aiding or abetting in procuring, a 18 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;
- 24 (20) The willful betrayal of a practitioner-patient privilege as 25 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:
- 36 (a) Alcohol;

4

5 6

7

19

20

21

22

23

26

27

2829

30 31

32

33

34

35

37

- (b) Controlled substances; or
- 38 (c) Legend drugs;
- 39 (24) Abuse of a client or patient or sexual contact with a client 40 or patient;

p. 4 HB 2356

(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.

--- END ---

p. 5 HB 2356