
SUBSTITUTE HOUSE BILL 2356

State of Washington 65th Legislature 2018 Regular Session

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

READ FIRST TIME 01/22/18.

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

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:

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

11 "THIS NOTICE MUST BE PROVIDED TO YOU UNDER WASHINGTON LAW.
12 This health care practitioner performs one or more stem cell
13 therapies that have not yet been approved by the United
14 States food and drug administration. You are encouraged to
15 consult with your primary care provider prior to undergoing a
16 stem cell therapy."

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

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

8 (4) This section does not apply to the following:

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

13 (b) An institution certified by the foundation for the
14 accreditation of cellular therapy, the national institutes of health
15 blood and marrow transplant clinical trials network, or AABB.

16 (5) Violations of this section constitute unprofessional conduct
17 under this chapter.

18 (6) For purposes of this section:

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

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

24 **Sec. 2.** RCW 18.130.180 and 2010 c 9 s 5 are each amended to read
25 as follows:

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

29 (1) The commission of any act involving moral turpitude,
30 dishonesty, or corruption relating to the practice of the person's
31 profession, whether the act constitutes a crime or not. If the act
32 constitutes a crime, conviction in a criminal proceeding is not a
33 condition precedent to disciplinary action. Upon such a conviction,
34 however, the judgment and sentence is conclusive evidence at the
35 ensuing disciplinary hearing of the guilt of the license holder of
36 the crime described in the indictment or information, and of the
37 person's violation of the statute on which it is based. For the
38 purposes of this section, conviction includes all instances in which
39 a plea of guilty or nolo contendere is the basis for the conviction

1 and all proceedings in which the sentence has been deferred or
2 suspended. Nothing in this section abrogates rights guaranteed under
3 chapter 9.96A RCW;

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

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

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

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

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

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

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

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

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

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

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

- 1 (9) Failure to comply with an order issued by the disciplining
2 authority or a stipulation for informal disposition entered into with
3 the disciplining authority;
- 4 (10) Aiding or abetting an unlicensed person to practice when a
5 license is required;
- 6 (11) Violations of rules established by any health agency;
- 7 (12) Practice beyond the scope of practice as defined by law or
8 rule;
- 9 (13) Misrepresentation or fraud in any aspect of the conduct of
10 the business or profession;
- 11 (14) Failure to adequately supervise auxiliary staff to the
12 extent that the consumer's health or safety is at risk;
- 13 (15) Engaging in a profession involving contact with the public
14 while suffering from a contagious or infectious disease involving
15 serious risk to public health;
- 16 (16) Promotion for personal gain of any unnecessary or
17 inefficacious drug, device, treatment, procedure, or service;
- 18 (17) Conviction of any gross misdemeanor or felony relating to
19 the practice of the person's profession. For the purposes of this
20 subsection, conviction includes all instances in which a plea of
21 guilty or nolo contendere is the basis for conviction and all
22 proceedings in which the sentence has been deferred or suspended.
23 Nothing in this section abrogates rights guaranteed under chapter
24 9.96A RCW;
- 25 (18) The procuring, or aiding or abetting in procuring, a
26 criminal abortion;
- 27 (19) The offering, undertaking, or agreeing to cure or treat
28 disease by a secret method, procedure, treatment, or medicine, or the
29 treating, operating, or prescribing for any health condition by a
30 method, means, or procedure which the licensee refuses to divulge
31 upon demand of the disciplining authority;
- 32 (20) The willful betrayal of a practitioner-patient privilege as
33 recognized by law;
- 34 (21) Violation of chapter 19.68 RCW;
- 35 (22) Interference with an investigation or disciplinary
36 proceeding by willful misrepresentation of facts before the
37 disciplining authority or its authorized representative, or by the
38 use of threats or harassment against any patient or witness to
39 prevent them from providing evidence in a disciplinary proceeding or
40 any other legal action, or by the use of financial inducements to any

1 patient or witness to prevent or attempt to prevent him or her from
2 providing evidence in a disciplinary proceeding;

3 (23) Current misuse of:

4 (a) Alcohol;

5 (b) Controlled substances; or

6 (c) Legend drugs;

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

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

16 (26) Violation of section 1 of this act.

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