

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

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

Approved March 22, 2018 3:55 PM

JAY INSLEE

Governor of the State of Washington

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

FILED

March 26, 2018

**Secretary of State
State of Washington**

ENGROSSED SUBSTITUTE HOUSE BILL 2356

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)

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) A license holder who is required to provide written notice
2 under subsection (1) of this section must also obtain a signed
3 consent form before performing the therapy. The consent form must be
4 signed by the patient, or, if the patient is legally not competent,
5 the patient's representative, and must state, in language the patient
6 could reasonably be expected to understand:

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

9 (b) The anticipated results of the proposed treatment;

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

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

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

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

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

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

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

33 (7) For purposes of this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

34 (17) Conviction of any gross misdemeanor or felony relating to
35 the practice of the person's profession. For the purposes of this
36 subsection, conviction includes all instances in which a plea of
37 guilty or nolo contendere is the basis for conviction and all
38 proceedings in which the sentence has been deferred or suspended.
39 Nothing in this section abrogates rights guaranteed under chapter
40 9.96A RCW;

- 1 (18) The procuring, or aiding or abetting in procuring, a
2 criminal abortion;
- 3 (19) The offering, undertaking, or agreeing to cure or treat
4 disease by a secret method, procedure, treatment, or medicine, or the
5 treating, operating, or prescribing for any health condition by a
6 method, means, or procedure which the licensee refuses to divulge
7 upon demand of the disciplining authority;
- 8 (20) The willful betrayal of a practitioner-patient privilege as
9 recognized by law;
- 10 (21) Violation of chapter 19.68 RCW;
- 11 (22) Interference with an investigation or disciplinary
12 proceeding by willful misrepresentation of facts before the
13 disciplining authority or its authorized representative, or by the
14 use of threats or harassment against any patient or witness to
15 prevent them from providing evidence in a disciplinary proceeding or
16 any other legal action, or by the use of financial inducements to any
17 patient or witness to prevent or attempt to prevent him or her from
18 providing evidence in a disciplinary proceeding;
- 19 (23) Current misuse of:
- 20 (a) Alcohol;
- 21 (b) Controlled substances; or
- 22 (c) Legend drugs;
- 23 (24) Abuse of a client or patient or sexual contact with a client
24 or patient;
- 25 (25) Acceptance of more than a nominal gratuity, hospitality, or
26 subsidy offered by a representative or vendor of medical or health-
27 related products or services intended for patients, in contemplation
28 of a sale or for use in research publishable in professional
29 journals, where a conflict of interest is presented, as defined by
30 rules of the disciplining authority, in consultation with the
31 department, based on recognized professional ethical standards;
- 32 (26) Violation of section 1 of this act.

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.

--- END ---