RCW 18.130.420 Stem cell therapies—Informed consent. (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 June 7, 2018.

(b) "Stem cell therapy" means a therapy involving the use of human cells, tissues, or cellular or tissue-based products. [2018 c 216 s 1.]