Showing changes in H.626 and adding advance directive prohibition

TO THE HONORABLE SENATE:

The Committee on Health and Welfare to which was referred Senate Bill No. 252 entitled "An act relating to stem cell therapies not approved by the U.S. Food and Drug Administration" respectfully reports that it has considered the same and recommends that the bill be amended by striking out all after the enacting clause and inserting in lieu thereof the following:

Sec. 1. 18 V.S.A. chapter 87 is added to read:

CHAPTER 87. STEM CELL ~~**THERAPIES**~~ **PRODUCTS**

§ 4501. DEFINITIONS

As used in this chapter:

(1) "Health care practitioner" means ~~**a physician licensed pursuant to 26 V.S.A. chapter 23 or 33, a physician assistant licensed pursuant to 26 V.S.A. chapter 31, a nurse licensed pursuant to 26 V.S.A. chapter 28, or a naturopathic physician licensed pursuant to 26 V.S.A. chapter 81**~~ **an individual licensed by the Board of Medical Practice or by a board attached to the Office of Professional Responsibility to provide professional health care services in this State**.

(2) **"Stem cell products" has the same meaning as "human cells, tissues, or cellular or tissue-based products" in 21 C.F.R. § 1271.3 as in effect on July 1, 2020.**

~~**"Human cells, tissues, or cellular or tissue-based products" has the same meaning as in 21 C.F.R. § 1271.3 as in effect on July 1, 2020.**~~

~~**(3) "Stem cell therapy" means a therapy involving the use of human cells, tissues, or cellular or tissue-based products.**~~

§ 4502. UNAPPROVED STEM CELL ~~**THERAPY**~~ **PRODUCTS**; NOTICE; ~~**INFORMED CONSENT**~~ **DISCLOSURE**

(a) Notice.

(1) A health care practitioner who ~~**performs stem cell therapy that is**~~ **administers one or more stem cell products that are** not approved by the U.S. Food and Drug Administration shall provide each patient with the following written notice prior ~~**to performing any unapproved therapy on**~~ **administering any such product to** the patient **for the first time**:

"THIS NOTICE MUST BE PROVIDED TO YOU UNDER VERMONT LAW. This health care practitioner ~~**performs one or more stem cell therapies**~~ **administers one or more stem cell products** that have not ~~**yet**~~ been approved by the U.S. Food and Drug Administration. You are encouraged to consult with your primary care provider prior to ~~**undergoing a stem cell therapy**~~ **having an unapproved stem cell product administered to you**."

(2) The written notice required by subdivision (1) of this subsection shall be at least 8.5 by 11 inches and printed in not less than 40-point type. The health care practitioner shall also prominently display the written notice at

the entrance and in an area visible to patients in the health care practitioner's office.

(b) **~~Informed consent~~ Disclosure**.

(1) A health care practitioner who **~~performs stem cell therapy that is~~ administers stem cell products that are** not approved by the U.S. Food and Drug Administration shall **~~obtain a signed consent form from each patient prior to performing any such therapy~~ provide a disclosure form to a patient for the patient's signature prior to each administration of an unapproved stem cell product**.

(2) **~~The consent form shall be signed by the patient, by the patient's parent or guardian if the patient is a minor, or, if the patient lacks capacity, by the patient's agent under an advance directive executed in accordance with chapter 231 of this title.~~**

~~(3)~~ The **~~consent~~ disclosure** form shall state, in language that the patient could reasonably be expected to understand:

(A) **~~the nature and character of the proposed therapy, including the therapy's~~ stem cell product's** U.S. Food and Drug Administration approval status;

(B) the anticipated **~~results of the proposed therapy~~ risks associated with administration of the unapproved stem cell product**;

(C) **the anticipated** ~~**risks**~~ **benefits associated with administration of the unapproved stem cell product; and**

(D) the **medically** recognized ~~**possible**~~ alternative forms of treatment~~**; and**~~

~~**(D) the recognized serious possible risks, complications, and anticipated benefits involved in the therapy and in the recognized possible alternative forms of treatment,**~~ including **the risks and benefits of those treatments and of** nontreatment.

(3)(A) The health care practitioner shall retain in the patient's medical record a copy of each disclosure form signed and dated by the patient.

(B) An agent under an advance directive shall not sign a disclosure form on behalf of a principal.

(c) Advertisements. A health care practitioner shall include the notice set forth in subdivision (a)(1) of this section in any advertisements for stem cell ~~**therapy that is**~~ **products that are** not approved by the U.S. Food and Drug Administration. In print advertisements, the notice shall be clearly legible and in a font size not smaller than the largest font size used in the advertisement. For all other forms of advertisements, the notice shall either be clearly legible in a font size not smaller than the largest font size used in the advertisement or clearly spoken.

(d) Nonapplicability. The provisions of this section shall not apply to the following:

(1) a health care practitioner who has obtained approval for an investigational new drug or device from the U.S. Food and Drug Administration for the use of human cells, tissues, or cellular or tissue-based products; or

(2) a health care practitioner who ~~**performs stem cell therapy**~~ **administers a stem cell product** pursuant to an employment or other contract to ~~**perform the therapy**~~ **administer stem cell products** 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**, formerly known as the American Association of Blood Banks**.

(e) Violations. A violation of this section constitutes unprofessional conduct under 3 V.S.A. § 129a and 26 V.S.A. § 1354.

Sec. 2. 3 V.S.A. § 129a is amended to read:

§ 129a. UNPROFESSIONAL CONDUCT

(a) In addition to any other provision of law, the following conduct by a licensee constitutes unprofessional conduct. When that conduct is by an applicant or person who later becomes an applicant, it may constitute grounds for denial of a license or other disciplinary action. Any one of the following

items or any combination of items, whether the conduct at issue was committed within or outside the State, shall constitute unprofessional conduct:

* * *

(27) For ~~**an osteopathic physician, nurse, or naturopathic physician**~~ **a health care practitioner**, failing to comply with one or more of the notice, ~~**informed consent**~~ **disclosure**, or advertising requirements in 18 V.S.A. § 4502 for ~~**stem cell therapies**~~ **administering stem cell products** not approved by the U.S. Food and Drug Administration.

* * *

Sec. 3. 26 V.S.A. § 1354 is amended to read:

§ 1354. UNPROFESSIONAL CONDUCT

(a) The Board shall find that any one of the following, or any combination of the following, whether the conduct at issue was committed within or outside the State, constitutes unprofessional conduct:

* * *

(39) use of the services of a physician assistant by a physician in a manner that is inconsistent with the provisions of chapter 31 of this title; ~~or~~

(40) use of conversion therapy as defined in 18 V.S.A. § 8351 on a client younger than 18 years of age; or

(41) failure to comply with one or more of the notice, ~~**informed consent**~~ **disclosure**, or advertising requirements in 18 V.S.A. § 4502 for ~~**stem cell**~~

~~therapies~~ administering stem cell products not approved by the U.S. Food and Drug Administration.

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Sec. 4. EFFECTIVE DATE

This act shall take effect on July 1, 2020.

and that after passage the title of the bill be amended to read: "An act relating to administering stem cell products not approved by the U.S. Food and Drug Administration"

(Committee vote: _____)

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Senator _____

FOR THE COMMITTEE