§ 4502. UNAPPROVED STEM CELL AND STEM CELL-RELATED PRODUCTS; NOTICE; DISCLOSURE

(a) Notice.

(1) A health care practitioner who administers one or more stem cell or stem cell-related products that are not approved by the U.S. Food and Drug Administration shall provide each patient with the following written notice prior to 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 administers one or more stem cell or stem cell-related products that have not been approved by the U.S. Food and Drug Administration. You are encouraged to consult with your primary care provider prior to having an unapproved stem cell or stem cell-related product administered to you."

(2)(A) The written notice required by subdivision (1) of this subsection (a) shall:

(i) be at least 8.5 by 11 inches and printed in not less than 40-point type; and

(ii) include information on methods for filing a complaint with the applicable licensing authority and for making a consumer inquiry, including to the Attorney General's Consumer Assistance Program.

(B) The health care practitioner shall also prominently display the written notice required by subdivision (1) of this subsection (a), along with the information required to be included by subdivision (A)(ii) of this subdivision (2), at the entrance and in an area visible to patients in the health care practitioner's office.

(b) Disclosure.

(1) A health care practitioner who administers stem cell or stem cell-related products that are not approved by the U.S. Food and Drug Administration shall provide a disclosure form to a patient for the patient's signature prior to each administration of an unapproved stem cell or stem cell-related product.

(2) The disclosure form shall state, in language that the patient could reasonably be expected to understand, the stem cell or stem cell-related product's U.S. Food and Drug Administration approval status.

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

(c) Advertisements. A health care practitioner shall include the notice set forth in subdivision (a)(1) of this section in any advertisements relating to the use of stem cell or stem cell-related 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 or clearance for an investigational new drug or device from the U.S. Food and Drug Administration for the use of stem cell or stem cell-related products;

(2) a health care practitioner who administers a stem cell or stem cell-related product pursuant to an employment or other contract to administer stem cell or stem cell-related 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; or

(3) a health care practitioner who has personally received a formal or informal determination from the U.S. Food and Drug Administration stating that approval is not necessary for the practitioner's specific usage of the stem cell or stem cell-related products.

(e) Violations. A violation of this section constitutes unprofessional conduct under 3 V.S.A. § 129a and 26 V.S.A. § 1354. (Added 2021, No. 61, § 1.)