

1 S.252

2 Introduced by Senator Lyons

3 Referred to Committee on

4 Date:

5 Subject: Health; health care providers; stem cell therapy; informed consent

6 Statement of purpose of bill as introduced: This bill proposes to require health
7 care providers who perform stem cell therapies that are not approved by the
8 U.S. Food and Drug Administration to provide notice of this fact to their
9 patients and in their advertisements and to obtain specific informed consent
10 prior to performing an unapproved therapy.

11 An act relating to stem cell therapies not approved by the U.S. Food and
12 Drug Administration

13 It is hereby enacted by the General Assembly of the State of Vermont:

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

15 CHAPTER 87. STEM CELL THERAPIES

16 § 4501. DEFINITIONS

17 As used in this chapter:

18 (1) “Health care practitioner” means a physician licensed pursuant to
19 26 V.S.A. chapter 23 or 33, a physician assistant licensed pursuant to

1 26 V.S.A. chapter 31, a nurse licensed pursuant to 26 V.S.A. chapter 28, or a
2 naturopathic physician licensed pursuant to 26 V.S.A. chapter 81.

3 (2) “Human cells, tissues, or cellular or tissue-based products” has the
4 same meaning as in 21 C.F.R. § 1271.3 as in effect on July 1, 2020.

5 (3) “Stem cell therapy” means a therapy involving the use of human
6 cells, tissues, or cellular or tissue-based products.

7 § 4502. UNAPPROVED STEM CELL THERAPY; NOTICE; INFORMED

8 CONSENT

9 (a) Notice.

10 (1) A health care practitioner who performs stem cell therapy that is not
11 approved by the U.S. Food and Drug Administration shall provide each patient
12 with the following written notice prior to performing any unapproved therapy
13 on the patient:

14 “THIS NOTICE MUST BE PROVIDED TO YOU UNDER VERMONT
15 LAW. This health care practitioner performs one or more stem cell therapies
16 that have not yet been approved by the U.S. Food and Drug Administration.
17 You are encouraged to consult with your primary care provider prior to
18 undergoing a stem cell therapy.”

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

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

3 (b) Informed consent.

4 (1) A health care practitioner who performs stem cell therapy that is not
5 approved by the U.S. Food and Drug Administration shall obtain a signed
6 consent form from each patient prior to performing any such therapy.

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

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

13 (A) the nature and character of the proposed therapy, including the
14 therapy's U.S. Food and Drug Administration approval status;

15 (B) the anticipated results of the proposed therapy;

16 (C) the recognized possible alternative forms of treatment; and

17 (D) the recognized serious possible risks, complications, and
18 anticipated benefits involved in the therapy and in the recognized possible
19 alternative forms of treatment, including nontreatment.

20 (c) Advertisements. A health care practitioner shall include the notice set
21 forth in subdivision (a)(1) of this section in any advertisements for stem cell

1 therapy that is not approved by the U.S. Food and Drug Administration. In
2 print advertisements, the notice shall be clearly legible and in a font size not
3 smaller than the largest font size used in the advertisement. For all other forms
4 of advertisements, the notice shall either be clearly legible in a font size not
5 smaller than the largest font size used in the advertisement or clearly spoken.

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

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

12 (2) a health care practitioner who performs stem cell therapy pursuant to
13 an employment or other contract to perform the therapy on behalf of or under
14 the auspices of an institution certified by the Foundation for the Accreditation
15 of Cellular Therapy, the National Institutes of Health Blood and Marrow
16 Transplant Clinical Trials Network, or AABB.

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

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

20 § 129a. UNPROFESSIONAL CONDUCT

1 (a) In addition to any other provision of law, the following conduct by a
2 licensee constitutes unprofessional conduct. When that conduct is by an
3 applicant or person who later becomes an applicant, it may constitute grounds
4 for denial of a license or other disciplinary action. Any one of the following
5 items or any combination of items, whether the conduct at issue was
6 committed within or outside the State, shall constitute unprofessional conduct:

7 * * *

8 (27) For an osteopathic physician, nurse, or naturopathic physician,
9 failing to comply with one or more of the notice, informed consent, or
10 advertising requirements in 18 V.S.A. § 4502 for stem cell therapies not
11 approved by the U.S. Food and Drug Administration.

12 * * *

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

14 § 1354. UNPROFESSIONAL CONDUCT

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

18 * * *

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

