Senate Calendar

WEDNESDAY, MARCH 10, 2021

SENATE CONVENES AT: 1:00 P.M.

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ACTION CALENDAR

NEW BUSINESS

Second Reading

Favorable

S. 39.

An act relating to the Judicial Branch fee report and electronic filing fees.

Reported favorably by Senator Benning for the Committee on Judiciary.

(Committee vote: 5-0-0)

Favorable with Recommendation of Amendment

S. 22.

An act relating to health care practitioners administering stem cell products not approved by the U.S. Food and Drug Administration.

Reported favorably with recommendation of amendment by Senator Hooker for the Committee on Health and Welfare.

The Committee 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 PRODUCTS

§ 4501. DEFINITIONS

As used in this chapter:

- (1) "Health care practitioner" means an individual licensed by the Board of Medical Practice or the Office of Professional Regulation to provide professional health care services in this State.
- (2)(A) "Stem cell and stem cell-related products" means any articles that contain or consist, or purport to contain or consist, of one or more of the following, when intended for implantation, transplantation, infusion, or transfer into a human recipient and when intended for use in the diagnosis, cure, mitigation, treatment, or prevention of any disease or condition based on or in connection with a proven or purported attribute of stem cells:

- (i) human cells, including cells from tissues such as bone marrow; adipose tissue; amniotic membrane; umbilical cord blood, when not autologous or in a first- or second-degree relative; placenta; and other tissue or cell sources;
 - (ii) intracellular or extracellular components or vesicles; or
 - (iii) amniotic fluid.
- (B) For purposes of this chapter, "stem cell and stem cell-related products" does not include the use of whole blood or blood products for routine transfusions or use of hematopoietic stem cells for reconstitution of bone marrow after treatment of blood-related cancers or diseases such as leukemias or lymphomas.

§ 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 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, 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.

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 a health care practitioner, failing to comply with one or more of the notice, disclosure, or advertising requirements in 18 V.S.A. § 4502 for administering stem cell or stem cell-related 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:

* * *

- (38) signing a blank or undated prescription form; or
- (39) [Repealed.]
- (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, disclosure, or advertising requirements in 18 V.S.A. § 4502 for administering stem cell or stem cell-related products not approved by the U.S. Food and Drug Administration.

* * *

Sec. 4. EFFECTIVE DATE

This act shall take effect on July 1, 2021.

(Committee vote: 5-1-0)

Joint Resolution For Action

J.R.S. 18.

Joint resolution providing for a Joint Assembly to vote on the retention of two Superior Judges and three Magistrates.

PENDING ACTION: Shall the resolution be adopted?

(For text of resolution, see Senate Journal of March 9, 2021, page 165.)

NOTICE CALENDAR

Second Reading

Favorable

S. 110.

An act relating to extending eligibility for Pandemic Emergency Unemployment Compensation.

Reported favorably by Senator Sirotkin for the Committee on Economic Development, Housing and General Affairs.

(Committee vote: 5-0-0)

JFO NOTICE

Grants and Positions that have been submitted to the Joint Fiscal Committee by the Administration, under 32 V.S.A. §5(b)(3):

JFO #3036 - \$3,800,000 to the VT Dept of Health from the Center for Disease Control and Prevention to increase and sustain the public health approach to suicide prevention. This grant includes funding for three (3) limited service positions. Two (2) positions in the Dept of Health: Public Health Programs Administrator and Public Health Analyst II. One (1) position in the Dept of Mental Health: Marketing and Outreach Coordinator. Grant amount is \$760,000 per year for 5 years.

[JFO received 2/16/2021]

JFO #3037 - \$135,000 to the VT Dept of Mental Health from Vibrant Emotional Health for the development of the 988-implementation plan to ensure compliance with the federal mandate for universal access to suicide and prevention services by July 16, 2022. [Note: One (1) limited service position is included within JFO #3036].

[JFO received 2/16/2021]

JFO #3038 - \$40,000 to the VT Agency of Commerce and Community Development from the Chittenden County Regional Planning Commission. ACCD is a sub-grantee of the Chittenden County Regional Planning Commission and is awarded a maximum of \$40,000; original funds are from the U.S. Economic Development Administration. Funds will be used for work related to the West Central Vermont Comprehensive Economic Development Strategy project.

[JFO received 2/18/2021]

JFO #3039 - \$1,000,000 to the VT Dept of Public Safety from the U.S. Dept of Justice to develop and implement approaches to address a range of criminal justice system problems. The majority of funds will be awarded as sub-grants to organizations with expertise in this subject matter.

[JFO received 3/3/2021]

FOR INFORMATION ONLY CROSSOVER DATES

The Joint Rules Committee established the following Crossover deadlines:

- (1) All **Senate/House** bills must be reported out of the last committee of reference (including the Committees on Appropriations and Finance/Ways and Means, except as provided below in (2) and the exceptions listed below) on or before **Friday, March 12, 2021**, and filed with the Secretary/Clerk so they may be placed on the Calendar for Notice the next legislative day Committee bills must be voted out of Committee by Friday March 12, 2021.
- (2) All **Senate/House** bills referred pursuant to Senate Rule 31 or House Rule 35(a) to the Committees on Appropriations and Finance/Ways and Means must be reported out by the last of those committees on or before **Friday**, **March 19, 2021**, and filed with the Secretary/Clerk so they may be placed on the Calendar for Notice the next legislative day.

Note: The Senate will not act on bills that do not meet these crossover deadlines, without the consent of the Senate Rules Committee.

Exceptions to the foregoing deadlines include the major money bills (the general Appropriations bill ("The Big Bill"), the Transportation Capital bill, the Capital Construction bill and the Fee/Revenue bills.