S.252, An act relating to stem cell therapies not approved by the U.S. Food and Drug Administration

Section-by-section summary as recommended by Senate Committee on Health & Welfare

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Amendment would amend bill title to be "An act relating to administering stem cell products not approved by the U.S. Food and Drug Administration"

Sec. 1. 18 V.S.A. chapter 87 – Stem Cell Products

The bill adds a new chapter in Title 18 on stem cell products.

- § 4501 – Definitions: the following terms are defined for use in the new chapter:
  - Health care practitioner – an individual licensed by the Board of Medical Practice or Office or Professional Regulation (OPR) to provide professional health care services in Vermont
  - Stem cell products – this term has the same meaning as "human cells, tissues, or cellular or tissue-based products" in federal regulation and applies to both homologous and nonhomologous use. The term also includes homologous use of minimally manipulated cell or tissue when used in applications that are not U.S. Food and Drug Administration (FDA)-approved.
- § 4502 – Unapproved stem cell products; notice; disclosure.
  - Requires a health care practitioner who administers stem cell products not approved by the FDA to provide each patient with a written notice before administering the product to the patient for the first time. The bill specifies the content and format of the notice and requires that it include information on methods for filing a complaint with the licensing authority and for making a consumer inquiry.
  - Requires the health care provider to prominently display the written notice and consumer protection information at the entrance and in an area visible to patients in the practitioner's office.
  - Requires a health practitioner who administers stem cell products not approved by the FDA have the patient sign a disclosure form prior to each administration of an unapproved stem cell product and to keep a copy of each signed form in the patient's medical record.
  - Requires a health care practitioner to include the notice in any advertisements relating to non-FDA-approved stem cell products and addresses both print and non-print forms of advertising.
  - Exempts from the section health care practitioners with FDA approval or clearance for an investigational new drug or device for the use of stem cell products and practitioners who administer the products under a contract with an institution certified by certain national organizations.
  - Specifies that a violation of the section constitutes unprofessional conduct under the Board of Medical Practice and OPR statutes.

Sec. 2. 3 V.S.A. § 129a – OPR unprofessional conduct statute

- Adds a health care practitioner's failure to comply with the notice, disclosure, and/or advertising requirements for administering non-FDA-approved stem cell products to the OPR unprofessional conduct statute

Sec. 3. 26 V.S.A. § 1354 – Board of Medical Practice unprofessional conduct statute

- Adds a health care practitioner's failure to comply with the notice, disclosure, and/or advertising requirements for administering non-FDA-approved stem cell products to the Board of Medical Practice unprofessional conduct statute

Sec. 4. Department of Health; advance directives; rulemaking

- Directs the Department of Health to amend its advance directive rules by January 1, 2021 to further clarify the scope of experimental treatments to which an agent may and may not consent for a principal

Sec. 5. Effective date

- Act takes effect on July 1, 2020