This act summary is provided for the convenience of the public and members of the General Assembly. It is intended to provide a general summary of the act and may not be exhaustive. It has been prepared by the staff of the Office of Legislative Counsel without input from members of the General Assembly. It is not intended to aid in the interpretation of legislation or to serve as a source of legislative intent.

Act No. 61 (S.22). Health; health care practitioners; stem cell products; stem cell-related products

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

This act requires a health care practitioner who administers one or more stem cell or stem cell-related products not approved by the U.S. Food and Drug Administration (FDA) to provide each patient with a written notice before administering a product to the patient for the first time. The act specifies the content and format of the notice and requires that it 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. The act requires the practitioner 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. It requires health care practitioners to include the notice in any advertisements relating to non-FDA-approved stem cell and stem cell-related products and addresses both print and nonprint forms of advertising. The act also requires health care practitioners administering non-FDA-approved stem cell and stem cell-related products to have the patient sign a disclosure form prior to each administration of an unapproved product, to keep a copy of each signed form in the patient's medical record, and to provide a copy of the form for the patient to take home.

The act exempts from its notice, advertising, and disclosure requirements health care practitioners with FDA approval or clearance for an investigational new drug or device for the use of stem cell or stem cell-related products, practitioners who administer the products under contract with an institution certified by certain national organizations, and practitioners who have personally received a determination from the FDA stating that approval is not necessary for the practitioner's specific usage of the products. The act also specifies that a health care practitioner's failure to comply with its notice, advertising, and disclosure requirements constitutes unprofessional conduct under the Board of Medical Practice and Office of Professional Regulation statutes.

Effective Date: July 1, 2021