A bill to be entitled

An act relating to the voluntary registration of stem cell providers; defining the term "stem cell"; authorizing a licensed physician who provides certain stem cell services to register with the Department of Health; requiring that such physician agree to adhere to certain good manufacturing practices under specified federal laws; authorizing manufacturers and distributors of stem cells or products containing stem cells to register with the department; requiring the department to establish and maintain an online registry identifying such physicians, manufacturers, and distributors and documenting certain physician agreements; requiring the department to update the information contained in the registry at least monthly; authorizing the department to adopt rules; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 381.4017, Florida Statutes, is created to read:

381.4017 Voluntary registration of stem cell providers.—

(1) For purposes of this section, the term "stem cell" means an allogenic or autologous cell that is altered or

processed to become undifferentiated, losing its original structural function, so that it can become differentiated into a specialized cell type. The term does not include cells that are only rinsed, cleaned, or sized and remain differentiated.

(2) A physician licensed under chapter 458 or chapter 459 who advertises, uses, or purports to use stem cells or products containing stem cells may register with the department. A physician who registers under this section shall agree to adhere to the current applicable good manufacturing practices for the collection, removal, processing, implantation, and transfer of stem cells, or products containing stem cells, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.; and 21 C.F.R. 1271, Human Cells, Tissues, and Cellular and Tissue-Based Products, in the performance of any procedure using or purporting to use stem cells or products containing stem cells.

(3) A manufacturer or distributor of stem cells or products containing stem cells who advertises, distributes, or operates in this state may register with the department.

(4) The department shall establish and maintain an online registry accessible on its website which identifies the physicians, manufacturers, and distributors registered under this section and which documents physician agreements to adhere to the current applicable good manufacturing practices. The department shall update the information contained in the

registry at least monthly.

(5) The department may adopt rules to implement this section.

Section 2. This act shall take effect July 1, 2020.