By the Committee on Health Policy; and Senator Hutson

588-03097-20 2020512c1

A bill to be entitled

An act relating to nonembryonic stem cell banks; creating s. 381.06017, F.S.; defining terms; providing that a nonembryonic stem cell bank that performs certain functions is deemed a clinic; requiring such nonembryonic stem cell banks to comply with specified requirements; prohibiting an entity other than certain nonembryonic stem cell banks and pharmacists from dispensing certain compounded drugs or products, with exceptions; prohibiting certain health care practitioners from practicing in a nonembryonic stem cell bank that is not licensed with the agency; providing for disciplinary action; requiring health care practitioners to adhere to specified regulations in the performance of certain procedures; requiring the agency to adopt specified rules; providing an effective date.

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

Section 1. Section 381.06017, Florida Statutes, is created to read:

381.06017 Nonembryonic stem cell banks; collection, manufacturing, storage, dispensing, and use of human nonembryonic stem cells.—

(1) DEFINITIONS.—As used in this section, the term:

(a) "Compounding" means combining, mixing, or altering the ingredients of one or more drugs or products to create another drug or product.

(b) "Dispense" has the same meaning as in s. 465.003(6).

(c) "Establishment" means a place of business which is at one general physical location and may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. The term includes multiple buildings with an intervening thoroughfare if the buildings are under common exclusive ownership, operation, and control. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.

(d) "Federal act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

(e) "Minimally manipulated" means:

1. For structural tissue, processing that does not alter the original characteristics of the tissue which relate to the tissue's utility for reconstruction, repair, or replacement; or

2. For cells or nonstructural tissue, processing that does not alter the relevant biological characteristics of the cell or tissue.

(f) "Nonembryonic stem cell," also referred to as a "somatic stem cell" or an "adult human stem cell," means an allogenic or autologous cell that is undifferentiated and unspecialized and that has the ability to divide for indefinite periods of time in a medium and to become a specialized cell. The term includes a human nonembryonic cell that is altered or processed to become undifferentiated, losing its original structural function, so that it can be differentiated into a specialized cell type. The term does not include cells that are minimally manipulated or are only rinsed, cleaned, or sized and

remain differentiated.

(g) "Nonembryonic stem cell bank" means a publicly or privately owned establishment that does any of the following:

1. Collects and stores human nonembryonic stem cells for use in a product or patient-specific medical administration.

2. Provides patient-specific health care services using human nonembryonic stem cells.

3. Advertises human nonembryonic stem cell services, including, but not limited to, collection, manufacturing, storage, dispensing, use, or purported use of human nonembryonic stem cells or products containing human nonembryonic stem cells, which have not been approved by the United States Food and Drug Administration or are not the subject of clinical trials approved by the United States Food and Drug Administration and which are intended to diagnose, cure, mitigate, treat, provide therapy for, or prevent an injury or a disease.

4. Performs any procedure that is intended to:

a. Collect or store human nonembryonic stem cells for any purpose; or

b. Diagnose, cure, mitigate, treat, provide therapy for, or prevent an injury or a disease with the use or purported use of human nonembryonic stem cells or any product containing human nonembryonic stem cells which has not been approved by the United States Food and Drug Administration or is not the subject of a clinical trial approved by the United States Food and Drug Administration.

5. Compounds human nonembryonic stem cells from human nonembryonic cells or tissue into products by combining, mixing, or altering the ingredients of one or more drugs or products to

create another drug or product.

6. Manufactures, through recovery, processing, manipulation, enzymatic digestion, mechanical disruption, or a similar process, human nonembryonic stem cells from human nonembryonic cells or tissue into undifferentiated human nonembryonic stem cells, causing the cells to lose their original structural function so that the nonembryonic stem cells may be differentiated into specialized cell types.

7. Dispenses human nonembryonic stem cells and products containing nonembryonic stem cells to any of the following for a specific patient pursuant to a valid prescription from a licensed health care practitioner authorized within the scope of his or her license to prescribe and administer human nonembryonic stem cells:

a. A pharmacy permitted under chapter 465.

b. A health care practitioner with privileges to practice at nonembryonic stem cell banks.

c. A health care practitioner's office, a health care facility, or a treatment setting where the health care practitioner has privileges to practice, for office use.

(h) "Office use" means the provision and administration of a drug, compounded drug, or compounded product to a patient by a health care practitioner in the practitioner's office or in a health care facility or treatment setting, including a hospital, ambulatory surgery center, or health care clinic licensed under chapter 395 or chapter 400. The term also includes the dispensing by a pharmacist at a nonembryonic stem cell bank that is also permitted as a pharmacy under chapter 465 to a nonembryonic stem cell bank within this state of any of the

following:

1. Human nonembryonic stem cells.

2. A compounded drug containing human nonembryonic stem cells.

3. A compounded product containing nonembryonic stem cells.

(2) DUTIES AND REGISTRATION.—A nonembryonic stem cell bank that advertises, collects, stores, manufactures, dispenses, compounds, uses, or purports to use nonembryonic stem cells or products containing nonembryonic stem cells is deemed a clinic as defined in s. 400.9905 and must comply with all of the following requirements:

(a) Adhere to the applicable current good manufacturing practices for the collection, removal, manufacturing, processing, compounding, and implantation of nonembryonic stem cells or products containing nonembryonic stem cells pursuant to the federal act and 21 C.F.R., parts 1270-1271.

(b) Obtain a health care clinic license from the agency pursuant to s. 400.991 and part II of chapter 408 and register each establishment separately, unless:

1. The clinic is a facility licensed under chapter 395; or

2. The clinic is affiliated with an accredited medical school that provides training to medical students, residents, or fellows.

(c) Have a physician medical director who is responsible for complying with all requirements related to licensure, operation of a nonembryonic stem cell bank, and good manufacturing practices under this section, part X of chapter 400, and the federal act and 21 C.F.R., parts 1270-1271.

(d) Notify the agency in writing on a form approved by the

agency within 10 days after termination of a physician medical director and notify the agency within 10 days after such termination of the identity of the physician medical director who has assumed responsibility for that nonembryonic stem cell bank. Failure to have a physician medical director practicing at the location of the licensed nonembryonic stem cell bank shall be the basis for a summary suspension of the nonembryonic stem cell bank's license pursuant to s. 400.607 or s. 120.60(6).

(e) Require a physician medical director to have a full, active, and unencumbered license issued under chapter 458 or chapter 459 and to actively practice at the nonembryonic stem cell bank location for which he or she has assumed responsibility.

(f) Maintain commercial and professional liability insurance in an amount not less than $250,000 per claim.

(g) Operate each establishment using the same name as the one used to obtain the health care clinic license from the agency. All invoices, packing slips, and other business records must list the same name.

(h) Obtain a pharmacy permit for each person and establishment before dispensing, offering office use for the compounding of human nonembryonic stem cells, or dispensing a compounded product for office use.

(i) Pay all costs associated with licensure, registration, and inspection.

(3) DISPENSING OF DRUGS OR COMPOUNDED DRUGS OR PRODUCTS.—

(a) A pharmacist at a nonembryonic stem cell bank that is also permitted as a pharmacy under chapter 465 may dispense any of the following to a stem cell bank within the state, for

office use:

1. Human nonembryonic stem cells;

2. A compounded drug containing human nonembryonic stem cells; or

3. A compounded product containing human nonembryonic stem cells.

(b) Human nonembryonic stem cells, compounded drugs containing human nonembryonic stem cells, or products containing human nonembryonic stem cells may not be sold or dispensed by any person or establishment other than the nonembryonic stem cell bank or pharmacist at the nonembryonic stem cell bank that manufactured the human nonembryonic stem cells or the compounded drug or product containing human nonembryonic stem cells, except that:

1. A health care practitioner who requests the dispensing of the human nonembryonic stem cells, compounded drug, or compounded product from the manufacturing nonembryonic stem cell bank may sell or dispense such items to his or her patient if the health care practitioner is authorized within the scope of his or her license to prescribe and administer human nonembryonic stem cells; or

2. A pharmacist, pharmacy, or establishment that requests the dispensing of the human nonembryonic stem cells, compounded drug, or compounded product from the manufacturing nonembryonic stem cell bank may sell or dispense such items to a health care practitioner who is authorized within the scope of his or her license to prescribe and administer human nonembryonic stem cells to patients.

(4) HEALTH CARE PRACTITIONER RESPONSIBILITIES.—

(a) A physician licensed under chapter 458 or chapter 459, an advanced practice registered nurse licensed under chapter 464, or a physician assistant licensed under chapter 458 or chapter 459 may not practice in a nonembryonic stem cell bank that is not licensed with the agency as required by the rules adopted pursuant to s. 400.9925. The license of a health care practitioner who violates this paragraph is subject to disciplinary action by the appropriate regulatory board.

(b) In the performance of any procedure collecting, storing, using, or purporting to use nonembryonic stem cells or products containing nonembryonic stem cells, a health care practitioner must adhere to the applicable current good manufacturing practices for the collection, removal, manufacturing, processing, compounding, and implantation of stem cells or products containing stem cells pursuant to the federal act and 21 C.F.R., parts 1270-1271.

(5) RULEMAKING.—The agency shall adopt rules necessary to administer the licensure and regulation of nonembryonic stem cell banks, including, but not limited to, rules regarding all of the following, which must be consistent with the best practices specified in the federal act and 21 C.F.R., parts 1270-1271:

(a) Advertising.

(b) Nonembryonic stem cell bank procedures and protocols for the collection, manufacturing, storing, dispensing, and use of nonembryonic stem cells, drugs containing nonembryonic stem cells, and products containing nonembryonic stem cells in accordance with the applicable current best practices.

(c) Adverse incident reporting.

(d) Informed consent.

(e) Recordkeeping, record retention, and availability of records for inspection.

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