A bill to be entitled

An act relating to nonembryonic stem cell banks; creating s. 381.06017, F.S.; defining terms; providing registration and permitting requirements for certain establishments; prohibiting a nonembryonic stem cell bank from performing certain processes on adult human nonembryonic stem cells or HCT/Ps under certain circumstances; 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 by the agency; providing for disciplinary action; requiring health care practitioners to adhere to specified regulations in the performance of certain procedures; requiring the Agency for Health Care Administration, in consultation with the Department of Health and the Department of Business and Professional Regulation, to adopt specified rules; amending s. 499.012, F.S.; authorizing the Department of Business and Professional Regulation to issue a prescription drug manufacturer permit to a certain nonembryonic stem cell bank; 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; collecting, manufacturing, storing, dispensing, concentrating, and using adult human nonembryonic stem cells and HCT/Ps.—

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

(a) "Adult human nonembryonic stem cells" means cells and cellular material that are derived from autologous or allogeneic human tissue intended for implantation, transplantation, infusion, or transfer into a human recipient.

(b) "Agency" means the Agency for Health Care Administration.

(c) "Allogeneic use" means the collection of human cells or tissue from one person and the implantation, transplantation, infusion, or transfer of those human cells or tissue into another person.

(d) "Autologous use" means the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from which they were collected.

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

(f) "Establishment" means a place of business that 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.

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

(h) "HCT/Ps" means human cells, tissues, or cellular or tissue-based products that are intended for implantation, transplantation, infusion, or transfer into a human recipient. This term includes adult human nonembryonic stem cells, but does not include any of the following:

1. Vascularized human organs for transplantation.

2. Whole blood, blood components, blood derivative products, or platelet-rich plasma that are exempt under 21 C.F.R. s. 607.65.

3. Human secretions, including milk, collagen, and cell factors, but not semen.

4. Minimally manipulated bone marrow that is for homologous use only and that is not combined with any other article except water, crystalloids, or sterilizing, preserving, or storage agents.

5. Ancillary products used in the manufacture of nonembryonic adult human allogeneic or autologous HCT/Ps.

6. Cells, tissue, or organs derived from animals.

7. In vitro diagnostic products.

8. Blood vessels recovered with an organ for transplantation.

(i) "Homologous use" means the repair, reconstruction, or supplementation of a recipient's cells or tissues with adult human nonembryonic stem cells or adult human nonembryonic HCT/Ps that perform the same basic function or functions in the recipient as in the donor.

(j) "Manufacture" means the preparing, deriving, compounding, propagating, processing, producing, or fabricating of any drug, device, or cosmetic.

(k) "Minimally manipulated" means:

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

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

3. The washing, rinsing, cleaning, sizing, shaping, or concentrating of adult human nonembryonic HCT/Ps which does not alter the relevant characteristics or basic functions of the tissue or cell.

(l) "Nonembryonic stem cell bank" means a publicly or privately owned establishment that operates its own laboratories, retains control over all aspects of processing and storage, is managed by a single entity, and performs any of the following activities in the course of its business:

1. Engages in the manufacture, use, implantation, transplantation, infusion, dispensing, transfer, or storage of adult human allogeneic and autologous nonembryonic stem cells.

2. Accepts, receives, carries, or delivers human allogeneic and autologous nonembryonic stem cells, drugs, or products that are approved by United States Food and Drug Administration and regulated as drugs, devices, or biological products by the FD&C Act, s. 351 of the PHS Act, or part I of chapter 499.

3. Recovers, collects, screens, and tests, in the facility,

adult human autologous nonembryonic HCT/Ps from a specific patient for implantation, transplantation, infusion, or transfer back into the same patient during a single surgery within the facility.

4. Provides patient-specific health care services using adult human autologous nonembryonic HCT/Ps in the facility during a single procedure.

5. Advertises adult human nonembryonic stem cell services or adult human autologous nonembryonic HCT/P services, including, but not limited to, the collection, manufacture implantation, transplantation, infusion, transfer, storage, dispensing, use, or purported use of United States Food and Drug Administration-approved adult human autologous nonembryonic stem cells or adult human autologous nonembryonic HCT/Ps that are intended to diagnose, cure, mitigate, treat, provide therapy for, or prevent an injury or a disease.

6. Performs any procedure that is intended to:

a. Collect or store adult human autologous nonembryonic HCT/Ps for autonomous homologous use; or

b. Diagnose, cure, mitigate, treat, provide therapy for, or prevent an injury or a disease through the use or purported use of adult human autologous nonembryonic HCT/Ps.

7. Compounds patient-specific adult human autologous nonembryonic HCT/Ps into a drug product by combining or mixing the patient-specific adult human nonembryonic HCT/Ps, at the prescriptive direction of a licensed physician authorized within the scope of his or her license to prescribe and administer adult human autologous nonembryonic HCT/Ps with one or more drugs or products to create a patient-specific drug or product.

8. Dispenses adult human autologous nonembryonic stem cells or HCT/Ps to any of the following for a specific patient pursuant to a valid order from a licensed physician authorized within the scope of his or her license to prescribe and administer adult human autologous nonembryonic HCT/Ps:

a. The specific patient's physician with privileges to practice at the nonembryonic stem cell bank.

b. For office use, the specific patient's physician's office or a health care facility or treatment setting where the physician has privileges to administer adult human autologous nonembryonic HCT/Ps.

(m) "Office use" includes the provision and administration of any United States Food and Drug Administration-approved adult human nonembryonic stem cell drug, compounded drug, or compounded product regulated as a drug, device, or any biological product under the FD&C Act, s. 351 of the PHS Act, or part I of chapter 499, to a patient's physician in the physician's office or in a health care facility or treatment setting, including a hospital, an ambulatory surgical center, or a health care clinic licensed under chapter 395 or chapter 400. The term also includes the patient-specific dispensing, provision, or administration of the patient's adult human autologous nonembryonic HCT/Ps.

(n) "PHS Act" means the Public Health and Safety Act, 42 U.S.C. ss. 262 et seq., and applicable regulations, including 21 C.F.R. parts 1270 and 1271.

(o) "Physician" means a person who is licensed to practice medicine under chapter 458 or osteopathic medicine under chapter 459.

(2) DUTIES AND REGISTRATION.—

(a) Establishments that manufacture adult human nonembryonic HCT/Ps are regulated by either s. 351 or s. 361 of the PHS Act and part I of chapter 499.

(b) Establishments that are regulated by s. 361 of the PHS Act must register with and submit a list of all HCT/Ps manufactured to the Food and Drug Administration and obtain a permit from the Department of Business and Professional Regulation if the HCT/P manufactured:

1. Is minimally manipulated;

2. Is intended only for homologous use;

3. Is manufactured through a process that does not involve the combination of the cells or tissue with another article, except water, crystalloids, or a sterilizing, preserving, or storing agent; and

4. For an adult human nonembryonic HCT/P, either:

a. Does not have a systemic effect and is not dependent upon the metabolic activity of living cells for their primary function; or

b. Has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function and is for autologous use or for allogeneic use in a first-degree or second-degree blood relative.

(c) Establishments that are regulated by s. 351 of the PHS Act must obtain approval from the United States Food and Drug Administration in the form of an approved investigational new drug application or a biological license application and must obtain a prescription drug manufacturing permit pursuant to s. 499.01(2)(a).

(d) Establishments that manufacture adult human nonembryonic HCT/Ps that do not meet the criteria described in paragraph (a) are exempt from the registration and listing requirements of s. 361 of the PHS Act, but must obtain a permit from, and submit a list of all HCT/Ps manufactured to, the Department of Business and Professional Regulation if the establishment:

1. Uses the adult human nonembryonic HCT/Ps for nonmedicinal scientific purposes; or

2. Removes human adult nonembryonic HCT/Ps from a patient, through a surgical procedure performed by a physician on that patient, and implants the same HCT/Ps into the same patient during that same surgical procedure, with the HCT/Ps being only minimal manipulated through washing, rinsing, cleaning, sizing, shaping, or concentrating that does not alter the original structural or relevant biological characteristics of the cells or tissues.

(e) A nonembryonic stem cell bank that manufactures adult human nonembryonic HCT/Ps may not perform enzymatic digestion on or mechanical disruption of or similarly process any adult human nonembryonic stem cell or HCT/P to alter the HCT/P's original structural characteristics or relevant biological characteristics or to isolate differentiated cells from undifferentiated cells that have lost their original structural function, so that the undifferentiated cells can be differentiated into a specialized cell type, unless the nonembryonic stem cell bank has first registered the HCT/P with the United States Food and Drug Administration and registered with the Department of Business and Professional Regulation as a

drug, device, or biological product manufacturer and complies with all applicable regulations under the FD&C Act, s. 351 of the PHS Act, 21 C.F.R. parts 1-1299, and part I of chapter 499.

(f) A nonembryonic stem cell bank that advertises, collects, stores, manufactures, dispenses, compounds, uses, or purports to use adult human nonembryonic stem cells or adult human autologous nonembryonic HCT/Ps is deemed a clinic as defined in s. 400.9905 and must comply with all of the following requirements:

1. Adhere to the applicable current good tissue practices for the collecting, removing, manufacturing, processing, using, concentrating, and implanting of adult human nonembryonic stem cells or products containing adult human nonembryonic stem cells pursuant to the FD&C Act, the PHS Act, 21 C.F.R. part 1271, and part I of chapter 499.

2. Adhere to the applicable current good manufacturing practices for the collecting, removing, manufacturing, processing, using, concentrating, compounding, and implanting of adult human autologous nonembryonic HCT/Ps so that it does not alter the relevant tissue or cellular characteristics or basic functions.

3. 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:

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

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

4. Have a physician medical director who is responsible for

the establishment's compliance with all requirements related to licensure, operation of a nonembryonic stem cell bank, and current good manufacturing practices under this section, part X of chapter 400, and the FD&C Act, the PHS Act, 21 C.F.R. parts 1-1299, and part I of chapter 499.

5. 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 is the basis for a summary suspension of the nonembryonic stem cell bank's license pursuant to s. 120.60(6) or s. 400.607.

6. Require a physician medical director with a full, active, and unencumbered license to actively practice at the nonembryonic stem cell bank location for which he or she has assumed responsibility.

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

8. 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.

9. Obtain a pharmacy permit for each person and establishment before dispensing, offering office use of, or compounding adult human nonembryonic stem cells with any other drug, compound, or product.

(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 for office use only any of the following to a stem cell bank within this state:

1. Adult human nonembryonic stem cells.

2. A compounded drug containing adult human nonembryonic stem cells.

3. A compounded product containing adult human nonembryonic stem cells.

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

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

2. A pharmacist, a pharmacy, or an establishment that receives or carries adult human nonembryonic stem cells, a compounded drug, or a compounded product that was manufactured by a nonembryonic stem cell bank may sell or dispense such items to a physician who is authorized within the scope of his or her license to prescribe and administer adult human nonembryonic

stem cells to patients.

(4) HEALTH CARE PRACTITIONER RESPONSIBILITIES.—

(a) A physician, 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 by 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 adult human nonembryonic stem cells or products containing adult human nonembryonic stem cells, a health care practitioner must adhere to the applicable current good tissue practices for the collecting, removing, manufacturing, processing, using, concentrating, compounding, and implanting of stem cells or products containing stem cells pursuant to the FD&C Act, the PHS Act, 21 C.F.R. part 1271, and part I of chapter 499.

(5) RULEMAKING.—The agency, in consultation with the Department of Health and the Department of Business and Professional Regulation, shall adopt rules to administer the licensure, inspection, 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 FD&C Act, the PHS Act, 21 C.F.R. parts 1270-1271, and part I of chapter 499:

(a) Advertising.

(b) Nonembryonic stem cell bank procedures and protocols

for the collecting, removing, manufacturing, storing, dispensing, concentrating, and using of adult human nonembryonic stem cells, other drugs containing adult human nonembryonic stem cells, and products containing adult human nonembryonic stem cells, in accordance with applicable current best practices.

(c) Adverse incident reporting.

(d) Informed consent.

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

Section 2. Paragraph (d) of subsection (1) of section 499.012, Florida Statutes, is amended to read:

499.012 Permit application requirements.—

(1)

(d) A permit for a prescription drug manufacturer, prescription drug repackager, prescription drug wholesale distributor, limited prescription drug veterinary wholesale distributor, or retail pharmacy drug wholesale distributor may not be issued to the address of a health care entity or to a pharmacy licensed under chapter 465, except as provided in this paragraph. The department may issue a prescription drug manufacturer permit to a nonembryonic stem cell bank that is licensed by the Agency for Health Care Administration pursuant to s. 400.991 and part II of chapter 408. The department may issue a prescription drug manufacturer permit to an applicant at the same address as a licensed nuclear pharmacy, which is a health care entity, even if the nuclear pharmacy holds a special sterile compounding permit under chapter 465, for the purpose of manufacturing prescription drugs used in positron emission tomography or other radiopharmaceuticals, as listed in a rule

adopted by the department pursuant to this paragraph. The purpose of this exemption is to assure availability of state-of-the-art pharmaceuticals that would pose a significant danger to the public health if manufactured at a separate establishment address from the nuclear pharmacy from which the prescription drugs are dispensed. The department may also issue a retail pharmacy drug wholesale distributor permit to the address of a community pharmacy licensed under chapter 465, even if the community pharmacy holds a special sterile compounding permit under chapter 465, as long as the community pharmacy does not meet the definition of a closed pharmacy in s. 499.003.

Section 3. This act shall take effect July 1, 2020.