STATE OF NEW YORK

11301

IN ASSEMBLY

May 11, 2026

Introduced by COMMITTEE ON RULES -- (at request of M. of A. Blumencranz) -- read once and referred to the Committee on Health

AN ACT to amend the public health law and the education law, in relation to establishing a framework for regenerative medicine and cell-based therapies

The People of the State of New York, represented in Senate and Assembly, do enact as follows:

Section 1. This act shall be entitled the "New York regenerative medicine advancement and patient protection act."

§ 2. Legislative intent. The legislature hereby finds and declares that:

1. Regenerative medicine, including cell-based and tissue-based therapies, has significant potential to improve healing, reduce pain, restore function, and advance treatment options for musculoskeletal injury, wound care, degenerative conditions, and other serious diseases.

2. New York should lead the nation in responsible biomedical innovation by fostering ethical, transparent, and patient-centered access to regenerative medicine while maintaining robust safeguards against fraud, misrepresentation, unsafe products, and unethical sourcing.

3. Patients deserve truthful advertising, meaningful informed consent, transparent disclosure of investigational status, and protection from deceptive or scientifically unsupported claims.

4. Physicians and health systems in New York should have a clear state framework for the lawful provision of qualifying regenerative medicine services consistent with federal law, professional standards, and evidence-based practice.

5. It is the intent of the legislature to promote innovation, attract research, support clinical excellence, and protect patients by creating a modern regulatory structure for regenerative medicine in New York state.

§ 3. The public health law is amended by adding a new article 27-EE to read as follows:

ARTICLE 27-EE

REGENERATIVE MEDICINE AND CELL-BASED THERAPIES

EXPLANATION--Matter in *italics* (underscored) is new; matter in brackets [-] is old law to be omitted.

LBD15450-01-6

§ 2790. Definitions. As used in this article:

1. "Regenerative medicine" means a therapeutic approach intended to repair, replace, restore, or regenerate human cells, tissues, or biologic function, including cell-based therapies, tissue-based therapies, orthobiologics, and other human cells, tissues, and cellular and tissue-based products.

2. "Human cells, tissues, and cellular and tissue-based products" or "HCT/Ps" shall have the same meaning as recognized under applicable federal law and regulation, including 21 C.F.R. Part 1271, as may be amended.

3. "Qualifying regenerative medicine protocol" means a regenerative medicine treatment, procedure, or protocol that:

a. is within the lawful scope of practice of a physician licensed under article one hundred thirty-one of the education law;

b. is performed in a hospital, diagnostic and treatment center, ambulatory surgery center, or physician office authorized by law;

c. uses only a product, biologic, tissue, or HCT/P that is sourced, manufactured, processed, stored, and transferred in compliance with applicable federal law;

d. is accompanied by the disclosures and informed consent required by this article; and

e. is not expressly prohibited by federal law.

4. "Physician" means a physician licensed pursuant to article one hundred thirty-one of the education law.

5. "Department" means the department of health.

6. "Registry" means the New York regenerative medicine registry established pursuant to section twenty-seven hundred ninety-five of this article.

7. "Material adverse event" means death, hospitalization, persistent or significant disability, congenital anomaly, life-threatening event, serious infection, tumor formation, blindness, or any other event designated by the commissioner by regulation.

8. "Ethically sourced" means not derived from tissue obtained through an abortion procedure and otherwise procured in compliance with applicable state and federal law.

§ 2791. Authorized use of qualifying regenerative medicine protocols. 1. A physician may perform or order a qualifying regenerative medicine protocol in New York state, provided that all requirements of this article and all applicable federal laws and regulations are satisfied.

2. Nothing in this article shall be construed to:

a. deem any product approved, licensed, or cleared by the United States food and drug administration if it has not been so approved, licensed, or cleared;

b. authorize conduct prohibited by federal law;

c. limit the authority of the state board for professional medical conduct; or

d. permit false, misleading, or deceptive advertising or claims of efficacy unsupported by competent scientific evidence.

3. Qualifying regenerative medicine protocols may include, but need not be limited to, protocols related to orthopedics, sports medicine, wound care, pain management, cartilage restoration, tendon and ligament injury, and other indications determined by the commissioner by regulation, provided such protocols comply with this article.

§ 2792. Product sourcing and facility requirements. 1. A physician shall not use a regenerative medicine product or protocol under this article unless the underlying product or material, where applicable:

a. is retrieved, processed, manufactured, stored, and distributed by an establishment registered with the United States food and drug administration when such registration is required by federal law;

b. is handled in accordance with applicable current good tissue practice, current good manufacturing practice, and other applicable federal quality standards;

c. is accompanied by sufficient documentation to identify the source establishment, chain of custody, lot information where applicable, expiration information where applicable, and any limitations, warnings, or contraindications; and

d. is ethically sourced.

2. Where an accreditation or certification exists for the source establishment, tissue bank, or related facility, the physician shall maintain documentation of such accreditation or certification in the patient record or related compliance file.

3. The commissioner may by regulation establish additional documentation, recordkeeping, and verification requirements to protect patient safety and ensure traceability.

§ 2793. Patient notice and informed consent. 1. Before furnishing a qualifying regenerative medicine protocol that involves a product, biologic, or protocol that has not been approved, licensed, or cleared by the United States food and drug administration for the specific indication for which it is being offered, the physician shall obtain written informed consent signed by the patient or the patient's lawful representative.

2. Such informed consent shall be written in plain language and shall include, at a minimum:

a. the nature and purpose of the proposed treatment;

b. whether the product or protocol is approved, licensed, cleared, investigational, off-label, or otherwise not approved by the United States food and drug administration for the specific indication at issue;

c. the reasonably anticipated benefits, if any;

d. the known material risks, complications, and side effects;

e. reasonably available alternative treatments, including no treatment;

f. a statement that outcomes cannot be guaranteed;

g. a statement advising the patient to consult with the patient's primary care physician or treating specialist, where appropriate;

h. an estimate of the patient's expected financial responsibility, including whether the treatment is likely not covered by insurance; and

i. any other information required by the commissioner. The physician shall provide the patient a copy of the signed informed consent.

§ 2794. Advertising and representations. 1. A physician, practice, clinic, or facility advertising regenerative medicine services shall not make any false, misleading, deceptive, or unsubstantiated claim.

2. Any advertisement for a regenerative medicine protocol that involves a product or indication not approved, licensed, or cleared by the United States food and drug administration shall include a clear and conspicuous notice stating:

"NOTICE REQUIRED BY NEW YORK LAW: This practice offers one or more regenerative medicine treatments that may not be approved, licensed, or cleared by the United States Food and Drug Administration for the specific condition being treated. Patients are encouraged to consult with their primary care provider or treating specialist before undergoing treatment."

3. Such notice shall be clearly legible and, in printed or digital advertising, shall appear in a type size and placement reasonably likely to be seen by an ordinary consumer.

4. No person shall advertise any regenerative medicine treatment as a cure unless such claim is supported by competent and reliable scientific evidence and is otherwise lawful.

§ 2795. New York regenerative medicine registry. 1. The department shall establish or designate a secure statewide regenerative medicine registry.

2. Every physician or facility providing a qualifying regenerative medicine protocol under this article shall report, in a manner determined by the commissioner:

a. the type of protocol performed;

b. the indication treated;

c. the type and source of product used, where applicable;

d. basic patient demographic information in de-identified form;

e. outcome measures designated by the commissioner; and

f. any material adverse event.

3. Data reported to the registry shall be de-identified to the fullest extent required by law and used for quality improvement, safety monitoring, public health analysis, and annual reporting.

4. The department shall publish an annual report summarizing utilization, safety signals, adverse events, and policy recommendations, except that no individually identifiable patient information shall be disclosed.

§ 2796. Material adverse event reporting. 1. A physician or facility providing a qualifying regenerative medicine protocol shall report any material adverse event to the department within seven calendar days of learning of the event, or within twenty-four hours where the event results in death or poses an immediate threat to public health.

2. Reporting under this section shall not relieve any person of any separate federal reporting obligations.

§ 2797. New York regenerative medicine innovation program. 1. There is hereby established within the department, in consultation with the empire state development corporation and the department of education, a regenerative medicine innovation program to:

a. promote New York as a national center for regenerative medicine research, manufacturing, and clinical excellence;

b. encourage collaborations among academic medical centers, community hospitals, licensed physicians, biotechnology companies, and tissue banks;

c. support translational research, workforce development, and responsible commercialization;

d. identify barriers in state law or regulation that impede ethical regenerative medicine innovation; and

e. recommend pathways to accelerate patient access consistent with federal law.

2. Subject to appropriation, the department may designate centers of regenerative medicine excellence at eligible institutions in New York state.

3. The department shall convene an advisory council consisting of physicians, scientists, bioethicists, patient advocates, manufacturers, and regulatory experts to advise on implementation of this article.

§ 2798. Rulemaking. The commissioner may promulgate rules and regulations necessary to implement this article, including rules governing documentation, registry reporting, patient notice, advertising standards, adverse event reporting, and additional qualifying indications.

§ 2799. Enforcement. 1. A violation of this article, or any regulation promulgated thereunder, may constitute professional misconduct, unprofessional conduct, or other sanctionable conduct as applicable.

2. The department, attorney general, and any other agency with lawful jurisdiction may enforce this article.

3. In addition to any other remedy provided by law, the commissioner may assess civil penalties not to exceed ten thousand dollars for each knowing violation of sections twenty-seven hundred ninety-three, twenty-seven hundred ninety-four, twenty-seven hundred ninety-five, or twenty-seven hundred ninety-six of this article.

4. Any person who knowingly falsifies registry data, conceals a material adverse event, or knowingly advertises a regenerative medicine treatment through materially false or fraudulent claims shall be guilty of a misdemeanor.

§ 4. Section 6530 of the education law is amended by adding a new subdivision 52 to read as follows:

52. Practicing or advertising regenerative medicine in violation of article twenty-seven-EE of the public health law, including failure to obtain required informed consent, material misrepresentation of regulatory status, failure to report a material adverse event, or use of a product knowingly sourced in violation of such article.

§ 5. The public health law is amended by adding a new section 2803-cc to read as follows:

§ 2803-cc. Regenerative medicine policies in licensed facilities. Every hospital, ambulatory surgery center, and diagnostic and treatment center offering regenerative medicine services shall adopt written policies governing credentialing, patient selection, informed consent, adverse event review, and compliance with article twenty-seven-EE of this chapter.

§ 6. Severability. If any clause, sentence, paragraph, section, or part of this act shall be adjudged invalid by any court of competent jurisdiction, such judgment shall not affect, impair, or invalidate the remainder thereof.

§ 7. This act shall take effect on the one hundred eightieth day after it shall have become a law. The commissioner of health is authorized to promulgate any rules and regulations necessary for the timely implementation of this act on or before such date.