STATE OF NEW YORK

8549

IN SENATE

May 9, 2018

Introduced by Sen. BOYLE -- read twice and ordered printed, and when printed to be committed to the Committee on Commerce, Economic Development and Small Business

AN ACT to amend the economic development law, in relation to the New York state biomedical and biotechnological translational research and entrepreneurship initiative

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

Section 1. Legislative intent. The legislature hereby finds and declares that a coordinated program of research, entrepreneurship, and public-private partnerships and collaborations centered in and with the state's public and private medical schools can significantly increase the speed and amount of commercialization of research from lab to market, materially expanding economic and job opportunities for all New Yorkers in this high growth sector and increasing the likelihood of high impact healthcare breakthroughs, which will improve the health and well-being of New Yorkers and potentially reduce health care costs.

The legislature further finds that although New York state's biomedical and biotechnological research and infrastructure includes many of the nation's top institutions, researchers and scientists, and has many natural advantages compared to other states, development has lagged behind the nation as a whole and many states in job growth and economic activity for a decade; and further, that as other states make significant and targeted investments to recruit top tier scientists and researchers, and develop incentives that are creating rapid growth, the gap between New York and other states will increase, along with a potential migration of scientific and research talent to other states in search of opportunity and professional advancement.

The legislature further finds that recent changes that have made New York's economic development programs more sophisticated and competitive can be combined with other statutory approaches and precedents to support and incentivize an effective plan for development of biomedical and biotechnological entrepreneurship by and through the medical schools in this state, and declares that the program enacted by this act will expand economic activity and job development; maintain and attract high quality scientists and researchers; increase resources available to the schools and researchers from grants, private investments, patents,

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

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royalties, and licensure, and leverage significant partnerships with public and private entities; enhance our scientific and research capabilities; and increase the speed of commercialization of research and the expansion of economic opportunity, which are in every sense to the benefit of the people of this state.

§ 2. The economic development law is amended by adding a new article 23 to read as follows:

ARTICLE 23

THE NEW YORK STATE BIOMEDICAL AND BIOTECHNOLOGICAL TRANSLATIONAL RESEARCH AND ENTREPRENEURSHIP INITIATIVE

Section 451. Short title.
452. Definitions.
453. New York state biomedical and biotechnological translational research and entrepreneurship initiative committee.
454. Application for designation as a New York state biomedical and biotechnological translational research and entrepreneurship initiative center.
455. Review and approval of applications.
456. Waiver in certain cases.
457. Operation and re-designation of New York state biomedical and biotechnological translational research and entrepreneurship initiative centers.
458. Scientific research and discovery bank program.
459. Unified contract.

§ 451. Short title. This article shall be known and may be cited as the "New York state biomedical and biotechnological translational research and entrepreneurship initiative".

§ 452. Definitions. As used in this article:

1. "Medical school" means a public or private medical school accredited by the liaison committee on medical education or the commission on osteopathic college accreditation, or such medical school and an affiliated entity, located in this state.

2. "New York state incubators" and "New York state innovation hotspots" or "incubators" and "hotspots" mean and refer to "New York state incubators" and "New York state innovation hotspots" designated pursuant to section sixteen-v of the urban development corporation act.

3. "Peer review committee" means the peer review committee created by the department and the department of health, consisting of scientific and research experts in biomedical and biotechnological development, and company representatives at the executive officer level engaged in making development, financing, and commercialization of biomedical and biotechnological research.

4. "Plan" means the multi-year plan that accompanies the application of a medical school to become a New York state biomedical and biotechnological translational research and entrepreneurship initiative center.

5. "Project" is the execution of an approved plan by a New York state biomedical and biotechnological translational research and entrepreneurship initiative center.

6. "START-UP NY" program means the START-UP program authorized pursuant to article twenty-one of this chapter, and the "tax-free NY area" has the same meaning as in article twenty-one of this chapter.

7. "State initiative committee" or "state committee" means the biomedical and biotechnological translational research and entrepreneurship initiative committee created by section four hundred fifty-three of this article.

8. "Translational research and entrepreneurship center" or "center" is the New York state biomedical and biotechnological translational research and entrepreneurship initiative center created at a medical school pursuant to this article.

9. "Unified contract" is the contract between the department and a medical school that includes all items necessary to the implementation and administration of the New York state biomedical and biotechnological translational research and entrepreneurship initiative project as described in this article by a center.

§ 453. New York state biomedical and biotechnological translational research and entrepreneurship initiative committee. The New York state biomedical and biotechnological translational research and entrepreneurship initiative committee is hereby created, to consist of the commissioners of the departments of health, education, economic development, labor, tax and finance, the chancellor of the state university of New York, the chancellor of the city university of New York, the president of the empire state development corporation, the director of the division of the budget, and the state comptroller. The committee shall be chaired by the commissioner of economic development, and co-chaired by the commissioner of health. Commissioners may be represented by designees at meetings of the committee.

1. Powers and duties. The committee shall:

(a) Establish guidelines appropriate to the activities required under this article.

(b) Designate as New York state biomedical and biotechnological transitional research and entrepreneurship initiative centers medical schools which meet the criteria established in this article.

(c) Approve waivers of regulations and procedures pursuant to section four hundred fifty-seven of this article.

(d) Establish a unified contract for projects pursuant to section four hundred fifty-nine of this article.

(e) Receive and review performance metrics reports from centers.

(f) Re-designate the centers every five years pursuant to this article.

(g) Develop resources and procedures to aid in commercialization of research and funding of entrepreneurial efforts created as a result of projects, including but not limited to such activities as procurement of goods or services from companies created in the projects; endorsing, collaborating, or upon request of a center, acting as a co-principal investigator or other level of participant on grants or other activities that will aid in furthering project activities; and such other activities as can aid rapid commercialization as are permissible under law.

(h) Oversee and make recommendations for approval of applications to the scientific research and discovery bank created by this article for the recruitment of out of state and retention of in-state star scientists and researchers.

(i) Upon request, provide technical assistance to applicants, and as may be needed for successful implementation of a project, including but not limited to assistance in identifying and obtaining resources and funding.

(j) Identify statutory requirements that the committee views as impediments to successful implementation of approved plans, and as necessary, submit requests to the legislature in accordance with article VII of the state constitution for specific legislative enactments necessary to remove such impediments.

(k) Enter into agreements between and among the members of the committee as necessary to delineate their respective roles regarding the cooperative provision of funding and assistance.

2. The committee may act through its chairs in all matters of oversight and implementation of the program authorized by this article.

§ 454. Application for designation as a New York state biomedical and biotechnological translational research and entrepreneurship initiative center. In response to a request for proposals, a medical school or a medical school and an affiliated entity may apply for funding and designation as a New York state biomedical and biotechnological translational research and entrepreneurship initiative center by submitting an application and plan to the commissioner. The commissioner shall forward all such applications to the peer review committee for review and recommendation as herein provided, and then to the state committee. In addition to such other items, warranties, and information as the state initiative committee may require, plans must show that the activities to be undertaken will commercialize research from lab to marketplace, demonstrate that the center meets the matching funds and entrepreneur relationship requirements hereunder, and meet a majority of the remainder of the following items:

1. Commitment: a multi-year commitment to implement the plan, over a period of not less than five years, demonstrated by a commitment of resources, personnel, and funds that the school will use, directly or through partnerships and collaborations, to provide and/or incentivize an integrated program of research, education, clinical practice, entrepreneurship, financing, partnerships, and rapid commercialization of research. Such demonstration may also include capital investments made or planned for new or rehabilitated research or laboratory space, continued support for activities after the conclusion of the project, and other activities demonstrating commitment.

2. Resources: a description of the actions and resources necessary to meet the plan objectives over its duration; a demonstration that the medical school has or is developing operational clinical facilities and expertise or evidence of bona fide collaborations and partnerships that can provide such facilities and expertise to successfully implement the plan; a demonstration that the project will have a professional management team with experience, expertise, or credentials in areas including but not limited to management, entrepreneurship, business development, or other equivalent areas. The demonstration may include recruitment plans or commitments for high level research professionals, including how the school would make use of the scientific research and discovery bank.

3. Entrepreneurial and research collaborations: evidence of bona fide entrepreneurial relationships with one or more incubators or hotspots, and research collaborations with other entities including but not limited to other research institutions, pharmaceutical and biomedical and biotechnology companies.

4. Leveraged and applied funding: a demonstration that the school already possesses or has a commitment for and will maintain during the plan period the required funding match ratio of at least two dollars for every state dollar provided pursuant to this article to an approved plan, and how the school will use other resources, partnerships, and collaborations to aid directly or indirectly in activities critical to the commercialization of research. Insofar as practicable, such matching funds should not consist of direct state grants from the department or from another state agency or state public authority, provided that noth-

ing in this subdivision shall be deemed to prohibit a medical school of the State University of New York which has been designated as a center from using a portion of its operating funds as matching funds.

5. Additional plans and programs: other plans and programs integral to the successful execution of the project, including but not limited to patent and intellectual property plans, training and educational programs, and educational integration with research and clinical activities.

6. Community support: a demonstration of community support from business and government leaders and organizations.

7. Best practices: a demonstration that the medical school has or will adopt best practices and use of multi-year metrics for performance, and that it will report data as requested or required to the department and the state initiative committee.

8. Performance metrics: anticipated annual and cumulative outcomes of the project in terms of direct, indirect, and retained jobs, investment, and economic and other activity, stated in a specific and measurable way, and research findings and progress.

9. Advisory council: an advisory council of five members or more that includes one or more executive officers of firms that have been created from research at the school, and individuals with expertise in areas appropriate to the specific developmental sector or concentration of clients, or to biomedical and biotechnological research and development, and to the mission and goal of the project.

§ 455. Review and approval of applications. Review of applications shall take place as follows:

1. The commissioner shall review applications and plans received for completeness, and then forward them to the peer review committee. No plan shall be approved by the state initiative committee that has received a designation of not recommended for further consideration (NRFC) by the peer review committee. No plans shall be forwarded by the commissioner to either committee that require that funds made available pursuant to this article shall be directly or indirectly utilized for research involving human reproductive cloning.

2. The members of the peer review committee shall be selected by the chair and the co-chair of the state initiative committee using guidelines approved by such committee, which shall include requirements concerning expertise and avoidance of conflict of interest. If necessary and deemed appropriate by the state initiative committee, plans may be submitted blind to the peer review panel. Peer review panels shall include a minimum of five members.

3. The peer review committee shall review and score plans based on the following criteria:

(a) scientific and technical merit;

(b) the level of scientific knowledge, technical capability, and/or clinical practice and other necessary plan components that would be required to be housed at the medical school, including improvements that may be anticipated based on the plan;

(c) the suitability of principal investigations, collaborators, and other researchers to the project, including the experience and training of staff and collaborators;

(d) the ongoing record of accomplishments and integrated expertise at the school or as proposed in the plan, including leadership approach, governance and organizational structure;

(e) plans for protection of human subjects;

(f) the scientific environment in which the work will be done;

(g) appropriateness of institutional support, equipment, and other physical resources; and

(h) such other information as the state initiative committee shall require.

4. An application receiving a low score by the peer review committee based on the criteria in subdivision three of this section, or which lacks significant and substantial merit, or which presents in the view of the peer review committee serious ethical problems in the protection of human subjects from research risks, or other serious ethical problems, shall be designated not recommended for further consideration (NRFC). Such plans shall be returned to the commissioner and by the commissioner to the state initiative committee with written recommendations for change.

5. The state initiative committee shall review and score plans based on the categories required in the application pursuant to section four hundred fifty-four of this article, and shall additionally consider the following:

(a) the anticipated effectiveness of the plan as evidenced by the existence of available resources dedicated to the plan and the commitment of the medical school;

(b) the ability of the applicant to undertake and complete the plan, the feasibility of meeting the metrics and goals provided for determining the success of the plan, the durability and extent of the relationships with incubators and hotspots, and with START-UP NY projects, and with private and other public collaborators;

(c) the ability of the applicant to provide the necessary data for an effective evaluation of the project;

(d) the amount of federal and private grants, or other resources that will be incentivized and made available to the school to assist in funding of the project; and

(e) such other measurable criteria as shall be determined by the committee.

6. Plans designated as not recommended for further consideration (NRFC) by the peer review committee or the state initiative committee shall be returned to the applicant with any recommendations for amendment and may be resubmitted in the following year.

7. The state initiative committee shall review the applications and plans submitted to it and recommend changes and determine funding levels and sources to be included in the unified contract, provided that not more than forty percent of funds, appropriated pursuant to this article shall be used for any single project in any year. Insofar as practicable in approving applications, the committee shall seek to provide a geographically balanced distribution among the regions of the state in designating New York state biomedical and biotechnological translational research and entrepreneurship initiative centers.

8. As soon as practicable after approving an application the committee shall notify the temporary president of the senate and the speaker of the assembly of its approval. Such notification shall identify the recipient and state the proposed location, the estimated project funding and award and provide a brief description of the project.

§ 456. Waiver in certain cases. To promote innovative approaches and maximize effective use of public monies and the likelihood of success in operation of approved New York state biomedical and biotechnological translational research and entrepreneurship initiative centers, and notwithstanding any other provision of law, the commissioner or director of any state agency that is a member of the state initiative committee

may waive, upon application by such center and subject to the approval of the state initiative committee and the director of the budget, any of such agency's regulatory or procedural requirements that may impede the successful implementation of a project undertaken by the center, provided that such waiver is consistent with applicable state and federal statutes and will not impair the general health or welfare of the people receiving services under such project or others. Such commissioner or director shall be authorized, in consultation with the director of the budget, to impose appropriate alternative standards in place of any waived requirements.

§ 457. Operation and re-designation of New York state biomedical and biotechnological translational research and entrepreneurship initiative centers. In addition to any other requirements of this article, a center will agree to provide data showing its success in meeting project plan goals, including year by year comparison of research activity and commercialization thereof, firm financing and equity capital raised, provided or leveraged from all sources, personnel employed on the project, and jobs created by and through the project. The department shall design simplified forms to aid in the submission of such data, which may be submitted electronically.

The chairs of the state initiative committee shall evaluate and report on the operations of the center using methods including but not limited to site visits, reports pursuant to specific information, and review evaluations. If the chairs determine the project is not progressing as agreed, the center will be notified of deficiencies and the center shall remedy any deficiencies in its operations in a timely manner. Such evaluations shall take place no less than once every three years or more often for any individual center at the discretion of the chairs, and shall result in a written report that includes programmatic and fiscal evaluation of the project and recommendations for improvement.

Failure to timely cure a deficiency after review shall result in disqualification of the medical school as a center.

A center shall be deemed re-designated upon application every five years unless it shall receive a negative evaluation from the peer review group on its application for re-designation, or if it shall fail to remedy identified defects in its operation made known to it pursuant to this section, or if the state initiative committee determines that such defects are of such a nature, involve fraud, or are of such extent that they cannot be remedied.

§ 458. Scientific research and discovery bank program. The scientific research and discovery bank program is hereby created, whose purpose shall be to provide funds to centers for recruitment of out of state and retention of in-state scientists and researchers necessary to the successful implementation of approved projects. Monies shall be made available to centers from funds appropriated for the purposes of this article, after review and upon approval by the state initiative committee pursuant to a plan submitted by a center. Such plan may be submitted at the time of the application or at any time during the implementation of the multi-year approved plan and must demonstrate to the satisfaction of the committee that the center has or will have during the period of the grant a match of two dollars for every state dollar provided pursuant to this section. Plans must show the timeline and usage of funds required and such other information as the committee shall require, including: the need for such funds and the manner in which such award would enhance the research capabilities of the center necessary to successful implementation of the project plan; the ability of the

researcher to leverage and attract federal funds, venture capital and private industry funds; and the willingness of such researcher to pursue entrepreneurial enterprises resulting in new business or the expansion of existing business in this state. The committee shall establish a schedule for payment of the award. Funds provided pursuant to this section must be applied directly to necessary expenses for recruitment and retention of scientists and researchers, and may not be used for indirect or other overhead costs of the medical school. Insofar as practicable, such matching funds should not consist of direct state grants from the department or from another state agency or state public authority, provided that nothing in this section shall be deemed to prohibit a medical school of the State University of New York which has been designated as a center from using a portion of its operating funds as matching funds. Funds used for match may include reasonable administrative costs associated with out of state recruitment or in-state retention.

§ 459. Unified contract. The commissioner on behalf of the state initiative committee shall enter into a unified contract with each center. The provisions of such contract shall include, but not be limited to: a description of project services and activities; the plan; allowable project costs; specific sources of funds that will support the approved costs, including governmental and non-governmental funds or revenues that are proposed to be used in support of project costs; and the allocation of costs by funding source. The form of such unified contract shall be developed in consultation with the division of the budget and the office of state comptroller. The comptroller is authorized pursuant to a certificate of allocation submitted by the division of the budget to interchange or transfer from appropriations made to the agencies of the committee or any other appropriation, as appropriate, such amounts as may be required to fulfill the obligations of the state pursuant to such unified contracts for payments of such obligations. The division of the budget shall provide the chairs of the senate finance committee and the assembly ways and means committee with quarterly reports of all interchanges and transfers which occur pursuant to this subdivision.

1. Allowable costs for a project shall include, but not be limited to costs reasonably incurred for:

(a) preparation of the plan;

(b) activities as approved in the project application;

(c) evaluation of the approved project; and

(d) renovations to existing structures as may be needed in furtherance of the plan, except that in no case shall the state support of such costs exceed either twenty-five percent of the amount to be provided pursuant to the contract or fifty percent of the total renovation costs, whichever is less.

2. Funding made available pursuant to this article shall not be used to supplant other funds for operations or projects of a center.

In addition to the foregoing requirements, a center shall agree to dedicate all funds from any support received pursuant to this article, except for funds received pursuant to paragraph (d) of subdivision one of this section, to operations of the center without deductions for overhead, indirect costs, or facilities and administration charges of the medical school, and to limit to ten percent or less the allocation of funds received through this article to administrative costs of the center.

§ 3. This act shall take effect on the first of September next succeeding the date on which it shall have become a law.