§ 4365. Powers and duties of the commissioner. 1. The commissioner, in consultation with the transplant council, may promulgate regulations to establish standards for banks and storage facilities other than those owned or operated by the office of mental health. Such standards may provide for the following: the organizational structure of banks and storage facilities; the geographic scope of licensed banks and storage facilities; donor selection and solicitation practices; tissue and non-transplant organ retrieval practices; transportation practices; required clinical laboratory tests for suitable donors, recipients and tissue; histocompatibility standards; allocation criteria; reporting requirements; record keeping requirements; accounting procedures; staff requirements; the content of agreements with hospitals from which tissues and non-transplant organs will be procured; and the content of agreements with organ procurement organizations, educational institutions, other banks and storage facilities, and other entities providing services to banks or storage facilities in connection with the procurement, storage, and distribution of tissue and non-transplant organs. The commissioner and the commissioner of mental health shall enter into a cooperative agreement to establish standards for banks and storage facilities owned or operated by the office of mental health which may include standards for donor selection and solicitation practices; tissue and non-transplant organ retrieval practices; transportation practices; reporting requirements; record keeping requirements; the content of agreements with hospitals from which tissues and non-transplant organs will be procured, and the content of agreements with other banks and storage facilities.

2. Notwithstanding any inconsistent provision of article five of this chapter, the commissioner, in consultation with the transplant council, may promulgate regulations to establish quality control standards governing tissue typing conducted by or at the request of organ procurement organizations and facilities performing transplant services. Such regulations may eliminate duplicative testing by laboratories by limiting within a service area the performance of histocompatibility matching and tissue typing services for cadaveric organ donations for transplantation in New York state.

3. At least sixty days prior to the commissioner's final approval of rules and regulations proposed pursuant to this article, other than emergency rules and regulations, the commissioner shall submit such proposed rules and regulations to the council for its review. The council shall review such rules and regulations and submit its recommendations to the commissioner within sixty days. The commissioner shall not act in a manner inconsistent with the recommendations of the council without first providing to the council a written explanation of the reasons therefor.

4. The commissioner, in consultation with the transplant council, shall promulgate regulations on the donation of ova. Such regulations shall include, but not be limited to:

(a) guidelines and procedures for obtaining fully informed consent from potential donors, including but not limited to a full disclosure of any known or potential health risks of the ova donation process;

(b) the development and distribution, in printed form and on the department's website, of informational material relating to the donation of ova;

(c) the establishment of a voluntary central tracking registry of ova donor information, as reported by banks and storage facilities licensed pursuant to this article upon the affirmative consent of an ova donor. Such registry shall provide a means for gathering and maintaining accurate information on the:

(i) number of ova and the number of times ova have been donated from a single donor;

(ii) health information of the donor at the time of the donation; and

(iii) other information deemed appropriate by the commissioner.

In addition, all such regulations shall maintain the anonymity of the donor and any resulting offspring and govern access to information maintained by the registry. Such registry shall comply with all state and federal laws and regulations related to maintaining the privacy and confidentiality of records contained within the registry; and

(d) the development of best practices and procedures, in consultation with the American college of obstetricians and gynecologists, American society for reproductive medicine and other medical organizations, for

ova donation, ova retrieval, and in vitro fertilization for the protection of the health and safety of the donor.

5. The commissioner may inquire into the operation of banks and storage facilities and may conduct periodic inspections of banks and storage facilities including methods, procedures, materials, staff and equipment.

6. Organ procurement organizations, banks, storage facilities, and other persons engaged in procurement activities shall submit, in a form prescribed by the department, periodic reports of procurement, storage and distribution activities and such other information as the commissioner may require to carry out the provisions of this article. Where available, the commissioner shall utilize information reported by organ procurement organizations to the organ procurement and transplantation network established pursuant to section three hundred seventy-two of the federal public health services act.

7. In consultation with the transplant council, the commissioner is authorized to establish subcategories of licenses based upon the tissue and non-transplant organs to be procured or stored by banks and storage facilities and the activities to be conducted and may include different standards for each subcategory of license.

8. Nothing contained within this article shall limit the authority of the council on human blood and transfusion services to adopt rules and regulations concerning blood and bone marrow in accordance with article thirty-one of this chapter.

9. The commissioner, in cooperation and consultation with the transplant council and other interested parties, shall develop and distribute, in printed form and on the department's internet website, informational materials relating to the live donation of organs and tissue, including, but not limited to:

(a) the benefits of live organ and tissue donation;

(b) the impact of the donation of organs or tissue on the donors' access to insurance and assistance;

(c) the reduction in federal adjusted gross income, for state personal income tax purposes, granted to living organ and tissue donors; and

(d) the protections and benefits granted pursuant to the living donor protection act of two thousand eighteen.