§ 4364. Licensure of banks and storage facilities. 1. No person shall own or operate a bank or storage facility that conducts procurement activity in New York state unless a license has been issued pursuant to this article.

2. An application for a license for a bank or storage facility shall contain the name of the operator, its officers, directors, principal stockholders, and controlling persons, a description of its organizational structure, the kind or kinds of procurement or storage services to be provided, the location and physical description of the bank or storage facility, and such other information as the department may require.

3. A license shall not be issued unless the department finds that the premises, equipment, personnel, rules and by-laws, and standards of service are fit and adequate and that the bank or storage facility will be operated in the manner required by this article.

4. Prior to approving an application for a license to operate a bank or storage facility which procures or stores tissue for transplantation or therapy purposes, the department shall consider:

(a) the applicant's ability to arrange for the acquisition and preservation of usable donated tissue within a designated geographic area of service and to arrange for the transportation of such tissue when necessary;

(b) the applicant's ability to obtain effective agreements for tissue procurement with hospitals;

(c) the applicant's ability to conduct and participate in systematic efforts, including professional and public education, to procure usable tissue from potential donors;

(d) the applicant's ability to establish and meet quality standards for the acquisition and storage of tissue;

(e) the applicant's ability to arrange for the selection and testing of donors and donated tissue, including the performance of donor selection and required laboratory tests including typing and processing;

(f) the applicant's ability to moderate and record temperature, including an adequate alarm notification system;

(g) the applicant's ability to establish a chain of custody for specimens;

(h) the applicant's ability to establish administrative, technical, and physical safeguards to protect patient records;

(i) the character and competence of the operator, its officers, directors, principal stockholders and controlling persons, including the quality of care provided through any health care entities operated or controlled by such persons; and

(j) with respect to banks and storage facilities created after the effective date of this paragraph, the existence and activities of other banks and storage facilities in the geographic area to be served by the applicant.

5. No hospital or other facility and no physician shall permit any person to procure tissue or non-transplant organs unless such person has been licensed in accordance with this article, or has been asked by a licensed bank or storage facility to procure a specified tissue or non-transplant organ. No bank or storage facility shall sell or otherwise transfer tissue for valuable consideration. Valuable consideration shall not include reasonable costs associated with the procurement, processing, storage and distribution of tissue. Nothing herein shall impair the provisions of section forty-three hundred seven of this chapter.

6. The commissioner is authorized to promulgate rules and regulations necessary to implement the provisions of this section.