§ 6808. Registering and operating establishments. 1. No person, firm, corporation or association shall possess drugs, prescriptions or poisons for the purpose of compounding, dispensing, retailing, wholesaling, or manufacturing, or shall offer drugs, prescriptions or poisons for sale at retail or wholesale unless registered by the department as a pharmacy, wholesaler, manufacturer or outsourcing facility.

2. Pharmacies.

a. Obtaining a registration. A pharmacy shall be registered as follows:

(1) The application shall be made on a form prescribed by the department.

(2) The application shall be accompanied by a fee of three hundred forty-five dollars.

(3) To secure and retain a registration, a pharmacy must be equipped with facilities, apparatus, utensils and stocks of drugs and medicines sufficient to permit the prompt and efficient compounding and dispensing of prescriptions, as prescribed by regulation.

b. Renewal of registration. All pharmacy registrations shall be renewed on dates set by the department. The triennial registration fee shall be two hundred sixty dollars or a pro rated portion thereof as determined by the department. At the time of renewal, the owner of every pharmacy shall report under oath to the department any facts required by the board of pharmacy.

c. Display of registration. The registration shall be conspicuously displayed at all times in the pharmacy. The names of the owner or owners of a pharmacy shall be conspicuously displayed upon the exterior of such establishment. The names so displayed shall be presumptive evidence of ownership of such pharmacy by such person or persons. In the event that the owner of a licensed pharmacy is not a licensed pharmacist, the pharmacy registration issued shall also bear the name of the licensed pharmacist having personal supervision of the pharmacy. In the event that such licensed pharmacist shall no longer have personal supervision of the pharmacy, the owner shall notify the department of such fact and

of the name of the licensed pharmacist replacing the pharmacist named on the license and shall apply for an amended registration showing the change. The amended registration must be attached to the original registration and displayed in the same manner. Both the owner and the supervising pharmacist shall be responsible for carrying out the provisions of this article.

d. Change of location. In the event that the location of a pharmacy shall be changed, the owner shall apply to the department for inspection of the new location and endorsement of the registration for the new location. The fee for inspection and endorsement shall be fifty dollars, unless it appears to the satisfaction of the department that the change in location is of temporary nature due to fire, flood or other disaster.

e. Conduct of a pharmacy. Every owner of a pharmacy is responsible for the strength, quality, purity and the labeling thereof of all drugs, toxic substances, devices and cosmetics, dispensed or sold, subject to the guaranty provisions of this article and the public health law. Every owner of a pharmacy or every pharmacist in charge of a pharmacy shall be responsible for the proper conduct of this pharmacy. Every pharmacy shall be under the immediate supervision and management of a licensed pharmacist at all hours when open. No pharmacist shall have personal supervision of more than one pharmacy at the same time.

f. A pharmacy as a department. When a pharmacy is operated as a department of a larger commercial establishment, the area comprising the pharmacy shall be physically separated from the rest of the establishment, so that access to the pharmacy and drugs is not available when a pharmacist is not on duty. Identification of the area within the pharmacy by use of the words "drugs", "medicines", "drug store", or "pharmacy" or similar terms shall be restricted to the area licensed by the department as a pharmacy.

g. Limited pharmacy registration. (1) When, in the opinion of the department, a high standard of patient safety, consistent with good patient care, can be provided by the registering of a pharmacy within a hospital, nursing home or extended care facility which does not meet all

of the requirements for registration as a pharmacy, the department may waive any requirements pertaining to full-time operation by a licensed pharmacist, minimum equipment, minimum space and waiting area, provided that when the waiver of any of the above requirements is granted by the board, the pharmaceutical services to be rendered by the pharmacy shall be limited to furnishing drugs to patients registered for treatment by the hospital, and to in-patients for treatment by the nursing home or extended care facility.

(2) When in the opinion of the department, a high standard of patient safety, consistent with good patient care, can be provided by the registering of a pharmacy within a facility distributing dialysis solutions for patients suffering from end stage renal disease and where the pharmaceutical services to be rendered by the pharmacy shall be limited to furnishing dialysis solutions to patients for whom such has been prescribed by a duly authorized prescriber, the department may waive certain requirements, including, but not limited to, full-time operation by a licensed pharmacist, minimum equipment, and minimum space and waiting area. Such solutions shall only be dispensed by employees who have completed an approved training program and who have demonstrated proficiency to perform the task or tasks of assemblying, labeling or delivering a patient order and who work under the general supervision of a licensed pharmacist who shall be responsible for the distribution, record keeping, labeling and delivery of all dialysis solutions dispensed by the distributor as required by the department.

(3) The department shall promulgate such rules or regulations consistent with this paragraph as are necessary to ensure the safe distribution of such dialysis solution, including establishment registration and proper record keeping, storage, and labeling.

(4) The initial registration fee and renewal fee for a limited pharmacy shall be three hundred forty-five dollars for each triennial registration period.

h. Applicant registration. An applicant for registration as a pharmacy shall be of good moral character, as determined by the department. In the case of a corporate applicant, the requirement shall extend to all officers and directors and to stockholders having a ten percent or greater interest in the corporation.

4. Wholesaler's or manufacturer's registration.

a. Obtaining a registration. A wholesaler or manufacturer shall be registered as follows:

(1) The application shall be made on a form prescribed by the department.

(2) The application shall be accompanied by a fee of eight hundred twenty-five dollars.

b. Renewal of registration. All wholesalers' and manufacturers' registrations shall be renewed on dates set by the department. The triennial registration fee shall be five hundred twenty dollars or a pro rated portion thereof as determined by the department.

c. Display of registration. The registration shall be displayed conspicuously at all times in the place of business.

d. Change of location. In the event that the location of such place of business shall be changed, the owner shall apply to the department for inspection of the new location and endorsement of the registration for the new location. The fee for inspection and endorsement shall be one hundred seventy dollars, unless it appears to the satisfaction of the department that the change in location is of a temporary nature due to fire, flood or other disaster.

5. Outsourcing facility's registration.

a. Obtaining a registration. An outsourcing facility shall be registered as follows:

(1) An application for initial registration or renewal of registration shall be made on a form prescribed by the department.

(2) An application for initial registration shall be accompanied by a fee of eight hundred twenty-five dollars.

b. Renewal of registration. All outsourcing facilities' registrations shall be renewed on a date set by the department. The triennial

registration fee shall be five hundred twenty dollars or a pro rated portion thereof as determined by the department.

c. Display of registration. The registration shall be displayed conspicuously in the place of business.

d. Change of location. In the event that the location of such place of business shall be changed, the owner shall apply to the department for inspection of the new location and endorsement of the registration for the new location. The fee for inspection and endorsement shall be one hundred seventy-five dollars, unless it appears to the satisfaction of the department that the change in location is of a temporary nature due to fire, flood or other disaster.

e. Report. Upon initially registering as an outsourcing facility and every six months thereafter, each outsourcing facility shall submit to the executive secretary of the state board of pharmacy a report:

(1) identifying the drugs compounded by such outsourcing facility during the previous 6-month period; and

(2) with respect to each drug identified under subparagraph one of this paragraph, providing the active ingredient; the source of such active ingredient; the National Drug Code number of the source drug or bulk active ingredient, if available; the strength of the active ingredient per unit; the dosage form and route of administration; the package description; the number of individual units produced; and the National Drug Code number of the final product, if assigned.

f. Conduct of outsourcing facility. Every owner of an outsourcing facility is responsible for the strength, quality, purity and labeling thereof of all compounded drugs, subject to the guaranty provisions of this article and the public health law. Every outsourcing facility shall be under the immediate supervision and management of a pharmacist licensed to practice in New York state.

g. Applicant for registration. An applicant for registration of an outsourcing facility shall be of good moral character, as determined by the department. In the case of a corporate applicant, the requirement

shall extend to all officers and directors and stakeholders having a ten percent or greater interest in the corporation.

6. Inspection. The state board of pharmacy and the department of education, and their employees designated by the commissioner, shall have the right to enter any pharmacy, wholesaler, manufacturer, outsourcing facility or vehicle and to inspect, at reasonable times, such factory, warehouse, establishment or vehicle and all records required by this article, pertinent equipment, finished and unfinished materials, containers, and labels.

7. Penalties. A pharmacy, wholesaler, manufacturer or outsourcing facility registered under this section shall be under the supervision of the board of regents and shall be subject to disciplinary proceedings and penalties in accordance with article one hundred thirty of this chapter in the same manner and to the same extent as individuals and professional service corporations with respect to their licenses and registrations, provided that failure to comply with the requirements of this section shall constitute professional misconduct.

8. Sale of drugs at auction. No controlled substance or substances and no poisonous or deleterious drugs or drugs in bulk or in opened containers shall be sold at auction unless the place where such drugs are sold at auction shall have been registered by the board, and unless such sale shall be under the personal supervision of a licensed pharmacist. Drugs in open containers shall not be sold at auction unless the seller shall have in his possession a certificate of the board showing that such drugs have been inspected and meet the requirements of this article. In the event that the drug so sold is one as to which this article or any federal statute or any regulation adopted pursuant to this article or an applicable federal statute require that the expiration date be stated on each package, such drug may not be sold at auction after such expiration date or when such expiration date will occur within a period of thirty days or less from the date of sale.

9. Supervision requirements for wholesalers transfilling medical oxygen. Wholesalers registered under this section which transfill

medical oxygen shall ensure any person responsible for supervising the transfilling of medical oxygen is:

a. a respiratory therapist certified by a national accrediting body;

b. a person holding a bachelor's degree in chemistry, microbiology, chemical engineering or a related field;

c. a person having two years of education beyond high school and two years experience in the handling of compressed medical gases satisfactory to the state board of pharmacy; or

d. a person having training in accordance with the requirements established in section 211.25 of title 21 of the code of federal regulations.