OFFICE OF THE PROFESSIONS
NEW YORK STATE EDUCATION DEPARTMENT

Pharmacy
Guide to Practice

The University of the State of New York
THE STATE EDUCATION DEPARTMENT

Office of the Professions
Division of Professional Licensing Services
89 Washington Avenue
Albany, NY 12234-1000
www.op.nysed.gov

January 2004

THE UNIVERSITY OF THE STATE OF NEW YORK

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NEW YORK STATE BOARD OF PHARMACY

New York is unique in placing its system of professional governance under the Board of Regents, a citizen body. Boards of professionals and public members advise the Regents and the Education Department on all aspects of professional education, licensing, practice, and discipline.

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Robert A. Mangione, Lynbrook, NY	12/01/03 – 11/30/08 (2nd)
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*Peggy Murrain, Great Neck, NY	12/01/03 – 11/30/08 (2nd)
John Navarra, Hauppauge, NY	10/01/06 – 09/30/11 (2nd)
*Carolyn Reres, Franklin Square, NY	12/01/03 – 11/30/08 (2nd)
Hao Jimmy Tran, Manhasset Hills, NY	10/01/06– 09/30/11 (2nd)
Daniel J. Villa, Three Mile Bay, NY	10/01/06– 09/30/11 (2nd)
Richard Zeitoun, Larchmont, NY	10/01/06– 09/30/11 (2nd)

*Public Member

Current listings of board members are available on the Office of the Professions' home page at www.op.nysed.gov.

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FOR FUTURE REFERENCE

IN THE EVENT OF AN EMERGENCY that impacts the licensed professions, the Office of the Professions will provide important information, specific to the situation, through our **Web site** (www.op.nysed.gov), our **automated phone system** (518-474-3817), and/or our **regional offices**. This information will include emergency provisions for professional practice as well as updates on scheduled events and services (licensing examinations, professional discipline proceedings, examination reviews, etc.).

WELCOME MESSAGE FROM THE DEPUTY COMMISSIONER

Dear New Professional Licensee:

On behalf of the New York State Board of Regents and the Education Department, I welcome you into the community of New York State licensed professionals. You have worked hard to earn your new professional license. Congratulations on your achievement! In New York State, through the Education Department's Office of the Professions, the Board of Regents licenses and regulates 44 professions and 31 related certificate areas, including:

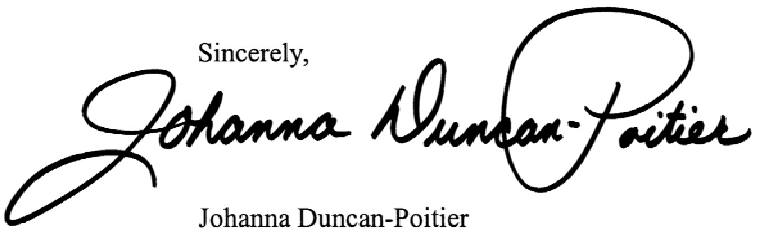
- Pharmacists, occupational therapists, nurses, certified social workers and other professionals who safeguard our health and well being.
- Accountants and other professionals who ensure the integrity of our business affairs.
- Architects, engineers, and other professionals who keep our roads and buildings safe.

Since 1891, New York's Board of Regents has ensured public protection, quality of professional preparation, and fairness for all professionals. The 16 Regents, representing all regions of the State, oversee the granting of more than 32,000 new licenses each year, registration of all 670,000 professionals every 2 or 3 years, and the investigation of over 7,000 professional misconduct complaints every year. You join the community of other active professionals in New York State, more than 19,000 of whom are pharmacists.

Your license carries with it certain expectations and responsibilities. It represents both your basic qualifications and your commitment to maintaining your competence and rendering quality professional services throughout your career. To support you in meeting your professional responsibilities, the Office of the Professions will help keep you up-to-date with changes in your profession through our Web site - www.op.nysed.gov - and at least one informational mailing a year. We will also respond to your questions and process your registration materials promptly. In our efforts to educate the public about their rights to professional services, we provide them with the tools to check the licensure and registration status of professionals and information about reporting professional misconduct and unlicensed practice. Our comprehensive approach will ensure that your professional license is backed by the integrity of an effective, unified system of professional regulation under the Board of Regents that has the protection of the public at its heart.

Congratulations again on your new profession and best wishes for a long and satisfying career.

Sincerely,



Johanna Duncan-Poitier
Deputy Commissioner
Office of the Professions and
Office of Higher Education

WELCOME MESSAGE FROM THE EXECUTIVE SECRETARY

Dear New Professional Licensee:

On behalf of the New York State Board of Pharmacy, I would like to welcome you to the practice of the profession of pharmacy in New York State. The State Board of Pharmacy, comprised of at least eleven members, including nine licensed pharmacists and at least two public members, assist the Board of Regents and the Department in the regulation of the profession. As you begin what we hope will be a rewarding career in New York State, there are a few things we would like to tell you.

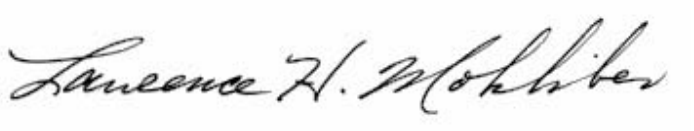
In New York State, you are licensed for life unless your license is surrendered or revoked following disciplinary action by the Board of Regents. When you are practicing in New York State, however, you are required to be registered, in addition to being licensed. Your initial period of registration begins with your date of licensure, and you must register every three years thereafter. You will automatically receive new registration materials in the mail four months before your registration expires. To ensure that you receive registration materials and important practice information promptly, licensure law requires that you inform us within 30 days if your name or address changes. If you do change your name or move, please notify us by submitting the Address/Name change form contained in this *Guide to Practice.* You may also obtain information on name/address changes on our Web site at www.op.nysed.gov, or by phone at (518) 474-3817, ext. 410.

The New York State Board of Regents, the Education Department, and the State Board of Pharmacy are committed to the protection of the public, as well as to ensuring that professional pharmacists maintain the highest standards of professional practice. To assist you, we have provided information on professional practice issues and frequently asked questions, including recommendations to help you establish sound practices. The Rules of the Board of Regents on Unprofessional Conduct, however, establish the basic requirements that you must follow in your practice. You will find these under Part 29 of the Regents Rules.

If you have questions related to scope of practice, please contact the Office of the State Board of Pharmacy, 89 Washington Avenue, Albany, New York 12234-1000, by phone at (518) 474-3817, ext. 130, fax at (518) 473-6995, or e-mail at pharmbd@mail.nysed.gov.

The members of the State Board of Pharmacy join me in wishing you years of satisfaction in the practice of pharmacy.

Sincerely,



Lawrence H. Mokhiber
Executive Secretary
State Board of Pharmacy

OFFICE OF THE PROFESSIONS
STRATEGIC PLAN

VISION

A regulatory system that promotes the highest quality of professional services for public protection.

MISSION

To protect the public by fostering high standards of professional licensure, practice and discipline.

GOALS

- The credentialing and discipline processes are fair, prompt, clear, and accurate.
- Accurate information will be provided promptly in a clear and courteous manner to consumers, licensees, and the interested public.
- Policies, practices, interpretations, standards, decisions, and processes for the licensed professions balance the needs and concerns of consumers and professionals, consistent with the law.
- All staff are informed, share in decision making, are clear about their role, have meaningful responsibility and opportunity to contribute, and have training to develop their potential.
- Partnerships are developed to promote diversity and increase awareness of careers in the licensed professions.

Your New York License and Registration

IMPORTANT INFORMATION ABOUT YOUR REGISTRATION TO PRACTICE IN NEW YORK STATE

- Your professional license is valid for life unless revoked or surrendered; however, you **must** register with the State Education Department every three years to practice your profession or use your professional title in New York State.
- **Month-of-birth registration –**

  Once licensed, about four months before your initial three-year registration expires, you will be sent a registration renewal application assigning you to a one-time *transitional registration period*. This period will end with the month prior to your date of birth between two and three years from the date of your first registration. This allows us to adjust your triennial registration cycle to coincide with the month of your date of birth and helps to ensure a speedy renewal of your registration. The registration fee for this transitional period will be prorated so that you pay only for the number of months included in the period. Thereafter, you will be registered for a three-year period beginning on the first day of your month of birth.

Remember that it is your responsibility to notify us of a change of address. You can access the license verification service on the Office of the Professions' Web site - www.op.nysed.gov - to confirm your registration expiration date.

For answers about…	*Contact:*
PRACTICE ISSUES OR THE RULES GOVERNING YOUR PROFESSION • Standards of Practice • Scope of Practice • Related areas	**NEW YORK STATE BOARD OF PHARMACY:** **Call:** (518) 474-3817 ext. 130 **Write:** New York State Board of Pharmacy 89 Washington Avenue Albany, New York 12234-1000 **Fax:** (518) 473-6995 **E-mail:** pharmbd@mail.nysed.gov
INACTIVE REGISTRATION • If you are not practicing your profession or using your title in New York, **you may inactivate** your registration at no cost. You must advise us of your decision to be inactive; otherwise, you will be expected to keep your registration current and pay all registration fees due. • If you decide to resume practice in New York after inactivating your license, you must re-register your license.	**TO INACTIVATE YOUR REGISTRATION OR TO RENEW AN INACTIVE OR LAPSED REGISTRATION:** **Call:** (518) 474-3817 ext. 410 **Write*:** Registration Unit Office of the Professions Division of Professional Licensing Services 89 Washington Avenue Albany, New York 12234-1000 **Fax*:** (518) 474-3004 **E-mail*:** opregfee@mail.nysed.gov **Licensure Status Information:** www.op.nysed.gov (Click on "Online Licensure Verification") *Be sure to include your name, profession, and license number.

Your New York License and Registration

For answers about…	*Contact:*
CHANGING YOUR ADDRESS OR NAME IN OUR RECORDS Education Law and Commissioner's Regulations require that you **notify us within 30 days of a change in your name or address.** You may use the form at the back of this packet to notify us of changes in your name or address or use one of the methods outlined in the box to the right.	**FOR ADDRESS OR NAME CHANGES:** **Call:** Records and Archives Unit at (518) 474-3817 ext. 380 **Write**: Records and Archives Unit Office of the Professions Division of Professional Licensing Services 89 Washington Avenue Albany, New York 12234-1000 **FAX:** (518) 486-3617 **E-mail:** oparchiv@mail.nysed.gov
REPLACING YOUR REGISTRATION CERTIFICATE OR YOUR LICENSE • Your **license parchment** is the permanent document issued at the time of your licensure. • Your renewable **registration certificate** indicates that you are currently registered to practice under that license in New York State. **An original signature of the licensee is required for replacement documents.**	**FOR AN APPLICATION TO REPLACE A LOST OR DESTROYED LICENSE:** **Call:** (518) 474-3817 ext. 380 **Write:** Records & Archives Unit Office of the Professions Division of Professional Licensing Services 89 Washington Avenue Albany, New York 12234-1000 **FAX:** (518) 486-3617 **E-mail:** oparchiv@mail.nysed.gov **TO REPLACE A LOST OR DESTROYED REGISTRATION CERTIFICATE:** **Write:** Registration Unit Office of the Professions Division of Professional Licensing Services 89 Washington Avenue Albany, New York 12234-1000 **Call:** (518) 474-3817 ext. 410 **FAX:** (518) 474-3004 **E-mail:** opregfee@mail.nysed.gov

NOTE

Your <u>notification</u> must include your name, profession, license number, social security number, date of birth, and both your old and new address and/or name. Please note: An original signature and notary certification is required for a name change; therefore, phone, fax, or e-mail notifications are not acceptable.

Your New York License and Registration

For answers about…	*Contact:*
VERIFYING YOUR NEW YORK LICENSE New York issues two types of written confirmation of licensure, both of which require **a written request and a fee.** Determine exactly which type is needed by the party to whom the information will be sent. **Verification:** states only whether an individual is licensed and currently registered. **Fee: $10** **Certification:** gives the basis of licensure, including professional school and licensing examination results. This statement will only be issued at the request of the licensee or another licensing authority. **Fee: $20**	**FOR A WRITTEN VERIFICATION OR CERTIFICATION:** **Send request and fee to:** Certifications and Verifications Unit Office of the Professions Division of Professional Licensing Services 89 Washington Avenue Albany, New York 12234-1000 **NO COST VERIFICATION OPTIONS:** **By phone:** (518) 474-3817 ext. 390 **On the Web: www.op.nysed.gov**
VERIFYING A PHARMACY ESTABLISHMENT REGISTRATION	**NO COST VERIFICATION OPTION:** On the Web: www.op.nysed.gov
UNLICENSED PRACTICE OR PROFESSIONAL MISCONDUCT You may contact the office of the State board for advice on practice issues. **The Office of the Professions' Office of Professional Discipline (OPD)** • Investigates and prosecutes complaints against licensed professionals; and • Works with other enforcement agencies in cases involving illegal (unlicensed) practice.	**TO FILE A COMPLAINT AGAINST A PROFESSIONAL LICENSED BY THE STATE EDUCATION DEPARTMENT* OR REPORT SOMEONE YOU BELIEVE IS PRACTICING WITHOUT A LICENSE, CALL 1-800-442-8106 OR CONTACT AN OFFICE OF THE PROFESSIONS REGIONAL OFFICE:** **Brooklyn and Staten Island:** (718) 246-3060 or 3061 **Bronx and Queens:** (718) 794-2457 or 2458 **Albany:** (518) 485-9350 **Long Island:** (631) 425-7758 **Manhattan:** (212) 961-4369 **Mid Hudson:** (914) 934-7550 **Buffalo:** (716) 842-6550 **Syracuse:** (315) 476-5081 **Rochester:** (585) 241-2810 **E-mail:** conduct@mail.nysed.gov *To report complaints against **physicians, physician assistants, and specialist assistants see specific instructions on page 35**.

Information about the Office of the Professions and the licensed professions is available on our home page: www.op.nysed.gov

THE PROFESSION OF PHARMACY

INTRODUCTION

Pharmacy is a professional practice which includes activities necessary for providing drugs for use by patients pursuant to the orders of persons authorized by State law to prescribe drugs. The essential elements of the practice are dispensing, counseling and consultation.

AUTHORIZATION TO PRACTICE PHARMACY BY PHARMACISTS AND PHARMACY INTERNS

Only a licensed person may use the title "pharmacist" or, unless exempt, may legally perform or offer to perform acts which come within the scope of the statutory definition of practice (Education Law sections 6512, 6513, 6803 and 6811). A limited permit authorizing practice by a "pharmacy intern" under the immediate and personal supervision of a licensed pharmacist may be issued to advanced pharmacy students and graduates of pharmacy programs (section 6806). Health professionals practicing within the scope of their respective professions if it includes dispensing, are exempt from the licensing requirement (sections 6505 and 6807).

The requirements and procedures for obtaining a pharmacist license are in Section 6805 of the Education Law and in Parts 59 and 63 of the Regulations of the Commissioner of Education. A licensee must register with the Education Department to practice in this State. Reregistration, every three years, requires the submission of a form accompanied by the fee set in law (section 6502 of the Education Law and Part 59 of the Regulations). All licensees are required to notify the Office of the Professions of name and addresses changes. See page 6 for details.

REGISTRATION OF PHARMACEUTICAL ESTABLISHMENTS

The Education Department registers pharmacies, wholesalers and manufacturers (Education Law section 6808 and part 63.6 of the Regulations). Registration by the Education Department is required of all individuals, partnerships or corporations who possess prescription drugs or prescription devices for the purpose of compounding, dispensing, retailing, wholesaling or manufacturing or who offer these materials for sale at retail or wholesale. The Department also registers establishments located in other states that ship or deliver prescription drugs into New York State.

Pharmacies may be owned by unlicensed persons or corporations provided that the actual practice of pharmacy is conducted only by licensed pharmacists. A separate registration is required for each pharmacy. A licensed pharmacist must be designated formally as the "supervising pharmacist" for each pharmacy. This pharmacist is personally responsible for the conduct of the practice of pharmacy at the specified pharmacy and for insuring compliance with all applicable laws, rules and regulations. The owners of manufacturing and wholesaling establishments are not required to be pharmacists. The supervisors of these establishments must meet requirements stated in the regulations. If you have any questions related to registration of establishments please contact the New York State Education Department, Office of the Professions, State Board of Pharmacy at (518) 474-3817 ext. 130, fax (518) 473-6995 or e-mail at pharmbd@mail.nysed.gov.

AUTHORIZED PRESCRIBERS

Individuals licensed and currently registered in the following professions are authorized to issue prescriptions in New York State:

- Dentists
- Midwives
- Nurse Practitioners
- Optometrists
- Physicians
- Physician Assistants
- Podiatrists
- Veterinarians

If you have questions regarding the particular aspects or scope of prescribing for these professionals please contact the appropriate professional board office. The mailing address for all offices listed below is: New York State Education Department, Office of the Professions, 89 Washington Avenue, Albany, New York 12234-1000.

DENTISTRY:

Milton Lawney, Executive Secretary, New York State Board for Dentistry
Phone: (518) 474-3817 ext. 550; Fax: (518) 473-6995; E-mail: dentbd@mail.nysed.gov

MEDICINE AND VETERINARY MEDICINE:

Thomas Monahan, Executive Secretary, New York State Boards for Medicine and Veterinary Medicine
Phone: (518) 474-3817 ext. 560; Fax: (518) 486-4846; E-mail: medbd@mail.nysed.gov and vetmedbd@mail.nysed.gov

NURSING:

Barbara Zittel, Executive Secretary, New York State Board for Nursing
Phone: (518) 474-3817 ext. 120; Fax: (518) 474-3706; E-mail: nursebd@mail.nysed.gov

OPTOMETRY:

Milton Lawney, Executive Secretary, New York State Board for Optometry
Phone: (518) 474-3817 ext. 591 ; Fax: (518) 474-6995; E-mail: optombd@mail.nysed.gov

PHARMACY AND MIDWIFERY:

Lawrence Mokhiber, Executive Secretary, New York State Boards of Pharmacy and Midwifery
Phone: (518) 474-3817 ext. 130; Fax: (518) 473-6995; E-mail: pharmbd@mail.nysed.gov and midwifbd@mail.nysed.gov.

PODIATRY:

Claudia Alexander, Executive Secretary, New York State Board for Podiatry
Phone: (518) 474-3817 ext. 180; Fax: (518) 402-5944; E-mail: podbd@mail.nysed.gov

REQUIRED REPORTING

Under the direction of the State Education Department, the Office of the State Board of Pharmacy processes, issues, and maintains registrations for all pharmacies, manufacturers, repackers, and wholesalers of drugs that are located in New York State or that ship or deliver prescription drugs into New York State from other jurisdictions. Holders of registrations, as well as individuals or entities seeking to transfer or otherwise modify a registration, must meet certain reporting requirements. Examples of instances in which you would be required to notify the Education Department's Office of the State Board of Pharmacy are provided below. To notify the State Board of Pharmacy, call (518) 474-3817 ext. 130, fax (518) 473-6995, e-mail pharmbd@mail.nysed.gov or write to:

State Board of Pharmacy
Office of the Professions
State Education Department
89 Washington Avenue
Albany, NY 12234

Transfer of Ownership – A new registration must be issued by the State Board of Pharmacy when an establishment and its assets are transferred from one individual, partnership, or corporation to another. To transfer ownership, an application for the new registration should be received by the State Board of Pharmacy at least six weeks prior to the proposed date of transfer. An inspection of the premises by the Office of the Professions is required. Applications are available by contacting the State Board Office.

Change in Corporate Officers and/or Principal Stockholders – The State Board of Pharmacy must be notified within 30 days of any change in officers and/or principal stockholders. For this requirement, a principal stockholder is any person holding ten percent or more of the stock of the corporation.

Fire, Flood or Disaster – The State Board of Pharmacy must be notified within 48 hours of damage caused by fire, flood, or disaster.

Change in Supervision – The State Board of Pharmacy must be notified within seven days of any change in the supervisor of a registered establishment.

Change of Location – An application must be filed with the State Board of Pharmacy at least 30 days prior to the expected date of relocation. An inspection of the premises by the Office of the Professions is required prior to the move. Applications are available by contacting the State Board.

Renovation of a Registered Premises – Any proposed renovation of registered premises must be reported to the State Board of Pharmacy prior to changes being made.

Change in Corporate Name or in Assumed (Trade) Names – Any changes in corporate name or in assumed (trade) names must be reported to the State Board of Pharmacy prior to use of the new name.

Temporary Closing of an Establishment – The State Board of Pharmacy must be notified before any temporary closing as well as before any subsequent reopening.

Discontinuance of a Registration – Before an establishment is closed or discontinued, proper arrangements must be made for all drugs, records and the registration certificate. A discontinuance form along with supporting documents, must be completed by a corporate officer and sent to the Office of the State Board of Pharmacy. Forms are available by contacting the State Board.

Sale of Drugs at Auction – The Office of the State Board of Pharmacy must be notified at least seven days before drugs are sold at auction. An inspector from the Office of the Professions will attend the auction. (See page 100)

To determine the registration status of an establishment or for assistance regarding a registration matter, please contact the Office of the State Board of Pharmacy as indicated on page 4. You can also verify the registration status of a pharmacy establishment on the Web at www.op.nysed.gov.

DISCONTINUATION PROCESS FOR PHARMACIES, MANUFACTURERS, REPACKERS AND WHOLESALERS

The process of discontinuing a pharmaceutical establishment registered with the New York State Board of Pharmacy is a very serious matter. The following guidelines should help the owner and supervisor in the process. Failure to provide the required documents and information to the State Board may result in charges of abandonment or other misconduct (29.7 (a)(20) page 73).

Before a pharmacy establishment is discontinued, a discontinuance form must be completed then signed and dated by a corporate officer and submitted to the Board Office. Forms are available by contacting the State Board of Pharmacy (See page 4). An inspection may be completed by the Office of the Professions. In addition, the owner and/or supervisor of the establishment should address the following:

Date of Closing – All drugs and devices must be removed from the establishment and the premises vacated by the registrant by the date of closing.

Prescription Drugs (non-controlled) and Devices – Prescription drugs and devices may be disposed of in a variety of methods. Full bottles of drugs may be sold to another registered establishment on a one-time basis to facilitate the closing of a pharmacy or manufacturer/wholesaler. Drugs may also be returned to wholesalers or manufacturers. In the case of a pharmacy, open bottles may be sold in one lot to a registered pharmacy. Copies of the Bills of Sale or credits must be submitted to the Board Office along with the discontinuance form.

Controlled Drugs – For guidance in the disposal of controlled substances contact the New York State Health Department, Bureau of Controlled Substances at (518) 402-0707. The Drug Enforcement Agency (DEA) should also be contacted at (212) 337-3900 to surrender the pharmacy's DEA registration.

Outdated and non-returnable/non-saleable drugs – Outdated and non-returnable, non-saleable drugs should be destroyed in a safe and environmentally correct manner. A medical waste refuge company should be contacted to destroy large quantities. A record of destruction should be retained and copies available if requested by the Office of the Professions.

Records – All records, including prescription files, must be retained for five years. The owner of the discontinued pharmacy shall notify the department as to the disposition of prescription records. Prescription records shall never be sold or given away to a person who does not currently possess a registration to operate a pharmacy. The Board Office must be apprised of the location of all records.

Signs – All signs that make reference to "Pharmacy", "Drug Store", "Apothecary", "Drugs" or any other similar terms must be removed from the premises.

Registration Certificate – The pharmacy establishment's registration certificate must be surrendered to the Pharmacy Board Office along with the discontinuance form.

GENERAL INFORMATION SOURCES

The following references are frequently requested by pharmacists as well as owners and supervisors of pharmacy establishments. Please contact the appropriate office or agency for the most current information.

NEW YORK STATE CONTACTS

- New York State Controlled Substances Act, Article 33 of the Public Health Law is available on the Web at www.assembly.state.ny.us

- Chapter 11 of the Administrative Rules and Regulations, Subchapter J, Part 80 - Rules and Regulations on Controlled Substances are available by contacting the:

  New York State Department of Health
  Bureau of Controlled Substances
  433 River Street, 5th Floor
  Troy, New York 12180
  Phone: (518) 402-0707
  Fax: (518) 402-0709
  E-mail: narcotic@health.state.ny.us
  Web: www.health.state.ny.us/nysdoh/narcotics

- Elderly Pharmaceutical Insurance Coverage (EPIC): 800-332-3742

- Department of Health (General Information Number): (518) 474-5422

- Medicaid Provider Enrollment: (518) 486-9440

- Medicaid Policy: (518) 486-3209

NEW YORK STATE COLLEGES OF PHARMACY

Long Island University
Arnold and Marie Schwartz College of Pharmacy and Health Sciences
75 DeKalb Avenue
Brooklyn, New York 11202
Phone: (718) 488-1234

St. John's University
College of Pharmacy and Allied Health Professions
Grand Central and Utopia Parkways
Jamaica, New York 11439
Phone: (718) 990-6411

State University of New York at Buffalo
School of Pharmacy and Pharmaceutical Sciences
Cooke Hall
Amherst, New York 14260
Phone: (716) 645-2823

Union University
Albany College of Pharmacy
106 New Scotland Avenue
Albany, New York 12208
Phone: (518) 445-7200

FEDERAL PUBLICATION RESOURCES

- Comprehensive Drug Abuse Prevention and Control Act of 1970, Public Law 91-513 is available by contacting the:

  U.S. Department of Justice
  99 10th Avenue
  New York, New York 10011
  (212) 337-1593

Information on:

- Federal Food, Drug and Cosmetic Act as amended January 1971
- Poison Prevention Packaging Act of 1970, Public Law 91-601
- Code of Federal Regulations, Title 21, Food and Drugs

Is available by contacting the:

Superintendent of Documents
U.S. Government Printing Office
Washington, DC 20402
Phone: (202) 512-1800
Web: www.access.gpo.gov

QUESTIONS AND ANSWERS FOR PHARMACISTS AND PHARMACIES

The New York State Education Department and the State Board of Pharmacy are pleased to provide you with information on recently approved rules and regulations that will affect your practice and provide for greater public protection. The information provided is intended for general use and is not law or rule. Pharmacists and other interested individuals should consult the appropriate statute(s), rule(s) or regulation(s) if they have an issue related to professional practice. This series of Questions and Answers is also available on the Office of the Professions Web site at: **www.op.nysed.gov**

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Patient Counseling

1. **When is a pharmacist or registered pharmacy intern required to counsel a patient?**

   Answer: A pharmacist or pharmacy intern **must** personally provide patient education (counseling):

   - before dispensing a medication to a new patient of the pharmacy;
   - before filling a new prescription for an existing patient of the pharmacy (i.e. introducing a new drug entity into the patient profile); and/or
   - if the dose, strength, route of administration, or directions for use has changed for an existing prescription previously dispensed to an existing patient of the pharmacy.

2. **Is a refill authorization or a prescription for continued therapy considered a new prescription?**

   Answer: **No**. Since the patient has been treated with the drug in the recent past, the patient will most likely be familiar with the medication's dosage form, route of administration, common side effects, etc. Therefore, you are not required to provide counseling unless the patient requests counseling when it is offered. The State Board of Pharmacy recommends, however, that counseling be provided to a patient if the patient has not been treated with the drug within the last 90 days.

3. **When a pharmacist or pharmacy intern provides counseling, what aspects of medication therapy should be covered?**

Answer: A pharmacist or pharmacy intern should use his/her professional judgment when deciding what to discuss with a patient during counseling. Depending on the situation, you may choose to discuss among the following:

- the name and description of the medication and known indications;
- dosage form, dosage, route of administration and duration of drug therapy;
- special directions and precautions for preparation, administration and use by the patient;
- common severe side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including how to avoid them, and actions required if they occur;
- techniques for self-monitoring drug therapy;
- proper storage;
- prescription refill information; and/or
- action to be taken in the event of a missed dose.

Pharmacists, pharmacy interns and all health care practitioners are required to provide patient education in a confidential manner.

4. **Are New York State registered mail-order and "Internet" pharmacies required to provide counseling to patients?**

Answer: **Yes**. Registered pharmacies that conduct business through the mail or by common carrier must include written notification that counseling is available and provide a toll-free number where the pharmacist or pharmacy intern can be readily reached. A pharmacist or pharmacy intern must be available to provide counseling.

If the pharmacist or pharmacy intern determines that there are potential drug therapy problems which could endanger the health of the patient, including but not limited to: therapeutic duplication, drug-drug interactions and drug-allergy interactions, the patient must be contacted prior to filling the prescription. Alternatively, the pharmacist or pharmacy intern may contact the prescriber and obtain permission to dispense an alternative drug.

If a prescriber gives approval for the dispensing of an alternative drug, the pharmacist must include a notice of the change with the order and make two documented attempts to telephone and inform the patient of the change within 48 hours of mailing or delivery. A telephone call is not required for generic substitution.

5. **If a patient is having a prescription refilled or having a prescription filled for medications previously received, are we still required to offer to provide counseling?**

Answer: **Yes**. An *offer* to provide counseling must be made every time a patient has a prescription refilled or has a prescription filled for a medication therapy that has been re-authorized by a prescriber. Any member of the pharmacy staff can make the offer to counsel on behalf of a pharmacist, including pharmacy interns, clerks, "technicians," etc. If a patient requests to be counseled, a pharmacist or pharmacy intern must be available to provide counseling.

If prescription drugs have been ordered through a registered pharmacy by mail or on the Web, the pharmacist must provide the patient with a written offer to counsel and a toll-free number where the pharmacist or pharmacy intern can be readily reached.

6. **Can I dispense a prescription to a patient if the patient declines counseling or simply refuses to be counseled?**

Answer: **Yes.** You must document the patient's decision to decline or refuse counseling in your pharmacy's records.

7. **How will counseling requirements be monitored and enforced?**

Answer: The Education Department and the Board of Pharmacy appreciate the vital role pharmacists play in the health care system. Counseling provides an opportunity for pharmacists to provide consumers with information necessary to comply with medication regimens or avoid potentially harmful interactions. Good patient counseling also helps to reduce prescription and medication errors. The Department will enforce this provision by incorporating observation of counseling in our routine inspections of pharmacies. We will also review counseling procedures whenever a prescription or counseling error is brought to our attention.

Assistance by Unlicensed Personnel

8. **Is there a limit to the number of unlicensed personnel (frequently called "pharmacy technicians") that may assist a pharmacist?**

Answer: **Yes**. Up to two unlicensed persons may assist a pharmacist with filling prescriptions. Staff involved in other duties not directly related to the filling of prescriptions are NOT counted in the 2:1 ratio.

9. **What is the effect of the recent change in the Rule of the Board of Regents that defines which functions unlicensed personnel may perform under the supervision of a pharmacist?**

Answer: In the past, the rule was occasionally misunderstood to include cashiers, delivery staff, etc. in the 2:1 ratio. The revision clarifies that staff not directly related to the filling of prescriptions are NOT counted in the ratio.

10. **Are registered pharmacy interns included in the 2:1 ratio?**

Answer: **No**. Registered pharmacy interns may practice as pharmacists under the supervision of a licensed pharmacist.

Retail Drug Price List

11. **What is the Drug Retail Price List?**

Answer: The Drug Retail Price List is a list of the 150 most frequently prescribed drugs, in the most common quantities. The list of 150 drugs will be updated annually by the State Board of Pharmacy and distributed to every New York State registered pharmacy.

12. **How will we receive a copy of the Drug Retail Price List?**

Answer: The State Education Department will distribute a paper copy to every pharmacy annually. Electronic versions are available to you on the Web at www.op.nysed.gov/pharm2003pricelist.htm. You may also request a copy by e-mailing the State Board of Pharmacy at pharmbd@mail.nysed.gov. Additionally, we will make copies available to pharmacy computer software vendors.

13. **Are New York State registered pharmacies required to make their Drug Retail Price List available to consumers?**

Answer: **Yes**. Every pharmacy that sells drugs at retail must make a Drug Retail Price List available with prices of the 150 most frequently prescribed drugs. The pharmacy must also display a sign in bold, block letters at least one inch in height that states "Drug Retail Price List Available Upon Request". Consumers may request a computer-generated list to take with them when they leave the pharmacy.

Pharmacies offering to dispense prescription drugs to consumers in New York State through the Internet are required to post a notice of availability of the drug retail price list and a toll-free number to obtain the list on your Web site. Pharmacies offering to dispense prescription drugs to consumers in New York State through mail order are required to include a printed notice with each delivery of a prescription drug informing the consumer of the availability of the drug retail price list and provide a toll-free telephone number to obtain the list.

14. **Does the Drug Retail Price list replace the Prescription Price Poster?**

Answer: **Yes**. You are no longer required to display the Prescription Price Poster.

15. **How often is a pharmacy required to update the selling price of the drugs on the list?**

Answer: You must update the list at least weekly.

16. **If our selling price changes during the week, can we legally charge the new price?**

Answer: **Yes**.

17. **Are we allowed to quote prescription prices over the phone?**

Answer: **Yes**, though you are not required to do so, you are encouraged to provide prescription prices to consumers over the phone upon request.

Registration of Out-of-State Establishments

18. **Are all pharmacy establishments located in other states now required to register to do business in New York State?**

Answer: **Yes**. Any establishment that routinely ships or delivers prescription drugs to professionals or patients in New York State must register with the Education Department through the State Board of Pharmacy. This includes manufacturers and wholesalers of drugs and registered pharmacies.

19. **Do the new requirements apply to-mail order and "Internet" pharmacies?**

Answer: **Yes**. The new law and regulations apply to all pharmacy establishments doing business in New York State.

20. **Are there any exceptions to this requirement?**

Answer: **Yes.** When transactions are isolated, the registration requirement may be waived. New regulations define isolated transactions as fewer than 600 prescriptions per year for pharmacies or sales that total less than $10,000 at wholesale, per calendar year. The Board of Pharmacy may also waive the registration requirement in an emergency.

21. **Is there a way to confirm that out-of-state establishments, including "Internet" pharmacies are properly registered?**

Answer: **Yes**. You can verify that manufacturers, wholesalers and pharmacies are registered on the Office of the Professions Web site at www.op.nysed.gov/opsearches.htm#rx . You can search for establishments located within New York State as well as those located elsewhere by name or registration number.

22. **What can I do if an out-of-state firm that routinely ships or delivers prescription drugs to professionals or patients in New York State is not listed among registered firms on the Web site?**

Answer: Please notify the Office of the State Board of Pharmacy by phone at (518) 474-3817 ext. 130 or by e-mail at pharmbd@mail.nysed.gov.

Further Information

23. **Who do I contact if I have additional questions or need more information?**

Answer: Please contact the State Board of Pharmacy by phone at (518) 474-3817 ext. 130; fax at (518) 473-6995; or by e-mail at pharmbd@mail.nysed.gov.

CONTINUING EDUCATION
QUESTIONS AND ANSWERS FOR PHARMACISTS

Education Law requires pharmacists renewing registration of a license to complete continuing education. A minimum of 45 contact hours (at least 23 live) is required in each three-year registration period. With each new registration period starting September 1, 2003 and for each registration period thereafter, at least three of the required hours must be formal continuing education on strategies and techniques to reduce medication and prescription errors.

The laws that apply to the continuing education requirements for pharmacists are found in Article 137 of New York's Education Law. They are available through the Office of the Professions' Web site at www.op.nysed.gov/title8.htm or upon request at (518) 474-3817, extension 320 or by e-mail at opforms@mail.nysed.gov.

Dates and Amounts of Continuing Education

1. How many hours of continuing education are required? May I take more then the specified number?

A minimum of 45 hours is required to be completed by New York State registered pharmacists during every three-year registration period except during the first three-year registration period following initial licensure. The majority (at least 23) of the hours must be completed through live courses. With each new registration period starting September 1, 2003 and for each registration period thereafter, as part of the 45 hours you will be required to complete at least 3 hours (home study or live) of formal continuing education on strategies and techniques to reduce medication and prescription errors.

If your registration period is for less than 3 years (36 months), your continuing education requirement is calculated at 1.25 hours for every month of the registration period. In all cases, more than half of the hours must be live credits. The 3 credits (home study or live) on techniques to reduce medication and prescription errors are required for every registration period.

You can take additional courses beyond the 45 hours required during a three-year renewal, **but the additional hours cannot be stored, carried forward or applied to a future registration period**. There is no minimum *annual* requirement.

2. What is an hour of continuing education?

An hour is one contact hour of at least 50 minutes duration. Some course providers may express continuing education hours in different units of measurement: One continuing education unit (CEU) equals 10 contact hours. To convert CEU's to contact hours, multiply the CEU's by 10. To convert contact hours to CEU's, divide the contact hours by 10.

One **semester hour** of college-level course work equals 15 contact hours; one **quarter hour** of college-level course work equals 10 contact hours.

3. Am I required to spread continuing education courses evenly over my registration period?

No. You may complete your continuing education at any time throughout your three-year registration period. You may take all courses in one year, if you wish.

To Whom does the Continuing Education Requirement Apply

4. Who is required to take continuing education?

Every pharmacist wishing to practice in New York State must complete continuing education. Therefore, all registered pharmacists beyond the initial term of registration must comply with continuing education requirements. *Failure to complete the required continuing education prior to the expiration of a registration period may subject you to charges of professional misconduct.*

5. I just graduated and received my license, and am in my first registration period. Do I need to begin taking continuing education immediately?

No. Practitioners do not need to take continuing education during their first three-year registration period following initial licensure. After that, 45 hours (23 live) are required over each three-year registration period.

6. I am seeking licensure or I am newly licensed in New York after practicing in another state. Am I required to complete continuing education?

If you received your original (out-of-state) license less than three years ago, you do not need any continuing education in New York yet. If you have been licensed for three years or more in another state before your New York license was issued, then you must meet New York's continuing education requirement of 45 contact hours (at least 23 live) of acceptable continuing education courses**.** The 45 credits must include at least 3 credits (home study or live) on techniques to reduce medication and prescription errors. You may count courses meeting New York's requirements taken within the 36 months prior to your New York application for licensure.

7. I am licensed in New York State but not registered because I am practicing in another jurisdiction. Do I need to complete continuing education before I can reactivate my registration in New York?

Yes. To reactivate your registration in New York, you will need 45 contact hours (at least 23 live) of acceptable continuing education courses. The 45 credits must include at least 3 credits (home study or live) on techniques to reduce medication and prescription errors. The continuing education must be in appropriate subject areas and offered by approved sponsors. Since you are actively practicing, you will be able to count continuing education credits earned up to **36** months prior to the month in which you reactivate your registration.

8. I am licensed in New York State but not registered and have not been practicing my profession. Do I need to complete continuing education before I can reactivate my registration in New York?

Yes. To reactivate your registration in New York, you will need 45 contact hours (at least 23 live) of acceptable continuing education courses. The 45 credits must include at least 3 credits (home study or live) on techniques to reduce medication and prescription errors. The continuing education must be in appropriate subject areas and offered by approved sponsors. Since you are not actively practicing, you will only be able to count continuing education credits earned up to **12** months prior to the month in which you reactivate your registration.

Continuing Education Courses and Sponsors

9. What types of continuing education are acceptable?

Formal courses in appropriate subjects offered by approved sponsors (providers) are acceptable. Both formal **self-study courses** and formal **courses in which you interact with an instructor** are acceptable. Self-study courses must constitute less than one-half of the total hours (a maximum of 22 contact hours out of 45).

10. What are "appropriate subjects" for continuing education?

Courses must contribute to the **professional practice of pharmacy**. Acceptable subjects include:

- **techniques to reduce medication and prescription errors** (mandatory 3 credits)
- **pharmacology of new or developing drugs;**
- **drug interactions;**
- **public health issues;**
- **infection control;**
- **child abuse reporting;**
- **sterile procedures;**
- **legal and regulatory issues;**
- **patient counseling;**
- **other topics that contribute to the professional practice of pharmacy; and**
- **other matters of health care, law, and ethics that contribute to the public's health and welfare.**

The subject matter must be related to professional practice. Therefore, courses in such subjects as HIV/AIDS management are acceptable. **Continuing Medical Education courses relevant to pharmacy practice**, such as courses in the pharmacology of new drugs, are acceptable; courses not related to pharmacy practice (e.g., surgery) are not. Similarly, epidemiology courses in graduate degree programs for pharmacists are acceptable; courses in those programs that are not so related (e.g., accounting, finance, statistics) are not acceptable.

11. Who are approved providers?

There are three types of approved sponsors (providers):

(1) Sponsors approved by the American Council on Pharmaceutical Education (ACPE) or by an equivalent organization that the State Board of Pharmacy determines to have equivalent standards (e.g., sponsors of continuing medical education). **ACPE publishes an annual directory of "Approved Providers of Continuing Pharmaceutical Education."** It is available from the Council at 311 West Superior Street, Suite 512, Chicago, IL 60610; telephone: (312) 664-3575; fax: (312) 664-4652; Web listing: www.acpe-accredit.org, click on "Provider Approval Program," then "Accredited Providers."

(2) Colleges, universities, and other degree-granting institutions offering degree (e.g., A.A.S., B.S., M.S., Pharm.D., Ph.D.) and certificate and diploma programs bearing degree credit that are registered by the Education Department or that are accredited by an equivalent accrediting agency, for courses in those registered or accredited programs. The **State Education Department has an Inventory of Registered Programs listing all degree-granting institutions in the State**. Contact the Office of Higher Education, State Education Department, Education Building, Washington Avenue, Albany, NY 12234; phone: (518) 474-5851, or find it at the State Education Department's Web site at www.nysed.gov.

(3) Sponsors approved directly by the Department. For information on **sponsors approved directly by the Department**, call (518) 474-3817, extension 130 or fax (518) 473-6995, or check the Office of the Professions Web site at **www.op.nysed.gov/pharm.htm**.

12. May I study on my own rather than take a formal live or self-study course?

No. Only formal courses offered by approved sponsors may be counted toward the continuing education requirement. Similarly, informal group "study clubs" of pharmacists that are not approved sponsors cannot be accepted. Formal courses offered by approved sponsors assure course content, effective evaluation, and record keeping by the provider.

13. Am I required to take self-study courses?

No. All of the courses may be "live" courses in which you interact with an instructor, if you wish.

14. Are "live courses" limited to those in which I'm in the same room with the instructor?

No. We consider a telecourse or teleconference in which you and the instructor can speak directly with each other to be a "live" course. Similarly, a course in which you and other practitioners discuss a taped presentation with a facilitator's assistance is a "live course." A course offered by computer in which you interact directly with the instructor in "real time" is a "live" course. On the other hand, a televised lecture with no means of direct interaction would not be acceptable as a "live" course, even if it is a live telecast.

15. Are Cardio-Pulmonary Resuscitation (CPR), Basic Life Support (BLS) and Advanced Cardiac Life Support (ACLS) courses acceptable continuing education?

Yes, including CPR, BLS and ACLS courses sponsored by the American Red Cross and the American Heart Association. You may count an initial CPR course for up to five hours of continuing education; a CPR recertification course for up to three hours; a BLS course for up to three hours; an initial ACLS course for up to twelve and an ACLS recertification for up to six hours. *(Note: First Aid courses are NOT acceptable.)*

16. Are Emergency Medical Technician (EMT) programs acceptable continuing education?

Yes, you may count an initial EMT Basic course for ten hours of continuing education and an EMT Basic recertification course for five hours.

17. May I count a continuing education course that I teach toward my requirement?

Yes. You may count **once** during a registration period the hours in a continuing education course you teach that an approved sponsor offers in an acceptable subject area.

Record Keeping and Reporting

18. What records will I have to keep?

You need to keep the following **five items of information** on each course for ***six years*** from the date you completed it: (1) **title** of the course or program and any identification number assigned to it by the sponsor, (2) **number of hours** completed, (3) the **sponsor's name** and any identifying number, (4) **verification** by the sponsor of your attendance, and (5) the **date and location** of the program or course. All five elements are likely to be provided on a certificate of completion from the sponsor.

19. How will I report having completed the continuing education requirements?

You will report your compliance with the continuing education requirements on your form to renew your registration. **You will be required to certify, under penalty of perjury, that you have completed the required hours of continuing education** and to submit your required fee (it includes the continuing education fee of $45 as set forth in Education Law).

20. Do I have to file copies of my records of continuing education?

Only if you are instructed to do so. You are required to make your continuing education records available for inspection by the Education Department upon request. **Random audits of continuing education records are conducted**.

21. If the Department conducts an audit of my continuing education records, what will I have to provide?

You will have to provide your **original records** of completion of each continuing education course to the Department. An official list/summary of your courses provided by a professional association such as PSSNY may be submitted in lieu of the certificates.

22. What if the audit reveals discrepancies?

You may be subject to disciplinary proceedings for professional misconduct. According to Section 29.1 of the Rules of the Board of Regents, willfully making or filing a false report is unprofessional conduct. Penalties may include censure and reprimand, fine, and/or suspension or revocation of your license to practice in New York State.

Options Available

23. Are there any exceptions to the continuing education requirement?

The Department may grant an adjustment (not an exemption) to the requirement for poor health, certified by a physician; a specific physical or mental disability, certified by an appropriate health-care professional; extended duty with the armed forces; or for extreme hardship which, in the Department's judgment, makes it impossible for the licensee to comply. Contact the State Board of Pharmacy for more information.

24. What if I fail to complete the required number of hours during a registration period?

A licensee who admits to noncompliance with the continuing education requirements when registering ***may request*** and ***may be granted*** a one-year conditional registration by the Education Department. Conditional registrations are not automatic and **cannot be renewed**. Conditional registrations have specific requirements including your agreement to: (1) complete the hours lacking from your previous registration, (2) complete the regular continuing education requirement at a rate of 1.25 contact hours per month during the conditional-registration period, (3) pay the regular registration fee indicated on your registration form, and (4) at the end of the conditional registration, provide proof of course completion and pay an additional registration fee equal to the fee paid when the conditional was requested.

25. What if I do not meet the continuing education requirement and simply do not renew my registration?

Fine, as long as you are not practicing your profession in New York State. Your status will remain "not registered" until you meet the continuing education requirement and submit a registration renewal application with the appropriate fee. If you practice your profession while unregistered or after the Department has denied renewal of your registration for failure to report completion of the required contact hours of continuing education, you will be subject to disciplinary proceedings for professional misconduct.

Contact Information

26. Who should I contact for more information on the continuing education requirement?

You should contact the Office of the State Board of Pharmacy, New York State Education Department, 89 Washington Avenue, 2nd floor, Albany, NY 12234-1000, phone: (518) 474-3817, option 1, extension 130, fax: (518) 473-6995, e-mail: pharmbd@mail.nysed.gov.

For current information on continuing education and for updates and any changes in the continuing education requirements, check the Office of the Professions Web site at: **www.op.nysed.gov**.

ELECTRONIC TRANSMITTAL OF PRESCRIPTIONS QUESTIONS AND ANSWERS

General Information

1. What is an electronically transmitted prescription?

   Answer: An electronically transmitted prescription is created, transmitted, recorded or stored by electronic means such as facsimile or computer systems.

2. Are there any special requirements when transmitting prescriptions electronically?

   Answer: YES. Prescribers and pharmacists must have a secure (encrypted or encoded) system for electronic transmission from computer to computer or PDA to fax machine. Any equipment used for electronic transmission of prescriptions should be so located to ensure the security and confidentiality of the transmission. Procedures for electronic transmission of prescriptions should be documented. Electronically transmitted prescriptions must:

   - contain the prescriber's signature or the electronic equivalent;
   - be protected from unauthorized access, alteration or use ; and
   - have the initials of the pharmacist or pharmacy intern entered into the pharmacy's records to indicate acceptance of the prescription by the pharmacy.

   The information retained electronically should be capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of data.

   Other electronic transfer requirements are outlined in the following questions and answers.

3. Who may transmit original prescriptions electronically?

   Answer: Only a person legally authorized to prescribe, or an employee expressly approved by the prescriber consistent with existing law, may transmit a prescription electronically (section 6810 of the Education Law). When electronic data-processing equipment is used, the input of drug information may be performed by an authorized prescriber or a pharmacist. If orders are entered by other personnel, the pharmacist must certify the accuracy of the information entered and verify the prescription prior to the dispensing of the medication.

4. Are pharmacists/prescribers obligated to transmit prescriptions electronically?

   Answer: NO. Electronic transmission of prescriptions is an option. Prescribers and pharmacists do not have to transmit prescriptions electronically.

5. Can a prescriber direct prescriptions to a particular pharmacy?

   Answer: NO. Patients have the right to choose the pharmacy where they wish to have their prescription filled. Practitioners who exert undue influence on a patient (known as steering) to have a prescription filled at any one pharmacy over another whether electronically transmitted or via a written or oral prescription are subject to charges of professional misconduct.

Pharmacist/Pharmacy Requirements

6. Is a pharmacist responsible for determining the authenticity of a prescription transmitted electronically?

   Answer: YES. Pharmacists are responsible for assuring the validity of all written, oral and electronically transmitted prescriptions. There are a number of ways to do this, such as using new software programs that require passwords, personal identification numbers (PINs) or other authentication of the prescriber. These programs also notify the pharmacist if an encrypted or encoded electronic message or "envelope" has been tampered with or altered. Prescribers and pharmacists must use compatible programs.

   The Board of Pharmacy, in an effort to assist practitioners, is sharing information on companies that have either indicated that they now have or are developing software that will provide secure electronic transmission of prescriptions. Please note that this information is neither an endorsement of the referenced companies and their products, nor a guarantee that the software meets or exceeds the requirements of the regulations. Each licensee is responsible for assuring that their hardware/software systems comply with all requirements.

   Prescriptions transmitted by facsimile also require careful attention. For faxed prescriptions, we suggest that pharmacists apply strategies similar to those now used to verify oral and written prescriptions received when authenticity is not apparent. The best professional judgment of the pharmacist is the key to a safe and effective process. The steps used to verify phoned prescriptions may also be useful for faxed prescriptions. These steps may include:

   - calling the prescriber's office to verify a prescription if the prescriber is not known to the pharmacist;
   - accepting a phoned-in prescription in lieu of the faxed or computer-transmitted prescription;
   - asking for proof of identity if the person picking up the prescription is not known to the pharmacist;
   - asking prescribers in the area to use an identifier on the faxed prescription form that indicates recopying or retransmittal. Such marks are commonly used to indicate if that document has been copied from an original;
   - ensuring that the prescribed drug, based on quantity, directions for use, etc., is consistent with the patient's medication profile;
   - using other methods such as installing "Caller ID" on the phone line that is used to receive fax prescriptions; and/or

- considering whether the prescribed drug is one with an abuse potential or otherwise has "street value."

Without special safeguards, e-mail transmissions do not independently assure the required confidentiality of patient records and do not, therefore, meet the definition of an electronically transmitted prescription in the new rules and regulations. If a pharmacist has reason to question the authenticity of the electronically-transmitted prescription, the pharmacist's professional judgment must prevail. If verification is not possible, the pharmacist can choose not to accept the electronically-transmitted prescription and can request transmission by another means from the prescriber.

7. Is a pharmacy required to print and maintain a hard copy of an electronically-transmitted prescription?

Answer: YES. Just as other records must be maintained under existing laws, printed copies of electronically transmitted prescriptions must be maintained for five (5) years. Likewise, facsimile copies must be maintained in a readable fashion for five (5) years.

8. What should a pharmacist do if he or she believes that dispensing a prescription will cause harm to the patient?

Answer: All pharmacies, including those providing prescriptions through a mail-order service, are required to maintain a medication profile for each patient and to check for adverse drug reactions. Each licensee must practice according to his or her best professional judgment and the law. If there are concerns that a prescription can cause harm to a patient, a pharmacist may contact the prescriber. If a pharmacist believes that a prescription can cause harm to a patient, even after discussion with the prescriber, the pharmacist can choose not to fill the prescription.

9. What should a pharmacist do if he or she believes a prescriber is ordering a prescription that is not consistent with the prescriber's scope of practice?

Answer: If a prescriber cannot legally order the prescription based upon the prescriber's scope of practice, the pharmacist must not fill the prescription.

Pharmacy Personnel

10. What changes have been made concerning the professional reference books that pharmacies are required to have?

Answer: Pharmacies are no longer required to have one specific reference book, the United States Pharmacopoeia Dispensing Information. However, pharmacies must have copies of current laws, rules and regulations governing the practice of pharmacy in New York. Pharmacists must also have ready access to current references such as books, CD-ROM or other on-line resources.

11. Has the ratio of unlicensed assistants to pharmacists been changed?

Answer: YES. Effective with the implementation of these regulations, pharmacists may now have the assistance of two unlicensed assistants at one time (Part 29.7(a)(22)

Rules of the Board of Regents). However, the responsibility of dispensing rests with the pharmacist. The pharmacist must check all prescriptions filled by an unlicensed assistant before they are dispensed.

12. Do registered pharmacy interns count in the ratio?

    Answer: NO. Registered pharmacy interns may practice as pharmacists under the supervision of a licensed pharmacist.

13. Has there been a change in what functions an unlicensed person may perform in a pharmacy?

    Answer: YES. Unlicensed persons may now key data into computer files. However, the pharmacist must verify all of the information prior to dispensing of a prescription by entering his or her initials or other personal identifier. The record of the dispensing must clearly identify the dispensing pharmacist. The responsibility of dispensing rests with the pharmacist.

Controlled Substances

14. May a controlled substance prescription be electronically transmitted?

    Answer: NO. A prescription for a controlled substance may not be transmitted electronically pursuant to Article 33 of the Public Health Law.

15. Can controlled substance refills be transferred from one pharmacy to another?

    Answer: NO.

Refills

16. May a non-controlled substance prescription with authorized refills remaining be refilled at another pharmacy?

    Answer: YES. One refill at a time from one pharmacist to another may be transferred at the express request of the patient.

17. Can all remaining authorized refills be transferred to another pharmacy at once?

    Answer: NO. Transfers of authorized refills must occur one at a time.

18. What happens to all the remaining authorized refills?

    Answer: The original pharmacy may continue to dispense the balance of the authorized refills.

Transfer of Prescriptions

19. What is the responsibility of the pharmacist who is transferring information for a prescription refill?

    Answer: To record the following:

    - the name of the patient;
    - that an authorized refill of the prescription has been transferred;
    - name, address and telephone number of the pharmacy to which it was transferred;
    - name of the pharmacist receiving the prescription information;
    - name of the pharmacist transferring the information; and
    - the date of the transfer.

20. What is the responsibility of the pharmacist who receives a refill transfer?

    Answer: To produce a hard copy of the prescription information, ensure that the term "refill transfer" appears on the face of the hard copy, and record the following:

    - the name of the patient;
    - that an authorized refill of the prescription has been transferred;
    - the name, address and telephone number of the pharmacy from which it was transferred;
    - the name of the pharmacist receiving the prescription information;
    - the name of the pharmacist transferring the information;
    - the date of the original prescription and most recent transfer; and
    - the original prescription number.

Confidentiality

21. Must a pharmacy obtain permission from a patient to enter in or access from a shared database the patient's medical and/or prescription information?

    Answer: YES.

22. Does such permission have to be documented?

    Answer: YES. The pharmacist is required to obtain permission that is documented as a patient's express written consent.

23. What if a person refuses to have his/her information entered into a shared database?

    Answer: A consumer may refuse to have his/her information entered into a shared database. The pharmacy that originally filled the prescription must place a "firewall" around the data. This "firewall" must prevent access to patient-specific information by an unauthorized individual at another location.

Further Information

24. Who do I contact for more information about the electronic transmission of prescriptions?

    Answer: The mailing address for all individuals and offices listed below is: Office of the Professions, State Education Building - 2nd floor, 89 Washington Avenue, Albany, New York 12234

    - **Dentistry**: New York State Board for Dentistry (518) 474-3817 ext. 550; Fax (518) 473-6995; E-mail dentbd@mail.nysed.gov.
    - **Medicine & Veterinary Medicine**: New York State Boards for Medicine & Veterinary Medicine (518) 474-3817 ext. 560; Fax (518) 486-4846; E-mail medbd@mail.nysed.gov and vetmedbd@mail.nysed.gov.
    - **Nursing**: New York State Board for Nursing (518) 474-3817 ext. 120; Fax (518) 474-3706; E-mail nursebd@mail.nysed.gov.
    - **Optometry**: New York State Board for Optometry (518) 474-3817 ext. 591; Fax (518) 473-6995; E-mail optombd@mail.nysed.gov.
    - **Pharmacy & Midwifery**: New York State Boards of Pharmacy & Midwifery (518) 474-3817 ext. 130; Fax (518) 473-6995; E-mail pharmbd@mail.nysed.gov and midwifbd@mail.nysed.gov.
    - **Podiatry**: New York State Board for Podiatry (518) 474-3817 ext. 180; Fax (518) 402-5944; E-mail podbd@mail.nysed.gov.

PROFESSIONAL MISCONDUCT

A license to practice a profession in New York State is in effect for life unless surrendered by the holder or revoked by the Board of Regents upon a finding of professional misconduct. Professional misconduct is defined in Article 130 section 6509 of Education Law and in Part 29 of the Rules of the Board of Regents which can be accessed on the Web at www.op.nysed.gov/part 29.htm. **It is the responsibility of every professional to be aware of the laws and regulations governing her or his profession.**

Professional misconduct includes:

- practicing beyond the authorized scope of practice;
- practicing fraudulently;
- practicing with gross negligence or gross incompetence or with negligence or incompetence on more than one occasion;
- practicing while the ability to practice is impaired by alcohol, drugs, or mental disability;
- being a habitual user of drugs;
- being convicted of a crime;
- unlawful fee splitting;
- delegating professional duties to an unauthorized person;
- physically or sexually abusing a patient;
- filing false reports;
- failing to maintain proper records;
- ordering excessive or unnecessary tests; and
- other serious matters.

The Office of the Professions investigates and prosecutes allegations of professional misconduct in all professions except medicine (which includes physicians, physician assistants, and specialist assistants) where it is the responsibility of the Office of Professional Medical Conduct (OPMC) of the New York State Department of Health.

REPORTING PROFESSIONAL MISCONDUCT OR UNLICENSED PRACTICE

Any person who suspects or has knowledge of professional misconduct should report the information to the appropriate Office of the Professions office listed below. **Complaints may be treated confidentially.** If an investigation develops sufficient evidence, disciplinary proceedings will be commenced. In the most serious cases, these proceedings may lead to the Regents suspending or revoking a license.

The public is placed at risk whenever an unlicensed person illegally practices a profession. The Office of the Professions has jurisdiction to investigate the practice of a profession by someone who is not licensed, which is a criminal act punishable as a Class E Felony. Any professional who discovers such illegal practice should immediately report the information to the appropriate office listed below. This should occur as soon as the illegal practice is suspected so that an investigation can be conducted and prompt action may be taken to protect the public and preserve the integrity of the profession involved.

To report professional misconduct for professions other than medicine or unlicensed practice, call, write, or e-mail the **Office of the Professions**.

- **Toll-free Professional Misconduct Hotline: 1-800-442-8106**
- **E-mail address: conduct@mail.nysed.gov.**

Complainants may also call or write any of the following regional offices:

- **Albany Regional Office:** New York State Education Department, Office of the Professions, Office of Professional Discipline, 80 Wolf Road, Suite 204, Albany, NY 12205 [phone: (518) 485-9350; fax: (518) 485-9361].

- **Bronx and Queens Regional Office:** New York State Education Department, Office of the Professions, Office of Professional Discipline, 2400 Halsey Avenue, Bronx, NY 10461 [phone: (718) 794-2457 or 2458; fax: (718) 794-2480].

- **Brooklyn and Staten Island Regional Office:** New York State Education Department, Office of the Professions, Office of Professional Discipline, 195 Montague Street, 4th Floor, Brooklyn, NY 11201 [phone: (718) 246-3060; fax: (718) 246-3096].

- **Buffalo Regional Office:** New York State Education Department, Office of the Professions, Office of Professional Discipline, 295 Main Street, Suite 756, Buffalo, NY 14203 [phone: (716) 842-6550; fax: (716) 842-6551].

- **Long Island Regional Office:** New York State Education Department, Office of the Professions, Office of Professional Discipline, 1121 Walt Whitman Road, Suite 301, Melville, NY 11747 [phone: (631) 425-7758; fax: (631) 425-9109].

- **Manhattan Regional Office:** New York State Education Department, Office of the Professions, Office of Professional Discipline, 163 West 125th Street, Room 819, New York, NY 10027 [phone: (212) 961-4369; fax: (212)-961-4361]

- **Mid-Hudson Regional Office:** New York State Education Department, Office of the Professions, Office of Professional Discipline, One Gateway Plaza, 3rd Floor, Port Chester, NY 10573 [phone: (914) 934-7550; fax: (914) 934-7607].

- **Rochester Regional Office:** New York State Education Department, Office of the Professions, Office of Professional Discipline, 220 Idlewood Road, Room 106, Rochester, NY 14618 [phone: (585) 241-2810; fax: (585) 241-2816].

- **Syracuse Regional Office:** New York State Education Department, Office of the Professions, Office of Professional Discipline, State Tower Building, 109 South Warren Street, Suite 320, Syracuse, NY 13202 [phone: (315) 476-5081; fax: (315) 476-5182].

To report misconduct by a physician, a physician assistant, or a specialist assistant, write or call the Office of Professional Medical Conduct, New York State Department of Health, 433 River Street, Suite 303, Troy, NY 12180-2299 [phone: 1-800-663-6114 or (518) 402-0836].

PROFESSIONAL ASSISTANCE PROGRAM

The Office of the Professions' Professional Assistance Program (PAP) assists licensed professionals with addictive illness. The program allows professionals to voluntarily and confidentially surrender their licenses while entering and receiving treatment/education in acceptable programs. The PAP is only available to licensees who have not harmed patients or clients. In some cases, successful completion of the program may act as an alternative to disciplinary action.

The Committee for Professional Assistance, composed primarily of experts in substance abuse, advises the Education Department on the administration of the program. A member of the appropriate State professional board sits ex officio on each PAP panel. The panels interview applicants and determine their suitability for the program, monitor progress, and determine the readiness of the licensee to resume professional practice.

For additional information about this program, contact the Professional Assistance Program, New York State Education Department, Office of the Professions, 80 Wolf Road, Suite 204, Albany, NY 12205; phone (518) 474-3817 ext. 480; or e-mail pap@mail.nysed.gov.

PAGE REFERENCE TO LAWS, RULES AND REGULATIONS

The following pages contain the laws and regulations that govern your professional practice as a pharmacist or pharmacy intern. It is important that you familiarize yourself with these laws and regulations. Pay particular attention to Part 29 of the Regents Rules, which defines unprofessional conduct. Please note that updates to laws and regulations are available on the Office of the Professions Web site: www.op.nysed.gov.

Laws and Regulations Specific to Pharmacy

Education Law

Article 137 – Pharmacy

Commissioner's Regulations

Part 52.29 – Pharmacy

Part 63 – Pharmacy

Note: Laws and regulations are current as of the date of publication.

Code of Federal Regulations

Title 21 – Code of Federal Regulations

Part 205 – Guideline for State Licensing of Wholesale Prescription Drug Distributors

Public Health Law

Part 80 – Possession and Sale of Hypodermic Syringes and Hypodermic Needles

Article 33 – Offenses, Violations and Enforcement

Part 415 – Nursing Homes – Minimum Standards (Excerpts from Chapter V – Medical Facilities)

Laws, Rules and Regulations Applicable to All Professions

Education Law

Article 130 – General Provisions

Subarticle 1 – Introductory Summary

Subarticle 2. – State Management

Note: Laws and regulations are current as of the date of publication.

Subarticle 3. – Professional Misconduct

Subarticle 4. – Unauthorized Acts

Regents Rules

Part 17 – Disciplinary Proceedings in the Professions

Part 24 – Committee on the Professions

Part 28 – Determination of good moral character in the professions

Part 29 – Unprofessional Conduct

Note: Laws and regulations are current as of the date of publication.

Commissioner's Regulations

Part 59 – General Provisions

Note: Laws and regulations are current as of the date of publication.

LAWS AND REGULATIONS SPECIFIC TO PHARMACY

EDUCATION LAW
Article 137
Pharmacy

§6800. Introduction.

This article applies to the profession of pharmacy. The general provisions for all professions contained in article one hundred thirty of this title apply to this article.

§6801. Definition of practice of pharmacy.

The practice of the profession of pharmacy is defined as the preparing, compounding, preserving, or the dispensing of drugs, medicines and therapeutic devices on the basis of prescriptions or other legal authority.

§6802. Definitions.

1. "Pharmacy" means any place, other than a registered store, in which drugs, prescriptions or poisons are possessed for the purpose of compounding, preserving, dispensing or retailing, or in which drugs, prescriptions or poisons are compounded, preserved, dispensed or retailed, or in which such drugs, prescriptions or poisons are by advertising or otherwise offered for sale at retail.

2. [Repealed]

3. "Formulary" means the latest edition of the official national formulary, and its supplement.

4. "Pharmacopeia", when not otherwise limited, means the latest edition of the official United States pharmacopeia, and its supplement.

5. "Homeopathic pharmacopeia" means the official homeopathic pharmacopeia of the United States, and its supplement.

6. "Official compendium" means the official United States pharmacopeia, official homeopathic pharmacopeia of the United States, official national formulary, or their supplements.

7. "Drugs" means:

a. Articles recognized in the official United States pharmacopeia, official homeopathic pharmacopeia of the United States, or official national formulary.

b. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals.

c. Articles (other than food) intended to affect the structure or any function of the body of man or animals.

d. Articles intended for use as a component of any article specified in paragraphs a, b, or c; but does not include devices or their components, parts or accessories.

8. "Cosmetics" means:

a. Articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance.

b. Articles intended for use as a component of any such articles; except that the term shall not include soap.

9. "Poison", where not otherwise limited, means any drug, chemical or preparation likely to be destructive to adult human life in quantity of sixty grains or less.

10. "Label" means a display of written, printed or pictorial matter upon the immediate container of any drug, device or cosmetic. Any requirement made by or under authority of this article, that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if there be any, of the retail package of such drug, device or cosmetic or is easily legible through the outside container or wrapper.

11. "Immediate container" does not include package liners.

12. "Labeling" means all labels and other written, printed or pictorial matter:

a. Upon any drug, device or cosmetic or any of its containers or wrappers, or

b. Accompanying such drug, device or cosmetic.

13. "Misbranding". If a drug, device or cosmetic is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading then in determining whether the labeling or advertisement is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the drug, device, or cosmetic to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual. No drug, device or cosmetic which is subject to, and complies with regulations promulgated under the provisions of the federal food, drug, and cosmetic act, relating to adulteration and misbranding shall be

deemed to be adulterated or misbranded in violation of the provisions of this article because of its failure to comply with the board's regulations, or the rules of the state board of pharmacy, insofar as the regulations are in conflict with regulations relating to adulteration and misbranding under the federal food, drug and cosmetic act.

14. "Antiseptic". The representation of a drug, device or cosmetic in its labeling, as an antiseptic, shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

15. "New drug" means:

a. Any drug not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested by the drug's labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to September first, nineteen hundred thirty-nine it was subject to the former federal food and drug act of June thirtieth, nineteen hundred six, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use;

b. Any drug, the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become recognized, but which has not otherwise than in such investigations been used to a material extent or for a material time under such conditions.

16. "Device" means instruments, apparatus, and contrivances, including their components, parts and accessories, intended:

a. For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; or

b. To affect the structure or any function of the body of man or animals.

17. The term "Federal Food, Drug and Cosmetic Act" means the Federal Food, Drug, and Cosmetic Act of the United States of America, approved June twenty-fifth, nineteen hundred thirty-eight, officially cited as public document number seven hundred seventeen-seventy-fifth congress (chapter six hundred seventy-five--third session), and all its amendments now or hereafter enacted.

18. "Wholesaler" means a person who bottles, packs or purchases drugs, devices or cosmetics for the purpose of selling or reselling to pharmacies or to other channels as provided in this article.

19. "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs, devices or cosmetics.

20. "Controlled substance" means any drug defined as a controlled substance by article thirty-three of the public health law.

21. "Manufacturer" means a person who compounds, mixes, prepares, produces, and bottles or packs drugs, cosmetics or devices for the purpose of distributing or selling to pharmacies or to other channels of distribution.

§6803. Practice of pharmacy and use of title "pharmacist".

Only a person licensed or otherwise authorized under this article shall practice pharmacy or use the title "pharmacist" or any derivative.

§6804. State board of pharmacy.

A state board of pharmacy shall be appointed by the regents on recommendation of the commissioner for the purpose of assisting the regents and the department on matters of professional licensing and professional conduct in accordance with section sixty-five hundred eight of this title. The board shall be composed of not less than nine pharmacists licensed in this state for at least five years. An executive secretary to the board shall be appointed by the regents on recommendation of the commissioner and shall be a pharmacist licensed in this state for at least five years. The board shall have power:

a. To regulate the practice of pharmacy and the employment of interns and employees in pharmacies,

b. To regulate and control the sale, distribution, character and standard of drugs, poisons, cosmetics, devices and new drugs,

c. To employ inspectors and chemists,

d. To prevent the sale or distribution of such drugs, poisons, cosmetics, devices and new drugs as do not conform to the provisions of this article or of the public health law,

e. To investigate alleged violations of the provisions of this article, through its own investigative personnel or those of other agencies, to conduct hearings, to levy money penalties, and to bring alleged violations to the notice of the attorney general, and

f. To issue limited permits or registrations.

§6805. Requirements for a professional license.

l. To qualify for a pharmacist's license, an applicant shall fulfill the following requirements:

(1) Application: file an application with the department;

(2) Education: have received an education, including a bachelor's or equivalent degree in pharmacy, in accordance with the commissioner's regulations;

(3) Experience: have experience satisfactory to the board and in accordance with the commissioner's regulations;

(4) Examination: pass an examination satisfactory to the board and in accordance with the commissioner's regulations;

(5) Age: be at least twenty-one years of age;

(6) Citizenship or immigration status: be a United States citizen or an alien lawfully admitted for permanent residence in the United States; provided, however that the board of regents may grant a one-time waiver for a pharmacist who otherwise meets the requirements of this article and provided further that the board of regents may grant an extension of such three-year waiver of not more than one year;
* NB effective until October 1, 2006

(7) Character: be of good moral character as determined by the department; and

(8) Fees: pay a fee of one hundred seventy-five dollars to the department for admission to a department conducted examination and for an initial license, a fee of eighty-five dollars for each re-examination, a fee of one hundred fifteen dollars for an initial license for persons not requiring admission to a department conducted examination, and a fee of one hundred fifty-five dollars for each triennial registration period.

2. On or before April first, nineteen hundred seventy-two, any person who holds a valid license as "druggist" in this state shall make application and on the payment of fees specified in this title be licensed by the department as a pharmacist. Such person shall have all of the rights, privileges, duties and responsibilities of a pharmacist.

§6806. Limited permits.

1. The department may issue a limited permit for employment as a "pharmacy intern" to:

a. A student enrolled in the last two years of a registered program in pharmacy, or

b. A graduate of a program in pharmacy which meets standards established by the commissioner's regulations who is engaged in meeting the experience requirements or whose application for initial licensure is pending with the department.

2. A pharmacy intern may, as determined by the commissioner's regulations, practice as a pharmacist under the immediate personal supervision of a licensed pharmacist.

3. A limited permit issued to a pharmacy intern shall have an expiration date of five years from the date of issue. Limited permits may be renewed once for a period not to exceed two years.

4. Fees. The fee for each limited permit issued to a pharmacy intern shall be seventy dollars.

§6807. Exempt persons.

1. This article shall not be construed to affect or prevent:

a. Unlicensed assistants from being employed in licensed pharmacies for purposes other than the practice of pharmacy;

b. Any physician, dentist, veterinarian or other licensed health care provider legally authorized to prescribe drugs under this title who is not the owner of a pharmacy, or registered store, or who is not in the employ of such owner, from supplying his patients with such drugs as the physician, dentist, veterinarian or other licensed health care provider legally authorized to prescribe drugs under this title deems proper in connection with his practice, provided, however, that all such drugs shall be dispensed in a container labeled with the name and address of the dispenser and patient, directions for use, and date of delivery, and in addition, such drug shall bear a label containing the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription specifically states on the prescription in his own handwriting, that the name of the drug and the strength thereof should not appear on the label; provided further that if such drugs are controlled substances, they shall be dispensed pursuant to the requirements of article thirty-three of the public health law;

c. Any merchant from selling proprietary medicines, except those which are poisonous, deleterious or habit forming, or materials and devices specifically exempted by regulations of the department or by the public health law;

d. Any personnel in an institution of higher learning from using prescription-required drugs on the premises for authorized research, experiments or instruction, in accordance with the department's regulations and, if such drugs are controlled substances, in accordance with title III of article thirty-three of the public health law; or

e. The necessary and ordinary activities of manufacturers and wholesalers, subject to the provisions of article thirty-three of the public health law.

2. a. Notwithstanding the provisions of paragraph b of subdivision one of this section, no prescriber who is not the owner of a pharmacy, or registered store, or who is not in the employ of such owner, may dispense more than a seventy-two hour supply of drugs, except for:

(1) persons practicing in hospitals as defined in section twenty-eight hundred one of the public health law;

(2) the dispensing of drugs at no charge to their patients;

(3) persons whose practices are situated ten miles or more from a registered pharmacy;

(4) the dispensing of drugs in a clinic, infirmary or health service that is operated by or affiliated with a post-secondary institution;

(5) persons licensed pursuant to article one hundred thirty-five of this title;

(6) the dispensing of drugs in a medical emergency as defined in subdivision six of section sixty-eight hundred ten of this article;

(7) the dispensing of drugs that are diluted, reconstituted or compounded by a prescriber;

(8) the dispensing of allergenic extracts; or

(9) the dispensing of drugs pursuant to an oncological or AIDS protocol.

b. The commissioner, in consultation with the commissioner of health, may promulgate regulations to implement this subdivision and may, by regulation, establish additional renewable exemptions for a period not to exceed one year from the provisions of paragraph a of this subdivision.

§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, store, wholesaler, or manufacturer.

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.

3. [Repealed]

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. 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, or registered store, 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.

6. Revocation or suspension. A pharmacy, store, wholesaler or manufacturer registration may be revoked or suspended by the committee on professional conduct of the state board of pharmacy in accordance with the provisions of article one hundred thirty.

7. 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.

§6808-a. Identification of Pharmacists.

Every pharmacist on duty shall be identified by a badge designed by the state board of pharmacy, which shall contain his name and title.

§6808-b. Registration of nonresident establishments.

1. Definition. The term "nonresident establishment" shall mean any pharmacy, manufacturer or wholesaler located outside of the state that ships, mails or delivers prescription drugs or devices to other establishments, authorized prescribers and/or patients residing in this state. Such establishments shall include, but not be limited to, pharmacies that transact business through the use of the internet.

2. Registration. All nonresident establishments that ship, mail, or deliver prescription drugs and/or devices to other registered establishments, authorized prescribers, and/or patients into this state shall be registered with the department; except that such registration shall not apply to intra-company transfers between any division, affiliate, subsidiaries, parent or other entities under complete common ownership and control. The provisions of this subdivision shall apply solely to nonresident establishments and shall not affect any other provision of this article.

3. Agent of record. Each nonresident establishment that ships, mails or delivers drugs and/or devices into this state shall designate a resident agent in this state for service of process pursuant to rule three hundred eighteen of the civil practice law and rules.

4. Conditions of registration. As a condition of registration, a nonresident establishment shall comply with the following requirements:

a. Be licensed and/or registered and in good standing with the state of residence;

b. Maintain, in readily retrievable form, records of drugs and/or devices shipped into this state;

c. Supply, upon request, all information needed by the department to carry out the department`s responsibilities under the laws and rules and regulations pertaining to nonresident establishments;

d. Comply with all statutory and regulatory requirements of the state where the nonresident establishment is located, for prescription drugs or devices shipped, mailed or delivered into this state, except that for controlled substances shipped, mailed

or delivered into this state, the nonresident pharmacy shall follow federal law and New York law relating to controlled substances;

e. The application shall be made in the manner and form prescribed by the department;

f. The application of establishments to be registered as a manufacturer or wholesaler of drugs and/or devices shall be accompanied by a fee as provided in section sixty-eight hundred eight of this article; and

g. The application of establishments to be registered as a nonresident pharmacy shall be accompanied by a fee of three hundred forty-five dollars and shall be renewed triennially at a fee of two hundred sixty dollars.

5. Additional requirements. Nonresident pharmacies registered pursuant to this section shall:

a. Provide a toll-free telephone number that is available during normal business hours and at least forty hours per week, to enable communication between a patient in this state and a pharmacist at the pharmacy who has access to the patient`s records; and

b. Place such toll-free telephone number on a label affixed to each drug or device container.

6. Disciplinary action. Except in emergencies that constitute an immediate threat to public health, the department shall not prosecute a complaint or otherwise take formal action against a nonresident establishment based upon delivery of a drug into this state or a violation of law, rule, or regulation of this state if the agency having jurisdiction in the state where the nonresident establishment is based commences action on the violation complained of within one hundred twenty days from the date that the violation was reported; provided however, that the department may prosecute a complaint or take formal action against a nonresident establishment if it determines that the agency having jurisdiction in the state where the nonresident establishment is based has unreasonably delayed or otherwise failed to take prompt and appropriate action on a reported violation.

7. Revocation or suspension. A nonresident establishment that fails to comply with the requirements of this section shall be subject to revocation or suspension of its registration and other applicable penalties in accordance with the provisions of article one hundred thirty of this chapter.

8. Exception. The department may grant an exception from the registration requirements of this section on the application of a nonresident establishment that restricts its sale or dispensing of drugs and/or devices to residents of this state to isolated transactions.

9. Rules and regulations. The department shall promulgate rules and regulations to implement the provisions of this section.

§6810. Prescriptions.

1. No drug for which a prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act or by the commissioner of health shall be distributed or dispensed to any person except upon a prescription written by a person legally authorized to issue such prescription. Such drug shall be compounded or dispensed by a licensed pharmacist, and no such drug shall be dispensed without affixing to the immediate container in which the drug is sold or dispensed a label bearing the name and address of the owner of the establishment in which it was dispensed, the date compounded, the number of the prescription under which it is recorded in the pharmacist's prescription files, the name of the prescriber, the name and address of the patient, and the directions for the use of the drug by the patient as given upon the prescription. The prescribing and dispensing of a drug which is a controlled substance shall be subject to additional requirements provided in article thirty-three of the public health law. The words "drug" and "prescription required drug" within the meaning of this article shall not be construed to include soft or hard contact lenses, eyeglasses, or any other device for the aid or correction of vision. Nothing in this subdivision shall prevent a pharmacy from furnishing a drug to another pharmacy which does not have such drug in stock for the purpose of filling a prescription.

2. A prescription may not be refilled unless it bears a contrary instruction and indicates on its face the number of times it may be refilled. A prescription may not be refilled more times than allowed on the prescription. The date of each refilling must be indicated on the original prescription. Prescriptions for controlled substances shall be refilled only pursuant to article thirty-three of the public health law.

3. A copy of a prescription for a controlled substance shall not be furnished to the patient but may be furnished to any licensed practitioner authorized to write such prescription. Copies of other prescriptions shall be furnished to the patient at his request, but such copies are issued for the informational purposes of the prescribers only, and shall be so worded.

4. (a) Oral prescriptions for controlled substances shall be filled pursuant to article thirty-three of the public health law. A pharmacist may fill an oral prescription for a drug, other than a controlled substance, made by a practitioner legally authorized to prescribe drugs. An oral authorization for the refill of a prescription, other than a prescription for a controlled substance, may be made by a practitioner legally authorized to prescribe drugs. The pharmacist receiving such oral authorization for the refill of a prescription shall write on the reverse side of the original prescription the date, time, and name of he practitioner authorizing the refill of the prescription. An oral prescription or an oral authorization for the refill of a prescription for the drug, other than a controlled substance, may be communicated by an employee of the prescribing practitioner; provided however the pharmacist shall:

(i) contemporaneously reduce such prescription to writing;

(ii) dispense the substance in conformity with the labeling requirements applicable to a written prescription; and

(iii) make a good faith effort to verify the employee's identity if the

employee is unknown to the pharmacist.

(b) Oral prescriptions for patients in general hospitals, nursing homes, residential health care facilities as defined in section twenty-eight hundred one of the public health law, hospitals as defined in subdivision ten of section 1.03 of the mental hygiene law, or developmental centers or developmental disabilities services offices listed in subdivision (b) of section 13.17 of the mental hygiene law, may be communicated to by a pharmacist serving as a vendor of pharmaceutical services based upon a contractual arrangement by an agent designated by and under the direction of the prescriber or the institution. Such agent shall be a health care practitioner currently licensed and registered under this title.

5. Records of all prescriptions filled or refilled shall be maintained for a period of at least five years and upon request made available for inspection and copying by a representative of the department. Such records shall indicate date of filling or refilling, doctor's name, patient's name and address and the name or initials of the pharmacist who prepared, compounded, or dispensed the prescription. Records of prescriptions for controlled substances shall be maintained pursuant to requirements of article thirty-three of the public health law.

6. (a) Every prescription written in this state by a person authorized to issue such prescription shall be on prescription forms containing one line for the prescriber's signature. The prescriber's signature shall validate the prescription. Imprinted conspicuously in eight point upper case type immediately below the signature line shall be the words: "THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PRESCRIBER WRITES 'd a w' IN THE BOX BELOW". Unless the prescriber writes d a w in such box in the prescriber's own handwriting, the prescriber's signature shall designate approval of substitution by a pharmacist of a drug product pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law. No other letters or marks in such box shall prohibit substitution. No prescription forms used or intended to be used by a person authorized to issue a prescription shall have 'd a w' preprinted in such box. Such box shall be placed directly under the signature line and shall be three-quarters inch in length and one-half inch in height. Immediately below such box shall be imprinted in six point type the words "Dispense As Written". Notwithstanding any other provision of law, no state official, agency, board or other entity shall promulgate any regulation or guideline modifying those elements of the prescription form's contents specified in this subdivision. To the extent otherwise permitted by law, a prescriber may modify only those elements of the prescription form's contents not specified in this subdivision. Notwithstanding any other provision of this section or any other law, when a generic drug is not available and the brand name drug originally prescribed is available and the pharmacist agrees to dispense the brand name product for a price that will not exceed the price that would have been charged for the generic substitute had it been available, substitution of a generic drug product will not be required. If the generic drug product is not available and a medical emergency situation, which for purposes of this section is defined as any condition requiring alleviation of severe pain or which threatens to cause disability or take life if not promptly treated, exists, then the pharmacist may dispense the brand name product at his regular price. In such instances the pharmacist must record the date, hour and nature of the medical emergency on the back of the prescription and keep a copy of all such prescriptions.

(b) The prescriber shall inform the patient whether he or she has prescribed a brand name or its generic equivalent drug product.

(c) The provisions of this subdivision shall not apply to a hospital as defined in article twenty-eight of the public health law.

(d) No prescriber shall be subjected to civil liability arising solely from authorizing, in accordance with this subdivision, the substitution by a pharmacist of a drug product pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law.

7. (a) No prescription for a drug written in this state by a person authorized to issue such prescription shall be on a prescription form which authorizes the dispensing or compounding of any other drug.

(b) With respect to drugs other than controlled substances, the provisions of this subdivision shall not apply to pharmacists employed by or providing services under contract to general hospitals, nursing homes, residential health care facilities as defined in section twenty-eight hundred one of the public health law, hospitals as defined in subdivision ten of section 1.03 of the mental hygiene law, or developmental centers or developmental disabilities services offices listed in subdivision (b) of section 13.17 of the mental hygiene law, who dispense drugs in the course of said employment or in the course of providing such services under contract. With respect to such pharmacists, each prescription shall be transcribed on a patient specific prescription form.

8. Every prescription (whether or not for a controlled substance) written in this state by a person authorized to issue such prescription and containing the prescriber's signature shall, in addition to such signature, be imprinted or stamped legibly and conspicuously with the printed name of the prescriber who has signed the prescription. The imprinted or stamped name of the signing prescriber shall appear in an appropriate location on the prescription form and shall not be entered in or upon any space or line reserved for the prescriber's signature. The imprinted or stamped name shall not be employed as a substitute for, or fulfill any legal requirement otherwise mandating that the prescription be signed by the prescriber.

9. No person, corporation, association or other entity, not licensed to issue a prescription pursuant to this title, shall wilfully cause prescription forms, blanks or facsimiles thereof to be disseminated to any person other than a person who is licensed to issue a prescription pursuant to this title. A violation of this subdivision shall be a class B misdemeanor punishable in

accordance with the provisions of the penal law.

§6811. Misdemeanors.

It shall be a class A misdemeanor for:

1. Any person knowingly or intentionally to prevent or refuse to permit any board member or department representative to enter a pharmacy or any other establishment for the purpose of lawful inspection;

2. Any person whose license has been revoked to refuse to deliver the license;

3. Any pharmacist to display his license or permit it to be displayed in a pharmacy of which he is not the owner or in which he is not employed, or any owner to fail to display in his pharmacy the license of the pharmacist employed in said pharmacy;

4. Any holder of a license to fail to display the license;

5. Any owner of a pharmacy to display or permit to be displayed in his pharmacy the license of any pharmacist not employed in said pharmacy;

6. Any person to carry on, conduct or transact business under a name which contains as a part thereof the words "drugs", "medicines", "drugstore", "apothecary", or "pharmacy", or similar terms or combination of terms, or in any manner by advertisement, circular, poster, sign or otherwise describe or refer to the place of business conducted by such person, or describe the type of service or class of products sold by such person, by the terms "drugs", "medicine", "drug store", "apothecary", or "pharmacy", unless the place of business so conducted is a pharmacy licensed by the department;

7. Any person to enter into an agreement with a physician, dentist, podiatrist or veterinarian for the compounding or dispensing of secret formula (coded) prescriptions;

8. Any person to sell or distribute any instrument or article, or any recipe, drug or medicine for the prevention of conception to a minor under the age of sixteen years; the sale or distribution of such to a person other than a minor under the age of sixteen years is authorized only by a licensed pharmacist but the advertisement or display of said articles, within or without the premises of such pharmacy is hereby prohibited;

Injunction

Injunctive relief against enforcement of subd. 8 of this section which prohibited distribution of contraceptives to persons under the age of 16, which prohibited distribution of contraceptives to any other persons by persons other than pharmacists, and which prohibited any display or advertisement of contraceptives was appropriate. Population Services Intern. V. Wilson, D.C.N.Y. 1975, 398 F. Supp. 321, 97 S.Ct. 2010, 431 U.S. 678, 52 L.Ed.2d 675.

9. Any person to manufacture, sell, deliver for sale, hold for sale or offer for sale of any drug, device or cosmetic that is adulterated or misbranded;

10. Any person to adulterate or misbrand any drug, device or cosmetic;

11. Any person to receive in commerce any drug, device or cosmetic that is adulterated or misbranded, and to deliver or proffer delivery thereof for pay or otherwise;

12. Any person to sell, deliver for sale, hold for sale, or offer for sale any drug, device or cosmetic in violation of this article;

13. Any person to disseminate any false advertisement;

14. Any person to refuse to permit entry or inspection as authorized by this article;

15. Any person to forge, counterfeit, simulate, or falsely represent, or without proper authority using any mark, stamp, tag, label or other identification device authorized or required by rules and regulations promulgated under the provisions of this article;

16. Any person to use for his own advantage, or reveal, other than to the commissioner or his duly authorized representative, or to the courts when relevant in any judicial proceedings under this article, any information acquired under authority of this article or concerning any method or process, which is a trade secret;

17. Any person to alter, mutilate, destroy, obliterate or remove the whole or any part of the labeling of, or the doing of any other act with respect to a drug, device, or cosmetic, if such act is done while such article is held for sale and results in such article being misbranded;

18. Any person to use on the labeling of any drug or in any advertising relating to such drug any representation or suggestion that an application with respect to such drug is effective under section sixty-eight hundred seventeen of this chapter or that such is in compliance with the provisions of such section;

19. Any person to violate any of the provisions of section sixty-eight hundred ten of this article;

20. Any person to violate any of the provisions of section sixty-eight hundred sixteen of this article;

21. Any person, to sell at retail or give away in tablet form bichloride of mercury, mercuric chloride or corrosive sublimate, unless such bichloride of mercury, mercuric chloride or corrosive sublimate, when so sold, or given away, shall conform to the provisions of national formulary XII. Nothing contained in this paragraph shall be construed to prohibit the sale and dispensing of bichloride of mercury in any form, shape, or color, when combined or compounded with one or more other drugs or excipients, for the purposes of internal medication only, or when sold in bulk in powder form, or to any preparation containing one-tenth of a grain or less of bichloride of mercury;

22. Any pharmacy to fail to properly post the list required by section sixty-eight hundred twenty-six of this article;

23. Any pharmacy to change its current selling price without changing

the listed price as provided by section sixty-eight hundred twenty-six of this article;

24. Any person to refuse to permit access to or copying of any record as required by this article; or

25. Any manufacturer to sell or offer for sale any drug not manufactured, prepared or compounded under the personal supervision of a chemist or licensed pharmacist or not labeled with the full name of the manufacturer or seller.

§6811-a. Certain drugs to be clearly marked or labeled.

1. No drug for which a prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act or by the commissioner of health may be manufactured or commercially distributed within this state in tablet or capsule form unless it has clearly marked or imprinted on each such tablet or capsule in conformance with the applicable plan required by subdivision three of this section:

(a) an individual symbol, number, company name, words, letters, marking or National Drug Code (hereinafter referred to as N. D. C.) number identifying the manufacturer or distributor of the drug; and

(b) an N. D. C. number, symbol, number, letters, words or marking identifying such drug or combination of drugs.

2. No drug for which any prescription is required by the provisions of the Federal Food, Drug and Cosmetic Act or by the commissioner of health contained within a bottle, vial, carton or other container, or in any way affixed or appended to or enclosed within a package of any kind, and designed or intended for delivery in such container or package to an ultimate consumer, shall be manufactured or distributed within this state unless such container or package has clearly and permanently marked or imprinted upon it in conformance with the applicable plan required by subdivision three of this section:

(a) an individual symbol, N. D. C. number, company name, number, letters, words or marking identifying the manufacturer or distributor of the drug;

(b) an N. D. C. number, symbol, number, letters, words or marking identifying such drug or combination of drugs; and

(c) whenever the distributor of the prescription drug product does not also manufacture the product the names and places of business of both shall appear on the label in words clearly distinguishing each.

3. (a) Each manufacturer and distributor shall prepare and submit to the commissioner of health a proposed plan of the manufacturer or distributor, as the case may be, to have its products comply with the marking and labeling requirements of this section.

(b) Such plan shall be in writing and shall give the respective dates by which the various products manufactured or distributed will each contain the required mark or label. The plan shall state the reasons why the projected date of compliance has been proposed and such other information deemed relevant or that the commissioner of health shall require.

(c) The commissioner may either approve the plan as proposed or, after consultation with the manufacturer or distributor, require an amendment or the commissioner may promulgate a plan for the manufacturer or distributor. No plan or amendment to the plan shall be effective until approved or promulgated by the commissioner of health upon a finding by him that the time limitations provided for therein are reasonable and will best carry out the intendment of this section.

4. Each manufacturer and/or distributor shall publish and make available, upon request, to the department of education, to each physician, dentist, pharmacy, hospital or other institution wherein such drugs may be used, a printed material which will identify each imprint used by the manufacturer or distributor. Updated materials shall be provided as changes occur, upon the filing of an annual request. The provisions of this subdivision shall be deemed to be complied with when a prescription drug product is included in the Physician's Desk Reference.

5. Every person, firm or corporation violating the provisions of this section for any prescription drug product shall be guilty of an offense punishable by a fine of not less than twenty-five hundred dollars nor more than ten thousand dollars. Any prescription drug product prepared or manufactured in violation of this section shall be contraband and subject to seizure either by the state board of pharmacy or by any law enforcement officer of the state.

6. The provisions of this section shall not apply to any tablet or capsule which contains a controlled substance as that term is defined by article thirty-three of the public health law or which is prepared or manufactured by a pharmacist duly licensed by the state which is made by him for the purpose of retail sale from his principal place of business and not intended for resale.

7. The commissioner of health may exempt a particular tablet or capsule from the requirements of this section, upon application by a manufacturer, on the grounds that labeling such a tablet or capsule is unfeasible because of size or texture or other unique characteristics.

8. (a) As used in this section, the term "distributor" means the person, firm, corporation or other entity which is not the actual manufacturer of a prescription drug product but which distributes such product for resale under the label of such person, firm, corporation or entity.

(b) For purposes of subdivision four "drug product" means the entire supply of the finished dosage form of the drug.

§6811-b. Door-to-door distribution of drugs prohibited.

It shall be a violation, punishable by a fine not to exceed two hundred fifty dollars, for a manufacturer, distributor, or seller of drugs or an employee or agent thereof to distribute a free sample of any drug, other than a cosmetic not intended for ingestion, to any residential dwelling unless the sample is given directly to a

person who is, or reasonably appears to be, over the age of eighteen. This section shall not be construed to permit distribution where otherwise prohibited by this chapter or any other law.

§6812. Special provisions.

1. Where any pharmacy registered by the department is damaged by fire the board shall be notified within a period of forty-eight hours, and the board shall have power to impound all drugs for analysis and condemnation, if found unfit for use. Where a pharmacy is discontinued, the owner of its prescription records shall notify the department as to the disposition of said prescription records, and in no case shall records be sold or given away to a person who does not currently possess a registration to operate a pharmacy.

2. Nothing in this article shall be construed as requiring the prosecution or the institution of injunction proceedings for minor violations of this article whenever the public interest will be adequately served by a suitable written notice of warning.

3. The executive secretary of the state board of pharmacy is authorized to conduct examinations and investigations for the purposes of this article through officers and employees of the United States, or through any health, food, or drug officer or employee of any city, county or other political subdivision of this state.

§6813. Seizure.

1. Any drug, device or cosmetic that is adulterated, misbranded or may not be sold under the provisions of this chapter, may be seized on petition or complaint of the board and condemned in the supreme court of any county in which it is found. Seizure shall be made:

a. by process pursuant to the petition or complaint, or

b. if the secretary or other officer designated by him has probable cause to believe that the article

(1) is one which may not be sold under the provisions of section sixty-eight hundred seventeen of this chapter, or

(2) is adulterated, or

(3) is so misbranded as to be dangerous to health. The article shall be seized by order of such officer. The order shall describe the article to be seized, the place where the article is located, and the officer or employee making the seizure. The officer, in lieu of taking actual possession, may affix a tag or other appropriate marking to the article giving notice that the article has been quarantined and warning all persons not to remove or dispose of it by sale or otherwise until permission for removal or disposal is given by the officer or the court. In case of seizures or quarantine, pursuant to such order, the jurisdiction of such court shall attach upon such seizure or quarantine, and a petition or complaint for condemnation shall be filed promptly.

2. The procedure for cases under this section shall conform as much as possible to the procedure for attachment. Any issue of fact joined in any case under this section shall be tried by jury on the demand of either party. The court at any time after seizure and up to the time of trial shall allow by order any party or his agent or attorney to obtain a representative sample of the condemned material, a true copy of the analysis on which the proceeding was based, and the identifying marks or numbers, if any, on the packages from which the samples analyzed were obtained.

3. Any drug, device or cosmetic condemned under this section shall be disposed of by destruction or sale as the court may direct after the decree in accordance with the provisions of this section. The proceeds of the sale, if any, shall be paid into the state treasury after deduction for legal costs and charges. However, the drug, device or cosmetic shall not be sold contrary to the provisions of this article. After entry of the decree, if the owner of the condemned articles pays the costs of the proceeding and posts a sufficient bond as security that the articles will not be disposed of contrary to the provisions of this article, the court may by order direct that the seized articles be delivered to the owner to be destroyed or brought into conformance with this article under supervision of the secretary. The expenses of the supervision shall be borne by the person obtaining the release under bond. Any drug condemned by reason of its being a new drug which may not be sold under this article shall be disposed of by destruction.

4. When the decree of condemnation is entered, court costs and fees, storage and other expense shall be awarded against the person, if any, intervening as claimant of the condemned articles.

5. In any proceeding against the board, or the secretary, or an agent of either, because of seizure, or quarantine, under this section, the board, or the secretary, or such agent shall not be liable if the court finds that there was probable cause for the acts done by them.

§6814. Records of shipment.

For the purpose of enforcing provisions of this article, carriers engaged in commerce, and persons receiving drugs, devices or cosmetics in commerce or holding such articles so received, shall, upon the request of an officer duly assigned by the secretary, permit such officer, at reasonable times, to have access to and to copy all records showing the movement in commerce of any drug, device or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof: and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of drug, device or cosmetic to which such request relates: Provided, that evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: Provided further, that carriers shall not be subject to the other provisions of this article by reason of their receipt, carriage, holding or delivery of drugs, devices or cosmetics in the usual course of business as carriers.

§6815. Adulterating, misbranding and substituting.

1. Adultered drugs. A drug or device shall be deemed to be adulterated:

a. (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations provided in this article.

b. If it purports to be, or is represented as, a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or, in the absence or inadequacy of such tests or methods of assay, then in accordance with tests or methods of assay prescribed by regulations of the board of pharmacy as promulgated under this article. Deviations from the official assays may be made in the quantities of samples and reagents employed, provided they are in proportion to the quantities stated in the official compendium. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because (1) it exceeds the standard of strength therefor set forth in such compendium, if such difference is plainly stated on its label; or (2) it falls below the standard of strength, quality, or purity therefor set forth in such compendium if such difference is plainly stated on its label, except that this clause shall apply only to such drugs, or classes of drugs, as are specified in regulations which the board shall promulgate when, as applied to any drug, or class of drugs, the prohibition of such difference is not necessary for the protection of the public health. Whenever a drug is recognized in both the United States pharmacopoeia and the homeopathic pharmacopoeia of the United States, it shall be subject to the requirements of the United States pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia.

c. If it is not subject to the provisions of paragraph b of this subdivision and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

d. If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

e. If it is sold under or by a name not recognized in or according to a formula not given in the United States pharmacopoeia or the national formulary but that is found in some other standard work on pharmacology recognized by the board, and it differs in strength, quality or purity from the strength, quality or purity required, or the formula prescribed in, the standard work.

2. Misbranded and substituted drugs and devices. A drug or device shall be deemed to be misbranded:

a. If its labeling is false or misleading in any particular.

b. If in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, that under clause (2) of this paragraph the board may establish reasonable variations as to quantity and exemptions as to small packages.

c. If any word, statement, or other information required by or under authority of this article to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

d. If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, beta eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the secretary, after investigation, found to be, and by regulations under this article, or by regulations promulgated by the board, designated as, habit forming; unless its label bears the name and quantity, or proportion, of such substance or derivative and in juxtaposition therewith the statement "Warning--May be habit forming."

e. If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2) in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the kind and quantity by percentage or amount of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: Provided, that, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the board.

f. Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions orby children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, that, where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the board shall promulgate regulations exempting such drug or device from such requirement.

g. If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: Provided,

that, the method of packing may be modified with the consent of the secretary in accordance with regulations promulgated by the board. Whenever a drug is recognized in both the United States pharmacopoeia and the homeopathic pharmacopoeia of the United States, it shall be subject to the requirements of the United States pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the homeopathic pharmacopoeia of the United States, and not to those of the United States pharmacopoeia.

h. (1) If it is a drug and its container is so made, formed or filled as to be misleading; (2) if it is an imitation of another drug; (3) if it is offered for sale under the name of another drug; or (4) if it bears a copy, counterfeit, or colorable imitation of the trademark, label, container or identifying name or design of another drug.

i. If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof.

j. Except as required by article thirty-three of the public health law, the labeling provisions of this article shall not apply to the compounding and dispensing of drugs on the written prescription of a physician, a dentist, a podiatrist or a veterinarian, which prescription when filled shall be kept on file for at least five years by the pharmacist or druggist. Such drug shall bear a label containing the name and place of business of the dispenser, the serial number and date of the prescription, directions for use as may be stated in the prescription, name and address of the patient and the name of the physician or other practitioner authorized by law to issue the prescription. In addition, such label shall contain the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription explicitly states on the prescription, in his own handwriting, that the name of the drug and the strength thereof should not appear on the label.

§6816. Omitting to label drugs, or labeling them wrongly.

1. a. Any person, who, in putting up any drug, medicine, or food or preparation used in medical practice, or making up any prescription, or filling any order for drugs, medicines, food or preparation puts any untrue label, stamp or other designation of contents upon any box, bottle or other package containing a drug, medicine, food or preparation used in medical practice, or substitutes or dispenses a different article for or in lieu of any article prescribed, ordered, or demanded, except where required pursuant to section sixty-eight hundred sixteen-a of this article, or puts up a greater or lesser quantity of any ingredient specified in any such prescription, order or demand than that prescribed, ordered or demanded, except where required pursuant to paragraph (g) of subdivision two of section three hundred sixty-five-a of the social services law, or otherwise deviates from the terms of the prescription, order or demand by substituting one drug for another, except where required pursuant to section sixty-eight hundred sixteen-a of this article, is guilty of a misdemeanor; provided, however, that except in the case of physicians' prescriptions, nothing herein contained shall be deemed or construed to prevent or impair or in any manner affect the right of an apothecary, druggist, pharmacist or other person to recommend the purchase of an article other than that ordered, required or demanded, but of a similar nature, or to sell such other article in place or in lieu of an article ordered, required or demanded, with the knowledge and consent of the purchaser. Upon a second conviction for a violation of this section the offender must be sentenced to the payment of a fine not to exceed one thousand dollars and may be sentenced to imprisonment for a term not to exceed one year. The third conviction of a violation of any of the provisions of this section, in addition to rendering the offender liable to the penalty prescribed by law for a second conviction, shall forfeit any right which he may possess under the law of this state at the time of such conviction, to engage as proprietor, agent, employee or otherwise, in the business of an apothecary, pharmacist, or druggist, or to compound, prepare or dispense prescriptions or orders for drugs, medicines or foods or preparations used in medical practice; and the offender shall be by reason of such conviction disqualified from engaging in any such business as proprietor, agent, employee or otherwise or compounding, preparing or dispensing medical prescriptions or orders for drugs, medicines, or foods or preparations used in medical practice.

b. The provisions of this section shall not apply to the practice of a practitioner who is not the proprietor of a store for the dispensing or retailing of drugs, medicines and poisons, or who is not in the employ of such a proprietor, and shall not prevent practitioners from supplying their patients with such articles as they may deem proper, and except as to the labeling of poisons shall not apply to the sale of medicines or poisons at wholesale when not for the use or consumption by the purchaser; provided, however, that the sale of medicines or poisons at whole-sale shall continue to be subject to such regulations as from time to time may be lawfully made by the board of pharmacy or by any competent board of health.

c. The provisions of this section shall not apply to a limited pharmacy which prepares a formulary containing the brand names and the generic names of drugs and of manufacturers which it stocks, provided that it furnishes a copy of such formulary to each physician on its staff and the physician signs a statement authorizing the hospital to supply the drug under any generic or non-proprietary name listed therein and in conformity with the regulations of the commissioner of education.

2. For the purposes set forth in this section, the terms prescription, order or demand shall apply only to those items subject to provisions of subdivision one of section sixty-eight hundred ten of this chapter. The written order of a physician for items not subject to provisions of subdivision one of section sixty-eight hundred ten of this chapter shall be construed to be a direction, a fiscal order or a voucher.

§6816-a. When substitution is required.

1. A pharmacist shall substitute a less expensive drug product containing the same active ingredients, dosage form and strength as the drug product prescribed, ordered or demanded,

provided that the following conditions are met:

(a) The prescription is written on a form which meets the requirements of subdivision six of section sixty-eight hundred ten of this article and the prescriber does not prohibit substitution, or in the case of oral prescriptions, the prescriber must expressly state whether substitution is to be permitted or prohibited. Any oral prescription that does not include such an express statement shall not be filled; and

(b) The substituted drug product is contained in the list of drug products established pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law; and

(c) The pharmacist shall indicate on the label affixed to the immediate container in which the drug is sold or dispensed the name and strength of the drug product and its manufacturer unless the prescriber specifically states otherwise. The pharmacist shall record on the prescription form the brand name or the name of the manufacturer of the drug product dispensed.

2. In the event a patient chooses to have a prescription filled by an out of state dispenser, the laws of that state shall prevail.

§6817. New drugs.

1. No person shall sell, deliver, offer for sale, hold for sale, or give away any new drug, unless

a. an application with respect thereto has become effective, or in the case of an investigational drug the sponsor has complied with the applicable requirements, under the federal food, drug, and cosmetic act, or

b. when not subject to such act, such drug has been tested and has not been found to be unsafe or ineffective for use under the conditions prescribed, recommended or suggested in the labeling thereof, and, prior to selling or offering for sale such drug, there has been filed with the department an application setting forth

(1) full reports of investigations which have been made to show whether or not such drug is safe and effective for use;

(2) a full list of the ingredients used as components of such drug;

(3) a full statement of the composition of such drug;

(4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drugs;

(5) such samples of such drug and of the ingredients used as components thereof as the board or secretary may require; and

(6) specimens of the labeling proposed to be used for such drug.

2. An application provided for in paragraph b of subdivision one shall become effective on the one hundred eightieth day after the filing thereof, except that if the secretary or board finds, after due notice to applicant and giving him an opportunity for a hearing, that the drug is not safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

3. A drug dispensed on a written or oral prescription of a physician, dentist, podiatrist or veterinarian (except a controlled substance), shall be exempt from the requirements of this section if such drug bears a label containing the name and place of business of the dispenser, the serial number and date of the prescription, directions for use as may be stated in the prescription and the name of the physician, dentist, podiatrist or veterinarian issuing the prescription and the name of the patient. In addition, such drug shall bear a label containing the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription explicitly states on the prescription, in his own handwriting, that the name of the drug and the strength thereof should not appear on the label.

4. The board shall promulgate regulations for exempting from the operation of this section drugs (and with the concurrence of the commissioner of health, pursuant to article thirty-three of the public health law, controlled substances) intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of drugs and labeled "For Investigational Use Only". Such regulations may, within the discretion of the board, among other conditions relating to the protection of the public health, provide for conditioning such exemptions upon:

a. The submission to the secretary before any clinical testing of a new drug is undertaken of reports by the manufacturer or sponsor of the investigation of such drug, of preclinical tests, including tests on animals of such drug adequate to justify the proposed clincial testing.

b. The manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator or to clinics for administration to human beings; and

c. The establishment and maintenance of such records and the making of such reports to the board by the manufacturer or the sponsor of the investigation of such drugs of data including, but not limited to, analytical reports by investigators obtained as the result of such investigational use of such drug as the board finds will enable it to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subdivision one of this section.

5. This section shall not apply to any drug which was licensed under the federal virus, serum, and toxin act of July first, nineteen hundred two (32 Stat. 728) or is licensed under section two hundred sixty-two of the public health service act of July first, nineteen hundred forty-four (58 Stat. 682), or under the federal virus, serums, toxins, antitoxins and analogous products act

of March fourth, nineteen hundred thirteen (37 Stat. 832).

§6818. Adulterated and misbranded cosmetics.

1. A cosmetic shall be deemed to be adulterated:

a. If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: Provided, that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon "Caution--this product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dying the eyelashes or eyebrows; to do so may cause blindness", and the labeling of which bears adequate directions for such preliminary testing. For the purpose of this paragraph and paragraph e the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

b. If it consists in whole or in part of any filthy, putrid, or decomposed substance.

c. If it has been prepared, packaged, packed, shipped or held in any insanitary condition or in any other condition whereby it may have been rendered injurious to health.

d. If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

e. If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by this article.

2. A cosmetic shall be deemed to be misbranded:

a. If its labeling is false or misleading in any particular.

b. If in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, that under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations.

c. If any word, statement, or other information required by or under authority of this article to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

d. (1) If its container is so made, formed, or filled as to be misleading; or (2) if it bears a copy, counterfeit, or colorable imitation of a trademark, label, or identifying name or design of another cosmetic.

§6818-a. Cosmetic samples.

1. No person engaged in the business of selling cosmetics shall provide for the use by or application to customers of any cosmetics, except for use or application to the hand or arm as a sample if such immediate container of cosmetics is to be used by or applied to more than one customer. For the purposes of this section, the term "cosmetic" shall not include perfume or cologne; or samples removed from the immediate container with a single use disposable applicator furnished to each customer; or samples dispensed from a tube, pump, spray or shaker container; or samples or applicators that have been cleansed before each use or application. The provisions of this section shall be deemed to have been satisfied if written instructions on the use or application of cosmetic samples pursuant to this section are clearly and visibly posted at or near the place of display of cosmetic samples. Nothing contained in this section shall prohibit the use or application of cosmetic samples by persons trained to apply cosmetics to customers in accordance with the provisions of this section.

2. Notwithstanding any other provision of this article, a violation of this section shall result in a civil penalty of one hundred dollars for the first offense and a civil penalty of two hundred fifty dollars for a second or subsequent offense.

§6819. Regulations making exceptions.

The board shall promulgate regulations exempting from any labeling requirement of this article drugs, devices and cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs, devices and cosmetics are not adulterated or misbranded under the provisions of this article upon removal from such processing, labeling, or repacking establishment.

§6820. Certification of coal-tar colors for drugs and cosmetics.

The board shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in drugs for purposes of coloring only and for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents.

§6821. Poison schedules; register.

1. The following schedules shall remain in force until revised by the board and approved by the department.

Schedule A. Arsenic, atropine, corrosive sublimate, potassium cyanide, chloral hydrate, hydrocyanic acid, strychnine and all other poisonous vegetable alkaloids and their salts and oil of bitter almond containing hydrocyanic acid.

Schedule B. Aconite, belladonna, cantharides, colchicum, conium cotton root, digitalis, ergot, hellebore, henbane, phytolacca, strophanthus, oil of savin, oil of tansy, veratrum viride and their pharmaceutical preparations, arsenical solutions, carbolic acid, chloroform, creosote, croton oil, white precipitate, methyl or wood alcohol, mineral acids, oxalic acid, paris green, salts of lead, salts of zinc, or any drug, chemical or preparation which is liable to be destructive to adult human life in quantities of sixty grains or less.

2. It shall be unlawful for any person to sell at retail or to furnish any of the poisons of schedules A and B without affixing or causing to be affixed to the bottle, box, vessel or package, a label with the name of the article and the word "poison" distinctly shown and with the name and place of business of the seller all printed in red ink together with the name of such poisons printed or written thereupon in plain, legible characters.

3. Manufacturers and wholesale dealers in drugs, medicines, pharmaceutical preparations, chemicals or poisons shall affix or cause to be affixed to every bottle, box, parcel or outer inclosure of any original package containing any of the articles of schedule A a suitable label or brand in red ink with the word "poison" upon it.

4. Every person who disposes of or sells at retail or furnishes any poisons included in schedule A shall before delivering the same enter in a book kept for that purpose the date of sale, the name and address of the purchaser, the name and the quantity of the poison, the purpose for which it is purchased and the name of the dispenser. The poison register must be always open for inspection by the proper authorities and must be preserved for at least five years after the last entry. Such person shall not deliver any of the poisons of schedule A or schedule B until he has satisfied himself that the purchaser is aware of its poisonous character and that the poison is to be used for a legitimate purpose. The provisions of this paragraph do not apply to the dispensing of drugs or poisons on a doctor's prescription.

5. The board may add to or may delete from any of the schedules from time to time as such action becomes necessary for the protection of the public.

§6822. Examinations and investigations.

The secretary is authorized to conduct examinations and investigations for the purposes of this article through officers and employees of the United States, or through any health, food, or drug officer or employee of any city, county or other political subdivision of this state, duly commissioned by the secretary as an officer of the board.

§6823. Factory inspection.

For purposes of enforcement of this article, officers duly designated by the secretary are authorized:

(1) to enter, at reasonable times, any factory, warehouse or establishment in which drugs, devices or cosmetics are manufactured, processed, packed, or held, for introduction into commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such drugs, devices or cosmetics in commerce; and

(2) to inspect, at reasonable times, such factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

§6824. Injunction proceedings.

In addition to the remedies hereinafter provided, the secretary is hereby authorized to apply to the court of the proper venue for an injunction to restrain any person from (a) introducing or causing to be introduced into commerce any adulterated or misbranded drug, device or cosmetic; or (b) from introducing or causing to be introduced in commerce any new drug which does not comply with the provisions of this article; or (c) from disseminating or causing to be disseminated a false advertisment, without being compelled to allege or prove that an adequate remedy at law does not exist.

§6825. Proof required in prosecution for certain violations.

1. In an action or proceeding, civil or criminal, against a person for violating such provisions of this article which relate to the possession of, compounding, retailing or dispensing of misbranded, substituted or imitated drugs, poisons or cosmetics, when it shall be necessary that an analysis be made for the purpose of establishing the quality of such drug, poison or cosmetic so as to determine the fact of misbranding, substituting or imitating, then it shall be required to prove at the trial or hearing of such action or proceeding, that the person, taking the same for analysis separated it into two representative parts, hermetically or otherwise effectively and completely sealed, delivered one such sealed part to the seller, manufacturer, wholesaler, pharmacist, druggist or storekeeper from whose premises such sample was taken and delivered the other part so sealed to the chemist designated by the state board of pharmacy; and the facts herein required to be proven shall be alleged in the complaint or information by which such action or proceeding was begun. The rules of the board shall be proven prima facie by the certificate of the secretary.

2. Any person accused of violation of any of the provisions of this article relating to adulterating, misbranding, substitution or imitation shall not be prosecuted or convicted or suffer any of the penalties, fines or forfeitures for such violation, if he establishes upon the hearing or trial that the drug, device or cosmetic alleged to be adulterated, misbranded, substituted or imitated was purchased by him under a written guaranty of the manufacturer or seller to the effect that said drug, device or cosmetic was not adulterated or misbranded, within the meaning of this article and proves that he has not adulterated, misbranded, substituted or imitated the same, provided the seller has taken due precaution to maintain the standard set for the drug, device or cosmetic. A guaranty, in order to be a defense to a prosecution or to prevent conviction or to afford protection, must state that the drug, device or cosmetic to which it refers is not adulterated, misbranded, substituted or imitated within the meaning of the provisions of this article and must state also the full name and place of business of the manufacturer, wholesaler, jobber or other person from whom the drug, device or cosmetic was purchased, and the date of purchase. The act, omission or failure of any officer, agent or other employee acting for or employed by any person within the scope of his authority or employment shall in every case be the act, omission or failure of such person as well as that of the officer, agent or other employee, and such person shall be equally liable for violations of this article by a partnership, association or corporation, and every member of the partnership or

association and the directors and general officers of the corporation and the general manager of the partnership, association or corporation shall be individually liable and any action, prosecution or proceeding authorized by this article may be brought against any or all of such persons. When any prosecution under this article is made on the complaint of the board, any fines collected shall be paid into the state treasury as provided by this article.

3. No publisher, radio-broadcast licensee, advertising agency, or agency or medium for the dissemination of advertising, except the manufacturer, packer, distributor, or seller of the commodity to which the false advertisement relates, shall be subject to the penalties provided by this article by reason of the dissemination by him of any false advertisement, unless he has refused, on the request of the secretary, to furnish the secretary the name and post-office address of the manufacturer, packer, distributor, seller or advertising agency, who caused him to disseminate such advertisement.

§6826. Drug retail price lists.

1. Every pharmacy shall compile a drug retail price list, which shall contain the names of the drugs on the list provided by the board and the pharmacy`s corresponding retail prices for each drug. Every pharmacy shall update its drug retail list at least weekly. Every pharmacy shall provide the drug retail price list to any person upon request.

2. a. The list provided by the board shall be prepared at least annually by the board and distributed to each pharmacy in the state. The list shall be a compendium of the one hundred fifty most frequently prescribed drugs together with their usual dosages for which a prescription is required by the provisions of the "Federal Food, Drug,and Cosmetic Act" (21 U.S.C. 301, et seq.; 52 Stat. 1040, et seq.), as amended, or by the commissioner of health. The board shall make the compendium list available to each pharmacy free of charge, both in printed form and in an electronic form that can be used to produce the pharmacy`s drug retail list.

b. The drug retail price list shall contain a notice which shall read: "Consult your pharmacist for the selection of the most economical drug product available to fill your prescription"

3. The pharmacy`s corresponding retail price means the actual price to be paid by a retail purchaser to the pharmacy for any listed drug at the listed dosage.

4. Pharmacies shall have a sign notifying people of the availability of the drug retail price list, conspicuously posted at or adjacent to the place in the pharmacy where prescriptions are presented for compounding and dispensing, in the waiting area for customers, or in the area where prescribed drugs are delivered.

5. Nothing contained herein shall prevent a pharmacy from changing and charging the current retail price at any time, provided that the listed price is updated at least weekly to reflect the new retail price.

6. The commissioner shall make regulations necessary to implement this section, including how this section is applied to mail-order and internet pharmacies.

§6827. Mandatory continuing education.

1. (a) Each licensed pharmacist required under article one hundred thirty of this chapter to register triennially with the department to practice in the state shall comply with provisions of the mandatory continuing education requirements prescribed in subdivision two of this section except as set forth in paragraphs (b) and (c) of this subdivision. Pharmacists who do not satisfy the mandatory continuing education requirements shall not practice until they have met such requirements, and they have been issued a registration certificate, except that a pharmacist may practice without having met such requirements if he or she is issued a conditional registration certificate pursuant to subdivision three of this section.

(b) Pharmacists shall be exempt from the mandatory continuing education requirement for the triennial registration period during which they are first licensed. In accord with the intent of this section, adjustment to the mandatory continuing education requirement may be granted by the department for reasons of health certified by an appropriate health care professional, for extended active duty with the armed forces of the United States, or for other good cause acceptable to the department which may prevent compliance.

(c) A licensed pharmacist not engaged in practice as determined by the department, shall be exempt from the mandatory continuing education requirement upon the filing of a statement with the department declaring such status. Any licensee who returns to the practice of pharmacy during the triennial registration period shall notify the department prior to reentering the profession and shall meet such mandatory education requirements as shall be prescribed by regulations of the commissioner.

2. During each triennial registration period an applicant for registration shall complete a minimum of forty-five hours of acceptable formal continuing education, as specified in subdivision four of this section, provided that no more than twenty-two hours of such continuing education shall consist of self-study courses. Any pharmacist whose first registration date following the effective date of this section occurs less than three years from such effective date, but on or after January first, nineteen hundred ninety-eight, shall complete continuing education hours on a prorated basis at the rate of one and one-quarter hours per month for the period beginning January first, nineteen hundred ninety-seven up to the first registration date thereafter. A licensee who has not satisfied the mandatory continuing education requirements shall not be issued a triennial registration certificate by the department and shall not practice unless and until a conditional registration certificate is issued as provided for in subdivision three of this section. Continuing education hours taken during one triennium may not be transferred to a subsequent triennium.

Note: Laws and regulations are current as of the date of publication.

3. The department, in its discretion, may issue a conditional registration to a licensee who fails to meet the continuing education requirements established in subdivision two of this section but who agrees to make up any deficiencies and complete any additional education which the department may require. The fee for such a conditional registration shall be the same as, and in addition to, the fee for the triennial registration. The duration of such conditional registration shall be determined by the department but shall not exceed one year. Any licensee who is notified of the denial of registration for failure to submit evidence, satisfactory to the department, of required continuing education and who practices pharmacy without such registration, may be subject to disciplinary proceedings pursuant to section sixty-five hundred ten of this chapter.

4. As used in subdivision two of this section, "acceptable formal continuing education" shall mean formal courses of learning which contribute to professional practice in pharmacy and which meet the standards prescribed by regulations of the commissioner. The department may, in its discretion and as needed to contribute to the health and welfare of the public, require the completion of continuing education courses in specific subjects. To fulfill this mandatory continuing education requirement, courses must be taken from a sponsor approved by the department, pursuant to the regulations of the commissioner.

5. Pharmacists shall maintain adequate documentation of completion of acceptable formal continuing education and shall provide such documentation at the request of the department. Failure to provide such documentation upon the request of the department shall be an act of misconduct subject to disciplinary proceedings pursuant to section sixty-five hundred ten of this chapter.

6. The mandatory continuing education fee shall be forty-five dollars, shall be payable on or before the first day of each triennial registration period, and shall be paid in addition to the triennial registration fee required by section sixty-eight hundred five of this article.

COMMISSIONER'S REGULATIONS
Part 52.29
Pharmacy

§52.29 Pharmacy.

(a) Definitions. As used in this section:

(1) General education content area shall mean coursework, which includes but is not limited to, each of the following curricular areas:

(i) social and behavioral sciences; and

(ii) humanities, including but not limited to English.

(2) Basis sciences content area shall mean coursework, which includes but is not limited to the following curricular areas:

(i) mathematics;

(ii) biological sciences, including but not limited to general biology; and

(iii) physical sciences, including but not limited to general and organic chemistry.

(3) Biomedical sciences content area shall mean coursework, which includes but is not limited to, each of the following curricular areas:

(i) anatomy;

(ii) physiology;

(iii) microbiology/immunology;

(iv) biochemistry;

(v) pathology; and

(vi) biostatistics.

(4) Pharmaceutical sciences content area shall mean coursework, which includes but is not limited to, each of the following curricular areas:

(i) pharmaceutical or medicinal chemistry;

(ii) basic pharmaceutics, including but not limited to compounding and dispensing;

(iii) biopharmaceutics;

(iv) pharmacokinetics;

(v) pharmacognosy or natural products;

(vi) pharmacology; and

(vii) pharmacy administration.

(5) Clinical sciences content area shall mean coursework in clinical applications using knowledge gained in the biomedical sciences content area and in the pharmaceutical sciences content area, including but not limited to coursework in each of the following curricular areas: clinical and practice foundations, disease processes, clinical pharmacology and therapeutics, and drug information and literature evaluation; and shall include an appropriate mix of clinical experiences in community and institutional pharmacies and in appropriate in-patient and out-patient settings.

(b) Curriculum. In addition to meeting all applicable provisions of this Part, to be registered as a program recognized as leading to licensure in pharmacy which meets the requirements of

section 63.1 of this Title, it shall be a program leading to the baccalaureate degree, its equivalent, or a higher academic degree, which includes:

(1) a total of at least 60 semester hours or its equivalent of preprofessional study consisting of a combination of coursework in the basic sciences content area and the general education content area, provided that a minimum of 20 semester hours or its equivalent shall be in the basic sciences content area and a minimum of 20 semester hours or its equivalent shall be in the general education content area; and

(2) a total of at least 90 semester hours or its equivalent of professional study consisting of a combination of coursework in the biomedical sciences content area, pharmaceutical sciences content area, and the clinical sciences content area, provided that a minimum of 15 semester hours or its equivalent shall be in the biomedical sciences content area, a minimum of 20 semester hours or its equivalent shall be in the pharmaceutical sciences content area, and a minimum of 15 semester hours or its equivalent shall be in the clinical sciences content area.

Part 63
Pharmacy

§63.1 Professional study of pharmacy.

(a) As used in this section, acceptable accrediting agency shall mean an organization accepted by the department as a reliable authority for the purpose of accreditation at the postsecondary level, applying its criteria for granting accreditation in a fair, consistent, and nondiscriminatory manner, such as an agency recognized for this purpose by the United States Department of Education.

(b) To meet the professional education requirement for admission to the licensing examination, the applicant shall present satisfactory evidence of either:

(1) completing a program in pharmacy leading to the baccalaureate degree, its equivalent, or a higher degree, that is either registered by the department pursuant to section 52.29 of this Title or accredited by an acceptable accrediting agency; or

(2) for applicants who apply for licensure prior to September 1, 2001, completing a nonregistered or nonaccredited program in pharmacy, including a foreign pharmacy program, of not less than three academic years of professional study, or the equivalent thereof, satisfactory to the department, and attaining Foreign Pharmacy Graduate Examination Committee Certification by the National Association of Boards of Pharmacy or its successor, or an equivalent certification acceptable to the department. The program of study in a foreign school of pharmacy shall culminate in the awarding of a degree, diploma or certificate in pharmacy recognized by the appropriate civil authorities of the country in which the school is located as meeting the educational requirement for entry into practice in that country; or

(3) for applicants who apply for licensure on or after September 1, 2001, completing a nonregistered or nonaccredited program in pharmacy, including a pharmacy program located in another country that is equivalent to a program registered by the department pursuant to section 52.29 of this Title and attaining Foreign Pharmacy Graduate Examination Committee Certification by the National Association of Boards of Pharmacy or its successor or an equivalent certification acceptable to the department. The program of study in another jurisdiction shall culminate in the awarding of a degree, diploma or certificate in pharmacy recognized by the appropriate civil authorities of the jurisdiction in which the school is located as meeting the educational requirements for entry into practice in that jurisdiction.

(c) A program of pharmacy education shall be considered completed upon certification of completion by the school in which such program was taken and proof that the applicant has been awarded the appropriate pharmacy degree, diploma or certificate.

§63.2 Experience.

For admission to the licensing examination:

(a) Graduates of registered or accredited programs leading to the bachelor's degree in pharmacy shall have completed at least six months of full-time experience, or the equivalent thereof, as a pharmacy intern in an internship program which meets the following requirements:

(1) Program requirement. The internship program shall be devoted to the preparing, compounding, preserving and dispensing of drugs, medicines and therapeutic devices and to the performance of the functions related thereto, such as the counseling of patients and the monitoring of drug regimens, under the supervision of a registered pharmacist.

(2) Time requirement. The six months shall be completed in accordance with the following:

(i) Any portion or all of the internship may be completed during periods subsequent to the successful completion of the first year of a professional education program in pharmacy and not concurrent with full-time enrollment in such a program.

(ii) Any portion or all of the internship may be completed subsequent to the award of a degree in pharmacy which meets the requirement of section 63.1 of this Part.

(iii) Part-time supervised practice completed pursuant to the provisions of subparagraphs (i) and (ii) of this paragraph may be granted proportionate credit. For

the calculation of equivalencies, *full-time* shall be defined as 40 hours per week.

(3) Preceptor pharmacist requirement. The registered pharmacist who supervises an intern shall be designated the preceptor pharmacist. Each preceptor pharmacist shall have practiced for at least one year immediately preceding assuming a preceptorship. The preceptor pharmacist shall have under his or her supervision not more than one full-time intern nor more than two part-time interns.

(4) Additional requirement. In each pharmacy which will serve for the training of interns, one intern may be engaged for each 5,000 prescriptions and/or drug orders dispensed annually and for a major fraction thereof over a multiple of 5,000.

(b) Graduates of nonregistered and nonaccredited programs, including foreign programs in pharmacy, shall be authorized to begin an internship only after passing Part I of the pharmacist licensing examination. Thereafter, the applicant shall complete not less than 12 months of full-time experience, or the equivalent thereof, in an internship program which meets the requirements of paragraphs (a)(1), (3) and (4) of this section. Upon completion of the internship program, the applicant may be admitted to the practical portions (Part II and III) of the examination.

(c) Graduates of registered or accredited programs leading to the Doctor of Pharmacy degree shall be considered to have completed the internship requirement.

§63.3 Licensing examinations.

(a) *Content.* The examination shall consist of three parts:

Part I.: Applied chemistry, mathematics, pharmacology and pharmaceutics and clinical pharmacy.

Part II.: Professional law, ethics and professional conduct, prescription and nonprescription required drugs and prescription problems.

Part III.: Prescription compounding and pharmacy practice.

(b) The department may accept satisfactory scores on an examination of the National Association of Boards of Pharmacy as meeting the requirements of Part I of the licensing examination.

(c) *Passing score.* The passing score in each part of the examination shall be 75.0, as determined by the State Board of Pharmacy.

(d) *Special condition.* A graduate of a registered or accredited program of education who has not completed the required practical experience may be admitted to Part I of the examination only.

§63.4 Limited permits.

(a) A limited permit, identifying the holder as a pharmacy intern and authorizing the practice of pharmacy under the immediate and personal supervision of a registered pharmacist, may be issued in accordance with the provisions of section 6806 of the Education Law to:

(1) an applicant, enrolled in a program of pharmacy education registered or approved by the department, who has completed at least the third year of a five-year program or its equivalent, provided that the applicant has completed the first year of professional study; or

(2) a graduate of a nonregistered or nonaccredited pharmacy program, including a foreign pharmacy program, for the purpose of completing the experience requirement set forth in section 63.2(b) of this Part.

(b) A limited permit shall be displayed conspicuously in the pharmacy where the pharmacy intern is engaged for supervised practice.

(c) A pharmacy intern may perform, under the supervision of a preceptor pharmacist, all of the functions delegated to pharmacists by law, rule or regulation.

§63.5 License as a pharmacist by endorsement.

For endorsement of a pharmacist license issued by another jurisdiction, the applicant shall:

(a) present evidence of having met all requirements of section 59.6 of this Title, except that the applicant shall have had, during the five years preceding the filing of the application, at least one year of satisfactory experience following licensure; and

(b) pass an examination of the laws, rules, regulations and professional conduct pertaining to the practice of pharmacy in New York administered by the department or an equivalent examination acceptable to the State Board of Pharmacy.

§63.6 Registration and operation of New York establishments.

(a) *General Provisions.* (1) The requirements of this section shall apply to establishments located in New York State. Section 63.8 of this Part sets forth requirements for the registration of nonresident establishments.

(2) A certificate of registration issued for the operation of a pharmacy, manufacturer or wholesaler shall be valid only for that address stated on the certificate. Endorsement of the certificate to another address may be made by the State Board of Pharmacy upon application to the board, the payment of the fee set forth in Education Law, section 6808, and a finding by the board that the new location meets the requirements of the applicable subdivisions of this section. An application for endorsement to another address shall be made not less than 30 days prior to the expected date of relocation.

(3) In the case of a corporation, the State Board of Pharmacy shall be notified within 30 days of any change in the officers of the corporation or in stockholders holding 10 percent or more of the stock in the corporation.

(4) No certificate of registration shall be issued or continued for the conduct of a pharmacy, manufacturer, or wholesaler unless the premises occupied by such registered establishment shall be equipped with proper sanitary appliances and kept in a clean and orderly manner.

(5) The State Board of Pharmacy shall be notified within a period of 48 hours whenever any establishment

registered by the board is damaged by fire, flood or other disaster.

(6) Signs on establishments. Except as otherwise provided for pharmacies in general merchandising establishments in paragraph (b)(5) of this section, a sign bearing the full name of the registrant shall be displayed prominently on the exterior of the premises in which a registered establishment is located, or in the directory and on the immediate entrance to the registered establishment if it is located in a multi-tenanted structure.

(7) Electronically transmitted prescriptions.

(i) For the purposes of this section, electronically transmitted prescription means a prescription created, recorded, transmitted or stored by electronic means, including but not limited to facsimile but excluding any such prescription for a controlled substance under Article 33 of the Public Health Law.

(ii) A pharmacist may, based upon his or her professional judgment, accept an electronically transmitted prescription from a prescriber, to the pharmacy of the patient's choice, subject to the following requirements:

(a) The prescription shall contain the signature, or the electronic equivalent of a signature, of the prescriber;

(b) In the case of an electronically transmitted prescription, other than facsimile transmission, such prescription shall be electronically encrypted, meaning protected to prevent access, alteration or use by any unauthorized person;

(c) A permanent hard copy of an electronically transmitted prescription shall be produced and maintained at the pharmacy for a period of five years from the date of the most recent filling. A permanent facsimile copy shall be considered a hard copy;

(d) Such transmission shall be processed in accordance with the requirements of section 29.7 of this Title; and

(e) In accepting an electronically transmitted prescription, the pharmacist shall be subject to the applicable requirements of Part 29 of this Title relating to unprofessional conduct, including but not limited to paragraphs (2) and (3) of subdivision (b) of section 29.1 of this Title.

(8) Refill transfers. Except for a prescription for a controlled substance under Article 33 of the Public Health Law, pharmacists at registered pharmacies may, at the express request and approval of a patient or a person authorized to act on behalf of the patient, transfer prescription information to, or accept a transfer from, another registered pharmacy or a pharmacy authorized to do business in another jurisdiction for the exclusive purpose of providing one authorized refill per transfer, subject to requirements of this paragraph.

(i) A pharmacist at a registered pharmacy may transfer original prescription information required by section 29.7 (a) (1) of this Title, to another pharmacy for the purpose of providing one authorized refill per transfer, provided that the original prescription information is transferred directly from one pharmacist to another pharmacist. Such transfer of prescription information may be accomplished by oral or written communication or by electronic transmission. The pharmacist at a registered pharmacy who transfers original prescription information shall record the following information:

(a) the fact that an authorized refill of the prescription has been transferred;

(b) the name, address and telephone number of the pharmacy to which it was transferred;

(c) the name of the pharmacist receiving the prescription information;

(d) the name of the pharmacist transferring the information; and

(e) the date of the transfer.

(ii) A pharmacist at a registered pharmacy may accept the original prescription for the purpose of providing one authorized refill per transfer, provided that the original prescription information is transferred from one pharmacist to another pharmacist. The pharmacist at a registered pharmacy who accepts the original prescription information shall:

(a) obtain all information required by section 29.7(a)(1) of this Title;

(b) produce a hard copy of such information and ensure that the term "refill transfer" appears on the face of the hard copy; and

(c) record the dates of original and most recent filling or transfer of the original prescription, the transferring pharmacy's name and address, the original prescription number from which the prescription was transferred, the name of the pharmacist transferring the prescription, and the name of the pharmacist receiving the transfer.

(iii) Systems providing for the electronic transfer of prescriptions shall not infringe on a patient's freedom of choice as to the provider of pharmaceutical care.

(iv) The hard copy of the transferred prescription shall be maintained for a period of five years from the date of filling.

(v) A pharmacy utilizing automated data processing systems to transfer a prescription refill or to accept a prescription refill shall satisfy the requirements of this subdivision and shall also meet the requirements of paragraph (9) of this subdivision if the pharmacy accesses a common electronic file or database used to maintain required personally identifiable dispensing information.

(9) A pharmacy that accesses a common electronic file or database

used to maintain required personally identifiable dispensing information shall only access such information upon the express request of the patient or a person authorized to act on behalf of the patient. Such common file shall contain complete records of each prescription and refill dispensed.

(b) *Pharmacies.* (1) To secure and retain registration, a pharmacy shall be equipped with at least the following utensils:

(i) weighing device sensitive to 6 mg;

(ii) metric weights, if needed for the operation of the device in subparagraph (i) of this paragraph;

(iii) devices capable of measuring volumes from 0.1 ml to 500 ml; and

(iv) a mortar and pestle.

(2) The registered area shall measure not less than 300 square feet and shall include a manufacturing, compounding and dispensing area of not less than 100 square feet. The pharmacy shall be equipped with storage facilities providing for the safe storage of drugs; with heating and ventilation adequate to safeguard the purity and potency of drugs; with adequate lighting; and with hot and cold running water in the compounding and dispensing area; provided, however, that a pharmacy which was registered initially prior to the effective date of this paragraph on the basis of meeting requirements less than those specified in this paragraph shall not be required to meet the requirements of this paragraph for the continuance of registration to the same registrant.

(3) The registered area shall include a refrigerator, sufficient in capacity to serve the needs of the pharmacy, that is equipped with a thermometer and providing at all times a storage temperature of 2 degrees to 8 degrees Centigrade (36 degrees to 46 degrees Fahrenheit). The use of such refrigerator shall be limited to the storage of drugs.

(4) The pharmacy shall possess copies of laws, rules and regulations governing the practice of pharmacy in New York, and other reference resources as may be necessary to carry on the practice of pharmacy.

(5) A pharmacy operated as a department of a general merchandising establishment shall be enclosed permanently by a partition at least nine feet six inches in height, except where the ceiling is less than nine feet six inches in height in which case the partition shall be from floor to ceiling. Identification of such department by use of words "drugs," "medicines," "drug store" or "pharmacy" or similar terms shall be restricted to the area registered by the department, except that nothing in this restriction shall prevent the placement on the exterior of such establishment of signs indicating the existence of a pharmacy therein. Such exterior signs may consist of the name of the registrant and/or the word *pharmacy*; provided, however, that when the word *pharmacy* is used, it may not be used in juxtaposition to a nonregistered name. When the pharmacy is not open during all the hours maintained by the general merchandising establishment, an exterior sign shall indicate clearly when the pharmacy is open and when it is closed.

(6) A pharmacy in which radioactive drugs are dispensed shall meet all requirements established by 10 NYCRR Part 16 for medical and academic facilities or by 12 NYCRR Part 38 for commercial facilities as evidenced by receipt by the pharmacy of an appropriate license issued by the New York State Department of Health or the New York State Department of Labor, and the additional requirements which follow.

(i) There shall be present at all hours when the pharmacy is open at least one pharmacist who:

(*a*) meets the minimal standards of training and experience required by 10 NYCRR Part 16 or by 12 NYCRR Part 38 for the use of radioactive materials; and

(*b*) has submitted to the State Board of Pharmacy evidence of either of the following:

(*1*) certification as a Nuclear Pharmacist by the Board of Pharmaceutical Specialties of the American Pharmaceutical Association; or

(2) completion of a minimum of 200 contact hours of didactic instruction in nuclear pharmacy in an accredited school or college of pharmacy, and a minimum of 500 hours of clinical nuclear pharmacy training under the supervision of a Board of Pharmaceutical Specialties certified nuclear pharmacist in a pharmacy providing nuclear pharmacy services, in a certified nuclear pharmacy residency program or in a nuclear pharmacy training program in an accredited school or college of pharmacy or the equivalent thereof as determined by the department.

(ii) In addition to the items and articles of equipment required by this subdivision, the pharmacy shall be equipped with at least the following:

(*a*) laminar flow hood;

(*b*) dose calibrator;

(*c*) exhaust hood and filter system;

(*d*) chromatography apparatus;

(*e*) apparatus or materials for the determination of pH;

(*f*) single-channel and/or multichannel scintillation detection system; and

(*g*) microscope.

(iii) A pharmacy which dispenses both radioactive drugs and nonradioactive drugs shall maintain a separate area for the storage and dispensing of radioactive drugs, which area shall

be secured from unauthorized personnel.

(7) Patient medication profile. Each pharmacist shall maintain a patient medication profile. Such medication profile shall include, but not be limited to, the patient's name, address, telephone number, gender, date of birth or age, known allergies and drug reactions, chronic diseases, a comprehensive list of medications and relevant devices and other information reported to the pharmacist appropriate for counseling an individual regarding use of prescription and over-the-counter drugs. Pharmacists or pharmacy interns shall conduct a prospective drug review before each prescription is dispensed or delivered to a patient or person authorized to act on behalf of the patient. Such review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-drug interactions, including serious interactions with over-the-counter drugs, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse. Patient medication profiles shall be maintained in a retrievable form for five years following the date of the most recent entry.

(8) Counseling.

(i) On-premises delivery. For a prescription that is delivered to a patient or a person authorized to act on behalf of the patient on the premises of the pharmacy, the pharmacist or pharmacy intern shall meet the requirements of this subparagraph. For a prescription that is delivered to a patient or a person authorized to act on behalf of a patient off the premises of a pharmacy through mail delivery, a delivery service or otherwise, the pharmacist or pharmacy intern shall meet the requirements of subparagraph (ii) of this paragraph.

(a) Prior to dispensing a prescription for the first time for a new patient of the pharmacy or a prescription for a new medication for an existing patient of the pharmacy and/or a change in the dose, strength, route of administration or directions for use of an existing prescription previously dispensed for an existing patient of the pharmacy, a pharmacist or pharmacy intern providing prescription services shall be required to personally counsel each patient or person authorized to act on behalf of a patient who presents a prescription, consistent with the provisions of section 29.1(b)(8) of this Title, in person in a face-to-face meeting whenever practicable, or by telephone, matters which in the exercise of the pharmacist's or pharmacy intern's professional judgment, the pharmacist or pharmacy intern deems appropriate, which may include:

(1) the name and description of the medication and known indications;

(2) dosage form, dosage, route of administration and duration of drug therapy;

(3) special directions and precautions for preparation, administration and use by the patient;

(4) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(5) techniques for self-monitoring drug therapy;

(6) proper storage;

(7) prescription refill information; and

(8) action to be taken in the event of a missed dose.

(b) The counseling of a patient or person authorized to act on behalf of a patient pursuant to clause (a) of this subparagraph shall be provided personally by the pharmacist or the pharmacy intern and shall not be delegated to an individual not authorized to practice pharmacy under a license or limited permit.

(c) In the event a patient refuses to supply information necessary for maintenance of a medication profile, or to accept counseling, as prescribed in clause (a) of this subparagraph, a pharmacist or pharmacy intern may fill a prescription as presented, without having violated the requirements of this subparagraph, provided that the refusal to provide such information or accept counseling is documented in the records of the pharmacy.

(d) In the event a patient or a person authorized to act on behalf of a patient seeks to obtain a refill of an existing prescription previously filled by the pharmacy or an authorization for continuation of an existing therapy, a pharmacist or pharmacy intern shall be available to provide counseling to the patient or person authorized to act on behalf of a patient, upon such person's request. In such circumstances and consistent with the requirements of paragraph (21) of subdivision (a) of section 29.7 of this Title, an offer to counsel the patient or a person authorized to act on behalf of a patient may be conveyed on behalf of the pharmacist or pharmacy intern by an unlicensed assistant. Such counseling shall be conducted only by a pharmacist or pharmacy intern.

(e) Nothing in this subparagraph shall prevent a pharmacist or pharmacy intern from refusing to dispense a prescription if, in his or her professional judgment, potential adverse effects, interactions or other therapeutic complications could endanger the health of the patient.

(ii) Off-premises delivery. For a prescription that is delivered to the patient or the person authorized to act on behalf of the patient off the premises of the pharmacy through mail delivery, a delivery service or otherwise, the pharmacist or pharmacy intern shall meet the requirements of this subparagraph.

(a) Upon dispensing a prescription, a pharmacist or pharmacy intern shall include with each prescription a written offer to counsel the patient or person authorized to act on behalf of the patient who presents the prescription. The written offer of counseling shall advise the patient or the person authorized to act on behalf of the patient of the availability of counseling on topics, which shall include but not be limited to, the topics listed in subclauses (1) through (8) of clause (a) of subparagraph (i) of this paragraph and that a licensed pharmacist or pharmacy intern authorized to practice pharmacy is available to provide the counseling. The written offer to counsel shall provide a telephone number at which a licensed pharmacist or pharmacy intern may be readily reached. For pharmacies engaged primarily in the mail order delivery of

prescriptions, that telephone number shall be toll-free for long distance calls.

(b) When a patient or person authorized to act on behalf of the patient requests counseling pursuant to the written offer of counseling, the pharmacist or pharmacy intern shall personally counsel that person, consistent with the provisions of section 29.1(b)(8) of this Title, to the extent the pharmacist or pharmacy intern deems appropriate in his or her professional judgment. Such counseling may include the topics listed in subclauses (1) through (8) of clause (a) of subparagraph (I) of this paragraph. Such counseling shall be conducted via telephone or in an in-person face-to-face meeting.

(c) Except for instances covered by clause (d) of this subparagraph, which applies in those cases, if upon presentation of the prescription, the pharmacist or pharmacy intern determines that the prescription is a prescriber approved alternative drug, meaning a change in the drug originally prescribed exclusive of generic substitutions, the pharmacist or pharmacy intern shall meet the following requirements in addition to the requirements of clauses (a) and (b) of this subparagraph:

(1) Upon dispensing the prescription, the pharmacist or pharmacy intern shall include with each prescription a special written notification that clearly advises the patient or the person authorized to act on behalf of the patient that a prescriber approved alternative drug has been dispensed, the directions for the use of such drug and the availability of counseling on the drug.

(2) Except for the cases set forth in subclause (3) of this clause, the pharmacist or pharmacy intern shall make a reasonable effort to contact the patient or person authorized to act on behalf of the patient by telephone in order to personally offer counseling to that person about the prescriber approved alternative drug and other matters which in the exercise of the pharmacist's or pharmacy intern's judgment, he or she deems appropriate, consistent with the provisions of section 29.1(b)(8) of this Title, including topics prescribed in subclauses (1) through (8) of clause (a) of subparagraph (i) of this paragraph. The effort to contact the patient or person authorized to act on behalf of the patient by telephone may commence after the drug is mailed or delivered to that person. A reasonable effort to contact the patient or the person authorized to act on behalf of the patient by telephone shall mean at least two attempts to reach the patient or person authorized to act on behalf of the patient through telephone calls placed to such person by 48 hours after mailing or delivering the prescription.

(3) The pharmacist or pharmacy intern shall not be required to make an effort to contact the patient or the person authorized to act on behalf of the patient by telephone, as prescribed in subclause (2) of this clause, if the patient or the person authorized to act on behalf of the patient does not have a telephone at which he or she may be reached, or if such person refuses to provide a telephone number at which he or she may be reached, or if such person has indicated to the pharmacy that he or she does not wish to be contacted by telephone for counseling.

(4) The pharmacy shall document the efforts made to contact the patient or the person authorized to act on behalf of the patient by telephone, or alternatively, the fact that the patient or person authorized to act on behalf of the patient either does not have a telephone at which he or she may be reached or refuses to provide a telephone number at which he or she may be reached or has indicated to the pharmacy that he or she does not wish to be contacted by telephone for counseling.

(5) The offer to counsel the patient or the person authorized to act on behalf of the patient shall be provided personally by the pharmacist or the pharmacy intern and shall not be delegated to an individual not authorized to practice pharmacy under a license or limited permit.

(6) If the offer of counseling is accepted, the pharmacist or pharmacy intern shall counsel the patient or the person authorized to act on behalf of the patient to the extent that the pharmacist or pharmacy intern deems appropriate in his or her professional judgment, as prescribed in subclause (2) of this clause.

(7) If the offer of counseling is not accepted, the refusal to accept counseling shall be documented in the records of the pharmacy.

(d) If upon presentation of the prescription, the pharmacist of pharmacy intern determines that there are potential drug therapy problems which could endanger the health of the patient, including but not limited to: therapeutic duplication, drug-drug interactions and drug-allergy interactions, the pharmacist or pharmacy intern shall be subject to the following requirements in addition to the requirements of clauses (a) and (b) of this subparagraph:

(1) Prior to dispensing the prescription, the pharmacist or pharmacy intern shall personally contact the patient or person authorized to act on behalf of the patient via telephone or through an in-person face-to-face meeting to offer counseling on the identified potential drug therapy problems and other matters which in the exercise of the pharmacist's or pharmacy intern's judgment, he or she deems appropriate, consistent with the provisions of section 29.1(b)(8) of this Title, including topics prescribed in subclauses (1) through (8) of clause (a) of subparagraph (i) of this paragraph.

(2) The offer to counsel the patient or the person authorized to act on behalf of the patient shall be provided personally by the pharmacist or the pharmacy intern and shall not be delegated to an individual not authorized to practice pharmacy under a license or limited permit.

(3) If the offer of counseling is accepted, the pharmacist or pharmacy intern shall counsel the patient or the person authorized to act on behalf of the patient to the extent that the pharmacist or pharmacy intern deems appropriate in his or her professional judgment, as prescribed in subclause (1) of this clause.

(4) If the offer of counseling is not accepted, the refusal to accept counseling shall be documented in the records of the pharmacy.

(5) Nothing in this subparagraph shall prevent a pharmacist or pharmacy intern from refusing to dispense a

prescription if, in his or her professional judgment, potential adverse effects, interactions or other therapeutic complications could endanger the health of the patient.

(9) Drug retail price lists.

Every registered pharmacy that sells prescription medications at retail shall meet the requirements of section 6826 of the Education Law. In accordance with subdivision (4) of section 6826 of the Education Law, such registered pharmacies shall have a sign notifying people of the availability of the drug retail price list, conspicuously posted at or adjacent to the place in the pharmacy where prescriptions are presented for compounding and dispensing, in the waiting area for customers, or in the area where prescribed drugs are delivered. The sign shall state in bold, block letters of at least one inche in height: "Drug Retail Price List Available Upon Request". Such registered pharmacies that offer to dispense prescription drugs to consumers through a website on the Internet shall post on such website a notice of the availability of the drug retail price list. Such registered pharmacies that offer to dispense prescription drugs to consumers through mail order shall include a printed notice with each delivery of a prescription drug informing the consumer of the availability of the drug retail price list and a toll-free telephone number to obtain the list.

(c) *Manufacturers and wholesalers.* (1) Except as provided in paragraph (2) of this subdivision, no manufacturer or wholesaler shall be registered pursuant to the provisions of subdivision 4 of section 6808 of the Education Law unless a registered pharmacist is present at all times when the establishment is open for business; provided, however, that such establishment may be under the supervision of a chemist who holds a bachelor's degree with a major in chemistry and who has at least two years of experience in the manufacturing, repacking and/or wholesaling of drugs satisfactory to the State Board of Pharmacy.

(2) Wholesalers who do not repack may designate as the supervisor a person who presents evidence of the completion of a minimum of two years of education beyond high school and who has at least two years of experience in the manufacturing, repacking and/or wholesaling of drugs satisfactory to the State Board of Pharmacy. Establishments which limit their operation to manufacturing and repacking of compressed medical gases and/or wholesaling of related respiratory therapy agents may be under the supervision of:

(i) a respiratory therapist certified by a national accrediting body;

(ii) a person holding a bachelor's degree in chemistry, microbiology, chemical engineering or a related field; or

(iii) 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.

(3) The supervisor of an establishment designated pursuant to paragraphs (1) and (2) of this subdivision shall not be at the same time the supervisor of any other establishment registered by the board.

(4) The size and facilities of a registered establishment shall be appropriate for the activities to be conducted therein. The area to be registered shall measure not less than 300 square feet. The registered area shall not be shared with or be devoted in part to any other business. The registered establishment shall be in compliance with at least the minimum requirements as provided in section 205.50 of title 21 of the *Code of Federal Regulations (Code of Federal Regulations*, 1991 edition, Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402: 1991--available at New York State Board of Pharmacy, 89 Washington Avenue, Albany, NY 12234-1000).

(5) Manufacturers or wholesalers shall sell drugs and/or devices only to those purchasers authorized by law. Records of the receipt and disposition of all drugs and/or devices shall be maintained for a period of five years and shall be available to the department for review and copying.

(6) Certification of manufacturers and wholesalers for export purposes. Any registered manufacturer or wholesaler may be issued a certificate by the executive secretary of the State Board of Pharmacy, authenticating said registration and identifying the specified drugs and/or devices as articles regularly offered for sale in New York. The fee for each certificate shall be $5.

(d) The Commissioner, upon recommendation of the Board of Pharmacy, may in his or her discretion waive regulations in this Part in order to allow the initiation and evaluation of demonstration projects using emerging technologies and practices in the profession of pharmacy, if the Commissioner determines that such waiver does not violate a statutory requirement or a Rule of the Board of Regents, is consistent with existing statutory and regulatory intent, and that such waiver will not diminish patient safety or consumer protections.

§63.7 Continuing education.

(a) As used in this section, *acceptable accrediting agency* shall mean an organization accepted by the department as a reliable authority for the purpose of accreditation at the postsecondary level, applying its criteria for granting accreditation in a fair, consistent, and nondiscriminatory manner, such as an agency recognized for this purpose by the United States Department of Education.

(b) *Applicability of requirement.* (1) Each licensed pharmacist, required under article 130 of the Education Law to register with the department to practice in New York State, shall comply with the mandatory continuing education requirements as prescribed in subdivision (c) of this section, except those licensees exempt from the requirement or who obtain an adjustment to the requirement pursuant to paragraph (2) of this subdivision.

(2) Exemptions and adjustments to the requirement. (i) Exemptions. The following licensees shall be exempt from the continuing education requirements, as prescribed in subdivision (c) of this section:

(*a*) licensees for the triennial registration period during which they are first licensed to practice pharmacy in New York State, exclusive of those first licensed to practice pharmacy in New York State pursuant to an endorsement of a license of another jurisdiction;

(*b*) licensees whose first registration date following January 1, 1997 occurs prior to January 1, 1998, for periods prior to such registration date; and

(c) licensees who are not engaged in the practice of pharmacy, as evidenced by not being registered to practice in New York State, except as otherwise provided in paragraph (c)(2) of this section to meet the education requirements for the resumption of practice after a lapse in practice for a licensee who has not lawfully practiced continuously in another jurisdiction throughout such lapse period.

(ii) Adjustments to the requirement. An adjustment to the continuing education requirement, as prescribed in subdivision (c) of this section, shall be made by the department, provided that the licensee documents good cause that prevents compliance, which shall include but not be limited to, any of the following reasons: poor health certified by an appropriate health care professional; or extended active duty with the Armed Forces of the United States; or extreme hardship which in the judgment of the department makes it impossible for the licensee to comply with the continuing education requirements in a timely manner.

(c) *Mandatory continuing education requirement.* (1) During each triennial registration period, meaning a registration period of three years' duration, an applicant for registration shall complete at least 45 hours of formal continuing education acceptable to the department, as defined in paragraph (4) of this subdivision, provided that no more than 22 hours of such continuing education shall consist of self-study courses. During registration periods beginning on or after September 1, 2003, a licensee shall complete as part of the 45 hours of formal continuing education, or pro-ration thereof, at least three hours of formal continuing education acceptable to the department in the processes and strategies that may be used to reduce medication and/or prescription errors. Any licensed pharmacist whose first registration date following January 1, 1997 occurs less than three years from that date, but on or after January 1, 1998, shall complete continuing education hours on a prorated basis at the rate of one and one-quarter hours of acceptable formal continuing education per month for the period beginning January 1, 1997 up to the first registration date thereafter. Such continuing education shall be completed during the period beginning January 1, 1997 and ending before the first day of the new registration period or at the option of the licensee during any time in the previous registration period.

(2) Requirement for lapse in practice. (i) A licensee returning to the practice of pharmacy after a lapse in practice, as evidenced by not being registered to practice in New York State, whose first registration date after such lapse in practice and following January 1, 1997 occurs less than three years from January 1, 1997, but on or after January 1, 1998, shall be required to complete:

(*a*) at least one and one-quarter hours of acceptable formal continuing education for each month beginning with January 1, 1997 until the beginning of the new registration period, which shall be completed for a licensee who has not lawfully practiced pharmacy continuously in another jurisdiction throughout such lapse period, in the 12-month period before the beginning of the new registration period; and for a licensee who has lawfully practiced pharmacy continuously in another jurisdiction throughout such lapse period, in the new registration period or at the option of the licensee in the period beginning 36 months before the commencement of the new registration period and ending at the conclusion of such registration period; and

(*b*) for a licensee who has not lawfully practiced pharmacy continuously in another jurisdiction throughout such lapse period, at least 15 hours of acceptable formal continuing education in each successive 12-month period of the new registration period; and for a licensee who has lawfully practiced pharmacy continuously in another jurisdiction throughout such lapse period, acceptable formal continuing education at the rate of one and one-quarter hours per month during the new registration period.

(ii) Except as prescribed in subparagraph (i) of this paragraph for registrations therein specified, the licensee who returns to the practice of pharmacy after a lapse in practice in which the licensee was not registered to practice in New York State and did not lawfully practice pharmacy continuously in another jurisdiction throughout the lapse period, shall be required to complete:

(*a*) the continuing education requirement applicable to the period of time the licensee was registered in the licensee's last registration period;

(*b*) at least one and one-quarter hours of acceptable formal continuing education for each month of lapsed registration up to a maximum of 45 hours, which shall be completed in the 12 months before the beginning of the new registration period; and

(*c*) at least 15 hours of acceptable formal continuing education in each succeeding 12-month period, after such registration is reissued, until the next registration date.

(iii) Except as prescribed in subparagraph (i) of this paragraph for registrations therein specified, the licensee who returns to the practice of pharmacy after a lapse in practice in which the licensee was not registered to practice in New York State but did lawfully practice pharmacy continuously in another jurisdiction throughout the lapse period, shall be required to complete:

(*a*) the continuing education requirement applicable to the period of time the licensee was

registered in the licensee's last registration period;

(*b*) at least one and one-quarter hours of acceptable formal continuing education for each month of lapsed registration up to a maximum of 45 hours, which shall be completed in the new registration period, or at the option of the licensee in the period beginning 36 months before the commencement of the new registration period and ending at the conclusion of the new registration period; and

(*c*) completion of the regular continuing education requirement at the rate of one and one-quarter hours of acceptable formal continuing education per month during the new registration period.

(3) Proration. If a registration period is less than three years in duration, a licensed pharmacist shall complete acceptable formal continuing education at the rate of one and one-quarter hours of continuing education per month for such registration period.

(4) To be acceptable to the department, formal continuing education shall be formal courses of learning which contribute to professional practice in pharmacy:

(i) in any one or more of the following curricular areas: pharmacology of new and developing drugs, or drug interactions, or public health issues, or infection control, or sterile procedures, or legal and regulatory issues, or patient counseling, or other topics which contribute to the professional practice in pharmacy as such practice is defined in section 6801 of the Education Law, or other matters of health care, law, and ethics which contribute to the health and welfare of the public; and

(ii) obtained from a sponsor approved by the department pursuant to subdivision (h) of this section.

(d) *Renewal of registration.* At each reregistration, licensed pharmacists shall certify to the department that they have either complied with the continuing education requirements, as prescribed in subdivision (c) of this section; or are subject to an exemption or adjustment to such continuing education requirements, as prescribed in subdivision (b) of this section.

(e) *Conditional registration.* (1) The department shall issue a conditional registration to a licensee who attests to or admits to noncompliance with the continuing education requirements of this section, provided that such licensee meets the following requirements:

(i) the licensee agrees to remedy such deficiency within the conditional registration period;

(ii) the licensee agrees to complete the regular continuing education requirement at the rate of one and one-quarter hours of acceptable formal continuing education per month during such conditional registration period; and

(iii) the licensee agrees to complete additional continuing education during such conditional registration period, which the department may require to ensure the licensee's proper delivery of pharmaceutical care consistent with the licensee's practice of pharmacy.

(2) The duration of such conditional registration shall not exceed one year and shall not be renewed or extended.

(f) *Licensee records.* Each licensee subject to this section shall maintain, or ensure access by the department to, a record of completed continuing education which includes: the title of the program, the number of hours completed, the sponsor's name and any identifying number, attendance verification, and the date and location of the program. Such records shall be retained for at least six years from the date of completion of the program and shall be available for review by the department in the administration of the requirements of this section.

(g) *Measurement of continuing education study.* Continuing education credit shall be granted only for formal programs of learning that meet the requirements set forth in subdivision (c) of this section. A minimum of 50 minutes of study shall equal one hour of continuing education credit. For credit-bearing university or college courses, each semester-hour of credit shall equal 15 hours of continuing education credit, and each quarter-hour of credit shall equal 10 hours of continuing education credit.

(h) *Sponsor approval.* (1) To be approved by the department, sponsors of continuing education to licensed pharmacists shall meet the requirements of either paragraph (2) or (3) of this subdivision.

(2) The department shall deem approved as a sponsor of continuing education to licensed pharmacists:

(i) a sponsor of continuing education that is approved by the Accreditation Council for Pharmacy Education or an equivalent. organization determined by the State Board for Pharmacy to have equivalent standards for approving sponsors of continuing education for professionals regulated by title VIII of the Education Law; or

(ii) a postsecondary institution for courses in programs that are registered pursuant to Part 52 of this Title or in equivalent programs that are accredited by an acceptable accrediting agency.

(3) Department review of sponsors. (i) The department shall conduct a review of sponsors that apply for approval to offer continuing education to licensed pharmacists and that are not deemed approved pursuant to the requirements of paragraph (2) of this subdivision

(ii) Organizations desiring to offer continuing education based upon a department review under this paragraph shall submit, with the fee as set forth in subdivision (i) of this section, an application for advance approval as a sponsor at least 90 days prior to the date for the commencement of such continuing education that documents that the organization:

(*a*) will offer courses of study in any one or more of the following curricular areas: pharmacology of new and developing drugs, or drug interactions, or public health issues, or infection control, or sterile procedures, or legal and regulatory issues, or patient counseling, or other topics which contribute to the professional practice in pharmacy

as such practice is defined in section 6801 of the Education Law, or other matters of health care, law, and ethics which contribute to the health and welfare of the public;

(*b*) is an organized educational entity, including but not limited to, a college of pharmacy; or a national, State, or local pharmacy association; or a hospital or health maintenance organization;

(*c*) provides course instructors who are qualified to teach the courses which will be offered, including but not limited to, faculty of a college of pharmacy accredited by an acceptable accrediting agency; or instructors who are authorities in the health sciences specially qualified, in the opinion of the State Board of Pharmacy, to conduct such courses;

(*d*) has a method of assessing the learning of participants, and describes such method; and

(*e*) will maintain records for at least six years from the date of completion of coursework, which shall include, but shall not be limited to, the name and curriculum vitae of the faculty, a record of attendance of licensed pharmacists in such course work, an outline of the course of instruction, date and location of the coursework, and the number of hours for completion of the coursework. In the event an approved sponsor discontinues operation, the governing body of such sponsor shall notify the department and shall transfer all such records as directed by the department.

(iii) Sponsors that are approved by the department pursuant to the requirements of this paragraph shall be approved for a three-year term.

(iv) The department may conduct site visits of or request information from a sponsor approved pursuant to the requirements of this paragraph to ensure compliance with such requirements, and a sponsor shall cooperate with the department in permitting such site visits and in providing such information.

(v) A determination by the department that a sponsor approved pursuant to the requirements of this paragraph is not meeting the standards set forth in this paragraph shall result in the denial or termination of the approved status of the sponsor.

(i) *Fees.* (1) At the beginning of each registration period, a mandatory continuing education fee of $45 shall be collected from licensees engaged in the practice of pharmacy in New York State, except for those exempt from the requirement pursuant to subparagraph (b)(2)(i) of this section. This fee shall be in addition to the registration fee required by section 6805 of the Education Law.

(2) Licensees applying for a conditional registration, pursuant to the requirements of subdivision (e) of this section, shall pay a fee that is the same as and in addition to, the fee for the triennial registration required by section 6805 of the Education Law. In addition, such licensees shall pay the $45 mandatory continuing education fee.

(3) Organizations desiring to offer continuing education to licensed pharmacists based upon a department review, pursuant to paragraph (h)(3) of this section, shall submit an application fee of $900 with its application for the issuance of a permit from the department to become an approved sponsor of a formal continuing education program. Application for a three-year renewal of the permit shall be accompanied by a fee of $900.

63.8 Registration of nonresident establishments.

(a) Definitions. For purposes of this section and section 6808-b of the Education Law:

(1) Nonresident establishment means any pharmacy, manufacturer or wholesaler located outside of New York State that ships, mails or delivers prescription drugs or devices to other establishments, authorized prescribers and/or patients residing in New York State. Such establishments shall include, but not be limited to, pharmacies that transact business through the use of the internet.

(2) Isolated transaction means for pharmacies, 600 or fewer prescriptions per calendar year for drugs and/or other devices delivered into New York State, and for manufacturers and wholesalers, sales that total less than $10,000 in value, at wholesale per calendar year, for drugs and/or devices delivered into New York State, except that upon application by a nonresident establishment, the department may deem a transaction to be an isolated transaction, when such transaction is necessary to protect the public health by addressing a temporary emergency shortage of a prescription drug and/or device in New York State.

(b) Registration requirements.

(1) All nonresident establishments that ship, mail, or deliver prescription drugs and/or devices to other registered establishments, authorized prescribers, and/or patients into New York State shall be registered with the department in accordance with this section and section 6808-b of the Education Law, except that such registration shall not apply to intra-company transfers between any division, affiliate, subsidiaries, parent or other entities under complete common ownership and control, and except that such registration shall not apply to nonresident establishments that have been granted an exception under subdivision (e) of this section.

(2) Application. Nonresident establishments shall apply to the department for registration upon forms prescribed by the department. The application for nonresident manufacturers or wholesalers of prescription drugs and/or devices shall be accompanied by a fee of $825. The application for nonresident pharmacies shall be accompanied by a fee of $345.

(3) Renewal of registration. All registrations for nonresident establishments shall be renewed on dates set by the department. The triennial registration fee for the renewal of a registration of a nonresident manufacturer or wholesaler shall be $520 or a prorated share thereof, as determined by the department. The triennial registration fee for the renewal of a registration of a nonresident pharmacy shall be $260 or a prorated share thereof, as determined by the department.

(4) Failure to register shall subject the nonresident establishment to the late fees set forth in section 6502(3) of the Education Law.

(5) In order to be registered nonresident establishments shall:

(i) be licensed and/or registered in good standing with the state of residence;

(ii) maintain, in readily retrievable form, records of drugs and/or devices shipped into New York State;

(iii) supply, upon request, all information needed by the department to carry out the department's responsibilities under law;

(iv) comply with all statutory and regulatory requirements of the state where the nonresident establishment is located, for prescription drugs or devices shipped, mailed, or delivered into New York State, except for controlled substances shipped, mailed, or delivered into New York State, the nonresident pharmacy shall follow Federal law and New York State law;

(v) designate a resident agent in this state for service of process pursuant to Rule 318 of the Civil Practice Law and Rules; and

(vi) meet the following requirements of the Education Law to the extent that they pertain to the delivery of prescription drugs and devices into New York State: Education Law, sections 6802, 6810, 6811, 6811-b, 6813, 6814, 6815, 6816, 6816-a, 6817, 6822, 6824, and 6825.

(6) Additional registration requirements for nonresident establishments that are pharmacies.

(i) Toll-free number. Nonresident establishments that are pharmacies shall provide a toll-free telephone number that is available during normal business hours at least 40 hours per week, to enable communication between a patient in New York State and a pharmacist at the pharmacy who has access to the patient's records, and place such toll free number on a label affixed to each drug or device container.

(ii) Drug retail price lists. Nonresident establishments that are pharmacies that sell prescription medications at retail shall meet the requirements of subdivisions (1), (2), (3), and (5) of section 6826 of the Education Law for a drug retail price list. Such pharmacies that offer to dispense prescription drugs to consumers in New York State through a website on the Internet shall post on such website a notice of the availability of the drug retail price list. Such registered pharmacies that offer to dispense prescription drugs to consumers in New York State through mail order shall include a printed notice with each delivery of a prescription drug informing the consumer of the availability of the drug retail price list and a toll-free telephone number to obtain the list.

(c) Disciplinary action.

(1) Nonresident pharmacies shall be subject to disciplinary action in accordance with the requirements of subdivision (6) of section 6808-b of the Education Law, section 6510 of the Education Law and implementing regulations, including but not limited to section 3.3 and Part 17 of this Title.

(2) A nonresident establishment shall be subject to disciplinary action for:

(i)professional misconduct, as defined in section 6509 of the Education Law;

(ii) unprofessional conduct, as defined in paragraphs (1), (2), (3), (5), (6), (7), (8), (9), (10), (11), (12)(i)(a), (13), and (14) of subdivision (b) of section 29.1 of this Title;

(iii) unprofessional conduct, as defined in paragraphs (1), (2), (4), (5), (6),(8), and (10) of subdivision (a) of section 29.2 of this Title;

(iv) unprofessional conduct, as defined in paragraphs (16), (17), and (19) of subdivision (a) of section 29.7 of this Title; and

(v) failure to meet the registration requirements prescribed in subdivision (b) of this section, any other requirements of this section, and the requirements of section 6808-b of the Education Law.

(3) In a disciplinary action, a nonresident establishment shall be subject to revocation or suspension of its registration and other applicable penalties in accordance with Article 130 of the Education Law.

(d) Notification of change of address or discontinuance. A registered nonresident establishment shall notify the department on forms prescribed by the department of a change of address of the establishment or the discontinuance of the establishment within 10 days after such change of address or discontinuance.

(e) Exception to registration requirements. Upon application by a nonresident establishment, the department may grant an exception to the registration requirements of this section to a nonresident establishment that restricts its sale or dispensing of prescription drugs and/or devices to residents of New York State to isolated transactions, as defined in subdivision (a) of this section.

CODE OF FEDERAL REGULATIONS
Title 21

Part 205
Guideline for State Licensing of Wholesale Prescription Drug Distributors

§205.1. Scope. This part applies to any person, partnership, corporation, or business firm in a State engaging in the wholesale distribution of human prescription drugs in interstate commerce.

§205.2. Purpose. The purpose of this part is to implement the Prescription Drug Marketing Act of 1987 by providing minimum standards, terms, and conditions for the licensing by State licensing authorities of persons who engage in wholesale distributions in interstate commerce of prescription drugs.

§205.3. Definitions.

(a) *Blood* means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(b) *Blood component* means that part of blood separated by physical or mechanical means.

(c) *Drug sample* means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(d) *Manufacturer* means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug.

(e) *Prescription drug* means any human drug required by Federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(f) *Wholesale distribution and wholesale distributor* means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales;

(2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;

(3) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this section, *common control* means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;

(5) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, *emergency medical* reasons includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(6) The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

(7) The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) The sale, purchase, or trade of blood and blood components intended for transfusion.

(g) *Wholesale distributor* means any one engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

§205.4. Wholesale drug distributor licensing requirement. Every wholesale distributor in a State who engages in wholesale distributions of prescription drugs in interstate commerce must be licensed by the State licensing authority in accordance with this part before engaging in wholesale distributions of prescription drugs in interstate commerce.

§205.5. Minimum required information for licensure.

(a) The State licensing authority shall require the following minimum information from each wholesale drug distributor as part of the license described in §205.4 and as part of any renewal of such license:

(1) The name, full business address, and telephone number of the licensee;

(2) All trade or business names used by the licensee;

(3) Addresses, telephone numbers, and the names of contact persons for

Note: Laws and regulations are current as of the date of publication.

all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;

(4) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(5) The name(s) of the owner and/or operator of the licensee, including:

(i) If a person, the name of the person;

(ii) If a partnership, the name of each partner, and the name of the partnership;

(iii) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the State of incorporation; and

(iv) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(b) The State licensing authority may provide for a single license for a business entity operating more than one facility within that State, or for a parent entity with divisions, subsidiaries, and/or affiliate companies within that State when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(c) Changes in any information in paragraph (a) of this section shall be submitted to the State licensing authority as required by such authority.

(Approved by the Office of Management and Budget under control number 0910-0251)

§205.6. Minimum qualifications.

(a) The State licensing authority shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the State:

(1) Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;

(2) Any felony convictions of the applicant under Federal, State, or local laws;

(3) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(5) Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with requirements to maintain and/or make available to the State licensing authority or to Federal, State, or local law enforcement officials those records required under this section; and

(8) Any other factors or qualifications the State licensing authority considers relevant to and consistent with the public health and safety.

(b) The State licensing authority shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

§205.7. Personnel. The State licensing authority shall require that personnel employed in wholesale distribution have appropriate education and/or experience to assume responsibility for positions related to compliance with State licensing requirements.

§205.8. Violations and penalties. (a) State licensing laws shall provide for the suspension or revocation of licenses upon conviction of violations of Federal, State, or local drug laws or regulations, and may provide for fines, imprisonment, or civil penalties.

(b) State licensing laws shall provide for suspension or revocation of licenses, where appropriate, for violations of its provisions.

§205.50. Minimum requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records. The State licensing law shall include the following minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:

(a) *Facilities.* All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition; and

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) *Security.*

(1) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(i) Access from outside the premises shall be kept to a minimum and be well-controlled.

(ii) The outside perimeter of the premises shall be well-lighted.

Note: Laws and regulations are current as of the date of publication.

(iii) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(2) All facilities shall be equipped with an alarm system to detect entry after hours.

(3) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) *Storage.* All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

(1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all stored drugs.

(d) *Examination of materials.*

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in paragraph (f) of this section shall be followed for all incoming and outgoing prescription drugs.

(e) *Returned, damaged, and outdated prescription drugs.*

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in paragraph (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(f) *Recordkeeping.*

(1) Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

(i) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

(ii) The identity and quantity of the drugs received and distributed or disposed of; and

(iii) The dates of receipt and distribution or other disposition of the drugs.

(2) Inventories and records shall be made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 2 years following disposition of the drugs.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within 2 working days of a request by an authorized official of a Federal, State, or local law enforcement agency.

(g) *Written policies and procedures.* Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the Food and Drug Administration or other Federal, State, or local law enforcement or

other government agency, including the State licensing agency;

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(iii) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, State, or national emergency.

(4) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for 2 years after disposition of the outdated drugs.

(h) *Responsible persons.* Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(i) *Compliance with Federal, State, and local law.* Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

(1) Wholesale drug distributors shall permit the State licensing authority and authorized Federal, State, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, local, and DEA regulations.

(j) *Salvaging and reprocessing.* Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State, or local laws or regulations that relate to prescription drug product salvaging or reprocessing, including parts 207, 210, and 211 of this chapter.

(Approved by the Office of Management and Budget under control number 0910-0251)

PUBLIC HEALTH LAW
Part 80
Possession and Sale of Hypodermic Syringes and Hypodermic Needles

§80.131 Prescription, sale and possession of hypodermic syringes and hypodermic needles.

(a) It shall be unlawful for any person to sell or furnish, to any other person or persons, a hypodermic syringe or hypodermic needle, except:

(1) pursuant to a written prescription of a practitioner; or

(2) to persons who have been authorized by the commissioner to obtain and possess such instruments; or

(3) in an emergency, pursuant to an oral prescription from a practitioner, if the pharmacist complies with the requirements of subdivision (b) of this section.

(4) pursuant to Section 80.137 of this Part

(b) (1) In an emergency, a practitioner may orally prescribe and a pharmacist may dispense, to an ultimate user, syringes and hypodermic needles, provided however, the pharmacist shall:

(i) contemporaneously reduce such oral prescription to a written memorandum indicating the name, address and phone number of the prescriber, name and address of the ultimate user, date on which the hypodermic needle and/or syringe was ordered, quantity prescribed, directions for use, and the fact that it is a telephone order; and

(ii) the pharmacist filling such oral prescription shall indicate on the face of the memoranda the date filled, and the serial number of the prescription under which it is recorded in the pharmacy prescription file, and sign the memorandum.

(2) The pharmacist shall make a good faith effort to verify the identity of both the practitioner and the ultimate user if not known to the pharmacist.

(3) No oral prescription shall be filled for a quantity of hypodermic syringes and/or needles which would exceed a 10-day supply.

(4) Within 72 hours after authorizing such an oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist a written prescription. If the pharmacist fails to receive such prescription, he shall record on the oral prescription memorandum: "Written prescription not received", and sign and date the recording.

(5) Written follow-up prescriptions from prescribers shall be attached to the corresponding oral prescription memorandum and shall be filed in accordance with this section.

(6) The pharmacist receiving such written follow-up prescriptions shall

endorse on the face of such prescription his signature, the date of filling, the serial number of the prescription under which it is recorded in the pharmacy prescription file and that such written prescription is a follow-up to the prior oral prescription. In addition, the pharmacist shall place on the back of the written follow-up prescription the date of receipt, the serial number and the date the oral prescription was filled, as follows:

> "Follow-up prescription to oral prescription, serial number ……, filled on …….., written prescription received ….."

(c) *Emergency* means that the immediate furnishing of a hypodermic syringe and/or needle is necessary for proper treatment, that no alternative is available and it is not possible for the practitioner to provide a written prescription at the time.

(d) It shall be unlawful for any person to obtain or possess a hypodermic syringe or hypodermic needle unless such possession has been authorized by the commissioner or is pursuant to a prescription.

(e) A written prescription shall include:

(1) the name, address and age of the person for whom intended;

(2) the name, address, telephone number and signature of practitioner.

(f) Any person selling or furnishing a hypodermic syringe or hypodermic needle pursuant to prescription shall record upon the face of the prescription, over his signature, the date of the sale or furnishing of the hypodermic syringe or hypodermic needle. Prescriptions and oral prescription memorandums shall be retained on file for a period of five years and be readily accessible for inspection by any public officer or employee engaged in the enforcement of this section. A prescription may be refilled not more than the number of times specifically authorized by the prescriber upon the prescription; provided, however, no such authorization shall be effective for a period longer than two years from the date the prescription is signed.

(g) All renewals shall be recorded on the reverse side of the written prescription and the date and quantity dispensed and the signature of the dispensing pharmacist shall be recorded.

§80.137 Expanded syringe access demonstration program.

(a) Definitions.

(1)Authorized provider" for the purposes of this section shall mean any of the following who have registered with the Department:

(i) a pharmacy licensed under article one hundred thirty-seven of the education law;

(ii) a health care facility licensed under article twenty-eight of the public health law; or

(iii) a health care practitioner who is otherwise authorized to prescribe the use of hypodermic needles or syringes within his or her scope of practice.

(2) "Safety insert", for the purposes of this section, shall mean a document that is either developed or approved by the commissioner and shall contain, at a minimum, the following information:

(i) information on the proper use of hypodermic syringes and needles;

(ii) the risk of blood-borne diseases that may result from the use of hypodermic syringes and needles;

(iii) methods for preventing the transmission or contraction of blood-borne diseases;

(iv) proper disposal practices for hypodermic syringes and needles, including information on safe disposal and the relevant provisions of the environmental conservation law relating to the unlawful release of regulated medical waste;

(v) the dangers of injection drug use and how to access drug treatment;

(vi) a toll-free number for information on the human immunodeficiency virus; and

(vii) a statement that it is legal for persons to possess syringes obtained pursuant to Article 33 of the Public Health Law.

(b) Registration.

(1) Authorized providers must register with the Department in order to sell or furnish hypodermic needles and/or syringes without a prescription pursuant to this section.

(2) Authorized providers must register with the Department in order to accept hypodermic needles and/or syringes for purposes of disposal. Failure of an entity to register shall not affect its obligations to accept needles and syringes originating from a private residence when such entity is already obliged to do so pursuant to Section 1389-dd of the Public Health Law.

(3) Registration shall be limited to authorized providers in good standing and will consist of submission to the Department of a completed application in a form prescribed by the commissioner, and receipt of the acceptance from the commissioner of such registration, prior to the initiation of the selling or furnishing of hypodermic needles and syringes without a prescription and or accepting hypodermic needles and/or syringes for disposal.

(4) The registration form must include, at a minimum, the following information:

(i) the name, address, license number, telephone number and fax number (if available) of the authorized provider;

(ii) the name, address, telephone and electronic mail address, if available, of the individual designated by the authorized provider to have administrative responsibility for the provider's participation in the expanded syringe access demonstration program;

(iii) an attestation that the authorized provider will abide by the provisions of this section and the provisions contained in the registration form with regard to the selling or furnishing of hypodermic needles or syringes without a prescription;

(iv) a description of how the registrant will cooperate in the safe disposal of used hypodermic needles or syringes, or will provide such services (pharmacies and health care practitioners are not required to provide such services); and

(v) the signature of the individual authorized to sign the registration form on behalf of the applicant.

(5) The registration period shall commence upon the acceptance of such registration by the commissioner and shall remain valid for a period to coincide with the maximum

allowed at the time of registration under Section 3381 of the Public Health Law or until notice of termination by the Department. Authorized providers shall notify the Department of any changes in the information provided to the Department. Changes or corrections to such information shall be submitted to the Department by the completion of a revised registration form as soon as possible but no later than 30 days after such change. Should an authorized provider choose to withdraw its registration, written notification of such intent must be provided to the Department. Such withdrawal shall not be effective until receipt of such written notice is acknowledged by the Department in writing.

(6) The name, address, and telephone number of the authorized provider may be used in the development of, or included in, a registry of authorized providers for the purpose of informing consumers of available authorized providers for the purposes of sale, furnishing, and/or disposal, as specified on the registration form.

(c) Upon the finding of a violation of this section or when a registrant is no longer in good standing, the commissioner may suspend, for a period up to one year, an authorized provider's ability to sell or furnish hypodermic needles or syringes**,** or to accept hypodermic needles or syringes for disposal under this Section. Entities otherwise obliged to accept hypodermic needles or syringes for disposal pursuant to Section 1389-dd of the Public Health Law shall not be relieved from such obligation.

(d) Requirements for authorized providers for the purpose of selling and furnishing of hypodermic needles and syringes without a prescription.

(1) After acceptance of the registration by the commissioner, an authorized provider may obtain and possess such hypodermic syringes and needles for such purpose, provided that:

(i) such sale or furnishing shall only be to a natural person eighteen years of age or older;

(ii) each sale or furnishing is limited to a quantity of ten or less; and

(iii) the sale or furnishing shall be accompanied by a safety insert as described in paragraph (a)(2) of this section. Such insert shall be attached to or included in the hypodermic syringe and/or needle packaging, or provided in brochure form, at the point of sale or furnishing.

(2) In addition, a pharmacy:

(i) shall not advertise to the public the availability for retail or furnishing of hypodermic syringes and needles without a prescription; and

(ii) shall, at any location where hypodermic syringes and needles are kept for retail furnishing, store such syringes and needles in a manner that makes them available only to authorized personnel and not openly available to customers.

(e) Authorized providers that accept needles and/or syringes for purposes of disposal shall adhere to state and local public health and environmental conservation laws, rules, and regulations related to the disposal of regulated medical waste.

(f) Possession. A natural person eighteen years of age or older may obtain and possess hypodermic syringes and needles obtained pursuant to this Section.

(g) Applicability. The provisions of this section shall not apply to any sale, furnishing, or possession of hypodermic needles or syringes which is lawful under Section 3381(1)(a) or (b) of the Public Health Law.

Article 33 – Title 7
Offenses, Violations and Enforcement

§ 3381. Sale and possession of hypodermic syringes and hypodermic needles.

1. It shall be unlawful for any person to sell or furnish to another person or persons, a hypodermic syringe or hypodermic needle except:
(a) pursuant to a written prescription of a practitioner; or
(b) to persons who have been authorized by the commissioner to obtain and possess such instruments; or
(c) by a pharmacy licensed under article one hundred thirty-seven of the education law, health care facility licensed under article twenty-eight of this chapter or a health care practitioner who is otherwise authorized to prescribe the use of hypodermic needles or syringes within his or her scope of practice; provided, however, that such sale or furnishing:
(i) shall only be to a person eighteen years of age or older;
(ii) shall be limited to a quantity of ten or less hypodermic needles or syringes; and
(iii) shall be in accordance with subdivision six of this section.

2. It shall be unlawful for any person to obtain or possess a hypodermic syringe or hypodermic needle unless such possession has been authorized by the commissioner or is pursuant to a written prescription, or is pursuant to subdivision six of this section.

3. Any person selling or furnishing a hypodermic syringe or hypodermic needle pursuant to a prescription shall record upon the face of the prescription, over his signature, the date of the sale or furnishing of the hypodermic syringe or hypodermic needle. Such prescription shall be retained on file for a period of five years and be readily accessible for inspection by any public officer or employee engaged in the enforcement of this section. Such prescription may be refilled not more than the number of times specifically authorized by the prescriber upon the prescription, provided however no such authorization shall be effective for a period greater than two years from the date the prescription is signed.

4. The commissioner shall, subject to subdivision six of this section, designate persons, or by regulation, classes of persons who may obtain hypodermic syringes and hypodermic needles without prescription and the manner in which such transactions may take place and the records thereof which shall be maintained.

Note: Laws and regulations are current as of the date of publication.

5. (a) The commissioner, in consultation with the commissioner of alcoholism and substance abuse services, the commissioner of the department of correctional services, the commissioner of the division of criminal justice services, the commissioner of the office of general services, the commissioner of the office of mental health, the commissioner of the office of mental retardation and developmental disabilities and the director of the division for youth shall develop a limited number of cooperative pilot projects to test the practicality and effectiveness of the distribution of syringes for human injection which are intended for single use and which are non-reusable. Such pilot projects shall be demonstrated throughout the state in high risk clinical settings of state operated facilities such as prisons, hospitals, youth detention facilities, developmental centers and other state operated facilities as the commissioner, in consultation with the above listed commissioners and directors determine appropriate.

(b) On or before June thirtieth, nineteen hundred ninety-eight, the commissioner and the commissioners and directors listed in paragraph (a) of his subdivision shall evaluate the pilot projects established pursuant to this subdivision, and shall submit a report of his or her evaluation to the governor, the temporary president of the senate, and the speaker of the assembly.

6. (a) A person eighteen years of age or older may obtain and possess a hypodermic syringe or hypodermic needle pursuant to paragraph (c) of subdivision one of this section.

(b) Subject to regulations of the commissioner, a pharmacy licensed under article one hundred thirty-seven of the education law, a health care facility licensed under article twenty-eight of this chapter or a health care practitioner who is otherwise authorized to prescribe the use of hypodermic needles or syringes within his or her scope of practice, may obtain and possess hypodermic needles or syringes for the purpose of selling or furnishing them pursuant to paragraph (c) of subdivision one of this section or for the purpose of disposing of them, provided that such pharmacy, health care facility or health care practitioner has registered with the department.

(c) Sale or furnishing of hypodermic syringes or hypodermic needles to direct consumers pursuant to this subdivision by a pharmacy, health care facility, or health care practitioner shall be accompanied by a safety insert. Such safety insert shall be developed or approved by thecommissioner and shall include, but not be limited to,

(i) information on the proper use of hypodermic syringes and hypodermic needles;

(ii)the risk of blood borne diseases that may result from the use of hypodermic syringes and hypodermic needles;

(iii) methods for preventingthe transmission or contraction of blood borne diseases;

(iv) proper hypodermic syringe and hypodermic needle disposal practices;

(v)information on the dangers of injection drug use, and how to access drug treatment;

(vi) a toll-free phone number for information on the human immunodeficiency virus; and

(vii) information on the safe disposal of hypodermic syringes and hypodermic needles including the relevant provisions of the environmental conservation law relating to the unlawful release of regulated medical waste. The safety insert shall be attached to or included in the hypodermic syringe and hypodermic needle packaging, or shall be given to the purchaser at the point of sale or furnishing in brochure form.

(d) In addition to the requirements of paragraph (c) of subdivision one of this section, a pharmacy licensed under article one hundred thirty-seven of the education law may sell or furnish hypodermic needles or syringes only if such pharmacy:

(i) does not advertise to the public the availability for retail sale or furnishing of hypodermic needles or syringes without a prescription; and (ii) at any location where hypodermic needles or syringes are kept for retail sale or furnishing, stores such needles and syringes in a manner that makes them available only to authorized personnel and not openly available to customers.

(e) The commissioner shall promulgate rules and regulations necessary to implement the provisions of this subdivision which shall include a requirement that such pharmacies, health care facilities and health care practioners cooperate in a safe disposal of used hypodermic needles or syringes.

(f) The commissioner may, upon the finding of a violation of this section, suspend for a determinate period of time the sale or furnishing of syringes by a specific entity.

7. The provisions of this section shall not apply to farmers engaged in livestock production or to those persons supplying farmers engaged in livestock production, provided that:

(a) Hypodermic syringes and needles shall be stored in a secure, locked storage container.

(b) At any time the department may request a document outlining:

(i) the number of hypodermic needles and syringes purchased over the past calendar year;

(ii) a record of all hypodermic needles used over the past calendar year; and

(iii) a record of all hypodermic needles and syringes destroyed over the past calendar year.

(c) Hypodermic needles and syringes shall be destroyed in a manner consistent with the provisions set forth in section thirty-three hundred eighty-one-a of this article.

* NB Effective until September 1, 2007

Part 415
Nursing Homes – Minimum Standards
(Excerpts from Chapter V – Medical Facilities)

§415.18 Pharmacy services.

(a) The facility shall provide pharmaceutical services and develop and implement policies and procedures that assure the accurate acquisition, receipt, dispensing and administering of all drugs and biologicals required to meet the needs of each resident. The facility shall provide routine and emergency drugs and biologicals directly to its residents, or obtain them under a contract as described in section 400.4 of this Title. The facility shall be licensed under article 33 of the Public Health Law and Part 80 of this Title.

(b) *Service consultation.* The facility shall employ or obtain the services of a registered pharmacist who:

(1) provides consultation on all aspects of the provision of pharmacy services in the facility;

(2) establishes a system of records of receipt and disposition of all controlled drugs; and

(3) determines that drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled consistent with the requirements of article 33 of the Public Health Law and Part 80 of this Title.

(c) *Drug regimen review.* (1) The drug regimen of each resident shall be reviewed at least once a month by a registered pharmacist.

(2) The pharmacist shall report any irregularities to the attending physician and the director of nursing, and these reports shall be acted upon promptly. The findings and corrective actions shall be regularly reviewed by the quality assessment and assurance committee established pursuant to section 415.27 of this Part.

(3) Psychotropic drugs may be administered only on the orders of a physician and only as part of a plan of care, developed in accordance with sections 415.4, 415.11 and 415.12 of this Part, designed to eliminate or modify the symptoms for which the drugs are prescribed.

(d) *Labeling of drugs and biologicals.* The facility shall label drugs and biologicals in accordance with currently accepted standards of practice and include the appropriate accessory and cautionary instructions and the expiration date. Labeling of all medications shall be in accordance with article 137 of the State Education Law and 8 NYCRR Part 29. Facilities which use a unit dose drug distribution system shall develop and implement an appropriate method of providing accessory and cautionary instructions.

(e) *Storage of drugs and biologicals.* (1) The facility shall store all drugs and biologicals in locked compartments under proper temperature controls, and permit access only to authorized personnel.

(2) The facility shall provide separately locked, permanently affixed, compartments for storage of controlled drugs and other drugs subject to abuse, except when the facility uses single unit package drug distribution systems in which the quantity stored is minimal and a missing dose can be readily detected. Storage of controlled substances shall be in accordance with article 33 of the Public Health Law and Part 80 of this Title.

(3) Poisons and medications for "external use only" shall be kept in a locked cabinet and separate from other medications.

(4) Medications whose shelf life has expired or which are otherwise no longer in use shall be disposed of or destroyed in accordance with State and Federal laws and regulations.

(f) *Return of unused medications.* (1) When services are provided by a cooperating vendor pharmacy, the facility shall establish policies and procedures which permit either the staff registered pharmacist or consultant registered pharmacist to return to the vendor pharmacy from which it was purchased any unused medications or drug products, provided such medication is sealed in unopened, individually packaged, units and within the recommended period of shelf life for the purpose of redispensing and which are in accord with the following provisions:

(i) Drug products which may be returned are limited to:

(*a*) oral and parenteral medication in single-dose hermetically sealed containers from which no doses have been withdrawn.

(*b*) parenteral medication in multiple-dose hermetically sealed containers from which no doses have been withdrawn.

(ii) The drug products returned show no obvious sign of deterioration.

(iii) Drug products packaged in manufacturer's unit-dose packages may be returned for redispensing provided that they are redispensed in time for use before the expiration date, if any, indicated on the package.

(iv) Drug products repackaged by the pharmacy into unit-dose or multiple-dose "blister packs" may be returned for redispensing provided that:

(*a*) the date on which the drug product was repackaged, its lot number and expiration date are indicated clearly on the package;

(*b*) not more than 90 days have elapsed from the date of the repackaging;

(c) a repackaging log is maintained by the pharmacy in the case of drug products repackaged in advance of immediate needs.

(v) "Blister packs".

(*a*) Partially used "blister packs" may be redispensed only

as returned.

(*b*) Partially used "blister packs" may not be emptied and repackaged.

(c) Additional units of medication may not be added to partially used "blister packs".

(vi) No drug product dispensed in bulk in a dispensing container may be returned.

(vii) No medication or drug product defined as a controlled substance in section 3306 of the Public Health Law may be returned.

(2) The vendor pharmacy to which such drug products are returned shall reimburse or credit the nursing home or purchaser of such drug products for the unused medication that is restocked and redispensed and shall not otherwise charge any individual resident or the State, if a resident is a recipient or beneficiary of a State-funded program, for unused medication or drug products returned for reimbursement or credit.

(g) *Emergency medications.* The facility shall ensure the provision of (an) emergency medication kit(s) as follows:

(1) The contents of each kit shall be approved by the medical director, pharmacist and director of nursing.

(2) Controlled substances shall be prohibited in emergency kits.

(3) The medication contents of each kit shall be limited to injectables except that the kit may also include:

(i) sublingual nitroglycerin; and

(ii) up to five noninjectable, prepackaged medications, not to exceed a 24-hour supply, which are the same noninjectable, prepackaged medications in all emergency kits throughout the facility.

(4) Each kit shall be kept and secured within or near the nurses' station.

(h) *Medications for leaves.* Medication shall be released to discharged residents or to a resident going on temporary leave. The medication supply in the facility may be used to supply the medications needed for a temporary leave of absence.

(i) *Verbal orders.* All medications administered to residents shall be ordered in writing by a legally authorized practitioner unless unusual circumstances justify a verbal order, in which case the verbal order shall be given to a licensed nurse, or to a licensed pharmacist, immediately reduced to writing, authenticated by the nurse or registered pharmacist and countersigned by the prescriber within 48 hours. In the event a verbal order is not signed by the prescriber or a designated alternate physician within 48 hours, the order shall be terminated and the facility shall ensure that the resident's medication needs are promptly evaluated by the medical director or another legally authorized prescribing practitioner.

Note: Laws and regulations are current as of the date of this publication..

LAWS, RULES AND REGULATIONS APPLICABLE TO ALL PROFESSIONS

EDUCATION LAW
Article 130
General Provisions

Subarticle 1
Introductory Summary

§6500. Introduction.

This title provides for the regulation of the admission to and the practice of certain professions. This first article applies to all the professions included in this title, except that prehearing procedures and hearing procedures in connection with the regulation of professional conduct of the profession of medicine and physician's assistants and specialist's assistants shall be conducted pursuant to the provisions of Title II-A of article two of the public health law. Each of the remaining articles applies to a particular profession.

§6501. Admission to a profession (licensing).

Admission to practice of a profession in this state is accomplished by a license being issued to a qualified applicant by the education department. To qualify for a license an applicant shall meet the requirements prescribed in the article for the particular profession and shall meet the requirements prescribed in section 3-503 of the general obligations law.

§6501-a. Disclosure with respect to loans made or guaranteed by the New York State Higher Education Services Corporation.

Every application for a license issued pursuant to the provisions of this article shall contain a question inquiring whether the applicant has any loans made or guaranteed by the New York state higher education services corporation currently outstanding, and if so, whether such applicant is presently in default on any such loan. The name and address of any applicant who answers either or both of such questions in the affirmative shall be transmitted to such corporation by the department prior to the date on which such license is issued.

§6502. Duration and registration of a license.

1. A license shall be valid during the life of the holder unless revoked, annulled or suspended by the board of regents or in the case of physicians, physicians practicing under a limited permit, physician's assistants, specialist's assistants and medical residents, the licensee is stricken from the roster of such licensees by the board of regents on the order of the state board for professional medical conduct in the department of health. A licensee must register with the department and meet the requirements prescribed in section 3-503 of the general obligations law to practice in this state.

2. The department shall establish the beginning dates of the registration periods for each profession and mail an application for registration conforming to the requirements of section 3-503 of the general obligations law to every licensee currently registered at least four months prior to the beginning of the registration period for the respective profession.

3. An application for registration and the required registration fee shall be submitted together with or as a part of the application for a license. A person initially licensed or a licensee resuming practice after a lapse of registration during the last two years of a triennial registration period shall receive a prorated refund of one-third of the total registration fee for each full year of the triennial period that has elapsed prior to the date of registration. Except as provided in subdivision three-a of this section, the department shall renew the registration of each licensee upon receipt of a proper application, on a form prescribed by the department and conforming to the requirements of section 3-503 of the general obligation law, and the registration fee. Any licensee who fails to register by the beginning of the appropriate registration period shall be required to pay an additional fee for late filing of ten dollars for each month that registration has been delayed. No licensee resuming practice after a lapse of registration shall be permitted to practice without actual possession of the registration certificate.

3-a. Prior to issuing any registration pursuant to this section and section sixty-five hundred twenty-four of this chapter, the department shall request and review any information relating to an applicant which reasonably appears to relate to professional misconduct in his or her professional practice in this and any other jurisdiction. The department shall advise the director of the office of professional medical conduct in the department of health of any information about an applicant which reasonably appears to be professional misconduct as defined in sections sixty-five hundred thirty and sixty-five hundred thirty-one of this chapter, within seven days of its discovery. The registration or re-registration of such applicant shall not be delayed for a period exceeding thirty days unless the director finds a basis for recommending summary action pursuant to subdivision twelve of section two hundred thirty of the public health law after consultation with a committee on professional conduct of the state board for professional medical conduct, if warranted. Re-registration shall be issued if the commissioner of health fails to issue a summary order pursuant to subdivision twelve of section two hundred

thirty of the public health law within ninety days of notice by the department pursuant to this subdivision. Re-registration shall be denied if the commissioner of health issues a summary order pursuant to subdivision twelve of section two hundred thirty of the public health law.

4. Any licensee who is not engaging in the practice of his profession in this state and does not desire to register shall so advise the department. Such licensee shall not be required to pay an additional fee for failure to register at the beginning of the registration period.

5. Licensees shall notify the department of any change of name or mailing address within thirty days of such change. Failure to register or provide such notice within one hundred eighty days of such change shall be willful failure under section sixty-five hundred thirty of this chapter.

6. The fee for replacement of a lost registration certificate or license or for registration of an additional office shall be ten dollars.

7. An additional fee of twenty-five dollars shall be charged for the licensure or registration of any applicant who submits a bad check to the department.

§6503. Practice of a profession.

Admission to the practice of a profession (1) entitles the licensee to practice the profession as defined in the article for the particular profession, (2) entitles the individual licensee to use the professional title as provided in the article for the particular profession, and (3) subjects the licensee to the procedures and penalties for professional misconduct as prescribed in this article (sections sixty-five hundred nine, sixty-five hundred ten, and sixty-five hundred eleven).

§6504. Regulation of the professions.

Admission to the practice of the professions (licensing) and regulation of such practice shall be supervised by the board of regents (section sixty-five hundred six) and administered by the education department (section sixty-five hundred seven), assisted by a state board for each profession (section sixty-five hundred eight).

§6505. Construction.

No definition of the practice of a profession shall be construed to restrain or restrict the performance of similar acts authorized in the definition of other professions.

§6505-a. Professional referrals.

There shall be no monetary liability on the part of, and no cause of action for damages shall arise against, any association or society of professionals authorized to practice under this title, or any employee, agent, or member thereof, for referring any person to a member of the profession represented by such association or society provided that such referral was made without charge as a service to the public, and without malice, and in the reasonable belief that such referral was warranted, based upon the facts disclosed.

§6505-b. Course work or training in infection control practices.

Every dentist, registered nurse, licensed practical nurse, podiatrist, optometrist and dental hygienist practicing in the state shall, on or before July first, nineteen hundred ninety-four and every four years thereafter, complete course work or training appropriate to the professional's practice approved by the department regarding infection control and barrier precautions, including engineering and work practice controls, in accordance with regulatory standards promulgated by the department, in consultation with the department of health, which shall be consistent, as far as appropriate, with such standards adopted by the department of health pursuant to section two hundred thirty-eight of the public health law to prevent the transmission of HIV/HBV in the course of professional practice. Each such professional shall document to the department at the time of registration commencing with the first registration after July first, nineteen hundred ninety-four that the professional has completed course work or training in accordance with this section, provided, however that a professional subject to the provisions of paragraph (f) of subdivision one of section twenty-eight hundred five-k of the public health law shall not be required to so document. The department shall provide an exemption from this requirement to anyone who requests such an exemption and who (i) clearly demonstrates to the department's satisfaction that there would be no need for him or her to complete such course work or training because of the nature of his or her practice or (ii) that he or she has completed course work or training deemed by the department to be equivalent to the course work or training approved by the department pursuant to this section. The department shall consult with organizations representative of professions, institutions and those with expertise in infection control and HIV and HBV with respect to the regulatory standards promulgated pursuant to this section.

Subarticle 2
State Management

§6506. Supervision by the Board of Regents

The board of regents shall supervise the admission to and the practice of the professions. In supervising, the board of regents may:

(1) Promulgate rules, except that no rule shall be promulgated concerning article 131-A of this chapter;

(2) Establish by rule, high school, preprofessional, professional and other educational qualifications required for licensing in the professions regulated by this title;

(3) Charter schools offering educational programs for the professions regulated by this title, and no such school shall operate in this state without such a charter, except Columbia University, any school chartered by special act of the legislature prior to September one, nineteen hundred seventy-one, and schools specifically authorized to conduct such programs by the regents;

(4) Appoint such committees as it deems necessary and compensate members of such committees who are not members of the board of regents or the department up to

one hundred dollars per day for each day devoted to committee functions, together with their necessary expenses;

(5) Waive education, experience and examination requirements for a professional license prescribed in the article relating to the profession, provided the board of regents shall be satisfied that the requirements of such article have been substantially met;

(6) Endorse a license issued by a licensing board of another state or country upon the applicant fulfilling the following requirements:

(a) Application: file an application with the department;

(b) Education: meet educational requirements in accordance with the commissioner's regulations;

(c) Experience: have experience satisfactory to the board and in accordance with the commissioner's regulations;

(d) Examination: pass an examination satisfactory to the board and in accordance with the commissioner's regulations;

(e) Age: be at least twenty-one years of age;

(f) Citizenship or immigration status: be a United States citizen or an alien lawfully admitted for permanent residence in the United States;

(g) Character: be of good moral character as determined by the department; and

(7) Direct the department to remedy any error, omission, delay or other circumstance in the issuance or registration of a license;

(8) Designate a professional conduct officer, who shall be the chief administrative officer of the office of the professions, or his designee, in connection with professional licensing and misconduct proceedings and criminal matters, such officer to be empowered to issue subpoenas and administer oaths in connection with such proceedings;

(9) Establish by rule, standards of conduct with respect to advertising, fee splitting, practicing under a name other than that of the individual licensee (when not specifically authorized), proper use of academic or professional degrees or titles tending to imply professional status, and such other ethical practices as such board shall deem necessary, except that no rule shall be established concerning article 131-A of this chapter; and

(10) Delegate to department officers the disposition of any licensing matters pursuant to rules.

§6507. Administration by the Education Department.

1. The commissioner and the department shall administer the admission to and the practice of the professions.

2. In administering, the commissioner may:

a. Promulgate regulations, except that no regulations shall be promulgated concerning article 131-A of this chapter;

b. Conduct investigations;

c. Issue subpoenas;

d. Grant immunity from prosecution in accordance with section 50.20 of the criminal procedure law to anyone subpoenaed in any investigation or hearing conducted pursuant to this title; and

e. Excuse, for cause acceptable to the commissioner, the failure to register with the department. Such excuse shall validate and authorize such practitioner's right to practice pending registration.

3. The department assisted by the board for each profession, shall:

a. Establish standards for preprofessional and professional education, experience and licensing examinations as required to implement the article for each profession. Notwithstanding any other provision of law, the commissioner shall establish standards requiring that all persons applying, on or after January first, nineteen hundred ninety-one, initially, or for the renewal of, a license, registration or limited permit to be a physician, chiropractor, dentist, registered nurse, podiatrist, optometrist, psychiatrist, psychologist or dental hygienist shall, in addition to all the other licensure, certification or permit requirements, have completed two hours of coursework or training regarding the identification and reporting of child abuse and maltreatment. The coursework or training shall be obtained from an institution or provider which has been approved by the department to provide such coursework or training. The coursework or training shall include information regarding the physical and behavioral indicators of child abuse and maltreatment and the statutory reporting requirements set out in sections four hundred thirteen through four hundred twenty of the social services law, including but not limited to, when and how a report must be made, what other actions the reporter is mandated or authorized to take, the legal protections afforded reporters, and the consequences for failing to report. Each applicant shall provide the department with documentation showing that he or she has completed the required training. The department shall provide an exemption from the child abuse and maltreatment training requirements to any applicant who requests such an exemption and who shows, to the department's satisfaction, that there would be no need because of the nature of his or her practice for him or her to complete such training;

b. Review qualifications in connection with licensing requirements; and

c. Provide for licensing examinations and reexaminations.

4. The department shall:

a. Register or approve educational programs designed for the purpose of providing professional preparation which meet standards established by the department.

b. Issue licenses, registrations, and limited permits to qualified applicants;

c. (i) Issue a certificate of authority to a qualified professional service corporation being organized under section fifteen hundred three of the business corporation law or to a university faculty practice corporation being organized under section fourteen hundred twelve of the not-for-profit corporation law on payment of a fee of ninety dollars, (ii) file a certified copy of each certificate of incorporation and amendment thereto within thirty days after the filing of such certificate or

amendment on payment of a fee of twenty dollars, (iii) file the annual statement required by section fifteen hundred fourteen of the business corporation law on payment of a fee of thirty-five dollars (iv) as of July first, nineteen hundred eighty-eight, file a triennial statement required on payment of a fee of one hundred five dollars. The first triennial period shall commence on July first, nineteen hundred eighty-eight.

d. Revoke limited permits on the recommendation of the committee on professional conduct for the profession concerned, except for limited permits issued to physicians, physician's assistants and specialist's assistants which shall be subject to sections two hundred thirty, two hundred thirty-a, two hundred thirty-b and two hundred thirty-c of the public health law;

e. Maintain public records of licenses issued and retain in its files identifying data concerning each person to whom a license has been issued;

f. Collect the fees prescribed by this title or otherwise provided by law;

g. Prepare an annual report for the legislature, the governor and other executive offices, the state boards for the professions, professional societies, consumer agencies and other interested persons. Such report shall include but not be limited to a description and analysis of the administrative procedures and operations of the department based upon a statistical summary relating to (i) new licensure, (ii) discipline, (iii) complaint, investigation, and hearing backlog, (iv) budget, and (v) the state boards for the professions. Information provided shall be enumerated by profession; and

h. Establish an administrative unit which shall be responsible for the investigation, prosecution and determination of alleged violations of professional conduct.

5. The commissioner and the department shall perform any other functions necessary to implement this title.

§6508. Assistance by state boards for the professions.

1. A board for each profession shall be appointed by the board of regents on the recommendation of the commissioner for the purpose of assisting the board of regents and the department on matters of professional licensing, practice, and conduct. The composition of each board shall be as prescribed in the article relating to each profession.

Within each board a committee on licensing may be appointed by the board chairman.

Except as provided in paragraph (a) of this subdivision, the membership of each professional licensing board shall be increased by one member, and each such board shall have at least one public representative who shall be selected by the board of regents from the general public.

a. The membership of the professional licensing boards created under sections sixty-five hundred twenty-three, sixty-eight hundred four, sixty-nine hundred three, and seventy-four hundred three of this chapter shall be increased by two members, and each such board shall have at least two public representatives, who shall be selected by the board of regents from the general public.

b. For the purposes of this title, a "public representative" shall be a person who is a consumer of services provided by those licensed or otherwise supervised or regulated by the boards created hereunder, and shall not be, nor within five years immediately preceding appointment have been:

(i) a licensee or person otherwise subject to the supervision or regulation of the board to which appointed; or

(ii) a person maintaining a contractual relationship with a licensee of such board, which would constitute more than two percentum of the practice or business of any such licensee, or an officer, director, or representative of such person or group of persons.

2. Each board, or its committee on licensing, shall select or prepare examinations, may conduct oral and practical examinations and reexaminations, shall fix passing grades, and assist the department in other licensing matters as prescribed by the board of regents.

3. Each board shall conduct disciplinary proceedings as prescribed in this article and shall assist in other professional conduct matters as prescribed by the board of regents.

4. Members of each board shall be appointed by the board of regents for five-year terms except that the terms of those first appointed shall be arranged so that as nearly as possible an equal number shall terminate annually. A vacancy occurring during a term shall be filled by an appointment by the board of regents for the unexpired term. Each state professional association or society may nominate one or more candidates for each appointment to be made to the board for its profession, but the board of regents shall not be required to appoint candidates so nominated. Former members of a board may be re-appointed by the board of regents, on the recommendation of the commissioner, to serve as members of the board solely for the purposes of disciplinary proceedings, proceedings relating to the moral character of an applicant for licensure, and proceedings relating to applications for the restoration of a professional license.

5. Each member of a board shall receive a certificate of appointment, shall before beginning his term of office file a constitutional oath of office with the secretary of state, shall receive up to one hundred dollars as prescribed by the board of regents for each day devoted to board work, and shall be reimbursed for his necessary expenses. Any member may be removed from a board by the board of regents for misconduct, incapacity or neglect of duty.

6. Each board shall elect from its members a chairman and vice-chairman annually, shall meet upon call of the chairman or the department, and may adopt bylaws consistent with this title and approved by the board of regents. A quorum for the transaction of business by the board shall be a majority of members but not less than five members.

7. An executive secretary to each board shall be appointed by the board of regents on recommendation of the commissioner. Such executive secretary shall not be a member of the board, shall hold office at the pleasure of, and shall have the powers, duties and annual salary prescribed by the board of regents.

§6509. Definitions of professional misconduct.

Each of the following is professional misconduct, and any licensee found guilty of such misconduct under the procedures prescribed in section sixty-five hundred ten shall be subject to the penalties prescribed in section sixty-five hundred eleven:

(1) Obtaining the license fraudulently,

(2) Practicing the profession fraudulently, beyond its authorized scope, with gross incompetence, with gross negligence on a particular occasion or negligence or incompetence on more than one occasion,

(3) Practicing the profession while the ability to practice is impaired by alcohol, drugs, physical disability, or mental disability,

(4) Being habitually drunk or being dependent on, or a habitual user of narcotics, barbiturates, amphetamines, hallucinogens, or other drugs having similar effects,

(5) (a) Being convicted of committing an act constituting a crime under:

(i) New York State law or,

(ii) Federal law or,

(iii) The law of another jurisdiction and which, if committed within this state, would have constituted a crime under New York State law;

(b) Having been found guilty of improper professional practice or professional misconduct by a duly authorized professional disciplinary agency of another state where the conduct upon which the finding was based would, if committed in New York state, constitute professional misconduct under the laws of New York state;

(c) Having been found by the commissioner of health to be in violation of article thirty-three of the public health law.

(d) Having his license to practice medicine revoked, suspended or having other disciplinary action taken, or having his application for a license refused, revoked or suspended or having voluntarily or otherwise surrendered his license after a disciplinary action was instituted by a duly authorized professional disciplinary agency of another state, where the conduct resulting in the revocation, suspension or other disciplinary action involving the license or refusal, revocation or suspension of an application for a license or the surrender of the license would, if committed in New York state, constitute professional misconduct under the laws of New York state.

(6) Refusing to provide professional service to a person because of such person's race, creed, color, or national origin,

(7) Permitting, aiding or abetting an unlicensed person to perform activities requiring a license,

(8) Practicing the profession while the license is suspended, or wilfully failing to register or notify the department of any change of name or mailing address, or, if a professional service corporation wilfully failing to comply with sections fifteen hundred three and fifteen hundred fourteen of the business corporation law or, if a university faculty practice corporation wilfully failing to comply with paragraphs (b), (c) and (d) of section fifteen hundred three and section fifteen hundred fourteen of the business corporation law,

(9) Committing unprofessional conduct, as defined by the board of regents in its rules or by the commissioner in regulations approved by the board of regents,

(10) A violation of section twenty-eight hundred three-d or twenty-eight hundred five-k of the public health law.

(11) A violation of section six thousand five hundred five-b of this chapter by a professional other than a professional subject to the provisions of paragraph (f) of subdivision one of section twenty-eight hundred five-k of the public health law.

(12) In the event that the department of environmental conservation has reported to the department alleged misconduct by an architect or professional engineer in making a certification under section nineteen of the tax law (relating to the green building tax credit) the board of regents, upon a hearing and a finding of willful misconduct, may revoke the license of such professional or prescribe such other penalty as it determines to be appropriate.

§6509-a. Additional definition of professional misconduct; limited application.

Notwithstanding any inconsistent provision of this article or of any other provision of law to the contrary, the license or registration of a person subject to the provisions of articles one hundred thirty-two, one hundred thirty-three, one hundred thirty-six, one hundred thirty-seven, one hundred thirty-nine, one hundred forty-one, one hundred forty-three, one hundred forty-four, one hundred fifty-six, one hundred fifty-nine and one hundred sixty-four of this chapter may be revoked, suspended or annulled or such person may be subject to any other penalty provided in section sixty-five hundred eleven of this article in accordance with the provisions and procedure of this article for the following: That any person subject to the above enumerated articles, has directly or indirectly requested, received or participated in the division, transference, assignment, rebate, splitting or refunding of a fee for, or has directly requested, received or profited by means of a credit or other valuable consideration as a commission, discount or gratuity in connection with the furnishing of professional care, or service, including x-ray examination and treatment, or for or in connection with the sale, rental, supplying or furnishing of clinical laboratory services or supplies, x-ray laboratory services or supplies, inhalation therapy service or equipment, ambulance service, hospital or medical supplies, physiotherapy or other therapeutic service or equipment, artificial limbs, teeth or eyes, orthopedic or surgical appliances or supplies, optical appliances, supplies or equipment, devices for aid of hearing, drugs, medication or medical supplies or any other goods, services or supplies prescribed for medical diagnosis, care or treatment under this chapter, except payment, not to exceed thirty-three and one-third per centum of any fee received for

x-ray examination, diagnosis or treatment, to any hospital furnishing facilities for such examination, diagnosis or treatment. Nothing contained in this section shall prohibit such persons from practicing as partners, in groups or as a professional corporation or as a university faculty practice corporation nor from pooling fees and moneys received, either by the partnerships, professional corporations, university faculty practice corporations or groups by the individual members thereof, for professional services furnished by any individual professional member, or employee of such partnership, corporation or group, nor shall the professionals constituting the partnerships, corporations or groups be prohibited from sharing, dividing or apportioning the fees and moneys received by them or by the partnership, corporation or group in accordance with a partnership or other agreement; provided that no such practice as partners, corporations or in groups or pooling of fees or moneys received or shared, division or apportionment of fees shall be permitted with respect to care and treatment under the workers` compensation law except as expressly authorized by the workers` compensation law. Nothing contained in this chapter shall prohibit a medical or dental expense indemnity corporation pursuant to its contract with the subscriber from prorationing a medical or dental expense indemnity allowance among two or more professionals in proportion to the services rendered by each such professional at the request of the subscriber, provided that prior to payment thereof such professionals shall submit both to the medical or dental expense indemnity corporation and to the subscriber statements itemizing the services rendered by each such professional and the charges therefor.

§6509-b. Additional definition of professional misconduct; arrears in payment of support; limited application.

1. The provisions of this section shall apply in all cases of licensee or registrant arrears in payment of child support or combined child and spousal support referred to the board of regents by a court pursuant to the requirements of section two hundred forty-four-c of the domestic relations law or pursuant to section four hundred fifty-eight-b of the family court act.

2. Upon receipt of an order from the court pursuant to one of the foregoing provisions of law, the board of regents, if it finds such person to be so licensed or registered, shall within thirty days of receipt of such order from the court, provide notice to the licensee or registrant of, and cause the regents review committee to initiate, a hearing which shall be held at least twenty days and no more than thirty days after the sending of such notice to the licensee or registrant. The hearing shall be held solely for the purpose of determining whether there exists as of the date of the hearing proof that full payment of all arrears of support established by the order of the court to be due from the licensee or registrant have been paid. Proof of such payment shall be a certified check showing full payment of established arrears or a notice issued by the court or by the support collection unit where the order is payable to the support collection unit designated by the appropriate social services district. Such notice shall state that full payment of all arrears of support established by the order of the court to be due have been paid. The licensee or registrant shall be given full opportunity to present such proof of payment at the hearing in person or by counsel. The only issue to be determined by the regents review committee as a result of the hearing is whether the arrears have been paid. No evidence with respect to the appropriateness of the court order or ability of the respondent party in arrears to comply with such order shall be received or considered by the committee.

3. Notwithstanding any inconsistent provision of this article or of any other provision of law to the contrary, the license or registration of a person subject to the provisions of this title and/or subject to the provisions of title two-A of article two of the public health law shall be suspended if, at the hearing provided for by subdivision two of this section, the licensee or registrant fails to present proof of payment as required by such subdivision. Such suspension shall not be lifted unless the court or the support collection unit, where the court order is payable to the support collection unit designated by the appropriate social services district, issues notice to the regents review committee that full payment of all arrears of support established by the order of the court to be due have been paid.

4. The board of regents shall inform the court of all actions taken hereunder as required by law.

5. This section applies to support obligations paid pursuant to any order of child support or child and spousal support issued under provisions of article three-A or section two hundred thirty-six or two hundred forty of the domestic relations law, or article four, five or five-A of the family court act.

6. Notwithstanding any inconsistent provision of this article or of any other provision of law to the contrary, the provisions of this section shall apply to the exclusion of any other requirements of this article and to the exclusion of any other requirement of law to the contrary.

6509-c. Additional definition of professional misconduct; failure to comply in paternity or child support proceedings; limited application.

1. The provisions of this section shall apply in all cases of licensee or registrant failure after receiving appropriate notice, to comply with a summons, subpoena or warrant relating to a paternity or child support proceeding referred to the board of regents by a court pursuant to the requirements of section two hundred forty-four-c of the domestic relations law or pursuant to section four hundred fifty-eight-b or five hundred forty-eight-b of the family court act.

2. Upon receipt of an order from the court pursuant to one of the foregoing provisions of law, the board of regents, if it finds such person to be so licensed or registered, shall within thirty days of receipt of such order from the court, provide notice to the licensee or registrant that his or her license or registration shall be suspended in sixty days unless the conditions as set forth in subdivision three of this section are met.

3. Notwithstanding any inconsistent provision of this article or of any other provision of law to the contrary, the license or registration of a person subject to the provisions of this title and/or subject to the provisions of title two-A of article two of the public health law shall be suspended unless the court terminates its order to commence suspension proceedings. Such suspension shall not be lifted unless the court issues an order to the board of regents terminating its order to commence suspension proceedings.

4. The board of regents shall inform the court of all actions taken hereunder as required by law.

5. This section applies to paternity or child support proceedings commenced under, and support obligations paid pursuant to any order of child support or child and

spousal support issued under provisions of section two hundred thirty-six or two hundred forty of the domestic relations law, or article four, five, five-A or five-B of the family court act.

6. Notwithstanding any inconsistent provision of this article or of any other provision of law to the contrary, the provisions of this section shall apply to the exclusion of any other requirements of this article and to the exclusion of any other requirement of law to the contrary.

§6510. Proceedings in cases of professional misconduct.

In cases of professional misconduct the proceedings shall be as follows:

1. Preliminary procedures.

a. Complaint. A complaint of a licensee's professional misconduct may be made by any person to the education department.

b. Investigation. The department shall investigate each complaint which alleges conduct constituting professional misconduct. The results of the investigation shall be referred to the professional conduct officer designated by the board of regents pursuant to section sixty-five hundred six of this article. If such officer decides that there is not substantial evidence of professional misconduct or that further proceedings are not warranted, no further action shall be taken. If such officer, after consultation with a professional member of the applicable state board for the profession, determines that there is substantial evidence of professional misconduct, and that further proceedings are warranted, such proceedings shall be conducted pursuant to this section. If the complaint involves a question of professional expertise, then such officer may seek, and if so shall obtain, the concurrence of at least two members of a panel of three members of the applicable board. The department shall cause a preliminary review of every report made to the department pursuant to section twenty-eight hundred three-e as added by chapter eight hundred sixty-six of the laws of nineteen hundred eighty and sections forty-four hundred five-b of the public health law and three hundred fifteen of the insurance law, to determine if such report reasonably appears to reflect conduct warranting further investigation pursuant to this subdivision.

c. Charges. In all disciplinary proceedings other than those terminated by an administrative warning pursuant to paragraph a of subdivision two of this section, the department shall prepare the charges. The charges shall state the alleged professional misconduct and shall state concisely the material facts but not the evidence by which the charges are to be proved.

d. Service of charges and of notice of hearing. A copy of the charges and notice of any hearing pursuant to subdivision two or three of this section shall be served on the licensee personally by the department at least fifteen days before the hearing. If personal service cannot be made after due diligence and such fact is certified under oath, a copy of the charges and the notice of hearing shall be served by certified mail, return receipt requested to the licensee's last known address by the department at least twenty days before the hearing.

e. Records and reports as public information. In all disciplinary proceedings brought pursuant to this section or in any voluntary settlement of a complaint between the licensee and the department, the department shall notify the licensee in writing that the record and reports of such disciplinary proceeding or of such voluntary settlement shall be considered matters of public information unless specifically excepted in this article, or in any other law or applicable rule or regulation.

2. Expedited procedures.

a. Violations. Violations involving professional misconduct of a minor or technical nature may be resolved by expedited procedures as provided in paragraph b or c of this subdivision. For purposes of this subdivision, violations of a minor or technical nature shall include, but shall not be limited to, isolated instances of violations concerning professional advertising or record keeping, and other isolated violations which do not directly affect or impair the public health, welfare or safety. The board of regents shall make recommendations to the legislature on or before June first, nineteen hundred eighty-one, for the further definition of violations of a minor or technical nature. The initial instance of any violation of a minor or technical nature may be resolved by the issuance of an administrative warning pursuant to paragraph b of this subdivision. Subsequent instances of similar violations of a minor or technical nature within a period of three years may be resolved by the procedure set forth in paragraph c of this subdivision.

b. Administrative warning. If a professional conduct officer, after consultation with a professional member of the state board, determines that there is substantial evidence of professional misconduct but that it is an initial violation of a minor or technical nature which would not justify the imposition of a more severe disciplinary penalty, the matter may be terminated by the issuance of an administrative warning. Such warnings shall be confidential and shall not constitute an adjudication of guilt or be used as evidence that the licensee is guilty of the alleged misconduct. However, in the event of a further allegation of similar misconduct by the same licensee, the matter may be reopened and further proceedings instituted as provided in this section.

c. Determination of penalty on uncontested minor violations. If a professional conduct officer, after consultation with a professional member of the state board, determines that there is substantial evidence of a violation of a minor or technical nature, and of a nature justifying a penalty as specified in this paragraph, the department may prepare and serve charges either by personal service or by certified mail, return receipt requested. Such charges shall include a statement that unless an answer is received within twenty days denying the charges, the matter shall be referred to a violations committee consisting of five members of the state board for the profession, at least one of whom shall be a public representative for determination. The violations panel shall be appointed by the executive secretary of the state board. The licensee shall be given at least fifteen days notice of the time and place of the meeting of the violations committee and shall have the right to appear in person and by an attorney and to make a statement to the committee in mitigation or explanation of the misconduct. The department may appear and make a statement in support of its position. The violations committee may issue a censure and reprimand, and in addition, or in the alternative, may impose a fine

not to exceed five hundred dollars for each specification of minor, or technical misconduct. If the fine is not paid within three months the matter may be reopened and shall be subject to the hearing and regents decision procedures of this section. The determination of the panel shall be final and shall not be subject to the regents decision procedures of this section. If an answer is filed denying the charges, the matter shall be processed as provided in subdivision three of this section.

d. Convictions of crimes or administrative violations. In cases of professional misconduct based solely upon a violation of subdivision five of section sixty-five hundred nine of this article, the professional conduct officer may prepare and serve the charges and may refer the matter directly to a regents review committee for its review and report of its findings, determination as to guilt, and recommendation as to the measure of discipline to be imposed. In such cases the notice of hearing shall state that the licensee may file a written answer, brief and affidavits; that the licensee may appear personally before the regents review committee, may be represented by counsel and may present evidence or sworn testimony on behalf of the licensee, and the notice may contain such other information as may be considered appropriate by the department. The department may also present evidence or sworn testimony at the hearing. A stenographic record of the hearing shall be made. Such evidence or sworn testimony offered at the meeting of the regents review committee shall be limited to evidence and testimony relating to the nature and severity of the penalty to be imposed upon the licensee. The presiding officer at the meeting of the regents review committee may, in his or her discretion, reasonably limit the number of witnesses whose testimony will be received and the length of time any witness will be permitted to testify. In lieu of referring the matter to the board of regents, the regents review committee may refer any such matter for further proceedings pursuant to paragraph b or c of this subdivision or subdivision three of this section.

3. Adversary proceedings. Contested disciplinary proceedings and other disciplinary proceedings not resolved pursuant to subdivision two of this section shall be tried before a hearing panel of the appropriate state board as provided in this subdivision.

a. Notice of hearing. The department shall set the time and place of the hearing and shall prepare the notice of hearing. The notice of hearing shall state (1) the time and place of the hearing, (2) that the licensee may file a written answer to the charges prior to the hearing, (3) that the licensee may appear personally at the hearing and may be represented by counsel, (4) that the licensee shall have the right to produce witnesses and evidence in his behalf, to cross-examine witnesses and examine evidence produced against him, and to issue subpoenas in accordance with the provisions of the civil practice law and rules, (5) that a stenographic record of the hearing will be made, and (6) such other information as may be considered appropriate by the department.

b. Hearing panel. The hearing shall be conducted by a panel of three or more members, at least two of whom shall be members of the applicable state board for the profession, and at least one of whom shall be a public representative who is a member of the applicable state board or of the state board for another profession licensed pursuant to this title. The executive secretary for the applicable state board shall appoint the panel and shall designate its chairperson. After the commencement of a hearing, no panel member shall be replaced. A determination by the administrative officer of a need to disqualify or remove any panel member will result in the disqualification or removal of the panel and cause a new panel to be appointed. In addition to said panel members, the department shall designate an administrative officer, admitted to practice as an attorney in the state of New York, who shall have the authority to rule on all motions, procedures and other legal objections and shall draft a report for the hearing panel which shall be subject to the approval of and signature by the panel chairperson on behalf of the panel. The administrative officer shall not be entitled to a vote.

c. Conduct of hearing. The evidence in support of the charges shall be presented by an attorney for the department. The licensee shall have the rights required to be stated in the notice of hearing. The panel shall not be bound by the rules of evidence, but its determination of guilt shall be based on a preponderance of the evidence. A hearing which has been initiated shall not be discontinued because of the death or incapacity to serve of one member of the hearing panel.

d. Results of hearing. The hearing panel shall render a written report which shall include (1) findings of fact, (2) a determination of guilty or not guilty on each charge, and (3) in the event of a determination of guilty, a recommendation of the penalty to be imposed. For the panel to make a determination of guilty, a minimum of two of the voting members of the panel must vote for such a determination. A copy of the report of the hearing panel shall be transmitted to the licensee.

4. Regents decision procedures.

a. Regents review committee. The transcript and report of the hearing panel shall be reviewed at a meeting by a regents review committee appointed by the board of regents. The regents review committee shall consist of three members, at least one of whom shall be a regent.

b. Regents review committee meetings. The review shall be based on the transcript and the report of the hearing panel. The licensee may appear at the meeting, and the regents review committee may require the licensee to appear. The licensee may be represented by counsel. The department shall notify the licensee at least seven days before the meeting (1) of the time and place of the meeting, (2) of his right to appear, (3) of his right to be represented by counsel, (4) whether or not he is required to appear, and (5) of such other information as may be considered appropriate. After the meeting, the regents review committee shall transmit a written report of its review to the board of regents. In cases referred directly to the regents review committee pursuant to paragraph d of subdivision two of this section, the review shall be based upon the charges, the documentary evidence submitted by the department, any answer, affidavits or brief the licensee may wish to submit, and any evidence or sworn testimony presented by the licensee or the department at the hearing, pursuant to

the procedures described by paragraph d of subdivision two of this section.

c. Regents decision and order. The board of regents (1) shall consider the transcript, the report of the hearing panel, and the report of the regents review committee, (2) shall decide whether the licensee is guilty or not guilty on each charge, (3) shall decide what penalties, if any, to impose as prescribed in section sixty-five hundred eleven of this article, and (4) shall issue an order to carry out its decisions. Such decisions shall require the affirmative vote of a majority of the members of the board of regents. If the board of regents disagrees with the hearing panel's determination of not guilty, it shall remand the matter to the original panel for reconsideration or to a new panel for a new hearing. The panel's determination of not guilty on reconsideration or a new hearing shall be final. The order shall be served upon the licensee personally or by certified mail to the licensee's last known address and such service shall be effective as of the date of the personal service or five days after mailing by certified mail. The licensee shall deliver to the department the license and registration certificate which has been revoked, annulled, suspended, or surrendered within five days after the effective date of the service of the order. If the license or registration certificate is lost, misplaced or its whereabouts is otherwise unknown, the licensee shall submit an affidavit to that effect, and shall deliver such license or certificate to the department when located.

5. Court review procedures. The decisions of the board of regents may be reviewed pursuant to the proceedings under article seventy-eight of the civil practice law and rules. Such proceedings shall be returnable before the appellate division of the third judicial department, and such decisions shall not be stayed or enjoined except upon application to such appellate division after notice to the department and to the attorney general and upon a showing that the petitioner has a substantial likelihood of success.

6. The provisions of subdivisions one through four of this section shall not be applicable to proceedings in cases of professional misconduct involving the medical profession, except as provided in paragraph m of subdivision ten of section two hundred thirty of the public health law.

7. Notwithstanding any other provision of law, persons who assist the department as consultants or expert witnesses in the investigation or prosecution of alleged professional misconduct, licensure matters, restoration proceedings, or criminal prosecutions for unauthorized practice, shall not be liable for damages in any civil action or proceeding as a result of such assistance, except upon proof of actual malice. The attorney general shall defend such persons in any such action or proceeding, in accordance with section seventeen of the public officers law.

8. The files of the department relating to the investigation of possible instances of professional misconduct, or the unlawful practice of any profession licensed by the board of regents, or the unlawful use of a professional title or the moral fitness of an applicant for a professional license or permit, shall be confidential and not subject to disclosure at the request of any person, except upon the order of a court in a pending action or proceeding. The provisions of this subdivision shall not apply to documents introduced in evidence at a hearing held pursuant to this chapter and shall not prevent the department from sharing information concerning investigations with other duly authorized public agencies responsible for professional regulation or criminal prosecution.

§6510-b. Temporary surrender of licenses during treatment for drug or alcohol abuse.

1. The license and registration of a licensee who may be temporarily incapacitated for the active practice of a profession licensed pursuant to title eight of this chapter, except professionals licensed pursuant to article one hundred thirty-one or article one hundred thirty-one-b thereof, and whose alleged incapacity is the result of a problem of drug or alcohol abuse which has not resulted in harm to a patient or client, may be voluntarily surrendered to the department, which may accept and hold such license during the period of such alleged incapacity or the department may accept the surrender of such license after agreement to conditions to be met prior to the restoration of the license. The department shall give written notification of such surrender to the licensing authorities of any other state or country in which the licensee is authorized to practice. In addition to the foregoing, the department shall also give written notification of such surrender, for professionals licensed pursuant to articles one hundred thirty-two, one hundred thirty-three, one hundred thirty-five, one hundred thirty-seven, one hundred thirty-nine and one hundred forty-one of this chapter to the commissioner of health or his designee, and where appropriate to each hospital at which the professional has privileges, is affiliated, or is employed. The licensee whose license is so surrendered shall notify all persons who request professional services that he or she has temporarily withdrawn from the practice of the profession. The department may provide for similar notification of patients or clients and of other interested parties, as appropriate under the circumstances of the professional practice and responsibilities of the licensee. The licensure status of such licensee shall be "inactive" and he or she shall not be authorized to practice the profession and shall refrain from practice in this state or in any other state or country. The voluntary surrender shall not be deemed to be an admission of disability or of professional misconduct, and shall not be used as evidence of a violation of subdivision three or four of section sixty-five hundred nine of this chapter, unless the licensee practices while the license is “inactive”; and any such practice shall constitute a violation of subdivision eight of said section. The surrender of a license under this subdivision shall not bar any disciplinary action except action based solely upon the provisions of subdivision three or four of section sixty-five hundred nine of this chapter, and only if no harm to a patient has resulted; and shall not bar any civil or criminal action or proceeding which might be brought without regard to such surrender. A surrendered license shall be restored upon a showing to the satisfaction of the department that the licensee is not incapacitated for the active practice of the profession, provided that the department may, by order of the commissioner, impose reasonable conditions on the licensee, if it determines that because of the nature and extent of the licensee’s former incapacity, such conditions are necessary to protect the health, safety and welfare of the public. Prompt written notification of such restoration shall be given to all licensing bodies which were notified of the temporary surrender of the license.

2. There shall be appointed within the department, by the board of regents, a committee on drug and alcohol abuse, which shall advise the board of regents on matters relating to practice by professional licensees

with drug or alcohol abuse problems, and which shall administer the provisions of this section. The board of regents shall determine the size, composition, and terms of office of such committee, a majority of the members of which shall be persons with expertise in problems of drug or alcohol abuse. The committee shall recommend to the board of regents such rules as are necessary to carry out the purposes of this section, including but not limited to procedures for the submission of applications for the surrender of a license and for the referral of cases for investigation or prosecution pursuant to section sixty-five hundred ten of this article if a licensee fails to comply with the conditions of an approved program of treatment. There shall be an executive secretary appointed by the board of regents to assist the committee. The executive secretary shall employ, or otherwise retain, the services of a registered professional nurse with appropriate qualifications in substance abuse and addiction to assist in the implementation of the program authorized by section six thousand five hundred ten-c of this article. Determinations by the committee relating to licensees shall be made by panels of at least three members of the committee designated by the executive secretary, who shall also designate a member of the state board for the licensee's profession as the ex-officio non voting member of each panel. In the case of a determination relating to a licensed nurse, at least one panel member must be a registered professional nurse licensed by the state.

3. Application for the surrender of a license pursuant to this section shall be submitted to the committee, and shall identify a proposed treatment or rehabilitation program, and shall include a consent to the release of all information concerning the licensee's treatment to the committee. All information concerning an application, other than the fact of the surrender of the license and the participation in the program and the successful completion or failure of or withdrawal from the program, shall be strictly confidential, and may not be released by the committee to any person or body without the consent of the licensee. The immunity from disciplinary action conferred by this section shall be conditioned upon the approval of the treatment or rehabilitation program by the committee and its successful completion by the applicant and the elimination of the incapacity to practice. Approval of a treatment or rehabilitation program by the committee shall not constitute a representation as to the probability of success of the program or any assumption of financial responsibility for its costs.

4. The immunity from disciplinary action conferred by this section may be revoked by the committee upon a finding that the licensee has failed to successfully complete the program or that the incapacity to practice has not been eliminated. Such revocation shall be made only after notice and an opportunity to be heard, but no adjudicatory hearing shall be required. The matter shall be referred for appropriate proceedings pursuant to section sixty-five hundred ten of this chapter. The license must be returned unless charges are served pursuant to section sixty-five hundred ten within thirty days after the revocation of the approval of the special treatment afforded by this section.

5. The commissioner is authorized to adopt regulations to carry out the purposes of this section, including but not limited to the notice of temporary inactive status to be required in different professions and practice situations and the measures required upon temporary withdrawal from practice.

6. No individual who serves as a member of a committee whose purpose is to confront and refer either to treatment or to the department licensees who are thought to be suffering from alcoholism or drug abuse shall be liable for damages to any person for any action taken by such individual provided such action was taken without malice and within the scope of such individual's function as a member of such committee, and provided further that such committee has been established by and functions under the auspices of an association or society of professionals authorized to practice under this title.

7. In addition to the provisions of section two thousand eight hundred three-e of the public health law, any entity licensed pursuant to articles thirty-six, forty and forty-four of the public health law, and any mental hygiene facilities, and correctional, occupational, school and college health services shall provide a report to the office of professional discipline when there is a suspension, restriction, termination, curtailment or resignation of employment or privileges in any way related to a licensed nurse that is impaired when the impairment is alleged to have been caused by a drug-related problem. Any person, facility, or corporation which makes a report pursuant to this section in good faith shall have immunity from any liability, civil or criminal, for having made such a report except where the conduct constitutes negligence, gross negligence or intentional misconduct. For the purpose of any proceeding, civil or criminal, the good faith of any person, facility or corporation required to make a report shall be presumed. Such presumption may be rebutted by any competent evidence.

§6510-c. Nurse peer assistance programs.

1. As used in this section: a. "Drug-related problem" means a problem or problems that are related to the use, misuse or addiction to drugs or alcohol.

b. "Participant" means an individual licensed pursuant to article one hundred thirty-nine of this title who has or may have a drug-related problem.

c. "Approved nurse peer assistance program" means a program operated by the New York State Nurses Association or a statewide professional association of nurses which has experience in providing peer assistance services to nurses who have drug-related problems which are designed to help a participant or a licensee's employer and has been approved by the department in accordance with criteria established in regulations of the commissioner.

d. "Peer assistance services" includes assessing the needs of a participant, including early identification of drug-related problems, and providing information, support, and advice as requested by a participant.

2. a. The department shall provide funds, including but not limited to a portion of the funds made available pursuant to the provisions of this section, for services provided by an approved nurse peer assistance program. Funds used to provide services shall not be used for the treatment of participants. Funded services shall include, but not be limited to:

(1) providing peer assistance services for nurses with drug-related problems;

(2) maintaining a toll-free telephone information line for anonymous nurses, their employers, and others to provide assistance in the identification of services and information for nurses dealing with drug-related problems;

(3) training monitors for the

professional assistance program;

(4) arranging for mental health consultants to assess nurses for the professional assistance program, as needed; and

(5) preparing written assessments of nurses who have been referred from the professional assistance program. b. An additional fee of fifteen dollars shall be paid at the time of application for licensure and first registration and every registration by those licensed pursuant to article one hundred thirty-nine of this title for the purpose of implementing this program. The funds made available under this provision shall be deposited in the office of professions special revenue account for its purposes in implementing this section. The department may use a portion of this amount for its administrative expenses incurred in implementing this program including, but not limited to, employment of personnel, the costs of approving and contracting with a peer assistance program as required by this section and outreach activities to promote this program.

3. No approved nurse peer assistance program or individual who serves in an approved nurse peer assistance program shall be liable in damages to any person for any action taken or not taken or recommendations made unless, based on the facts disclosed by a participant, the conduct of the program or person with respect to the person asserting liability constituted negligence, gross negligence, or intentional misconduct.

4. All information concerning a participant gathered by the approved nurse peer assistance program shall be strictly confidential and may not be released to any person or body without the consent of the participant, except upon the order of a court in a pending action or proceeding. Aggregate data may be released to the committee on drug and alcohol abuse.

§6510-d. Voluntary non-disciplinary surrender of a license.

A professional who is licensed pursuant to article one hundred thirty-nine of this title may voluntarily surrender a license to the committee on drug and alcohol abuse when such licensee requests to be monitored and/or receive peer support services in relation to the use, misuse or addiction to drugs. The committee shall accept such voluntary non-disciplinary surrender of a license and provide for expedited reinstatement of the license if the licensee meets criteria set by the committee. Such criteria will include, but not be limited to, confidence that the licensee's use of drugs and/or alcohol has not resulted in harm to a patient or client and the licensee is not incapacitated, unfit for practice or a threat to the health, safety and welfare of the public. Such voluntary surrender, if accepted by the committee, shall result in an immediate reinstatement of the license and shall provide immunity from a violation of subdivision three or four of section six thousand five hundred nine of this article and cannot be deemed an admission or used as evidence in professional misconduct. Acceptance by the committee shall not require a report to the department of health or to any employer or licensing authority of another jurisdiction, nor require any disclosure to patients or to the public that such license has been temporarily surrendered, except if it is subsequently determined by the department that a participant being monitored by the department is found to have used drugs and/or alcohol which has resulted in harm to a patient or client.

§6511. Penalties for professional misconduct.

The penalties which may be imposed by the board of regents on a present or former licensee found guilty of professional misconduct (under the definitions and proceedings prescribed in sections sixty-five hundred nine and sixty-five hundred ten of this article) are:

(1) censure and reprimand,

(2) suspension of license, (a) wholly, for a fixed period of time; (b) partially, until the licensee successfully completes a course of retraining in the area to which the suspension applies; (c) wholly, until the licensee successfully completes a course of therapy or treatment prescribed by the regents;

(3) revocation of license,

(4) annulment of license or registration,

(5) limitation on registration or issuance of any further license,

(6) a fine not to exceed ten thousand dollars, upon each specification of charges of which the respondent is determined to be guilty,

(7) a requirement that a licensee pursue a course of education or training, and

(8) a requirement that a licensee perform up to one hundred hours of public service, in a manner and at a time and place as directed by the board. The board of regents may stay such penalties in whole or in part, may place the licensee on probation and may restore a license which has been revoked, provided, in the case of licensees subject to section two hundred thirty of the public health law, notice that the board is considering such restoration is given to the office of professional medical conduct at least thirty days before the date on which such restoration shall be considered. Upon the recommendation of the office of professional medical conduct, the board of regents may deny such restoration. Any fine imposed pursuant to this section or pursuant to subdivision two of section sixty-five hundred ten of this article may be sued for and recovered in the name of the people of the state of New York in an action brought by the attorney general. In such action the findings and determination of the board of regents or of the violations committee shall be admissible evidence and shall be conclusive proof of the violation and the penalty assessed.

Subarticle 4
Unauthorized Acts

§6512. Unauthorized practice a crime.

1. Anyone not authorized to practice under this title who practices or offers to practice or holds himself out as being able to practice in any profession in which a license is a prerequisite to the practice of the acts, or who practices any profession as an exempt person during the time when his professional license is suspended, revoked or annulled, or who aids or abets an unlicensed person to practice a profession,

or who fraudulently sells, files, furnishes, obtains, or who attempts fraudulently to sell, file, furnish or obtain any diploma, license, record or permit purporting to authorize the practice of a profession, shall be guilty of a class E felony.

2. Anyone who knowingly aids or abets three or more unlicensed persons to practice a profession or employs or holds such unlicensed persons out as being able to practice in any profession in which a license is a prerequisite to the practice of the acts, or who knowingly aids or abets three or more persons to practice any profession as exempt persons during the time when the professional licenses of such persons are suspended, revoked or annulled, shall be guilty of a class E felony.

§6513. Unauthorized use of a professional title a crime.

1. Anyone not authorized to use a professional title regulated by this title, and who uses such professional title, shall be guilty of a class A misdemeanor.

2. Anyone who knowingly aids or abets three or more persons not authorized to use a professional title regulated by this title, to use such professional title, or knowingly employs three or more persons not authorized to use a professional title regulated by this title, who use such professional title in the course of such employment, shall be guilty of a class E felony.

§6514. Criminal proceedings.

1. All alleged violations of sections sixty-five hundred twelve or sixty-five hundred thirteen of this article shall be reported to the department which shall cause an investigation to be instituted. All alleged violations of section sixty-five hundred thirty-one of the education law shall be reported to the department of health which shall cause an investigation to be instituted. If the investigation substantiates that violations exist, such violations shall be reported to the attorney general with a request for prosecution.

2. The attorney general shall prosecute such alleged offenses in the name of the state, provided, however, in the event of alleged violations of article one hundred fifty-five of this title, a district attorney may prosecute such alleged offenses in the name of the state provided, however, that any district attorney may prosecute such offenses where they are incidental to a criminal prosecution instituted by him under other statutes.

3. All criminal courts having jurisdiction over misdemeanors are hereby empowered to hear, try and determine alleged violations under this title, which constitute misdemeanors, without indictment and to impose applicable punishment of fines or imprisonments or both. It shall be necessary to prove in any prosecution under this title only a single prohibited act or a single holding out without proving a general course of conduct.

4. A proceeding before a committee on professional conduct shall not be deemed to be a criminal proceeding within the meaning of this section.

§6515. Restraint of unlawful acts.

Where a violation of this title is alleged to have occurred, the attorney general or the department, in the event of alleged violations of article one hundred fifty-five of this title occurring in cities having a population of one million or more, the corporation counsel may apply to the supreme court within the judicial district in which such violation is alleged to have occurred for an order enjoining or restraining commission or continuance of the unlawful acts complained of. The court shall have jurisdiction of the proceedings and shall have power to grant such temporary relief or restraining order as it deems just and proper. In any such proceeding it shall be unnecessary to allege or prove that an adequate remedy at law does not exist or that irreparable damage would result if such order were not granted. The remedy provided in this section shall be in addition to any other remedy provided by law or to the proceedings commenced against a licensee under this title.

§6516. Civil enforcement proceedings and civil penalties.

1. Issuance of cease and desist order. Whenever the department has reasonable cause to believe that any person has violated any provision of section sixty-five hundred twelve or sixty-five hundred thirteen of this article, the department may issue and serve upon such person a notice to cease and desist from such violation. Such cease and desist order shall be served personally by the department. If personal service can not be made after due diligence and such fact is certified under oath, a copy of the order shall be made by certified mail, return receipt requested, to the person`s last known address by the department.

2. Contents of cease and desist order. The cease and desist order shall be in writing and shall describe with particularity the nature of the violation, including a reference of the specific provision or provisions of law alleged to have been violated and an order to the respondent to cease any unlawful activity. The cease and desist order shall advise the respondent (a) of the right to contest the order by requesting a hearing within thirty days of the service of the cease and desist order before a hearing officer designated by the department (b) of the right to request a stay of the cease and desist order at the time a hearing is requested and (c) shall set forth the respondent`s rights at such a hearing pursuant to subdivision five of this section.

3. Civil penalties. Civil penalties up to five thousand dollars may be imposed for each violation and the respondent may be ordered to make restitution to any person who has an interest in any money or property, either real or personal, acquired by the respondent as a result of a violation. Whenever the department concludes that civil penalties and/or restitution may be warranted because of the egregiousness of the unlawful activity, it may serve, along with the cease and desist order, a notice of a hearing on the allegations of unlawful activity and the department`s intention to order the respondent to make restitution and/or impose a civil penalty. The notice should specify the civil penalty sought for each violation.

4. Request for hearing. If the respondent to a cease and desist order contests the cease and desist order, the respondent shall request a hearing conducted by the department within thirty days of the receipt of the cease and desist order. Such a hearing shall be scheduled, and the requesting party notified of the date, within fifteen days of the receipt of the request for a hearing. If the respondent requests a stay of the cease and desist order, the hearing officer shall determine whether the cease and desist order should be stayed in whole or in part within five working days of the request for a stay. The respondent may file a written answer to the cease and desist order prior to the hearing. A stenographic record of the hearing shall be made.

5. Conduct of hearing. The evidence in support of the cease and desist order shall be presented by an attorney for the department. The respondent may appear personally and may be represented by counsel at the hearing, may produce witnesses and evidence in his or her behalf at the hearing, may cross-examine witnesses and examine evidence produced against him or her at the hearing, and may issue subpoenas in accordance with section three hundred four of the state administrative procedure act. The hearing officer shall not be bound by the rules of evidence, but his or her determination that a violation of section sixty-five hundred twelve or sixty-five hundred thirteen of this article has occurred shall be based on a preponderance of the evidence. A hearing which has been initiated shall not be discontinued because of the death or incapacity of the hearing officer. In the event of a hearing officer`s death or incapacity to serve, a new hearing officer shall be designated by the department to continue the hearing. The new hearing officer shall affirm in writing that he or she has read and considered evidence and transcripts of the prior proceedings.

6. Results of hearing. The hearing officer designated by the department shall render a written report which shall include (a) findings of fact, (b) a determination on each violation alleged in the cease and desist order, (c) a determination as to whether to accept, reject, or modify any of the terms of the cease and desist order in whole or in part, and (d) the civil penalty imposed, if any. A copy of the hearing officer`s written report shall be served upon the respondent with a notice setting forth the respondent`s rights to an administrative appeal within ten days of the conclusion of the hearing.

7. Appeals. The decision of the hearing officer shall be final, except that it may be appealed to a regents review committee within twenty days of the receipt of the hearing officer`s report. The initiation of an appeal shall not in and of itself affect the validity or terms of the cease and desist order. The regents review committee shall consist of three members, at least one of whom shall be a regent. The review shall be based on the transcript and the report of the hearing officer. The respondent may appear at the meeting, and the regents review committee may require the respondent to appear. The respondent may be represented by counsel. The department shall notify the respondent at least ten days before the meeting (a) of the time and place of the meeting, (b) of the right to appear, (c) of the right to be represented by counsel, (d) whether or not the respondent is required to appear, and (e) of such other information as may be considered appropriate. After the meeting, the regents review committee shall transmit a written report of its review to the board of regents. The board of regents (i) shall consider the transcript, the report of the hearing officer, and the report of the regents review committee, (ii) shall decide whether the respondent has violated each charge in the cease and desist order, (iii) shall decide what penalties, if any, to impose as prescribed in this section, and (iv) shall issue an order to carry out its decisions. Such decisions shall require the affirmative vote of a majority of the members of the board of regents. The order shall be served upon the respondent personally or by certified mail to the respondent`s last known address and such service shall be effective as of the date of the personal service or five days after mailing by certified mail. The decisions of the board of regents under this section may be reviewed in a proceeding pursuant to article seventy-eight of the civil practice law and rules brought in the supreme court, Albany county. Such decisions shall not be stayed or enjoined except upon application to such supreme court pursuant to article sixty-three of the civil practice law and rules with notice to the department and to the attorney general.

8. General enforcement of cease and desist order. In any case where the cease and desist order is confirmed by the board of regents or where the respondent does not request an administrative hearing within the allotted time or does not appeal the decision of the hearing officer within the allotted time, an action or proceeding may be filed in the name of the state of New York seeking a restraining order, injunction, appropriate writ, or judgment against any person who violates the terms of the cease and desist order.

9. Special enforcement of civil monetary penalties. Provided that no appeal is pending on the imposition of such civil penalty, in the event such civil penalty imposed by the department remains unpaid, in whole or in part, more than forty-five days after written demand for payment has been sent by first class mail to the address of the respondent, a notice of impending default judgment shall be sent by first class mail to the respondent. The notice of impending default judgment shall advise the respondent: (a) that a civil penalty was imposed on the respondent; (b) the date the penalty was imposed; (c) the amount of the civil penalty; (d) the amount of the civil penalty that remains unpaid as of the date of the notice; (e) the violations for which the civil penalty was imposed; and (f) that a judgment by default will be entered in the supreme court, Albany county unless the department receives full payment of all civil penalties due within twenty days of the date of the notice of impending default judgment. If full payment shall not have been received by the department within thirty days of mailing of the notice of impending default judgment, the department shall proceed to enter with such court a statement of the default judgment containing the amount of the penalty or penalties remaining due and unpaid, along with proof of mailing of the notice of impending default judgment. The filing of such judgment shall have the full force and effect of a default judgment duly docketed with such court pursuant to the civil practice law and rules and shall in all respects be governed by that chapter and may be enforced in the same manner and with the same effect as that provided by law in respect to execution issued against property upon judgments of a court of record. A judgment entered pursuant to this subdivision shall remain in full force and effect for eight years notwithstanding any other provision of law.

REGENTS RULES
Part 17
Disciplinary Proceedings in the Professions

Note: Laws and regulations are current as of the date of publication.

§17.1 Complaints or other information.

All complaints or other information relating to licensees authorized to practice a profession under title VIII of the Education Law shall be referred to the director of the Office of Professional Discipline.

§17.2 Investigation.

The director of the Office of Professional Discipline or that officer's designee shall, in matters involving possible professional misconduct, initiate an investigation of each such complaint or other information.

§17.3 Prosecution or settlement of disciplinary proceedings.

Prosecution or settlement of disciplinary proceedings shall be conducted as provided in title VIII of the Education Law, and as provided in this Part.

§17.4 Reports.

The director of the Office of Professional Discipline or that officer's designee shall submit a report by April first of each year on the status of cases investigated during the previous year, as well as on the disposition of any criminal or civil matters processed through the office, to the chairman of the State Board for each of the professions supervised by the Board of Regents.

§17.5 Consent orders.

Disciplinary proceedings conducted pursuant to the provisions of title VIII of the Education Law may be disposed of in accordance with the following procedure:

(a) A licensee who is under investigation, or against whom charges have been voted, who admits guilt to at least one of the acts of misconduct alleged or charged, in full satisfaction of all allegations or charges, or who does not contest the allegations or charges or who cannot successfully defend against at least one of the acts of misconduct alleged or charged, shall notify the director of the Office of Professional Discipline or the director's designee.

(b) If the director of the Office of Professional Discipline or the director's designee, a designated member of the State Board for the applicable profession, and the licensee agree to a statement by the licensee admitting guilt to one or more of the allegations or charges or setting forth a decision not to contest the allegations or charges or stating that the licensee cannot successfully defend against such allegations or charges and agreeing to a proposed penalty, and if a designated member of the Board of Regents thereafter agrees to such statement and proposed penalty, and if the Committee on the Professions thereafter agrees to such statement and proposed penalty, a written application, signed by all the above except the Committee on the Professions, shall be submitted by the licensee to the Board of Regents based upon the statement and proposed penalty consenting to the issuance of an order of the Commissioner of Education or his or her designee effectuating such penalty. The provisions of this section shall apply to licensees subject to disciplinary proceedings conducted pursuant to title VIII of the Education Law. They shall be applicable to individuals licensed or registered pursuant to articles 131 or 131-B of title VIII of the Education Law for those cases in which charges of professional misconduct were served on or before July 26, 1991, the effective date of Chapter 606 of the Laws of 1991. They shall also be applicable to licensees and registrants subject to article 137 of the Education Law. With respect to such licensees subject to articles 131 or 131-B of title VIII of the Education Law, the agreement of the director of the Office of Professional Medical Conduct or that officer's designee, and of the Commissioner of Health or his or her designee, to the statement and proposed penalty and their signatures on the application shall be required in lieu of the agreement and signature of the director of the Office of Professional Discipline. With respect to such licensees subject to the provisions of articles 131 or 131-B of title VIII of the Education Law, the term *State Board* as used in this section means the State Board for Professional Medical Conduct. With respect to licensees and registrants subject to article 137 of the Education Law, the agreement of the executive secretary of the State Board for Pharmacy to the statement and proposed penalty and his or her signature on the application shall also be required.

(c) The application shall be in such form and shall contain such substance as is acceptable to the director of the Office of Professional Discipline or the director's designee.

(d) In the event an application is not granted by the Board of Regents, nothing contained therein shall be binding upon the licensee or construed to be an admission of any act of misconduct alleged or charged, and such application shall not be used against the licensee in any way. Any such application shall be kept in strict confidence during the pendency of the disciplinary proceeding. In addition, such denial by the Board of Regents shall be without prejudice to the continuance of the disciplinary proceeding and the final determination by the Board of Regents pursuant to the provisions of the Education Law.

(e) In the event the Board of Regents grants the application, the commissioner or his or her designee shall issue an order in accordance therewith.

§17.6 Surrender of license.

Disciplinary proceedings conducted pursuant to the provisions of title VIII of the Education Law may be disposed of in accordance with the following procedure:

(a) A licensee who is under investigation or against whom charges have been voted, who wishes to surrender his or her license to practice any of the professions enumerated in title VIII, shall notify the director of the Office of Professional Discipline or that officer's designee.

(b) An application to surrender a license shall be based upon a statement that the licensee admits guilt to at least one of the acts of misconduct alleged or charged, in full satisfaction of all allegations or charges, or does not contest the allegations or charges, or cannot successfully defend against at least one of the acts of misconduct alleged or charged. If the director or the director's designee, a designated member of the State Board for the applicable profession, and the licensee agree to such statement, and if a designated member of the Board of Regents thereafter agrees to such statement, and if the Committee on the Professions thereafter agrees to such statement, a written application, signed by the licensee, shall be submitted to the Board of Regents. The application shall be in such form and shall contain such substance as is acceptable to the director of the Office of Professional Discipline or the director's designee. The provisions of this section shall apply to licensees subject to disciplinary proceedings conducted pursuant

to title VIII of the Education Law. They shall be applicable to individuals licensed or registered pursuant to articles 131 or 131-B of title VIII of the Education Law for those cases in which charges of professional misconduct were served on or before July 26, 1991, the effective date of Chapter 606 of the Laws of 1991. They shall also be applicable to licensees and registrants subject to article 137 of the Education Law. With respect to such licensees subject to articles 131 or 131-B of title VIII of the Education Law, the agreement of the director of the Office of Professional Medical Conduct or that officer's designee and the Commissioner of Health or his or her designee to the statement, and their signature on the application, shall be required in lieu of the agreement and signature of the director of the Office of Professional Discipline. With respect to such licensees subject to articles 131 or 131-B of title VIII of the Education Law, the term *State Board* as used in this section means the State Board for Professional Medical Conduct. With respect to licensees and registrants subject to article 137 of the Education Law, the agreement of the executive secretary of the State Board of Pharmacy to the statement and his or her signature on the application shall also be required.

(c) In the event the application is not granted by the Board of Regents, nothing contained therein shall be binding upon the licensee or construed to be an admission of any act of misconduct alleged or charged, and such application shall not be used against the licensee in any way. The application shall be kept in strict confidence during the pendency of the disciplinary proceeding. In addition, any such denial by the Board of Regents shall be made without prejudice to the continuance of any disciplinary proceeding and the final determination by the Board of Regents pursuant to the provisions of the Education Law.

(d) In the event the Board of Regents grants the application, the commissioner or his or her designee shall issue an order in accordance therewith.

§17.7 Violation of probation.

(a) Upon the receipt of information indicating that the respondent may be in violation of any of the terms or conditions of respondent's probation, the department shall conduct an investigation.

(b) The director of the Office of Professional Discipline shall review the results of the investigation and if the director determines that a violation of probation proceeding is warranted, the director shall give notice to the respondent, by letter, of the facts forming the basis of the alleged violation of respondent's probation. The respondent, in said letter, shall be requested to indicate whether there is any dispute as to the facts, and shall be informed that if respondent disputes any of the facts the respondent shall be entitled to a hearing thereon.

(c) If the respondent does not dispute the facts forming the basis of the alleged violation of probation, the matter shall be submitted to the Regents Review Committee for its review and recommendations(s) [sic] as to whether, based upon the undisputed facts, there has been a violation of the terms or conditions of respondent's probation and, if so, as to the measure of discipline to be imposed upon the respondent.

(d) If the respondent disputes any of the facts forming the basis of the alleged violation of probation, the respondent shall be afforded a hearing before a hearing officer appointed by the commissioner to hear and make findings of fact, conclusions of law and recommendation(s). The department shall give the respondent at least 10 days' notice of the hearing, 15 if by mail. The evidence in support of the application shall be presented by counsel on behalf of the department and the respondent shall also have the right to be represented by counsel. The department and the respondent have the right to produce witnesses and other evidence, to cross-examine witnesses, and to examine any other evidence produced at the hearing. A stenographic record of the hearing will be made, and the hearing officer shall not be bound by the rules of evidence, but the findings of fact and conclusions of law of the hearing officer shall be based upon substantial evidence.

(e) The report of the hearing officer shall be reviewed by the Regents Review Committee.

(f) The Regents Review Committee shall notify the respondent, at least seven days before its meeting, of the time and place of such meeting, and shall also notify the respondent of the opportunity to appear in person and to be represented by counsel at such meeting.

(g) The Regents Review Committee shall transmit the report of the hearing officer and a written report of its review to the Board of Regents. The final determination shall be made by the Board of Regents, and the commissioner or his or her designee shall issue an order implementing such determination.

(h) The measure of discipline to be imposed for any violation of probation may be to continue the respondent on probation for a period in addition to the period of probation imposed in the original order, or to terminate the probation, vacate the stay of execution, and impose any measure of discipline authorized by section 6511 of the Education Law. A violation of probation shall constitute unprofessional conduct, and may constitute the basis for proceedings under either the provisions of section 6510 of the Education Law or of this Part.

§17.8 Hearing panel; administrative officers.

Findings of fact, recommendations as to penalties to be imposed, and any other actions taken by a hearing panel in disciplinary proceedings, except as hereinafter set forth, shall be made by majority vote. Any determination of guilt shall require a minimum of a four fifths vote of the hearing panel. An administrative officer, admitted to practice as an attorney in the State of New York, shall rule on all motions, procedures and other legal objections, and draft a report which shall reflect the determination and recommendation of the panel and be subject to the approval of and signature by the panel chairperson on behalf of the panel. The administrative officer shall not be entitled to a vote.

§17.9 Summary suspensions.

(a) If the director of the Office of Professional Discipline or that officer's designee believes that the public health, safety or welfare imperatively requires emergency action against a professional license, certificate, registration, permit or other authorization of the licensee to practice under title VIII of the Education Law, the director or the director's designee may make an application, on behalf of the department, to the Board of Regents for the summary suspension of said authorization pending the prompt institution prosecution and completion of formal disciplinary proceedings as provided under section 6510 of the Education Law.

(b) Summary suspension proceedings shall be commenced by the service on the licensee of a notice of hearing and a verified petition. The notice of hearing shall state the time and place of oral argument on the application for summary suspension and the regent designated by the chancellor to hear the matter, and shall include a copy of this rule. The notice of hearing and petition shall be personally served upon the licensee no later than five days prior to the date set for oral argument. If personal service cannot be made after due diligence, the notice of hearing and petition may be served by certified mail, to the licensee's last known address, not less than eight days prior to the date set for oral argument. The petition shall set forth the basis for the application and shall include sworn statements upon personal knowledge and/or exhibits demonstrating probable cause to believe that respondent has committed professional misconduct and that the public health, safety or welfare imperatively requires emergency action to summarily suspend respondent's license. A verified answer and any sworn statements and supporting exhibits may be served by respondent upon the director of the Office of Professional Discipline or the director's designee no later than two days prior to the date set for oral argument. The director of the Office of Professional Discipline or the director's designee may serve a verified reply, together with any sworn statement and supporting exhibits, to the answer no later than the day prior to the date of oral argument. The answer and/or reply may be served by certified mail by mailing to the addressee no later than three and two days, respectively, prior to the date set for oral argument. The petition, answer and reply, together with any sworn statement and supporting exhibits, shall be transmitted at the time of service of each paper to the regent designated to hear the case. Saturdays, Sundays and legal holidays shall be excluded in calculating the periods of time set forth in this subdivision.

(c) At the oral argument, the Office of Professional Discipline and respondent and/or his or her attorney shall have the right to be heard, but no testimony shall be taken and no transcript of oral arguments shall be required. No further papers shall be submitted at the oral argument except by permission of the regent designated to conduct the proceeding.

(d) The regent designated by the chancellor to conduct the proceeding shall submit a written report of his or her conclusions and recommendation(s) to the Board of Regents, which shall determine whether to grant or deny the application for summary suspension. A determination by the Board of Regents granting the application must be based upon a finding that the public health, safety or welfare imperatively requires emergency action.

(e) Any determination of the Board of Regents shall be without prejudice to the department or licensee in any subsequent formal disciplinary proceeding.

REGENTS RULES
Part 24
Committee on the Professions

§24.1 Membership.

The Committee on the Professions shall consist of three department officers designated by the Board of Regents pursuant to section 6506(10) of the Education Law.

§24.2 Purpose.

The Committee on the Professions shall review and make recommendations or determinations in licensing and disciplinary matters as provided in this Part or pursuant to referrals from the Board of Regents.

§24.3 Standards.

The Committee on the Professions shall review and determine questions of the preprofessional or professional education of applicants for licensure or other authorizations to practice in accordance with the following standards.

(a) *Preprofessional education.*

(1) The Committee on the Professions may accept graduation from a professional program which is either registered by the department or nationally accredited in lieu of a maximum of six semester hours of preprofessional education.

(2) The Committee on the Professions may accept postsecondary study satisfactory to the department and performed after completion of professional study requirements in lieu of a maximum of 30 semester hours of required preprofessional study.

(b) *Professional education.* As the equivalent of a professional program registered by the department, the Committee on the Professions may accept a professional program which is:

(1) offered by an institution accredited by an accrediting organization acceptable to the department or recognized by appropriate civil authorities of the country in which the school is located as an acceptable program of preparation for professional practice;

(2) designed and conducted by the degree-granting institution to prepare graduates for the professional practice of the profession in the State or country in which the institution is located; and

(3) demonstrated to be the substantial equivalent in scope, content and resources to a program meeting the requirements established by Part 52 of this Title for the registration of a professional licensure qualifying program in the State.

(c) *Waiver of citizenship requirement for an alien physician.* The Committee on the Professions shall be authorized to grant a one-time three-year waiver of the citizenship requirement for medical licensure to an alien physician, provided that such applicant:

(1) applies for medical licensure;

(2) meets all requirements for a medical license except citizenship;

(3) agrees to maintain lawful immigration status; and

(4) agrees to practice in an area

which has been designated by the State Education Department as medically underserved.

§24.4 Review of appeals - education or experience.

The Committee on the Professions may review and determine appeals for licensing determinations of the department staff relating to education or experience requirements if the chairman of the committee determines that the appeal involves a substantial or novel question which should be reviewed by the committee.

§24.5 Review of appeals - license surrender and restoration.

The Committee on the Professions shall review and determine appeals pursuant to section 18.7 of this Title relating to the voluntary surrender and restoration of licenses.

§24.6 Review of questions of moral character.

The Committee on the Professions shall review and determine questions of moral character in accordance with the provisions of Part 28 of this Title.

§24.7 Review in other cases.

(a) The Committee on the Professions shall review and submit its recommendation to the Board of Regents for final determinations in the following cases:

(1) applications pursuant to Education Law, section 6506(5), for the waiver of an education, experience or examination requirement on the ground that the requirement has been substantially met; and

(2) petitions for restoration of a professional license which has been revoked or surrendered pursuant to sections 6510 or 6510-a of the Education Law or title II-A of article 2 of the Public Health Law. For individuals served prior to June 20, 1997 with an order of revocation, acceptance of surrender, or denial of an application for restoration or reinstatement by vote of the Board of Regents, at least one year shall have elapsed from the date of such service for the acceptance by the department of a petition to the Board of Regents for restoration of a license or certificate, except that a period of time during which the license was suspended during the pendency of the discipline proceeding may reduce the one-year waiting period. For individuals served on or after June 20, 1997 with an order of revocation, acceptance of surrender, or denial of an application for restoration or reinstatement by vote of the Board of Regents, at least three years shall have elapsed from the date of such service for the acceptance by the department of a petition to the Board of Regents for restoration of a license or certificate, except that a period of time during which the license was suspended during the pendency of the discipline proceeding may reduce the three-year waiting period. This section shall not apply to restoration of licenses which have been temporarily surrendered pursuant to Education Law, section 6520-b, or Public Health Law, section 230(13).

(i) Materials submitted in response to the Committee on the Professions' recommendation to the Board of Regents shall be filed no later than 15 days following the postmarked date of the written notification of the decision or recommendation of the Committee on the Professions.

(ii) If an applicant has failed to remain current with developments in the profession, and a substantial question is presented as to the applicant's current fitness to enter in to the active practice of the profession, the Board of Regents may require that the applicant take and obtain satisfactory grades on a proficiency examination satisfactory to the department prior to the issuance of a license or limited permit.

(iii) An applicant shall pay to the department a fee of $750 at the time he or she submits an application for the restoration of a professional license, which has been revoked or surrendered as prescribed in this paragraph.

(b) The Committee on the Professions shall review and determine whether to agree to the following:

(1) a statement upon which an application for a consent order is based and proposed penalty, pursuant to section 17.5 of this Title; and

(2) a statement upon which an application to surrender a license is based, pursuant to section 17.6 of this Title.

§24.8 Unacceptable practice protocols.

The Committee on the Professions shall review and determine appeals from findings of unacceptable practice protocols involving nurse practitioners and collaborating physicians.

§24.9 Reconsideration.

An application for reconsideration of a determination made by the Committee on the Professions or by the Board of Regents following a Committee on the Professions recommendation may be accepted upon a showing that the original action was based on an error of law, or that there is new and material evidence which was not previously available, or that circumstances have changed subsequent to the original determination.

REGENTS RULES
Part 28
Determination of Good Moral Character in the Professions

§28.1 Determination of good moral character.

The determination of whether an applicant for authorization to practice a profession, under title VIII of the Education Law, is of good moral character shall be made in accordance with the procedures specified in this Part.

Note: Laws and regulations are current as of the date of publication.

§28.2 Information.

All information indicating that an applicant has been convicted of a crime, or has committed an act which raises a reasonable question as to the applicant's moral character, shall be referred to the director of the Office of Professional Discipline or his or her designee.

§28.3 Investigation.

The director of the Office of Professional Discipline, or his or her designee, shall arrange for a full and complete investigation of the circumstances surrounding such conviction or act. If it is determined that a reasonable question exists as to the applicant's moral character, then the director, or his or her designee, shall submit the results of the investigation, including any letters of reference from peers or others which may have been submitted by the applicant, to a panel of the appropriate professional State Board for its review. The panel shall consist of three or more members of the State Board.

§28.4 Review.

Upon such review, the panel, by majority vote, may conclude in favor of the applicant to the effect that the moral character of the applicant is adequate for licensure, thereby fulfilling that licensure requirement, and the applicant and the director of the Division of Professional Licensing Services shall be notified of such conclusion by the Office of Professional Discipline. If, upon such review, the panel concludes, by a majority vote, that a substantial question exists as to the moral character of the applicant, the applicant shall be notified thereof. Upon the written request of the applicant, within 30 days after receipt of such notice, the department shall schedule a hearing on such question.

§28.5 Hearing.

The applicant shall be given 15 days' notice, by mail, of the time and place of the hearing and a statement of the matters asserted which raised the question of the applicant's moral character. The applicant may be represented at the hearing by an attorney, may cross-examine witnesses, may produce witnesses, and may present evidence in support of the applicant's good moral character. The hearing, at which a verbatim record shall be taken, shall take place before a panel consisting of three or more members of the appropriate professional State Board, and before an administrative officer admitted to practice as an attorney in the State of New York, designated by the department. Such administrative officer shall have authority to rule on all motions, procedures and other legal objections, but shall not be entitled to vote in the determination of the panel. The determination of the panel shall be made by a majority vote of the panel and shall be rendered in a written report which shall be drafted by the administrative officer, shall reflect the determination and recommendations of the panel, and shall be subject to the approval of and signature by the panel chairperson on behalf of the panel. Copies of the report shall be forwarded to the director of the Division of Professional Licensing Services and to the applicant.

§28.6 Appeal.

The applicant or the director of the Office or Professional Discipline may appeal the determination of the panel concerning the licensure requirement of good moral character by filing a written notice of appeal therefrom with the Committee on the Professions within 30 days after service of the report of the panel upon the party taking the appeal. In the event no appeal is taken from the determination of the panel, the determination of the panel shall be final. In the event either party appeals from the determination of the panel, the appellant may submit a brief to the Committee on the Professions and the opposing party within 30 days after filing the notice of appeal. An answering brief may be filed by the opposing party with the Committee on the Professions within 20 days after the receipt by the opposing party of the brief submitted by the appellant. The Committee on the Professions may affirm, reverse or modify the determination of the panel and/or make such other determination as it may deem just and proper under the circumstances. The determination of the Committee on the Professions shall be final and copies thereof shall be forwarded to the applicant and to the director of the Office of Professional Discipline.

§28.7 Reapplication.

Whether or not the applicant appeals from the determination of the panel, the applicant may reapply for licensure to the director of the Division of Professional Licensing Services after the expiration of 18 months from the date of service of the report of the panel.

§28.8 Proficiency examination.

If the Committee on the Professions determines that the applicant otherwise meets the moral character requirements, but has failed to remain current with developments in the profession, and a substantial question is presented as to the applicant's current fitness to enter into the active practice of the profession, the Committee on the Professions may require that the applicant take and obtain satisfactory grades on a proficiency examination satisfactory to the department prior to the issuance of a license or limited permit.

REGENTS RULES
Part 29
Unprofessional Conduct

§29.1 General provisions.

(a) Unprofessional conduct shall be the conduct prohibited by this section. The provisions of these rules applicable to a particular profession may define additional acts or omissions as unprofessional conduct and may establish exceptions to these general prohibitions.

(b) Unprofessional conduct in the practice of any profession licensed, certified or registered pursuant to title VIII of the Education Law, except for cases involving those professions licensed, certified or registered pursuant to the provisions of Article 131 or 131-B of such law in which a statement of charges of professional

misconduct was not served on or before July 26, 1991, the effective date of chapter 606 of the Laws of 1991, shall include:

(1) willful or grossly negligent failure to comply with substantial provisions of Federal, State or local laws, rules or regulations governing the practice of the profession;

(2) exercising undue influence on the patient or client, including the promotion of the sale of services, goods, appliances or drugs in such manner as to exploit the patient or client for the financial gain of the practitioner or of a third party;

(3) directly or indirectly offering, giving, soliciting, or receiving or agreeing to receive, any fee or other consideration to or from a third party for the referral of a patient or client or in connection with the performance of professional services;

(4) permitting any person to share in the fees for professional services, other than: a partner, employee, associate in a professional firm or corporation, professional subcontractor or consultant authorized to practice the same profession, or a legally authorized trainee practicing under the supervision of a licensed practitioner. This prohibition shall include any arrangement or agreement whereby the amount received in payment for furnishing space, facilities, equipment or personnel services used by a professional licensee constitutes a percentage of, or is otherwise dependent upon, the income or receipts of the licensee from such practice, except as otherwise provided by law with respect to a facility licensed pursuant to article 28 of the Public Health Law or article 13 of the Mental Hygiene Law;

(5) conduct in the practice of a profession which evidences moral unfitness to practice the profession;

(6) willfully making or filing a false report, or failing to file a report required by law or by the Education Department, or willfully impeding or obstructing such filing, or inducing another person to do so;

(7) failing to make available to a patient or client, upon request, copies of documents in the possession or under the control of the licensee which have been prepared for and paid for by the patient or client;

(8) revealing of personally identifiable facts, data or information obtained in a professional capacity without the prior consent of the patient or client, except as authorized or required by law;

(9) practicing or offering to practice beyond the scope permitted by law, or accepting and performing professional responsibilities which the licensee knows or has reason to know that he or she is not competent to perform, or performing without adequate supervision professional services which the licensee is authorized to perform only under the supervision of a licensed professional, except in an emergency situation where a person's life or health is in danger;

(10) delegating professional responsibilities to a person when the licensee delegating such responsibilities knows or has reason to know that such person is not qualified, by training, by experience or by licensure, to perform them;

(11) performing professional services which have not been duly authorized by the patient or client or his or her legal representative;

(12) advertising or soliciting for patronage that is not in the public interest:

(i) Advertising or soliciting not in the public interest shall include, but not be limited to, advertising or soliciting that:

(*a*) is false, fraudulent, deceptive or misleading;

(*b*) guarantees any service;

(*c*) makes any claim relating to professional services or products or the cost or price therefor which cannot be substantiated by the licensee, who shall have the burden of proof;

(*d*) makes claims of professional superiority which cannot be substantiated by the licensee, who shall have the burden of proof; or

(*e*) offers bonuses or inducements in any form other than a discount or reduction in an established fee or price for a professional service or product.

(ii) The following shall be deemed appropriate means of informing the public of the availability of professional services:

(*a*) informational advertising not contrary to the foregoing prohibitions; and

(*b*) the advertising in a newspaper, periodical or professional directory or on radio or television of fixed prices, or a stated range or prices, for specified routine professional services, provided that if there is an additional charge for related services which are an integral part of the overall service being provided by the licensee, the advertisement shall so state, and provided further that the advertisement indicates the period of time for which the advertised prices shall be in effect.

(iii) (*a*) all licensees placing advertisements shall maintain, or cause to be maintained, an exact copy of each advertisement, transcript, tape or videotape thereof as appropriate for the medium used, for a period of one year after its last appearance. This copy shall be made available for inspection upon demand of the Education Department;

(*b*) a licensee shall not compensate or give anything of value to representatives of the press, radio, television or other communications media in anticipation of or in return for professional publicity in a news item;

(iv) Testimonials, demonstrations, dramatizations, or other portrayals of professional practice are permissible provided that they otherwise comply with the rules of professional conduct and further provided that the following conditions are satisfied:

(*a*) the patient or client expressly authorizes the portrayal in writing;

(*b*) appropriate disclosure is included to prevent any misleading information or imagery as to the identity of the patient or client;

(*c*) reasonable disclaimers are included as to any statements made or results achieved in a particular matter;

(*d*) the use of fictional situations or characters may be used if no testimonials are included; and

(*e*) fictional client testimonials are not permitted;

(13) failing to respond within 30 days to written communications from the Education Department or the Department of Health and to make available any relevant records with respect to an inquiry or complaint about the licensee's unprofessional conduct. The period of 30 days shall commence on the date when such communication was delivered personally to the licensee. If the communication is sent from either department by registered or certified mail, with return receipt requested, to the address appearing in the last registration, the period of 30 days shall commence on the date of delivery to the licensee, as indicated by the return receipt;

(14) violating any term of probation or condition or limitation imposed on the licensee by the Board of Regents pursuant to Education Law, section 6511.

§29.2 General provisions for health professions.

(a) Unprofessional conduct shall also include, in the professions of:

acupuncture
athletic training
audiology
certified dental assisting
chiropractic
dental hygiene
dentistry
dietetics/nutrition
licensed practical nursing
massage therapy
medicine
midwifery
occupational therapy
occupational therapy assistant
ophthalmic dispensing
optometry
pharmacy
physical therapist assistant
physical therapy
physician assistant
podiatry
psychology
registered professional nursing
respiratory therapy
respiratory therapy technician
social work
specialist assistant
speech-language pathology, except for cases involving those professions licensed, certified or registered pursuant to the provisions of article 131 or 131-B of the Education Law in which a statement of charges of professional misconduct was not served on or before July 26, 1991, the effective date of chapter 606 of the Laws of 1991:

(1) abandoning or neglecting a patient or client under and in need of immediate professional care, without making reasonable arrangements for the continuation of such care, or abandoning a professional employment by a group practice, hospital, clinic or other health care facility, without reasonable notice and under circumstances which seriously impair the delivery of professional care to patients or clients;

(2) willfully harassing, abusing or intimidating a patient either physically or verbally;

(3) failing to maintain a record for each patient which accurately reflects the evaluation and treatment of the patient. Unless otherwise provided by law, all patient records must be retained for at least six years. Obstetrical records and records of minor patients must be retained for at least six years, and until one year after the minor patient reaches the age of 21 years;

(4) using the word "Doctor" in offering to perform professional services without also indicating the profession in which the licensee holds a doctorate;

(5) failing to exercise appropriate supervision over persons who are authorized to practice only under the supervision of the licensed professional;

(6) guaranteeing that satisfaction or a cure will result from the performance of professional services;

(7) ordering of excessive tests, treatment, or use of treatment facilities not warranted by the condition of the patient;

(8) claiming or using any secret or special method of treatment which the licensee refuses to divulge to the State Board for the profession;

(9) failing to wear an identifying badge, which shall be conspicuously displayed and legible, indicating the practitioner's name and professional title authorized pursuant to the Education Law, while practicing as an employee or operator of a hospital, clinic, group practice or multiprofessional facility, registered pharmacy, or at a commercial establishment offering health services to the public;

(10) entering into an arrangement or agreement with a pharmacy for the compounding and/or dispensing of coded or specially marked prescriptions;

(11) with respect to all professional practices conducted under an assumed name, other than facilities licensed pursuant to article 28 of the Public Health Law or article 13 of the Mental Hygiene Law, failing to post conspicuously at the site of such practice the names and the licensure field of all of the principal professional licensees engaged in practice at that site (*i.e.*, principal partners, officers or principal shareholders);

(12) issuing prescriptions for drugs and devices which do not contain the following information: the date written, the prescriber's name, address, telephone number, profession and registration number, the patient's name, address, and age, the name, strength and quantity of the prescribed drug or device, as well as the directions for use by the patient. In addition, all prescriptions for controlled substances shall meet the requirements of article 33 of the Public Health Law; and

(13) failing to use scientifically accepted infection prevention techniques appropriate to each profession for the

cleaning and sterilization or disinfection of instruments, devices, materials and work surfaces, utilization of protective garb, use of covers for contamination-prone equipment and the handling of sharp instruments. Such techniques shall include but not be limited to:

(i) wearing of appropriate protective gloves at all times when touching blood, saliva, other body fluids or secretions, mucous membranes, nonintact skin, blood-soiled items or bodily fluid-soiled items, contaminated surfaces, and sterile body areas, and during instrument cleaning and decontamination procedures;

(ii) discarding gloves used following treatment of a patient and changing to new gloves if torn or damaged during treatment of a patient; washing hands and donning new gloves prior to performing services for another patient; and washing hands and other skin surfaces immediately if contaminated with blood or other body fluids;

(iii) wearing of appropriate masks, gowns or aprons, and protective eyewear or chin-length plastic face shields whenever splashing or spattering of blood or other body fluids is likely to occur;

(iv) sterilizing equipment and devices that enter the patient's vascular system or other normally sterile areas of the body;

(v) sterilizing equipment and devices that touch intact mucous membranes but do not penetrate the patient's body or using high-level disinfection for equipment and devices which cannot be sterilized prior to use for a patient;

(vi) using appropriate agents, including but not limited to detergents for cleaning all equipment and devices prior a sterilization or disinfection;

(vii) cleaning, by the use of appropriate agents, including but not limited to detergents, equipment and devices which do not touch the patient or that only touch the intact skin of the patient;

(viii) maintaining equipment and devices used for sterilization according to the manufacturer's instructions;

(ix) adequately monitoring the performance of all personnel, licensed or unlicensed, for whom the licensee is responsible regarding infection control techniques;

(x) placing disposable used syringes, needles, scalpel blades, and other sharp instruments in appropriate puncture-resistant containers for disposal; and placing reusable needles, scalpel blades, and other sharp instruments in appropriate puncture-resistant containers until appropriately cleaned and sterilized;

(xi) maintaining appropriate ventilation devices to minimize the need for emergency mouth-to-mouth resuscitation;

(xii) refraining from all direct patient care and handling and handling of patient care equipment when the health care professional has exudative lesions or weeping dermatitis and the condition has not been medically evaluated and determined to be safe or capable of being safely protected against in providing direct patient care or in handling patient care equipment; and

(xiii) placing all specimens of blood and body fluids in well-constructed containers with secure lids to prevent leaking; and cleaning any spill of blood or other body fluid with an appropriate detergent and appropriate chemical germicide.

(b) Unprofessional conduct shall also include, in those professions specified in section 18 of the Public Health Law and in the professions of acupuncture and massage, failing to provide access by qualified persons to patient information in accordance with the standards set forth in section 18 of the Public Health Law. In the professions of acupuncture and massage, qualified persons may appeal the denial of access to patient information in the manner set forth in section 18 of the Public Health Law to a record access committee appointed by the executive secretary of the appropriate State Board. Such record access review committees shall consist of not less than three, nor more than five members of the appropriate State Board.

§29.7 Special provisions for the profession of pharmacy.

(a) The requirements of this section set forth for written prescriptions shall also be applicable to electronically transmitted prescriptions, as defined in paragraph (7) of subdivision (a) of section 63.6 of this Title, unless otherwise indicated. Unprofessional conduct in the practice of pharmacy shall include all conduct prohibited by sections 29.1 and 29.2 of this Part except as provided in this section, and shall also include the following:

(1) Dispensing a written prescription which does not bear the name, address and age of the patient for whom it is intended; the date on which it was written; the name, strength, if applicable, and the quantity of the drug prescribed; directions for use, if applicable; and, the name, address, telephone number, profession and signature of the prescriber; provided that the pharmacist may record on the prescription the address and age of the patient, the strength and quantity of the drug prescribed, the directions for use and the prescriber's address, telephone number and profession if these are missing or unclear. If the address and age of the patient and the address, telephone number and profession of the prescriber are missing from the prescription, the pharmacist shall not be required to enter any of these items on the prescription if the information is otherwise readily available in the records of the pharmacy. Prescription labels must be legible. An order for a drug to be dispensed for an inpatient in a health care facility by the pharmacy of that facility may be transmitted to the pharmacy in accordance with written procedures approved by the medical or other authorized board of the facility. The items of information required by this paragraph which are found in the records regularly maintained by the facility and which are not essential to the execution of the order need not appear on the order which is transmitted to the pharmacy. A drug which is dispensed for an inpatient in a health care facility by the pharmacy of that facility may be labeled in accordance with the policy adopted by the medical or other authorized board of the facility. That policy shall insure that all information required by law to be placed on prescription labels is readily available to all concerned parties and that accuracy and safety prevail in the dispensing process. The address of a patient in a hospital or other health care facility may, for the purpose of a prescription, be

that of the facility. An order for a drug for a particular patient issued by a practitioner authorized to prescribe, and transmitted to a pharmacy for dispensing, shall constitute a prescription. Prescriptions written for controlled substances shall meet the requirements of Article 33 of the Public Health Law.

(2) Failure by a pharmacist to reduce to writing a prescription transmitted orally, which writing shall include all the information required by paragraph (1) of this subdivision and the signature or readily identifiable initials of the receiver of the oral prescription, provided that oral prescriptions for controlled substances shall meet the requirements of article 33 of the Public Health Law.

(3) Failure by a pharmacist dispensing a prescription to enter on the prescription the date of dispensing and to sign or initial legibly the prescription in such a manner as not to interfere with any other information on the prescription; provided that when the prescription is dispensed by an intern, the prescription shall bear the signature or readily identifiable initials of the intern and of the pharmacist who is supervising the intern.

(4) Refilling a prescription without entering on the reverse of the prescription the date of the refill and the signature or readily identifiable initials of the pharmacist and of the intern, if applicable, dispensing the refill, except as provided in paragraph (8) of this subdivision. As a refill instruction, the pharmacist may accept a number of times, a time period, such as one year, or the Latin phrase pro re nata (abbreviated prn-meaning "as needed"). In the case of the latter, the pharmacist shall refill the prescription once only. The pharmacist receiving on oral order to refill a prescription shall reduce the order to writing and shall sign or initial it legibly as the recipient of the oral order. When a prescription is refilled, the date placed on the label shall be the date of the refill.

(5) Using or substituting without authorization one or more drugs in the place of the drug or drugs specified in a prescription. Unauthorized use or substitution occurs if the same is done without the knowledge and consent of the prescriber. If other than the ingredients specified are utilized by the pharmacist in compounding or dispensing the prescription, improper substitution shall be presumed unless there shall be entered upon the reverse of the original prescription information setting forth the facts of the substitution, the date, time and manner in which authorization for substitution was given and the signature of the pharmacist who received such authorization.

(6) Failure to identify a generic product dispensed on a prescription by writing the name of the manufacturer and of the distributor, if different, on the prescription and on the label, except as otherwise provided in Education Law, section 6816-a(1)(c).

(7) Failure to number prescriptions consecutively and file them in a numerical or other form which provides for ready retrieval of the prescriptions; provided that orders for drugs to be dispensed for inpatients in a health care facility, including but not limited to a general hospital, in the pharmacy of that facility under a drug distribution system approved by the medical or other authorized board of the facility, need not be numbered if the orders are otherwise readily available and retrievable; and, provided further that prescriptions for controlled substances shall be filed in accordance with the provisions of article 33 of the Public Health Law.

(8) Failure to maintain in a form which provides for ready retrieval of prescriptions a daily record of all prescriptions filled and refilled which identifies clearly the practitioner who ordered the prescription, the patient for whom the prescription is intended, the signature or readily identifiable initials of the pharmacist who filled or refilled the prescription, and the number assigned to the prescription where applicable. The record of the dispensing of a drug for an inpatient in a health care facility, including but not limited to general hospital, by the pharmacy of that facility may be maintained in a form which is consistent with the record of the total health service provided to the patient provided the information required by this paragraph is readily retrievable and available. Original prescriptions filed in accordance with the provisions of paragraph (7) of this subdivision may constitute the record of the initial filling of those prescriptions. The daily record may be maintained by a manual system or, alternatively, by an electronic data processing system which meets the following requirements:

(i) The system shall provide adequate safeguards against improper manipulation or alteration of stored records.

(ii) Arrangements shall be made which assure completeness and continuity of prescription records if the relationship between a pharmacy and a supplier of data processing services terminates for any reason.

(iii) The system shall provide retrieval of information regarding original dispensing and the refilling of prescriptions.

(iv) A pharmacist, and a pharmacy intern, if applicable, using a computerized system shall sign or initial the original prescription at the time of the first dispensing as provided in paragraph (3) of this subdivision and the initials of the pharmacist shall be entered into the computer record of the dispensing.

(v) For all refills of a prescription, the records introduced into the system shall be sufficient if:

(*a*) the initials of the pharmacist who dispensed the refill are entered by such pharmacist at the time of dispensing; and

(*b*) a printout is produced of all prescriptions filled and refilled each day and the pharmacist(s) whose initials appear(s) on the printout sign(s) the printout to indicate that it is a accurate record.

(vi) A pharmacy that employs a computerized system shall have an auxiliary procedure which shall be used for documentation of all new and refilled prescriptions dispensed during system downtime. The auxiliary procedure shall provide for the entry into the computer of all data collected during the downtime, and the pharmacist shall insure that the maximum number of refills authorized on the original prescription has not been exceeded.

(vii) Only pharmacists and pharmacy interns shall enter prescription data into the computerized system and access the data, except as provided in paragraph (21) of this subdivision.

(9) Except as otherwise provided in 16 CFR Part 1700 (Code of Federal Regulations, 1984 edition, Superintendent of Public Documents, U.S. Government Printing Office, Washington, DC 20402: 1984, available at New York State Board of Pharmacy, Office of the Professions, State Education Building – 2nd floor, 89 Washington Avenue, Albany, NY 12234), failure to package a drug in a child-resistant

container unless either the prescriber or the patient requests otherwise. Such request shall be documented in the records of the pharmacy. Child-resistant containers shall not be reused.

(10) Failure by a supervising pharmacist to provide adequate supervision of a registered establishment. A supervising pharmacist must be a full-time employee of the establishment. For the purposes of this section, full-time shall be deemed to be 30 or more hours per week. In those circumstances in which an establishment operates for less than 30 hours per week, the supervising pharmacist shall be employed for a majority of the hours that the establishment operates. The State Board of Pharmacy shall be notified within seven days of any change in the identity of the supervising pharmacist of a registered establishment. Such notification shall be made by the owner of the registered establishment.

(11) Advertisements of the prices of prescription drugs which do not comply with the following provisions:

(i) The advertised price shall be in effect for a period of time stated in the advertisement.

(ii) When the advertising of prescription prices forms part of a larger advertisement which includes the offering of general merchandise, the advertising pertaining to prescription prices shall be separated physically, such as by a box, from the advertising pertaining to general merchandise.

(iii) Nothing in this subdivision shall be construed to prevent the use in advertising of a statement to the effect that the price for which any prescription will be filled is available on request.

(iv) Such advertisement shall comply with the "Prescription Drug Consumer Price Listing" requirements set forth in section 200.200 of title 21 of the Code of Federal Regulations (1984 edition, Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402: 1984, available at New York State Board of Pharmacy, Office of the Professions, State Education Building – 2nd floor, 89 Washington Avenue, Albany, NY 12234).

(12) Advertising or soliciting professional practice by means of providing physicians, or others authorized to prescribe, with prescription blanks imprinted with either the name of the pharmacist or the name of the pharmacy.

(13) Failing to make prescription fee or price information readily available by providing such information upon request and upon the presentation of a prescription for pricing or dispensing. Nothing in this section shall be construed to prohibit the quotation of price information on a prescription drug to a potential consumer by telephone.

(14) Placing in stock of any pharmacy any part of any prescription compounded or dispensed which is returned by a patient; provided, however, that in a health care facility, including but not limited to a general hospital, which has its own pharmacy and in which unit-dose medication is dispensed to inpatients, each dose being individually sealed and labeled with the name of the drug, dosage strength, manufacturer's control number and expiration date, the unused unit dose of medication may be returned to the pharmacy of the facility for redispensing; and provided further that unused medication may be returned to pharmacies by residential health care facilities in accordance with the provisions of 10 NYCRR 415.18(f) or by other facilities, including but not limited to county correctional facilities, provided that such other facilities utilize standards, policies and procedures determined by the State Board of Pharmacy to be equivalent to those enumerated in 10 NYCRR 415.18(f).

(15) Repacking of drugs in a pharmacy, except by a pharmacist or under his/her immediate and personal supervision. Labels on repacked drugs shall bear sufficient information for proper identification and safety. A repacking record shall be maintained, including the name, strength, lot number, quantity and name of the manufacturer and/or distributor of the drug repacked, the date of the repacking, the number of packages prepared, the number of dosage units in each package, the signature of the person performing the repacking operation, the signature of the pharmacist who supervised the repacking, and such other identifying marks added by the pharmacy for internal recordkeeping purposes. Drugs repacked for in-house use only shall have an expiration date 12 months, or 50 percent of the time remaining to the manufacturer's expiration date, whichever is less, from the date of repacking. For the repacking of drugs by manufacturers and wholesalers, the provisions of parts 210 and 211 of title 21, Code of Federal Regulations (1984 edition, Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402: 1984, available at New York State Board of Pharmacy, Office of the Professions, State Education Building – 2nd floor, 89 Washington Avenue, Albany, NY 12234), shall apply. Repacking records shall be maintained for five years and shall be made available to the department for review and copying.

(16) Holding for sale, offering for sale and selling adulterated and/or misbranded drugs, devices and cosmetics. Any drug, device or cosmetic shall be deemed to be adulterated and/or misbranded if:

(i) it is not manufactured in accordance with the good manufacturing practices specified in parts 210 and 211 of title 21, Code of Federal Regulations (1984 edition, Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402: 1984, available at New York State Board of Pharmacy, Office of the Professions, State Education Building – 2nd floor, 89 Washington Avenue, Albany, NY 12234), provided that a drug manufactured by a pharmacy for in-house use may be manufactured in accordance with protocols, including documentation by means of a batch record, which insure the meeting of established standards for purity and potency; and

(ii) at any time it fails to meet standards for purity, potency, labeling, safety and effectiveness established under the Federal Food, Drug and Cosmetic Act, as amended (June 1981, Superintendent of Public Documents, U.S. Government Printing Office, Washington, DC 20402, available at New York State Board of Pharmacy, Office of the Professions, State Education Building – 2nd floor, 89 Washington Avenue, Albany, NY 12234).

(17) Holding for sale, offering for sale, or selling:

(i) any drug later than the date, if any, marked upon the label as indicative of the date beyond which the contents cannot be expected beyond reasonable doubt to be safe and effective; provided, however, that when such drug is identified as an outdated drug by segregation from regular stock or by other means, the holding of such drug beyond its expiration date shall not be deemed a violation of this paragraph. When

the expiration date is expressed by month and year, the expiration date shall be the last day of the month indicated; or

(ii) any drug, the nature of which requires storage under special conditions of temperature control as indicated either on the labeling, in the directions for storage of said drug contained in an official compendium, or as directed by common prudence, unless such special condition of temperature control shall have been complied with during the entire period of time in which such drug has been held for sale.

(18) The sale of drugs at auction without filing with the State Board of Pharmacy, at least seven days prior to the date of said auction, a notice giving the date, time and place of the auction. At such auction, drugs in bulk or in open containers may be sold in one lot only to a registered pharmacy. The drugs shall be removed to the premises of the purchaser promptly and the board notified as to the disposition of such drugs; provided, however, that drugs found, by the representative of the board assigned to such auction, to be unfit for human use by virtue of age, adulteration and/or misbranding shall be destroyed voluntarily in the presence of the said representative or shall be quarantined by the representative pending action for seizure and destruction.

(19) Holding for sale, offering for sale, selling or distributing a new drug or an investigational new drug, which is not recognized as a new drug or an investigational new drug under the provisions of part 310 or 312 of title 21, Code of Federal Regulations (1984 edition, Superintendent of Public Documents, U.S. Government Printing Office, Washington, DC 20402: 1984, available at New York State Board of Pharmacy, Office of the Professions, State Education Building – 2nd floor, 89 Washington Avenue, Albany, NY 12234).

(20) Abandoning the premises of a registered establishment. Premises shall be deemed abandoned if the registrant vacates the premises without surrendering the certificate of registration to the State Board of Pharmacy and without making appropriate arrangements for the disposal of prescription-required drugs.

(21) Aiding and abetting an unlicensed person to dispense drugs.

(i) Subject to the limitations set forth in subparagraph (ii) of this paragraph, an unlicensed person may assist a pharmacist in the dispensing of drugs by:

(*a*) receiving written or electronically transmitted prescriptions, except that in the case of electronically transmitted prescriptions the pharmacist or pharmacy intern shall review the prescription to determine whether in his or her professional judgment it shall be accepted by the pharmacy, and if accepted, the pharmacist or pharmacy intern shall enter his or her initials into the records of the pharmacy;

(*b*) typing prescription labels;

(*c*) keying prescription data for entry into a computer-generated file or retrieving prescription data from the file, provided that such computer-generated file shall provide for verification of all information needed to fill the prescription by a pharmacist prior to the dispensing of the prescription, meaning that the pharmacist shall review and approve such information and enter his or her initials or other personal identifier into the record-keeping system prior to the dispensing of the prescription or of the prescription refill;

(*d*) getting drugs from stock and returning them to stock;

(*e*) getting prescription files and other manual records from storage and locating prescriptions;

(*f*) counting dosage units of drugs;

(*g*) placing dosage units of drugs in appropriate containers;

(*h*) affixing the prescription label to the containers;

(*i*) preparing manual records of dispensing for the signature or initials of the pharmacist; and

(*j*) handling or delivering completed prescriptions to the patient or the person authorized to act on behalf of the patient and, in accordance with section 63.6(b)(8) of this Title, advising the patient or person authorized to act on behalf of the patient of the availability of counseling to be conducted by the pharmacist or pharmacist intern.

(ii) Limitations on assistance by an unlicensed person.

(*a*) No pharmacist shall obtain the assistance of more than two unlicensed persons in the performance of the activities set forth in clauses (b)-(j) of subparagraph (i) of this paragraph. The pharmacist shall provide the degree of supervision of such persons as may be appropriate to ensure compliance with the provisions of this Part and Part 63 of this Title. Individuals who are responsible for the act of placing drugs which are in unit-dose packaging into medication carts as part of an approved unit-dose drug distribution system for patients in institutional settings shall be exempt from such ratio, provided that such individuals are not also engaged in performing the activities set forth in clauses (*b*)-(*j*) of subparagraph (i) of this paragraph.

(b) Unlicensed persons shall not be authorized to:

(*1*) receive oral prescriptions from prescribers;

(*2*) interpret and evaluate a prescription for conformance with legal requirements, authenticity, accuracy and interaction of the prescribed drug with other known prescribed and over-the-counter drugs;

(*3*) make determinations of therapeutic equivalency as such determinations apply to generic substitution;

(*4*) measure, weigh, compound or mix ingredients;

(*5*) sign or initial any record of dispensing required to be maintained by law;

(*6*) counsel patients; or

(*7*) perform any other function involving the exercise of professional judgment.

(*c*) No drug which is dispensed with the assistance of an unlicensed person, as provided in subparagraph (i) of this paragraph, shall be dispensed without the review and approval of the pharmacist.

(b) Nothing in this Part shall be construed to prevent the ownership of a firm or corporate practice in this State by an unlicensed person or persons or to prevent any contractual arrangement computing the salary of professional employees or the amount due the owner of such firm or corporation or a person leasing space or equipment to such firm or corporation on the basis of a percentage of the receipts from the performance of professional services. This

provision shall apply in lieu of section 29.1(b)(4) of this Part.

(c) The requirements of this section and sections 29.1 and 29.2 of this Part shall be applicable to nonresident establishments, as defined in section 6808-b of the Education Law, to the extent prescribed in section 63.8 of this Title.

COMMISSIONER'S REGULATIONS
Part 59
General Provisions

§59.1 Applicability.

(a) As used in this Subchapter, *license* shall mean a permanent authorization, issued pursuant to title VIII of the Education Law, to practice a profession or to use a professional title.

(b) The provisions of this Part shall apply to admission to the licensing examination and to the issuance of licenses in each of the professions supervised by the Board of Regents except as may otherwise be provided in this Subchapter with respect to specific professions.

§59.2 Education requirements.

(a) An applicant for a professional license shall satisfy all education requirements before being admitted to a professional licensing examination, except that the department may accept professional examination grades earned in another state or jurisdiction of the United States prior to completion of professional education if the applicant was licensed in that jurisdiction on the basis of said examination and both the grades and the examination satisfy requirements in this State. Education requirements for a professional license shall include any preprofessional education or experience required as a prerequisite for admission to a registered program of professional education. The department, in its discretion, may accept in satisfaction of a professional education requirement, the completion of an approved or registered program or a program accredited by a professional accreditation organization acceptable to the department. The department, in its discretion, may also accept graduation by a transfer student from such a program, provided such student has completed not less than the final year of professional education in such program subsequent to the date of approval, registration or accreditation of the program and approval of the accrediting organization by the department. The department may accept graduation by a transfer student from an unaccredited program of professional education, provided such student satisfies the educational requirements of statute and regulation in accordance with this Part and as otherwise provided in this Subchapter with respect to the specific profession, and further provided that such student completes not less than the final year in the unaccredited program to which he has transferred.

(b) Education and experience required for the issuance of a license or limited permit shall have been performed in accordance with all requirements of the jurisdiction in which it took place. The department may require contemporaneous evidence of the education and/or experience required for the issuance of a license or limited permit.

(c) Applicants who seek to meet the education requirement for licensure through programs that are not registered by the department or accredited by a professional accreditation organization acceptable to the department in accordance with this Subchapter, shall submit adequate evidence of verification of his or her educational credentials by an acceptable independent credentials verification organization, unless the department determines that such credentials are verified by an acceptable independent credentials verification organization through alternative means prescribed in this Subchapter for a particular profession or no acceptable independent credentials verification organization exists for the particular profession. An acceptable independent credentials verification organization shall mean an organization which the department determines is a reliable verifier of educational credentials and meets requirements that include but are not limited to the following: the organization is a verifier of educational credentials of applicants for licensure in the particular profession, has satisfactory procedures in place to ensure the accuracy of the information it collects, has satisfactory recordkeeping and reporting procedures, and verifies such credentials directly with the educational institution from which the credential was earned. Any cost of such independent verification shall be the responsibility of the applicant, pursuant to arrangements between the applicant and the independent credentials verification organization, and shall not be payable to the department. The verification of educational credentials by an acceptable independent credentials verification organization for authenticity purposes as prescribed in this subdivision shall not constitute a determination by the department that the licensure requirements have been met.

§59.3 English proficiency requirement.

An applicant for licensure whose application is based upon credit granted for the completion of courses of study in a country where English is not the principal language spoken shall demonstrate proficiency in English by passing an examination in English proficiency acceptable to the department or by passing a licensing examination acceptable to the department given in English.

§59.4 Citizenship or immigration status requirements.

In those professions where citizenship or immigration status is required for licensure, an applicant shall submit evidence satisfactory to the department of compliance with such requirement.

§59.5 Professional examinations.

(a) The department may develop its own examinations or may select in whole or in part examinations developed or administered by other organizations. Unless specifically authorized by the department, no examination shall be deemed acceptable which has been used in its entirety during the five years previous to the current

administration.

(b) Applications for admission to a licensing examination, including all required fees shall be completed and filed not less than 60 days prior to the examination. When the department finds that the application is complete and that the requirements for admission to an examination have been met, it will issue to the applicant an admission card which will include the date, time and place of the examination and entitle the applicant to admission thereto.

(1) The department may accept applications for admission to department conducted examinations after the filing date for such examinations provided that the department is able to review and process such applications in a timely manner and that there are adequate examination facilities and materials available. Such applications shall require the payment of the late filing fee enumerated in Section 59.9 of this Part, which shall be in addition to the regular admission or reexamination fee. If, upon review of a late application, the department determines that the applicant is ineligible to be admitted to the examination, the department shall retain the late filing fee. In the event that the department is unable to review a late application, the late filing fee shall be refunded.

(2) The department may waive the late filing fee or delay the required date for filing in cases where notification to the applicant of the results of the previous examination are released less than 75 days prior to the next examination.

(c) For the purpose of identification for admission to the examination, the applicant shall present the current admission card with a photograph attached and, at the conclusion of the examination, return the card to the department representative conducting the examination. A candidate shall permit fingerprints to be taken during each part of an examination.

(d) Licensing examinations shall be held at times and places determined by the commissioner and conducted under the following conditions. Any candidate violating such conditions may be dismissed from the examination by the department representative, and the examination paper of such candidate shall be deemed a failure. At the discretion of the department, such candidate may be denied admission to subsequent licensing examinations.

(1) No candidate shall enter any examination more than 60 minutes after the scheduled admission time, nor shall any candidate leave the examination until 60 minutes have elapsed from the scheduled admission time. No candidate shall leave a department administered practical or clinical examination until dismissed by the chief examiner.

(2) Compensatory time may be granted candidates arriving late for an examination, at the discretion of the department.

(3) A candidate shall not obtain unauthorized possession of examination materials.

(4) During the examination, no candidate shall give or receive help, or communicate with any other candidate in any way, except upon the express permission of the department representative.

(5) A candidate shall bring into the examination room only such books and other materials as are indicated on the admission card and permitted by the department.

(6) A candidate shall not remove from the examination room any of the materials provided for an examination, and shall not reproduce or reconstruct any portion of the examination or answer paper, or aid in such reproduction or reconstruction by any means, unless authorized by the department. Such materials include examination booklets, individual examination questions, answer sheets or score sheets, instructions and any reference tables or papers which were provided by the department and which may have been used in the course of the examination.

(e) Papers will be scored and candidates notified of success or failure by the department or its designee. If the candidate has failed, the department will advise when and on what basis the candidate may be reexamined and of any procedure for review of the failed examination.

(f) The passing score in each component of each part of the licensing examination shall be determined as provided by law and shall be computed without rounding. In those examinations administered by the department, unless otherwise provided in the regulations pertaining to a specific profession, a candidate may retain credit for scores earned on examination parts for a period not to exceed five years from the examination date. A candidate who is reexamined in a part already passed shall not retain credit for such part from earlier examinations. In those professions which use national or regional examinations administered by the Department, this subdivision shall apply whether or not the examination is taken in the State of New York.

(g) In those professions where reviews of examination papers are permitted, candidates will be allowed to review only those parts of the examination which they failed with a score of 60 or higher. In those professions which permit candidates to pass on average all scores used in computing the average are reviewable. A request for review of an examination paper or score may be made in writing to the department not later than 30 days after examination grades are released by the department. A candidate shall not remove from the reviewing site any of the materials provided for the review of an examination given previously, and shall not reproduce or reconstruct any portion of the examination or the answer paper, or aid in such reproduction or reconstruction by any means, unless authorized by the department. No one other than the candidate will be permitted access to examination materials. Where examinations are offered under contract with testing agencies, reviews shall be consistent with these contracts, where applicable. All reviews shall be conducted at sites selected and supervised by the department or an authorized testing agency.

(h) An applicant who has been admitted to a professional licensing examination conducted by the department and subsequently fails to appear for such an examination twice shall forfeit any remaining fee credits for that examination. The applicant, upon subsequently applying for readmission to that examination, shall pay all required admission fees.

§59.6 License by endorsement.

An applicant for endorsement of a license issued by another jurisdiction shall establish that the applicant:

(a) meets all requirements of section 6506 (6) of the Education Law;

(b) has had satisfactory professional experience of at least two years following initial licensure, unless a different period is provided in the regulations pertaining to a particular profession; and

(c) has not attempted unsuccessfully a licensing examination used by the State of New York either prior to or after making application for licensure by endorsement, unless such applicant has later passed a comparable licensing examination.

§59.7 Licenses and initial registrations.

When the candidate fulfills all requirements for licensure, the department shall issue a first registration certificate and a license. The first registration shall be for the remainder of the applicable registration period. Pursuant to section 6502 of the Education Law the registration fee shall be prorated for those persons newly licensed and registered, or reactivating registration, during the second or third year of a registration period.

§59.8 Registration for professional practice.

(a) Each licensee shall be responsible for registering with the department. Failure to register shall subject the practitioner to the late fee set forth in section 6502 (3) of the Education Law. Any practitioner who willfully refuses to register shall be subject to the penalties set forth in section 6511 of such law.

(b) A licensee not practicing or using a restricted title in New York State or an individual practicing only in a setting which is exempt from licensure in accordance with law may allow registration to lapse without being subject to the late fee set forth in section 6502 of the Education Law, by notifying the department of their cessation of practice or exemption in the State. At such time as the licensee may choose to resume practice or enter practice in a nonexempt setting in New York State, a registration certificate may be issued upon the filing of a proper application and the payment of the required registration fee.

(c) Registration certificates shall be conspicuously displayed by each licensee in each office in which the profession is practiced. In instances where licensees regularly practice at more than one professional office, registration certificates shall be obtained for each office bearing the licensee's name and the exact address of each such office upon making proper application to the department and submitting a fee. Where practice is carried on in other than individual offices, each licensee shall have a current registration certificate available for inspection at all times.

(d) Registration periods for each profession shall be in accordance with schedules established by the department.

(e) Each professional practitioner shall notify the department in writing of any change of name or address not later than 30 days after such change.

(f) When an applicant or licensee pays a fee by a personal check and it is subsequently not honored by the issuing institution, the applicant or licensee must subsequently pay by a certified check, a bank check, or a money order. The replacement payment shall include any late and penalty charges required under section 6502 (3) and (7) of the Education Law.

(g) Any licensee who fails to submit a replacement registration payment as required in subdivision (f) of this section, shall have his or her registration voided 60 days from the date the department sends notification that said fee was not honored by the issuing institution.

§59.9 Special service fees.

The department will charge the following fees for special services not otherwise provided by Education Law:

(a) for the issuance of a trainee permit in ophthalmic dispensing, $25;

(b) for certification of completion of pharmacy internship, $20;

(c) for admission to the fundamental theory section of the examination in landscape architecture, $50 and for each subsequent reexamination, $50, the remainder of the fee set forth in section 7324 of the Education Law to be paid prior to admission to the remainder of the examination;

(d) for certification of licensure or examination grades to another jurisdiction, $20;

(e) for certification in acupuncture of a licensed physician or dentist, $150;

(f) for the issuance of an additional registration certificate, $10;

(g) for the issuance of a letter of eligibility to undertake clinical clerkships, $30;

(h) for the issuance of a Medical Science Knowledge Profile (MSKP) or satisfactory equivalent examination certificate to undertake clinical clerkships, $20;

(i) for review by the department of an examination conducted by the department, $25;

(j) for rescoring of an examination conducted by the department, $20;

(k) for verification by the department of the transcript of an applicant or licensee, $20;

(l) for admission to the Special Purpose Examination (SPEX) in medicine, $175;

(m) for late filing for admission to a licensing examination, $50;

(n) for written verification of licensure and/or registration status, $10; and

(o) for reregistration of a licensee whose six-month registration has expired due to his or her failure to satisfy child support or combined child and spousal support obligations as prescribed in section 3-503 of the General Obligations Law, an amount equal to the licensee's registration fee.

§59.10 Professional service corporations.

(a) Applications to the State Education Department for the issuance of a certificate pursuant to Business Corporation Law, section 1503 (b) (ii), shall be made by submitting to the department a fully executed certificate of incorporation which complies with the provisions of such section and of section 1512 of such law, and which sets forth or has annexed to it an affidavit of one of the original officers, directors or shareholders of the corporation setting forth the name of each individual who is to be one of the original shareholders, directors or officers of the corporation.

(b) If the name of a proposed professional service corporation contains the name of a deceased person, the certificate of incorporation, when submitted to the department for the issuance of a certificate pursuant to Business Corporation Law,

section 1503 (b) (ii) shall be accompanied by an affidavit of one of the subscribers to the certificate of incorporation establishing compliance with the provisions of Business Corporation Law, section 1512 (a) (2).

(c) A certificate pursuant to Business Corporation Law, section 1503 (b) (ii) may be issued when:

(1) the proposed name of the corporation appropriately describes the profession practiced and the services to be provided; and

(2) if the proposed name of the corporation includes a reference to a specialized area of professional practice, satisfactory evidence is submitted of compliance with any provision of Part 29 of this Title, rules of the Board of Regents restricting or regulating the use of specialty titles or announcements of limitations of practice in the particular profession.

§59.11 Refunds.

Monies received by the State Education Department pursuant to section 110 of the Education Law, may be refunded as follows:

(a) Full refunds may be granted when:

(1) the fee submitted is an overpayment;

(2) the requested service cannot be provided;

(3) a written request for the refund of a registration fee is received prior to the beginning of that registration period; or

(4) a registrant who has paid a registration fee is deceased prior to the beginning of that registration period and a written refund request is received within one year of the date of death.

(b) Partial refunds not to exceed 50 percent of the licensure application fee may be granted if an applicant for any practice authorization elects to withdraw such application prior to the issuance or denial by the department of such authorization, and such applicant has not been admitted to a department conducted examination. Each applicant who has at any time withdrawn an application and received a refund shall be required to pay in full all fees upon submitting any subsequent application.

§59.12 Training regarding child abuse and maltreatment reporting.

(a) All persons applying on or after January 1, 1991 for the issuance or renewal of a license/registration or limited permit in medicine, chiropractic, dentistry, dental hygiene, registered professional nursing, podiatry, optometry, psychology and any other professions listed in section 6507 (3) (a) of the Education Law shall submit documentation acceptable to the department of the completion of two hours of coursework or training regarding the identification and reporting of child abuse and maltreatment and obtained either from a provider approved by the department pursuant to Part 57 of this Title or as a matriculant in a registered program under Section 52.2 (c) (12) of this Title, unless the applicant receives an exemption from such requirement as provided in subdivision (b) of this section.

(b) The department may exempt an applicant or licensee from the coursework or training requirement of subdivision (a) of this section upon receipt of a written application for such exemption establishing that there would be no need to complete the coursework or training because the nature of the applicant's/licensee's practice excludes contact with children. It is the professional responsibility of the licensee who holds an exemption to notify the department in writing, within 30 days, when the nature of the practice changes to the extent that the basis for the exemption ceases to exist.

§59.13 Training regarding infection control practices.

(a) Commencing July 2, 1994, all persons applying for the issuance of a license or renewal of a registration in dentistry, registered professional nursing, licensed practical nursing, podiatry, optometry, dental hygiene, or any other profession subject to the requirements of section 6505-b of the Education Law shall affirm to the department, and maintain and/or submit such documentation as the department may require, that they have completed, in the four years immediately preceding such application, course work or training in infection control and barrier precautions which is approved by the department, pursuant to Part 58 of this Title, or which is approved as part of a program registered pursuant to Part 52 of this Title. As provided in subdivision (b) of this section, an applicant may be exempted from the infection control and barrier precautions course work or training requirement; or as provided in subdivision (c) of this section, may be exempted from the requirement to document the completion of such course work or training.

(b) The department may exempt an applicant for registration from the course work or training required pursuant to subdivision (a) of this section either upon receipt of:

(1) a written application for such exemption establishing that there would be no need to complete the course work or training because the nature of the applicant's/licensee's practice does not require the use of infection control techniques or barrier precautions; or

(2) documentation satisfactory to the department that the applicant/licensee has completed course work or training equivalent to that approved by the department, pursuant to Part 58 of this Title.

(c) Maintenance or submittal of documentation pursuant to subdivision (a) of this section is not required of any dentist or podiatrist who is subject to the provisions of paragraph (f) of subdivision (1) of section 2805-k of the Public Health Law and who attests at the time of registration that documentation requirements have been met as required in the Public Health Law.

(d) If there are changes in the nature of the practice of a licensee who has been granted an exemption under paragraph (b) (1) of this section and such changes require the licensee to use infection control techniques or barrier precautions, the licensee shall notify the department in writing of the change within 30 days of such change. If the licensee has not taken approved course work or training in infection control and barrier precautions during the four years immediately preceding the change in practice, the licensee shall obtain such course work or training within 90 days of the change in practice.

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FORM AD/NAME

The University of the State of New York
THE STATE EDUCATION DEPARTMENT
Office of the Professions
Division of Professional Licensing Services
www.op.nysed.gov

OFFICE USE

ADDRESS/NAME CHANGE FORM

INSTRUCTIONS

Use this form to report a change in your address and/or name. Please read these instructions carefully and be sure you complete the appropriate sections of this form. Please print clearly in ink.

- **For address changes only:** Complete Sections I, II, and IV. ***For address changes only***, you may fax this form to the Records and Archives Unit at 518-486-3617 or provide the required information by E-mail: oparchiv@mail.nysed.gov. Your records will be updated. Currently registered licensed professionals will be sent a new registration certificate.
- **For name changes only:** Complete Sections I, III, IV and V. **Name changes** require an original notarized signature in your new name and cannot be accepted prior to your official change of name. Sign the Section IV affidavit and have your signature notarized by a notary public. Currently registered licensed professionals will be sent a new registration certificate.
- **For address and name changes:** Complete all sections.

Licensed professionals can check the Office of the Professions' Web site at www.op.nysed.gov to verify your name, city, state, registration expiration date, and license number on record.

NOTE: Important information and registration renewals will be sent to the address on file for you. ***You must notify the Department in writing within 30 days if your address or name changes.***

Section I: Your General Information

1. Name (currently on record): _____

2. Social Security Number: ☐☐☐ ☐☐ ☐☐☐☐ Birth Date: Month ☐☐ Day ☐☐ Year ☐☐

   Telephone: Home: _____ - _____ - _____ Work: _____ - _____ - _____

   E-mail: _____ Fax: _____ - _____ - _____

3. Are you reporting an address and/or name change? ☐ address change ☐ name change ☐ both

4. Effective date of change: _____ / _____ / _____ **(Note: Changes cannot be accepted until *after* the effective date.)**

5. Licensure status in New York State:

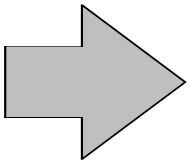
   ☐ I am an applicant for licensure in New York State for the licensed profession(s) of: _____
   ☐ I am currently licensed in New York State in the profession(s) of: *(see list of professions on page 2)*
   (see list of professions on page 2)

   _____ New York State license number: ☐☐☐☐☐☐
   _____ New York State license number: ☐☐☐☐☐☐
   _____ New York State license number: ☐☐☐☐☐☐
   _____ New York State license number: ☐☐☐☐☐☐

Section II: Address Change (please print)

Information Currently On Record		**New Information**
Apt./Bldg. _____		Apt./Bldg. _____
Street _____		Street _____
City _____		City _____
State _____		State _____
Zip Code ☐☐☐☐☐ - ☐☐☐☐		Zip Code ☐☐☐☐☐ - ☐☐☐☐
Province or Country (if not U.S.)		Province or Country (if not U.S.)
_____		_____

Section III: Name Change (please print) If you are reporting a name change, please sign using your **NEW** name in Section IV. Your new signature must be notarized for any name changes. **If you are currently registered you will receive a new registration certificate.**

Information Currently On Record		**New Information**
Last Name _____		Last Name _____
First Name _____		First Name _____
Middle or Initial _____		Middle or Initial _____

☐ Check here if you wish to have your existing license parchment replaced with one in your **NEW** name. Enclose your **original parchment** and a **$10 check or money order** made payable to the New York State Education Department with your request. You will be sent a new parchment.

Section IV: Affidavit

I declare and affirm that the statements above are true, complete, and correct. I understand that any false or misleading information in, or in connection with, my application or this notification may be cause for denial or loss of licensure and may result in criminal prosecution.

_____ _____

Signature *Date*

Section V: For Name Changes Only: Notary Certification And Identification

State of _____ County of _____ On the _____ day of _____ in the year _____ before me, the undersigned, personally appeared _____, personally known to me or proved to me on the basis of satisfactory evidence to be the individual whose name is subscribed to this application and acknowledged to me that he/she executed the application and swore that the statements made by him/her in the application and all supporting materials are true, complete, and correct.

Notary Public signature _____

Notary ID number _____

Notary Stamp

Expiration date _____ / _____ / _____
Month Day Year

Professional Titles Licensed Under Education Law

(See item #5 on page 1 of the form.)

Acupuncturist
Architect
Athletic Trainer
Audiologist
Certified Clinical Laboratory Technician
Certified Dental Assistant
Certified Public Accountant
Certified Shorthand Reporter
Chiropractor
Clinical Laboratory Technologist
Creative Arts Therapist
Cytotechnologist
Dental Hygienist
Dentist
Dietitian/Nutritionist
Interior Designer
Landscape Architect
Land Surveyor
Licensed Clinical Social Worker
Licensed Master Social Worker
Licensed Practical Nurse
Marriage and Family Therapist
Massage Therapist
Medical Physicist
Mental Health Counselor
Midwife
Nurse Practitioner
Occupational Therapist
Occupational Therapy Assistant
Ophthalmic Dispenser
Optometrist
Pharmacist
Physical Therapist
Physical Therapist Assistant
Physician
Podiatrist
Professional Engineer
Psychoanalyst
Psychologist
Public Accountant
Registered Physician Assistant
Registered Professional Nurse
Registered Specialist Assistant
Respiratory Therapist
Respiratory Therapy Technician
Speech-Language Pathologist
Veterinarian
Veterinary Technician

New Applicants mail to → New York State Education Department, Office of the Professions, Division of Professional Licensing Services, (insert name of profession from above list) Unit, 89 Washington Avenue, Albany, NY 12234-1000.

Licensees mail to → New York State Education Department, Office of the Professions, Division of Professional Licensing Services, Records and Archives Unit, 89 Washington Avenue, Albany, NY 12234-1000.

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Office of the Professions
Division of Professional Licensing Services
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Albany, NY 12234-1000

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