Board of Pharmacy Update
January 28, 2017

Kimberly A Leonard, RPh
Executive Secretary
NYS Board of Pharmacy
NYS BOARD OF PHARMACY
The Board is established to serve the residents of New York State and State Boards members must be dedicated to public protection and quality professional preparation and conduct.
Responsibilities

State Boards are responsible for assisting the Board of Regents and the Education Department on matters of professional licensing, practice, and professional conduct by:

- Advising the Department concerning appropriate requirements for licensure;
- Selecting or developing appropriate licensing examinations;
- Reviewing applications for licensure;
- Advising on issues of professional practice; and
- Participating in disciplinary proceedings.
www.op.nysed.gov/prof/pharm/
Pharmacy

Laws, Rules & Regulations
Consumer Information
Contact Information
License Statistics
Board Members Only
Professional Assistance Program

Pharmacists
License Requirements
License Application Forms
Practice Issues
FAQs
Continuing Education
Administration of Immunizations
Electronic Prescribing

Pharmacy Establishments
Registration Requirements & Forms
Listing of Outsourcing Facilities
Pharmacy

Pharmacy refers to the preparation and dispensing of drugs as well as the counseling of patients in the proper use of these drugs.

When your pharmacist counsels you about your prescription, the pharmacist may discuss the following information with you:

- The medicine's name
- What it is supposed to do
- When the medicine should be taken and for how long
- How the medicine should be taken
- Common side effects
- Foods, drinks, other medicines, or activities you should avoid while taking the medicine
- What you should do if you miss a dose
- How you should store the medicine
- If there are any refills of the prescription

Read more about this profession.

Last Updated: January 14, 2014
Frequently Asked Questions

**Pharmacy**

- Laws, Rules & Regulations
- Consumer Information
- Contact Information
- License Statistics
- Board Members Only
- Professional Assistance Program

**Pharmacists**

- License Requirements
- License Application Forms
- Practice Issues
- FAQs
- Continuing Education
- Administration of Immunizations
- Collaborative Drug Therapy Management
- Nuclear Pharmacist Certification
- Electronic Prescribing

**Pharmacy Establishments**

- Registration Requirements & Forms
- Listing of Outsourcing Facilities

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**Frequently Asked Questions**

- Administration of Immunizations (July 2015)
- Collaborative Drug Therapy Management- CDTM (November 2016)
- Continuing Education (March 2015)
- Electronic Transmittal of Prescriptions (March 2016)
- Licensure Transfer (Reciprocity) (August 2008)
- Limited (Intern) Permit (September 2016)
- Patient Confidentiality (November 2009)
- Pharmacist Licensure Exams (October 2011)
- Pharmacy Personnel and Required References in the Pharmacy (November 2009)
- Prescription Refills (November 2009)
- Questions and Answers for Pharmacists and Pharmacies (July 2003)
- Transfer of Prescriptions (November 2009)

Last Updated: November 30, 2016
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Last Updated: January 14, 2014
VERIFICATION OF REGISTRATION
PRIVELEGED AND STATUS

Office of the Professions

Online Services

Verification Searches

The information furnished at this web site is from the Office of Professions' official database and is updated daily, Monday through Friday. The Office of Professions considers this information to be a secure, primary source for license verification.

License Information *

10/01/2016

Name: KING HEATHER
Address: CLIFTON PARK NY
Profession: PHARMACY
License No: 045204
Date of Licensure: 07/30/97
Additional Qualification: 1 - Immunization Privilege
Status: REGISTERED
Registered through last day of: 11/17

* Use of this online verification service signifies that you have read and agree to the terms and conditions of use. See HELP glossary for further explanations of terms used on this page.

- Use your browser's back key to return to licensee list.
- You may search to see if there has been recent disciplinary action against this licensee.
- Note: The Board of Regents does not discipline physicians (medicine), physician assistants, or specialist assistants. The status of individuals in these professions may be impacted by information provided by the NYS Department of Health. To search for the latest disciplinary actions against individuals in these professions, please check the New York State Department of Health's Office of Professional Medical Conduct homepage.
ESTABLISHMENT VERIFICATION

New York registers establishments located within the State as well as those located outside NYS that do business in the State. More information concerning the registration of pharmacy establishments can be found here.

Search for Pharmacy Establishments, by Name or Registration number:

Establishment Type:
- AL - ALL TYPES
- PHARMACY - NYS
- PHARMACY - Out-of-State

Search by:
- LN - LEGAL NAME
- TN - TRADE NAME (doing business as)

New York State

County:
- ALL COUNTIES
- ALBANY
- ALLAGANY
- BRONX
- BROOME

Status:
- ACTIVE
- INACTIVE (Transferred/Discontinued)
- BOTH ACTIVE AND INACTIVE

Search | Reset

Registration Number:

024528

Search | Reset

Search for Business Entity, by Name:

Please note: sole-practitioners, practicing under their own name, can be located by searching for individual licensees above.

Profession:
- Accounting Firms
- Acupuncture
- Architecture
- Architecture & Engineering
- Architecture & Landscape Architecture
- Athletic Trainer
- Audiology
- Certified Behavior Analyst Assistant

Professional Business Entity Name:

Search | Reset
Verification Searches

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Pharmacy Establishment Information *

10/01/2016

Type: PHARMACY
Legal Name: NEW YORK STATE EDUCATION DEPARTMENT
Trade Name:
Street Address:
STATE BOARD OF PHARMACY
89 WASHINGTON AVE.
WEST WING - 2ND. FLOOR
ALBANY, NY 12234-0000

Registration No: 024528
Date First Registered: 10/22/99
Registration Begins: 11/01/16
Registered through: 10/31/19
Supervisor: 20 039595 LEONARD KIMBERLY A
Establishment Status: ACTIVE
Successor: NONE

* Use of this online verification service signifies that you have read and agree to the terms and conditions of use. See HELP glossary for further explanations of terms used on this page.

- Use your browser's back key to return to establishment list.
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Education Law 6808
Rules of the Board of Regents Part 29.7

SUPERVISING PHARMACIST
A pharmacist who is unable or unwilling to assume the responsibilities of the title of Supervising Pharmacist should not accept this appointment.
Responsibilities

• Proper record keeping
• Inventory management
• Insuring coverage of the pharmacy by licensed pharmacists
• Insuring unauthorized refills or drugs are dispensed
• Insuring proper security for the registered area
• Preventing unauthorized entry
Duties of Supervising Pharmacist

• Supervise the storage, sale, dispensing or compounding of drugs, poisons and restricted devices (i.e., hypodermis needles and syringes).
• Instruct **ALL** employees, either orally or in writing, at regular intervals relative to the appropriate activities in connection with the practice of pharmacy.
• When a Supervising Pharmacist is to be absent from a pharmacy at any time, he/she should be certain that another qualified pharmacist is present during his/her absence as provided under Education Law.
• Be certain that the pharmacy is properly registered and operating in accordance with the present laws, rules and regulations.
• Use "reasonable" means to determine that the drugs being held for sale meet established standards (federal and state).
• Issue verbal and written notice to each of his/her subordinates concerning the laws, rules and regulations (federal, state, and local) relative to proper pharmacy practice.
• Insure that no prescription required drugs or devices are sold at wholesale unless the pharmacy possesses a New York State Board of Pharmacy wholesaler registration.
Discussion

• How many hours does a supervising pharmacist need to work?
• How long can a supervising pharmacist be on vacation or sick leave?
• Who is responsible for notifying the board of a change in supervision?
• How many days do I have to notify the board of a change in supervision?
Education Law 6808, 6808-b, 6810, 6831
Regulations of the Commissioner Part 63.6, 63.8
Rules of the Board of Regents Part 29.7

COMPOUNDING VS OUTSOURCING
Compounding Quality Act

Part of the Drug Quality and Security Act (DQSA) that was signed into law November 27, 2013

Compounding Quality Act - Title 1

- Amended 503A
- Added 503B
503A- TRADITIONAL PHARMACY PRACTICE

Provides pharmacies exemptions from 3 sections of the Federal Food, Drug, and Cosmetic Act (FDCA)

- Compliance with current good manufacturing practices (CGMP) (section 501(a)(2)(B));
- Labeling with adequate directions for use (section 502(f)(1)); and
- FDA approval prior to marketing (section 505)
Congressional Intent

“It is the intent of conferees to ensure the continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing under the guise of compounding. Section 503A establishes parameters under which compounding is appropriate and lawful. The conditions set forth in Section 503 A should be used by the state boards of pharmacy and medicine for proper regulation of pharmacy compounding in addition to existing state-specific regulations.”

Joint Explanatory Statement of the Committee of Conference (1997) (emphasis added)
503A Conditions for Pharmacy Compounding

- Compounded for an identified individual patient based on receipt of a valid prescription

- Drug is compounded pursuant to the prescription in limited quantities by a pharmacist or physician
Drug is compounded in compliance with United States Pharmacopoeia (USP) chapters related to pharmacy compounding of bulk drug substances

Bulk substances:

- Requires a USP monograph OR
- Component of an FDA approved human drug product OR
- Appears on FDA list of bulk drug substances
503A Conditions for Pharmacy Compounding (cont’d)

- Drug is compounded using bulk drug substances that are manufactured by an FDA registered establishment
- Drug is compounded using bulk drug substances that accompanied by valid certificates of analysis
- Drug is compounded using ingredients (other than bulk drug substances) that comply with the standards of an applicable USP or NF monograph, if one exists, and the USP 795 & 797
### 503A Conditions for Pharmacy Compounding (cont’d)

- Drug is not on the list of drugs withdrawn or removed from the market because they were unsafe or not effective.
- Drug is not a product that is essentially copies of commercially available drug products.
- Drug is not a product identified by FDA as too difficult to compound.
503A Enforcement

NYS Board of Pharmacy will continue oversight and regulation of the practice of pharmacy, including prescription compounding.

FDA intends to work cooperatively with states to address compounding activities that are in violation of FD&C Act, including 503A.
503A Enforcement (cont’d)

Enforcement action by FDA

- Produced in insanitary conditions, mislabeled, does not meet purity and quality standards
- Misbranded, adulterated or unapproved
OUTSOURCING FACILITY

503B- OUTSOURCING FACILITY (OF)

• Provides that compounders of sterile drugs may register as “outsourcing facilities” and as such, qualify for certain exemptions from applicable FDCA manufacturer requirements, such as product approval and labeling requirements but NOT the requirement for compliance with current good manufacturing practices (CGMP).
503B OUTSOURCING FACILITY

- Is engaged in the compounding of STERILE drugs
- Has elected to register as an outsourcing facility
- Complies with all of the conditions in section 503B
- Is NOT required to be a licensed pharmacy, but compounding must be by or under the direct supervision of a licensed pharmacist
- May or may not obtain prescriptions for identified individual patients
503B OUTSOURCING FACILITY

Provide compounded drug to hospitals and health care providers with drugs that have been prepared under CGMP requirements and federal oversight.
503B CONDITIONS FOR OUTSOURCING FACILITY - FEDERAL

- Must comply with Current Good Manufacturing Practices (CGMP)
- Must be compounded under the supervision of a licensed pharmacist
- Will be inspected by the FDA
- Must report adverse events
- Report products compounded to the FDA
503B CONDITIONS FOR OUTSOURCING FACILITY – NY STATE

• OF’s located in or shipping 503B products into the state must be registered with the Board of Pharmacy
• Have an annual inspection
• Have a NYS registered pharmacist as supervisor
• Report all products produced every 6 months
• Report all adverse events
• Maintain registration with the FDA
FDA REFERENCES

• Compounding Quality Act- Title I of the Drug Quality and Security Act of 2013
• Insanitary Conditions at Compounding Facilities Draft Guidance
• Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act
• Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
• Compounding: Inspections, Recalls, and other Actions
Pharmacy Programs

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<td>1258</td>
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- 7 accredited colleges of pharmacy in NYS
- 8\textsuperscript{th} program, Binghamton University's School of Pharmacy and Pharmaceutical Sciences was approved by the NYS Board of Regents and is pending ACPE precandidate status
HIV Post Exposure Prophylaxis

S8129/A10724

Authorizes a physician or nurse practitioner to issue a non-patient specific order to a pharmacist for dispensing up to a 7 day starter pack of HIV post exposure prophylaxis medication following a potential HIV exposure

• Amends Education Law §6801
• Regulations are needed
Professional Assistance Program

• Assists professionals who have substance abuse problems, but who have not harmed patients or clients
• Professionals may voluntarily surrender their licenses while receiving treatment rather than face charges of professional misconduct.
• All applications to the program are confidential.
Professional Assistance Program

For further information to help yourself, a colleague, or a friend, telephone or write the Professional Assistance Program at:

Professional Assistance Program
80 Wolf Road
Suite 204
Albany, New York 12205-2643
518-474-3817, ext. 480 (voice)
518-485-9378 (fax)
Email: pap@nysed.gov
NY State Education Department
Office of the Professions
State Board of Pharmacy
89 Washington Avenue
Albany, New York 12234-1000
518-474-3817, ext. 130 (voice)
518-473-6995 (fax)
E-mail: pharmbd@nysed.gov

http://www.op.nysed.gov/prof/pharm/