

# *Survey of Pharmacy Law*

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### **Organizational Law**

#### **(1) Board Description**

1. What is the year of the first enactment?
2. What is the board designation or state agency?
3. What entity makes the rules and regulations?
4. What is the number of compliance officers or inspectors?
5. What is the board's fiscal year?
6. How is the board financed?

#### **(2) Board Membership**

1. Does the board have pharmacist members?
  - 1.1. What is the number of pharmacist board members?
  - 1.2. Must the pharmacist board members be actively practicing?
  - 1.3. What is the number of practice years required?
  - 1.4. What is the term length in years?
  - 1.5. How many terms are pharmacist members limited to?
2. Does the board have public members?
  - 2.1. What is the number of public board members?
  - 2.2. What is the term length in years?
  - 2.3. How many terms are public members limited to?
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  - 3.1. What is the number of pharmacy technician board members?

### **Licensing Law**

#### **(3) Examination Requirements**

1. Does the state require examinations?
  - 1.1. Which examinations are required?
2. Does the state require the NAPLEX?
  - 2.1. Does the state participate in the NAPLEX score transfer program?
  - 2.2. What is the validity period for a NAPLEX score transfer?
  - 2.3. Does the state limit the number of attempts for the NAPLEX?
    - 2.3.1. How many attempts are allowed for the NAPLEX?
3. Does the state require the MPJE?
  - 3.1. Does the state limit the number of attempts for the MPJE?
    - 3.1.1. How many attempts are allowed for the MPJE?

#### **(4) Pharmacy Practice Experience Hour Requirements**

1. What is the number of hours of practical experience required by the Board?

2. What is the number of hours of practical experience required post-graduation?
  3. In which academic year does Board recognition of pharmacy internship/externship credit begin?
  4. What is the number of hours of college-supervised experience recognized by the Board?
- (5) Registration for Interns/Preceptors/Training Sites
1. Does the Board require the licensure or registration of training sites?
  2. Does the Board require the licensure or registration of preceptors?
  3. Does the Board require the licensure or registration of interns?
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    - 3.2. What is the intern renewal registration fee?
    - 3.3. What is the duration of an intern registration?
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- (6) Foreign Pharmacist Licensure
1. Does the state issue licenses to foreign-educated pharmacists?
    - 1.1. Does the state require FPGEC certification?
    - 1.2. What are the required hours of practical experience?
    - 1.3. Is appearance before the Board required?
    - 1.4. Does the state require FPGEC certification for 1993-2004 graduates of CCAPP-accredited professional programs?
- (7) Issuance of Initial Pharmacist Licensure
1. What is the board or regulatory agency that issues licenses?
  2. What is the age at which an initial license can be obtained?
  3. What is the initial certificate fee?
  4. Does the state issue temporary initial licenses?
  5. Are criminal history record checks required for initial licensure as a pharmacist?
- (8) Issuance of Pharmacist Licenses Through License Transfer
1. Does the Board issue pharmacist licenses through licensure transfer?
    - 1.1. Is a Board hearing required?
    - 1.2. What is the number of Board hearings per year?
    - 1.3. Does the Board issue a temporary license?
    - 1.4. Is FPGEC certification required for all foreign-educated license transfer applicants?
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  - 3. Does the state register technicians?
  - 4. Does the state require national certification?
  - 5. Does the state require criminal history checks for pharmacy technician licensure or registration?
  - 6. What is the pharmacy technician registration fee?
  - 7. What is the pharmacy technician registration renewal schedule?
  - 8. Does the state have pharmacy technician training requirements?
  - 9. Does the state require pharmacy technicians to complete accredited pharmacy technician education/training?
  - 10. Does the state have pharmacy technician CPE requirements?
    - 10.1. How many CPE hours are required for pharmacy technicians?
  - 11. Is there a pharmacy technician examination requirement?
  - 12. Can the Board deny, revoke, suspend, or restrict pharmacy technician registration?
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  - 1. May a pharmacy technician in the hospital/institutional setting accept called-in prescriptions from physician's offices?
  - 2. May a pharmacy technician in the hospital/institutional setting enter prescriptions into pharmacy computers?
  - 3. May a pharmacy technician in the hospital/institutional setting check the work of other technicians?
    - 3.1. Is there a requirement for technology?
  - 4. May a pharmacy technician in the hospital/institutional setting call physicians for refill authorization?
  - 5. May a pharmacy technician in the hospital/institutional setting compound medications for dispensing?
  - 6. May a pharmacy technician in the hospital/institutional setting transfer prescription orders?
- (13) Pharmacy Technicians in Community Setting
  - 1. May a pharmacy technician in the community setting accept called-in prescriptions from physician's offices?
  - 2. May a pharmacy technician in the community setting enter prescriptions into pharmacy computers?
  - 3. May a pharmacy technician in the community setting check the work of other technicians?
  - 4. May a pharmacy technician in the community setting call physicians for refill authorization?

5. May a pharmacy technician in the community setting compound medications for dispensing?
6. May a pharmacy technician in the community setting transfer prescription orders?
7. May a pharmacy technician in the community setting administer vaccines, as permitted by state laws or regulations?
8. May a pharmacy technician in the community setting perform point-of-care testing?

(14) Pharmacy Licensure Requirements

1. What is the number of pharmacy license categories?
2. Must nonresident pharmacies be licensed for registered?
3. Must nonresident pharmacists be licensed?
4. Does the state issue separate licenses for sterile compounding pharmacies?
5. Does the state issue separate licenses for sterile compounding facilities that are registered with FDA as outsourcing facilities?
6. Does the state have a separate license category for specialty pharmacy?
7. What is the initial pharmacy licensure or registration fee?
8. What is the pharmacy licensure renewal fee?
9. What is the pharmacy licensure renewal schedule?
10. What is the pharmacy licensure initial controlled substance fee?
11. What is the pharmacy licensure controlled substance renewal fee?
12. What is the pharmacy licensure controlled substance renewal schedule?
13. Does the state recognize NABP Digital Pharmacy Accreditation?
14. Does the state recognize VPP?
15. Does the state require VPP?
16. Does the state have a minimum number of hours requirement for the PIC to work each week?
17. Does the state require the PIC to be an employee?

(15) Wholesale Prescription Drug Distributor License Requirements

1. Is the Board of Pharmacy responsible for licensing wholesale distributors?
2. What is the initial wholesale distributor licensure or registration fee?
3. What is the wholesale distributor renewal fee?
4. What is the wholesale distributor renewal schedule?
5. Does the state have a third-party logistics provider law?
6. Does the state license out-of-state wholesalers?
7. Does the state require wholesale distributors of nonprescription drugs to be licensed?
8. Are criminal history record checks required for wholesale distributors?
9. Does the state recognize NABP Drug Distributor Accreditation?
10. Does the state recognize NABP Supply Chain Inspection?
11. Does the state require NABP Supply Chain Inspection?
12. Does the state require a Supply Chain Inspection for the licensure of wholesale drug distributors?
  - 12.1. How recent must the inspection be?
13. Does the state require a Supply Chain Inspection for the licensure of third-party logistics providers?
  - 13.1. How recent must the inspection be?

(16) Device Wholesale Distributor Licensure Requirements

1. Does the state license device manufacturers?
  - 1.1. Which agency?
2. Does the state license dispensers of prescription medical devices that are not pharmacies?
  - 2.1. Which agency?
3. Does the state license dispensers of nonprescription medical devices that are not pharmacies?
  - 3.1. Which agency?
4. Does the state require wholesale distributors of prescription medical devices to be licensed?
  - 4.1. Which agency?
5. Does the state require wholesale distributors of durable medical equipment to be licensed?
  - 5.1. Which agency?
6. Does the Board of Pharmacy have regulatory authority over wholesale distributors of nonprescription and/or prescription medical devices?

(17) Manufacturer and Outsourcing Facility Licensure Requirements

1. Does the state license virtual manufacturers?
2. Does the state license resident outsourcing 503B facilities?
  - 2.1. How are resident outsourcing 503B facilities licensed?
3. Does the state license nonresident outsourcing 503B facilities?
  - 3.1. How are nonresident outsourcing 503B facilities licensed?
4. Does the state require NABP drug distributor accreditation for 503B outsourcing facilities?
5. Does the state license or register manufacturers?
  - 5.1. How are manufacturers licensed?
6. Does the state permit community pharmacies to dispense compounded products procured from 503B outsourcing facilities?

**Drug Law**

(18) Drug Control Regulations

1. Does the state have a Food, Drug, and Cosmetic Act?
2. Does the state have a Dangerous Drug Law?
3. Does the state have a Controlled Substances Act?
  - 3.1. Are precursors or substances placed in a controlled substance schedule?
  - 3.2. Are controlled substances or drugs of concern scheduled differently than the federal Controlled Substances Act?
    - 3.2.1. Which drugs are scheduled differently than the federal Controlled Substances Act?
  - 3.3. Are there quantity limits for controlled substances?
    - 3.3.1. What quantity limits are imposed?
4. Does the state have laws or regulations on over-the-counter sale of pseudoephedrine?
5. Does the state have laws or regulations on dispensing medical oxygen?
6. Does the state have medical marijuana laws?
7. Does the state have cannabidiol laws?

(19) Drug Product Selection Laws

1. What is the state drug formulary?
2. Does the state use the two-line Rx format?
3. Does the state require permissive or mandatory drug product substitution?
4. How does the state prevent substitution?
5. How does the state require the pharmacy to pass on cost savings?
6. Does the state require patient notification of the substitution?
7. Has the state designated a list of drugs that are not substitutable (i.e., narrow therapeutic index drugs)?
8. Does the state have any interchangeability requirements for biosimilars or biologics?

(20) Prescription Requirements

1. Is a prescription order valid for a non-controlled legend drug from an out-of-state provider?
2. Is a prescription order valid for a controlled substance from an out-of-state prescriber?
3. Is a prescription order valid if based on an online questionnaire?
4. Is a prescription order needed to buy syringes or needles?
5. Are syringes or needles restricted to sale only in a pharmacy?
6. Is there a time limit on prescription refills?
  - 6.1. What is the limit?
7. Does the state allow the sale of Schedule V preparations over-the-counter?
8. Does the state require identification for Schedule II controlled substances prescriptions?
9. Does the state require identification of controlled substance prescriptions other than Schedule II?
10. Does the state allow the use of preprinted prescription forms for non-controlled substances?
11. Does the state require expiration or beyond-use date on prescription vial labels in community practice?
12. How long must prescription records be maintained?
13. Are there any size, design, layout, security features, or other formatting requirements for prescription pads?

(21) Electronic Prescriptions

1. Does the state require electronic transmission of prescriptions?

(22) Prescription Monitoring Program Requirements

1. Does the state have mandatory PDMP reviewing requirements?
2. Does the state require the reporting of drugs to the PDMP other than those that are federally controlled?
  - 2.1. Which non-federally controlled drugs are required to be reported?
3. Does the state require a PDMP waiver submission?
  - 3.1. How often does the PDMP waiver submission need to be renewed?

(23) Patient Counseling Requirements

1. Is patient counseling required for Medicaid patients?
2. Is patient counseling required for non-Medicaid patients?
3. Is patient counseling required for new patients?
4. Is patient counseling required for refill prescriptions?
5. Must patient counseling be performed personally, face-to-face, by the pharmacist?

6. Are patient profiles mandated?

(24) Prescribing Authority

7. What is the prescribing authority for a physician assistant?
8. What is the prescribing authority for an advanced practice registered nurse?
9. What is the prescribing authority for a clinical nurse specialist?
10. What is the prescribing authority for a certified nurse midwife?
11. What is the prescribing authority for a midwife (non-APRN)?
12. What is the prescribing authority for a certified nurse practitioner?
13. What is the prescribing authority for a certified registered nurse anesthetist?
14. What is the prescribing authority for a doctor of homeopathy (limited to course of practice)?
15. What is the prescribing authority for an optometrist?
16. What is the prescribing authority for an emergency medical technician paramedic?
17. What is the prescribing authority for a naturopathic doctor?

(25) Dispensing Authority

18. Does a medical doctor have dispensing authority?
19. Does a doctor of osteopathic medicine have dispensing authority?
20. Does a dentist have dispensing authority?
21. Does a podiatrist have dispensing authority?
22. Does a veterinarian have dispensing authority?
23. Does a doctor of homeopathy have dispensing authority?
24. Does a physician assistant have dispensing authority?
25. Does an advanced practice registered nurse have dispensing authority?
26. Does a clinical nurse specialist have dispensing authority?
27. Does a certified nurse midwife have dispensing authority?
28. Does a midwife have dispensing authority?
29. Does a certified nurse practitioner have dispensing authority?
30. Does an optometrist have dispensing authority?
31. Does a naturopathic doctor have dispensing authority?

(26) Possession of Non-Controlled Legend Drugs

1. May a medical doctor have possession of non-controlled legend drugs?
2. May a doctor of osteopathic medicine have possession of non-controlled legend drugs?
3. May a dentist have possession of non-controlled legend drugs?
4. May a podiatrist have possession of non-controlled legend drugs?
5. May a veterinarian have possession of non-controlled legend drugs?
6. May a doctor of homeopathy have possession of non-controlled legend drugs?
7. May a physician assistant have possession of non-controlled legend drugs?
8. May an advanced practice registered nurse have possession of non-controlled legend drugs?
9. May a clinical nurse specialist have possession of non-controlled legend drugs?
10. May a certified nurse midwife have possession of non-controlled legend drugs?
11. May a midwife have possession of non-controlled legend drugs?
12. May a certified nurse practitioner have possession of non-controlled legend drugs?
13. May an optometrist have possession of non-controlled legend drugs?
14. May a naturopathic doctor have possession of non-controlled legend drugs?
15. May a pharmacist have possession of non-controlled legend drugs?

(27) Possession of Controlled Substances

1. May a medical doctor have possession of controlled substances?
2. May a doctor of osteopathic medicine have possession of controlled substances?
3. May a dentist have possession of controlled substances?
4. May a podiatrist have possession of controlled substances?
5. May a veterinarian have possession of controlled substances?
6. May a doctor of homeopathy have possession of controlled substances?
7. May a physician assistant have possession of controlled substances?
8. May an advanced practice registered nurse have possession of controlled substances?
9. May a clinical nurse specialist have possession of controlled substances?
10. May a certified nurse midwife have possession of controlled substances?
11. May a midwife have possession of controlled substances?
12. May a certified nurse practitioner have possession of controlled substances?
13. May an optometrist have possession of controlled substances?
14. May a naturopathic doctor have possession of controlled substances?
15. May a pharmacist have possession of controlled substances?

(28) Independent Pharmacist Practice

1. May pharmacists initiate, modify, and/or discontinue drug therapy pursuant to a collaborative practice agreement or protocol?
2. May pharmacists administer drugs?
3. May pharmacists independently administer immunizations to adults in accordance with CDC and ACIP schedules?
4. May pharmacists order lab tests?
5. May pharmacists administer tests?
6. What type(s) of tests?
7. May pharmacists interpret tests?
8. May pharmacists prescribe based upon test outcome(s)?
9. May pharmacists prescribe naloxone?
10. Do pharmacists have independent authority to prescribe (not including collaborative practice agreements and statewide protocols)?
11. Does the state issue controlled substances licenses to pharmacists?

(29) Remote Pharmacy Practice

1. May pharmacists practice medication therapy management outside of a pharmacy setting?
2. Can prescription order entry occur outside of a licensed pharmacy?
3. Can product verification occur outside of a licensed pharmacy?

(30) Miscellaneous State Pharmacy Laws

1. Does the board allow centralized prescription filling facilities to be utilized?
2. Is prescriber ownership of a pharmacy prohibited?
3. Does the state have "freedom of choice" legislation?
4. Does the state have laws or regulations on dispensing prescription medical devices?
5. Does the state require pharmacies to conduct self-inspections?
6. Does the board require pharmacies to maintain any type of continuous quality improvement program to monitor and prevent quality-related events?
7. Does the board have regulations aimed at relieving pharmacist workload?
8. Does the board have regulatory oversight of pharmacy benefit managers?
9. Does the state allow drug repository or donation programs?

10. Does the state permit the return and reuse of medications?
11. Does the state have laws or regulations on the disposal of medications?
12. Does the state allow the practice of telepharmacy?

(31) State References to USP Chapters

1. Does the Board require compliance with USP Chapter 795 Pharmaceutical Compounding - Nonsterile Preparations?
  - 1.1. Which version should licensees comply with?
  - 1.2. Does the board adopt the chapter by reference?
2. Do statutes, regulations, or policy incorporate the standards of USP Chapter 795?
3. Does the Board require compliance with USP Chapter 797 Pharmaceutical Compounding - Sterile Preparations?
  - 3.1. Which version should licensees comply with?
  - 3.2. Does the board adopt the chapter by reference?
4. Do statutes, regulations, or policy incorporate the standards of USP Chapter 797?
5. Does the Board require compliance with USP Chapter 800 Hazardous Drugs - Handling in Healthcare Settings?
  - 5.1. Which version should licensees comply with?
  - 5.2. Does the board adopt the chapter by reference?
6. Do statutes, regulations, or policy incorporate the standards of USP Chapter 800?

## Census Data

1. What is the number of pharmacists licensed by the state?
2. What is the number of pharmacists with in-state addresses?
3. What is the number of pharmacists working in ambulatory/community pharmacy practice settings?
4. What is the number of pharmacists working in hospital pharmacy practice settings?
5. What is the number of pharmacists working in manufacturing/wholesale practice settings?
6. What is the number of pharmacists working in teaching/government practice settings?
7. What is the number of pharmacists working in "other" practice settings?
8. What is the number of pharmacy interns?
9. What is the number of pharmacy technicians?
10. What is the number of pharmacies?
11. What is the number of resident outsourcing facilities?
12. What is the number of nonresident outsourcing facilities?
13. What is the number of sterile compounding licenses/registrations?
14. What is the number of licensed hospital/institutional pharmacies?
15. What is the number of licensed independent community pharmacies?
16. What is the number of licensed chain pharmacies?
17. What is the number of licensed out-of-state or nonresident pharmacies?
18. What is the number of manufacturers?
19. What is the number of wholesale distributors?
20. What is the number of nonresident wholesale distributors?