

2014

Prepared for:

Allergan
State Government Affairs
Irvine, CA

BOARDS OF PHARMACY REGULATING PHYSICIAN DISPENSING



195 International Parkway, Suite 102
Lake Mary, FL 32746

EXECUTIVE SUMMARY

Several states have statutes and regulations where a state's Board of Pharmacy either permits or controls the dispensing of prescription medications by physicians. While the Board of Pharmacy in each of these states has the statutory authority to regulate physician dispensing, the approach in each state is somewhat different.

In some states, it is the Board of Pharmacy that simply *allows* physicians to dispense. Beyond this allowance, the Board requires no other actions by the dispensing physicians. These Boards impress upon those practitioners who wish to dispense to follow the regulations set forth for pharmacists when dispensing.

Other Boards of Pharmacy take a much more active role with dispensing physicians. A physician who wishes to dispense must obtain a license from the Board of Pharmacy before he/she may begin dispensing. The statutes in these states frequently mandate that a physician licensed to dispense must follow the regulations of the Board of Pharmacy. Below is a table showing the regulatory board for practitioner dispensing.

| State | Practitioner Dispensing Permitted | Licensure Required | Permitted or Licensed to Dispense by: |
|----------------|-----------------------------------|--------------------|---------------------------------------|
| Alabama | Yes | required | Board of Medicine |
| Arizona | Yes | required | Board of Medicine |
| DC | Yes | required | Board of Medicine |
| Florida | Yes | required | Board of Pharmacy |
| Georgia | Yes | required | Board of Pharmacy |
| Idaho | Yes | required | Board of Medicine |
| Indiana | Yes | required | Board of Medicine |
| Iowa | Yes | required | Board of Medicine |
| Louisiana | Yes | required | Board of Medicine |
| Maryland | Yes | required | Board of Medicine |
| Michigan | Yes | required | Board of Pharmacy |
| Minnesota | Yes | required | Board of Pharmacy |
| Missouri | Yes | required | Board of Medicine |
| Nebraska | Yes | required | Board of Pharmacy |
| Nevada | Yes | required | Board of Pharmacy |
| North Carolina | Yes | required | Board of Pharmacy |
| Ohio | Yes | required | Board of Pharmacy |
| Oklahoma | Yes | required | Board of Medicine |
| Oregon | Yes | required | Board of Pharmacy |
| Rhode Island | Yes | not required | Board of Pharmacy |
| South Carolina | Yes | required | Board of Pharmacy |
| South Dakota | Yes | required | Board of Pharmacy |
| Virginia | Yes | required | Board of Pharmacy |
| West Virginia | Yes | required | Board of Medicine |
| Wyoming | Yes | required | Board of Medicine |

The following exhibits are examples of the statutes and regulations for five states where the Boards of Pharmacy have varying degrees of authority over practitioner dispensing.

Rhode Island - Allows physicians to dispense under the rules of the Board of Pharmacy.

Statute TITLE 5 Businesses and Professions

CHAPTER 5-19.1 Pharmacies

§ 5-19.1-22 Authorized practices. – Nothing contained in this chapter shall apply to any practitioner with authority to prescribe who does not keep open shop for the retailing, dispensing of medicines and poisons, nor prevent him or her from administering or supplying to his patients such articles as he or she may deem fit and proper. Nothing in this chapter shall apply to, nor in any manner interfere with, the business of a general merchant in selling and distributing non-narcotic, nonprescription medicines or drugs which are prepackaged, fully prepared by the manufacturer for use by the consumer, and labeled in accordance with the requirements of the state and federal food and drug acts.

History of Section.
(P.L. 2001, ch. 60, § 2.)

Regulation [R5-19.1-PHAR]

PART I Definitions

Section 1.0 Definitions

1.38 "Dispense" or "dispensing" means the interpretation of a prescription or order for a drug, biological, or device and, pursuant to that prescription or order, the proper selection, measuring, compounding, labeling, or packaging necessary to prepare that prescription or order for delivery or administration.

1.92 "Practitioner" means a physician, physician assistant, dentist, veterinarian, nurse or other person duly authorized by law in the state in which they practice to prescribe drugs.

PART II Pharmacists/Licensure Requirements

Section 2.0 Licensure Requirement

Authorized Practices

2.2 In accordance with §5-19.1-22 of the Act, nothing in the Act or these Regulations shall apply to any practitioner with authority to prescribe who does not keep open shop for the retailing, dispensing of medicines and poisons, nor prevent him or her from administering or supplying to his patients such articles as he or she may deem fit and proper.

Virginia- For a practitioner to dispense he/she must be licensed by the Board of Pharmacy.

Statute Chapter 33 of Title 54.1 of the Code of Virginia

Pharmacy

§ 54.1-3304. Licensing of physicians to dispense drugs; renewals.

For good cause shown, the Board may grant a license to any physician licensed under the laws of Virginia authorizing such physician to dispense drugs to persons to whom a pharmaceutical service is not reasonably available. This license may be renewed annually. Any physician or osteopath so licensed shall be governed by the regulations of the Board of Pharmacy when applicable.

(1976, c. 614, § 54-524.34:1; 1980, c. 288; 1988, c. 765.)

§ 54.1-3304.1. Authority to license and regulate practitioners.

The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts.

(1988, c. 904, § 54-524.34:2; 1989, c. 510.)

Regulation 18 VAC 110-20-10 et seq.

18VAC110-20-410. Permitted physician licensed by the board.

A. Pursuant to §54.1-3304 of the Code of Virginia, physicians licensed by the board to dispense drugs, when pharmacy services are not reasonably available, shall be subject to the following sections of this chapter. For purposes of this section, the terms "pharmacist," "pharmacist-in-charge," "pharmacy," and "PIC" in the sections listed below shall be deemed to mean the physician permitted by the board:

1. 18VAC110-20-110 C and D;
2. 18VAC110-20-130 A;
3. 18VAC110-20-140 A, C;
4. 18VAC110-20-150 except that these requirements shall not apply to physicians licensed prior to August 25, 2004, unless the dispensing area is relocated or remodeled;
5. 18VAC110-20-160;
6. 18VAC110-20-180;
7. 18VAC110-20-190 A, B, and C;
8. 18VAC110-20-200;
9. 18VAC110-20-210; and
10. 18VAC110-20-240 through 18VAC110-20-410.

B. A physician may apply for a special or limited use permit in accordance with 18VAC110-20-120.

Florida - For a practitioner to dispense he/she must be licensed and inspected annually by the Board of Pharmacy.

Statute 465.0276, F.S. Dispensing Practitioner

(1)(a) A person may not dispense medicinal drugs unless licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section.

(b) A practitioner registered under this section may not dispense a controlled substance listed in Schedule II or Schedule III as provided in s. 893.03. This paragraph does not apply to:

1. The dispensing of complimentary packages of medicinal drugs which are labeled as a drug sample or complimentary drug as defined in s. 499.028 to the practitioner's own patients in the regular course of her or his practice without the payment of a fee or remuneration of any kind, whether direct or indirect, as provided in subsection (5).

2. The dispensing of controlled substances in the health care system of the Department of Corrections.

3. The dispensing of a controlled substance listed in Schedule II or Schedule III in connection with the performance of a surgical procedure. The amount dispensed pursuant to the subparagraph may not exceed a 14-day supply. This exception does not allow for the dispensing of a controlled substance listed in Schedule II or Schedule III more than 14 days after the performance of the surgical procedure. For purposes of this subparagraph, the term "surgical procedure" means any procedure in any setting which involves, or reasonably should involve:

a. Perioperative medication and sedation that allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal or tactile stimulation and makes intra- and postoperative monitoring necessary; or

b. The use of general anesthesia or major conduction anesthesia and preoperative sedation.

4. The dispensing of a controlled substance listed in Schedule II or Schedule III pursuant to an approved clinical trial. For purposes of this subparagraph, the term "approved clinical trial" means a clinical research study or clinical investigation that, in whole or in part, is state or federally funded or is conducted under an investigational new drug application that is reviewed by the United States Food and Drug Administration.

5. The dispensing of methadone in a facility licensed under s. 397.427 where medication-assisted treatment for opiate addiction is provided.

6. The dispensing of a controlled substance listed in Schedule II or Schedule III to a patient of a facility licensed under part IV of chapter 400.

(2) A practitioner who dispenses medicinal drugs for human consumption for a fee or remuneration of any kind, whether direct or indirect, must:

(a) Register with her or his professional licensing board as a dispensing practitioner and pay a fee not to exceed \$100 at the time of such registration and upon each renewal of her or his license. Each appropriate board shall establish such fee by rule.

(b) Comply with and be subject to all laws and rules applicable to pharmacists and pharmacies, including, but not limited to, this chapter and chapters 499 and 893 and all federal laws and federal regulations.

Physician Dispensing

(c) Before dispensing any drug, give the patient a written prescription and orally or in writing advise the patient that the prescription may be filled in the practitioner's office or at any pharmacy.

(3) The department shall inspect any facility where a practitioner dispenses medicinal drugs pursuant to subsection (2) in the same manner and with the same frequency as it inspects pharmacies for the purpose of determining whether the practitioner is in compliance with all statutes and rules applicable to her or his dispensing practice.

(4) The registration of any practitioner who has been found by her or his respective board to have dispensed medicinal drugs in violation of this chapter shall be subject to suspension or revocation.

(5) A practitioner who confines her or his activities to the dispensing of complimentary packages of medicinal drugs to the practitioner's own patients in the regular course of her or his practice, without the payment of fee or remuneration of any kind, whether direct or indirect, and who herself or himself dispenses such drugs is not required to register pursuant to this section. The practitioner must dispense such drugs in the manufacturer's labeled package with the practitioner's name, patient's name, and date dispensed, or, if such drugs are not dispensed in the manufacturer's labeled package, they must be dispensed in a container which bears the following information:

- (a) Practitioner's name;
- (b) Patient's name;
- (c) Date dispensed;
- (d) Name and strength of drug; and
- (e) Directions for use.

(Ed.) No rule promulgated by Florida's Board of Pharmacy specifically addresses dispensing practitioners, since the statute makes it clear that a dispensing practitioner is to follow all of the regulations that a pharmacist must follow.

North Carolina - For a practitioner to dispense he/she must be licensed by the Board of Pharmacy.

Statute § 90-85.21. Pharmacy permit.

(b) Each physician who dispenses prescription drugs, for a fee or other charge, shall annually register with the Board on the form provided by the Board, and with the licensing board having jurisdiction over the physician. Such dispensing shall comply in all respects with the relevant laws and regulations that apply to pharmacists governing the distribution of drugs, including packaging, labeling, and record keeping. Authority and responsibility for disciplining physicians who fail to comply with the provisions of this subsection are vested in the licensing board having jurisdiction over the physician. The form provided by the Board under this subsection shall be as follows:

Application For Registration
With The Pharmacy Board
As A Dispensing Physician

1. Name and Address of Dispensing Physician _____
2. Affix Dispensing Label Here _____
3. Physician's North Carolina License Number _____
4. Are you currently practicing in a professional association registered with the North Carolina Medical Board?
_____ Yes _____ No. If yes, enter the name and registration number of the professional corporation:

5. I certify that the information is correct and complete.

Signature Date

Regulation 21 NCAC 46 .1912 APPLICATION FOR REGISTRATION AS A DISPENSING PHYSICIAN.

The form for application for registration as a dispensing physician is entitled "Application for Registration with the Pharmacy Board as a Dispensing Physician", and appears in G.S. 90-85.21 (b). All applicants for registration as a dispensing physician shall complete this form for original and renewal applications. Information requested includes name and address of dispensing physician, physician's North Carolina license number, whether the physician is currently practicing in a professional association registered with the North Carolina Board of Medical Examiners, the name and registration number of the professional corporation, if applicable, and a certification that the information given is correct and complete.
History Note: Authority G.S. 90-85.6; 90-85.21; Eff. February 1, 1991.

Georgia - Allows physicians to dispense under the rules of the Board of Pharmacy.

Statute Georgia Pharmacy Practice Act OCGA 26-4-130.

(d) All practitioners who dispense drugs shall make all records required to be kept under subsection (c) of this Code section available for inspection by the board.

(e) Any practitioner who desires to dispense drugs shall notify, at the time of the renewal of that practitioner's license to practice, that practitioner's respective licensing board of that practitioner's intention to dispense drugs. That licensing board shall notify the board regarding each practitioner concerning whom that board has received a notification of intention to dispense drugs. The licensing board's notification shall include the following information:

- (1) The name and address of the practitioner;
- (2) The state professional license number of the practitioner;
- (3) The practitioner's Drug Enforcement Administration license number; and
- (4) The name and address of the office or facility from which such drugs shall be dispensed and the address where all records pertaining to such drugs shall be maintained.

(f) The board shall have the authority to promulgate rules and regulations governing the dispensing of drugs pursuant to this Code section.

(g) This Code section shall not apply to practitioners who provide to their patients at no cost manufacturer's samples of drugs.

Regulation CHAPTER 480-28 PRACTITIONER DISPENSING OF DRUGS

480-28-.03 Notification of Intent to Dispense. Amended.

(1) Any practitioner who intends for his/her agent to dispense drugs shall notify, at the time of the renewal of that practitioner's license to operate, that practitioner's respective licensing board of that practitioner's intention to dispense drugs. The licensing board shall notify the Georgia State Board of Pharmacy regarding each practitioner whom that Board has received a notification of intention to dispense drugs. The licensing board's notification shall include the following information:

- (a) The name and address of the practitioner;
- (b) The state professional license number of the practitioner;
- (c) The practitioner's Drug Enforcement Administration license number; and
- (d) The complete name and address of the office or facility from which drugs shall be dispensed and the complete address where all records pertaining to such drugs shall be maintained.

Authority O.C.G.A. Secs. 26-4-4, 26-4-27, 26-4-28, 26-4-130. History. Original Rule entitled "Notification of Intent to Dispense" adopted. F. Sept. 15, 1987; eff. Oct. 15, 1987. Repealed: New Rule of same title adopted. F. July 24, 2002; eff. Aug. 13, 2002.