

## Virginia Board of Pharmacy

### Physicians Dispensing Drugs

Dispensing by a physician means the providing of drugs to patients to take with them away from the physician's place of practice. Physicians in Virginia may dispense under certain circumstances without being required to obtain a license to dispense from the Board of Pharmacy. Those circumstances include the dispensing of manufacturer's samples appropriately labeled as samples and not for sale, dispensing in a bona fide medical emergency, and dispensing when pharmaceutical services are not otherwise available. Any other type of dispensing by a physician requires the physician to obtain a license from the Board of Pharmacy. The Board offers two types of license to physicians.

#### **Permitted Physicians – Practice as a pharmacy**

One type of license, pursuant to § 54.1-3304 authorizes the Board to license a physician to practice pharmacy when good cause is shown that pharmacy services are not otherwise readily available. This type of license is usually granted to physicians working in rural areas where there is not a pharmacy within at least 15 to 20 miles and there are only a handful of these types of licenses still current. With this type of license, a physician may also fill prescriptions of other practitioners.

#### **Physicians Selling Drugs**

The second and more common type of dispensing license for physicians is the license for a practitioner of the healing arts to sell controlled substances. The term "controlled substances" in Virginia includes any drug in Schedule I through VI which is all prescription drugs, not just those drugs which are DEA controlled substances. Another confusing term is the term "sell" or "sale". Many physicians question why they are required to have this license if they do not charge a patient for the drugs dispensed. The term "sale" is defined in the Drug Control Act as "gift, barter, or exchange". Therefore a charge is not required in order for dispensing to become a "sale". With this license a physician must comply with a set of regulations which relate specifically to this license. If there is more than one physician dispensing within a single practice, each dispensing physician must obtain this license. Effective June 4, 2016, a permit from the Board of Pharmacy must also be obtained for the facility from which practitioners of the healing arts dispense controlled substances and it shall meet compliance with the regulations for practitioners of the healing arts to sell controlled substances. Physicians licensed to sell controlled substances may dispense from any facility permitted for this purpose.

While the regulation allows for a pharmacy technician, or trained nurse or trained physician assistant to assist the licensed physician in preparing the drug for dispensing, the physician is responsible for conducting a prospective drug review, offering to counsel the patient, inspecting the prescription product to verify its accuracy in all respects, and placing his initials on the record of sale as certification of the accuracy of, and the responsibility for, the entire transaction. The physician may not delegate the responsibility of dispensing a drug to a nurse practitioner or physician assistant; hence, no drug may be dispensed when a physician is not on-site.

Within this category of licensure, it is possible to request a **limited-use license**. Pursuant to Regulation 18VAC110-30-20 and the delegation of authority to the Executive Director as set

forth in Bylaws of the Board, a physician may apply for a limited-use license, when the scope, degree or type of services provided to the patient is of a limited nature. Under a limited-use license, a waiver of the square footage requirement for the controlled substances selling and storage area may be provided. Additionally, a waiver of the security system may be provided when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

There is one other exception to the pharmacy act which allows physicians acting on behalf of the state or a local health department to dispense without having to obtain licensure from the Board of Pharmacy. It has been interpreted that this authority can be delegated to other persons authorized to prescribe within the health department system, such as nurse practitioners, since there is no direct prohibition against such delegation, as is the case with the physician selling drugs license.

***Excerpts from the Code of Virginia—Pharmacy Act and Medical Practice Act related to physician dispensing***

**§ 54.1-3301. Exceptions.**

This chapter shall not be construed to:

1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any physician acting on behalf of the Virginia Department of Health or local health departments, in the compounding of his prescriptions or the purchase and possession of drugs as he may require;
2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health departments, from administering or supplying to his patients the medicines that he deems proper under the conditions of § 54.1-3303 or from causing drugs to be administered or dispensed pursuant to §§ 32.1-42.1 and 54.1-3408, except that a veterinarian shall only be authorized to dispense a compounded drug, distributed from a pharmacy, when (i) the animal is his own patient, (ii) the animal is a companion animal as defined in regulations promulgated by the Board of Veterinary Medicine, (iii) the quantity dispensed is no more than a 72-hour supply, (iv) the compounded drug is for the treatment of an emergency condition, and (v) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian;
3. Prohibit the sale by merchants and retail dealers of proprietary medicines as defined in Chapter 34 (§ 54.1-3400 et seq.) of this title;
4. Prevent the operation of automated drug dispensing systems in hospitals pursuant to Chapter 34 (§ 54.1-3400 et seq.) of this title;
5. Prohibit the employment of ancillary personnel to assist a pharmacist as provided in the regulations of the Board;
6. Interfere with any legally qualified practitioner of medicine, osteopathy, or podiatry from purchasing, possessing or administering controlled substances to his own patients or providing controlled substances to his own patients in a bona fide medical emergency or providing manufacturers' professional samples to his own patients;
7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic pharmaceutical agents, from purchasing, possessing or administering those controlled substances as

specified in § 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own patients those controlled substances as specified in § 54.1-3222 and the TPA formulary, providing manufacturers' samples of these drugs to his own patients, or dispensing, administering, or selling ophthalmic devices as authorized in § 54.1-3204;

8. Interfere with any physician assistant with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2952.1, to prescribe according to his practice setting and a written agreement with a physician or podiatrist;

9. Interfere with any licensed nurse practitioner with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe according to his practice setting and a written or electronic agreement with a physician;

10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle of the prescription drug ordered at no cost to the practitioner or patient. The practitioner may dispense such medication at no cost to the patient without holding a license to dispense from the Board of Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In lieu of dispensing directly to the patient, a practitioner may transfer the donated drug with a valid prescription to a pharmacy for dispensing to the patient. The practitioner or pharmacy participating in the program shall not use the donated drug for any purpose other than dispensing to the patient for whom it was originally donated, except as authorized by the donating manufacturer for another patient meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent patient program pursuant to this subdivision. A participating pharmacy, including a pharmacy participating in bulk donation programs, may charge a reasonable dispensing or administrative fee to offset the cost of dispensing, not to exceed the actual costs of such dispensing. However, if the patient is unable to pay such fee, the dispensing or administrative fee shall be waived;

11. Interfere with any legally qualified practitioner of medicine or osteopathy from providing controlled substances to his own patients in a free clinic without charge when such controlled substances are donated by an entity other than a pharmaceutical manufacturer as authorized by subdivision 10. The practitioner shall first obtain a controlled substances registration from the Board and shall comply with the labeling and packaging requirements of this chapter and the Board's regulations; or

12. Prevent any pharmacist from providing free health care to an underserved population in Virginia who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of this Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) files a copy of the license or certificate issued in such other jurisdiction with the Board, (v) notifies the Board at least five business days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that

such licensure exemption shall only be valid, in compliance with the Board's regulations, during the limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any pharmacist whose license has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a pharmacist who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.

This section shall not be construed as exempting any person from the licensure, registration, permitting and record keeping requirements of this chapter or Chapter 34 of this title.

**§ 54.1-3302. Restrictions on practitioners of the healing arts.**

A practitioner of the healing arts shall not sell or dispense controlled substances except as provided in §§ 54.1-2914 and 54.1-3304.1. Such exceptions shall extend only to his own patients unless he is licensed to practice 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.

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

A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any practitioner of the healing arts to dispense controlled substances within the Commonwealth unless licensed by the Board to sell controlled substances.

B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances. Facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances shall be exempt from fees associated with obtaining and renewing such permit.

**§ 54.1-2914. Sale of controlled substances and medical devices or appliances; requirements for vision care services.**

A. A practitioner of the healing arts shall not engage in selling controlled substances unless he is licensed to do so by the Board of Pharmacy. However, this prohibition shall not apply to a doctor of medicine, osteopathy or podiatry who administers controlled substances to his patients or provides controlled substances to his patient in a bona fide medical emergency or when pharmaceutical services are not available. Practitioners who sell or dispense controlled substances shall be subject to inspection by the Department of Health Professions to ensure compliance with Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of this title and the Board of Pharmacy's regulations. This subsection shall not apply to physicians acting on behalf of the Virginia Department of Health or local health departments.

B. A practitioner of the healing arts who may lawfully sell medical appliances or devices shall not sell such appliances or devices to persons who are not his own patients and shall not sell such articles to his own patients either for his own convenience or for the purpose of supplementing his income. This

subsection shall not apply to physicians acting on behalf of the Virginia Department of Health or local health departments.

C. A practitioner of the healing arts may, from within the practitioner's office, engage in selling or promoting the sale of eyeglasses and may dispense contact lenses. Only those practitioners of the healing arts who engage in the examination of eyes and prescribing of eyeglasses may engage in the sale or promotion of eyeglasses. Practitioners shall not employ any unlicensed person to fill prescriptions for eyeglasses within the practitioner's office except as provided in subdivision A 6 of § 54.1-2901. A practitioner may also own, in whole or in part, an optical dispensary located adjacent to or at a distance from his office.

D. Any practitioner of the healing arts engaging in the examination of eyes and prescribing of eyeglasses shall give the patient a copy of any prescription for eyeglasses and inform the patient of his right to have the prescription filled at the establishment of his choice. No practitioner who owns, in whole or in part, an establishment dispensing eyeglasses shall make any statement or take any action, directly or indirectly, that infringes on the patient's right to have a prescription filled at an establishment other than the one in which the practitioner has an ownership interest.

Disclosure of ownership interest by a practitioner as required by § 54.1-2964 or participation by the practitioner in contractual arrangements with third-party payors or purchasers of vision care services shall not constitute a violation of this subsection.