

HOUSE BILL NO. 1006

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health and Human Services

on _____)

(Patron Prior to Substitute—Delegate Tran)

A BILL to amend and reenact § 54.1-3304.1 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 54.1-3222.1, relating to TPA-certified optometrists; selling and dispensing Schedule VI controlled substances; requirements.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3304.1 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-3222.1 as follows:

§ 54.1-3222.1. Selling and dispensing Schedule VI controlled substances by TPA-certified optometrist; requirements.

A. A TPA-certified optometrist may sell and dispense any Schedule VI controlled substances, as defined in § 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), directly to a patient for the treatment of conditions of the eye and its adnexa, provided that:

1. The TPA-certified optometrist is authorized to prescribe the Schedule VI controlled substance pursuant to § 54.1-3222; and

2. Such selling or dispensing is extended only to the optometrist's own patients, and such sale or dispensation complies with the provisions of this section.

B. A TPA-certified optometrist shall not engage in selling or dispensing a Schedule VI controlled substance unless he is licensed to do so by the Board of Pharmacy. The premises of a TPA-certified optometrist who sells or dispenses a Schedule VI controlled substance shall be subject to inspection by the Department of Health Professions to ensure compliance with Chapter 33 (§ 54.1-3300 et seq.), the Drug Control Act (§ 54.1-3400 et seq.), and the Board of Pharmacy's regulations.

C. A TPA-certified optometrist shall (i) be present on the premises at the time the Schedule VI controlled substance is sold and dispensed to a patient and be actively involved in the dispensing process; (ii) inform the patient of the appropriate use of the Schedule VI controlled substance being sold and dispensed; and (iii) comply with all applicable Board of Optometry and Board of Pharmacy regulations concerning the storage, packaging, labeling, recordkeeping, and reporting of the controlled substances sold and dispensed.

D. Dispensing and selling pursuant to this section shall be limited to (i) finished pharmaceutical products that are dispensed and sold strictly in accordance with the manufacturer's labeling and that are in the

33 *manufacturer's original, unaltered form; (ii) drugs intended solely for patient self-administration outside the*
34 *optometrist's office; and (iii) prescriptions that are topical, ophthalmic, or oral in form. No pharmaceutical*
35 *product dispensed or sold pursuant to this section shall be compounded, repackaged, or otherwise altered by*
36 *the optometrist.*

37 *E. Nothing in this section shall be construed to otherwise expand the administrative or prescriptive*
38 *authority of a doctor of optometry.*

39 *F. The Board of Optometry, in consultation with the Board of Pharmacy, may promulgate regulations to*
40 *implement the provisions of this section, including provisions for the storage, packaging, labeling,*
41 *recordkeeping, and reporting of controlled substances dispensed by a TPA-certified optometrist.*

42 **§ 54.1-3304.1. Authority to license and regulate practitioners; permits.**

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

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

51 C. The Board of Pharmacy may issue a limited-use license for the purpose of dispensing Schedule VI
52 controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes
53 and needles for the administration of prescribed controlled substances to a doctor of medicine, osteopathic
54 medicine, or podiatry, an advanced practice registered nurse, or a physician assistant, provided that such
55 limited-use licensee is practicing at a nonprofit facility. Such facility shall obtain a limited-use permit from
56 the Board and comply with regulations for such a permit.

57 *D. The Board of Pharmacy may issue a limited-use license to a TPA-certified optometrist for the purpose*
58 *of dispensing and selling of Schedule VI controlled substances consistent with the provisions of*
59 *§ 54.1-3222.1.*

60 **2. That the Board of Optometry and the Board of Pharmacy may promulgate regulations as necessary**
61 **to implement the provisions of this act and such initial regulations shall be exempt from the**
62 **Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia). The Board of Pharmacy's**
63 **regulations may include provisions for the issuance of a limited-use license consistent with the**

64 provisions of this act.