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SENATE BILL NO. 1403

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare and Institutions
on February 9, 2017)

(Patron Prior to Substitute—Senator Dunnavant)

A *BILL to amend and reenact §§ 2.2-4006 and 54.1-3443 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 54.1-3408.05, relating to descheduling or rescheduling controlled substances.*

Be it enacted by the General Assembly of Virginia:

1. That §§ 2.2-4006 and 54.1-3443 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-3408.05 as follows:

§ 2.2-4006. Exemptions from requirements of this article.

A. The following agency actions otherwise subject to this chapter and § 2.2-4103 of the Virginia Register Act shall be exempted from the operation of this article:

1. Agency orders or regulations fixing rates or prices.

2. Regulations that establish or prescribe agency organization, internal practice or procedures, including delegations of authority.

3. Regulations that consist only of changes in style or form or corrections of technical errors. Each promulgating agency shall review all references to sections of the Code of Virginia within their regulations each time a new supplement or replacement volume to the Code of Virginia is published to ensure the accuracy of each section or section subdivision identification listed.

4. Regulations that are:

a. Necessary to conform to changes in Virginia statutory law or the appropriation act where no agency discretion is involved. However, such regulations shall be filed with the Registrar within 90 days of the law's effective date;

b. Required by order of any state or federal court of competent jurisdiction where no agency discretion is involved; or

c. Necessary to meet the requirements of federal law or regulations, provided such regulations do not differ materially from those required by federal law or regulation, and the Registrar has so determined in writing. Notice of the proposed adoption of these regulations and the Registrar's determination shall be published in the Virginia Register not less than 30 days prior to the effective date of the regulation.

5. Regulations of the Board of Agriculture and Consumer Services adopted pursuant to subsection B of § 3.2-3929 or clause (v) or (vi) of subsection C of § 3.2-3931 after having been considered at two or more Board meetings and one public hearing.

6. Regulations of the regulatory boards served by (i) the Department of Labor and Industry pursuant to Title 40.1 and (ii) the Department of Professional and Occupational Regulation or the Department of Health Professions pursuant to Title 54.1 that are limited to reducing fees charged to regulants and applicants.

7. The development and issuance of procedural policy relating to risk-based mine inspections by the Department of Mines, Minerals and Energy authorized pursuant to §§ 45.1-161.82 and 45.1-161.292:55.

8. General permits issued by the (a) State Air Pollution Control Board pursuant to Chapter 13 (§ 10.1-1300 et seq.) of Title 10.1 or (b) State Water Control Board pursuant to the State Water Control Law (§ 62.1-44.2 et seq.), Chapter 24 (§ 62.1-242 et seq.) of Title 62.1 and Chapter 25 (§ 62.1-254 et seq.) of Title 62.1, (c) Virginia Soil and Water Conservation Board pursuant to the Dam Safety Act (§ 10.1-604 et seq.), and (d) the development and issuance of general wetlands permits by the Marine Resources Commission pursuant to subsection B of § 28.2-1307, if the respective Board or Commission (i) provides a Notice of Intended Regulatory Action in conformance with the provisions of § 2.2-4007.01, (ii) following the passage of 30 days from the publication of the Notice of Intended Regulatory Action forms a technical advisory committee composed of relevant stakeholders, including potentially affected citizens groups, to assist in the development of the general permit, (iii) provides notice and receives oral and written comment as provided in § 2.2-4007.03, and (iv) conducts at least one public hearing on the proposed general permit.

9. The development and issuance by the Board of Education of guidelines on constitutional rights and restrictions relating to the recitation of the pledge of allegiance to the American flag in public schools pursuant to § 22.1-202.

10. Regulations of the Board of the Virginia College Savings Plan adopted pursuant to § 23.1-704.

11. Regulations of the Marine Resources Commission.

12. Regulations adopted by the Board of Housing and Community Development pursuant to (i) Statewide Fire Prevention Code (§ 27-94 et seq.), (ii) the Industrialized Building Safety Law (§ 36-70 et

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60 seq.), (iii) the Uniform Statewide Building Code (§ 36-97 et seq.), and (iv) § 36-98.3, provided the
61 Board (a) provides a Notice of Intended Regulatory Action in conformance with the provisions of
62 § 2.2-4007.01, (b) publishes the proposed regulation and provides an opportunity for oral and written
63 comments as provided in § 2.2-4007.03, and (c) conducts at least one public hearing as provided in
64 §§ 2.2-4009 and 36-100 prior to the publishing of the proposed regulations. Notwithstanding the
65 provisions of this subdivision, any regulations promulgated by the Board shall remain subject to the
66 provisions of § 2.2-4007.06 concerning public petitions, and §§ 2.2-4013 and 2.2-4014 concerning
67 review by the Governor and General Assembly.

68 13. Amendments to regulations of the Board to schedule a substance ~~in Schedule I or II~~ pursuant to
69 subsection D or E of § 54.1-3443.

70 14. Waste load allocations adopted, amended, or repealed by the State Water Control Board pursuant
71 to the State Water Control Law (§ 62.1-44.2 et seq.), including but not limited to Article 4.01
72 (§ 62.1-44.19:4 et seq.) of the State Water Control Law, if the Board (i) provides public notice in the
73 Virginia Register; (ii) if requested by the public during the initial public notice 30-day comment period,
74 forms an advisory group composed of relevant stakeholders; (iii) receives and provides summary
75 response to written comments; and (iv) conducts at least one public meeting. Notwithstanding the
76 provisions of this subdivision, any such waste load allocations adopted, amended, or repealed by the
77 Board shall be subject to the provisions of §§ 2.2-4013 and 2.2-4014 concerning review by the Governor
78 and General Assembly.

79 15. Regulations of the Workers' Compensation Commission adopted pursuant to § 65.2-605, including
80 regulations that adopt, amend, adjust, or repeal Virginia fee schedules for medical services, provided the
81 Workers' Compensation Commission (i) utilizes a regulatory advisory panel constituted as provided in
82 subdivision F 2 of § 65.2-605 to assist in the development of such regulations and (ii) provides an
83 opportunity for public comment on the regulations prior to adoption.

84 B. Whenever regulations are adopted under this section, the agency shall state as part thereof that it
85 will receive, consider and respond to petitions by any interested person at any time with respect to
86 reconsideration or revision. The effective date of regulations adopted under this section shall be in
87 accordance with the provisions of § 2.2-4015, except in the case of emergency regulations, which shall
88 become effective as provided in subsection B of § 2.2-4012.

89 C. A regulation for which an exemption is claimed under this section or § 2.2-4002 or 2.2-4011 and
90 that is placed before a board or commission for consideration shall be provided at least two days in
91 advance of the board or commission meeting to members of the public that request a copy of that
92 regulation. A copy of that regulation shall be made available to the public attending such meeting.

93 **§ 54.1-3408.05. Use of FDA-approved substance upon publication of final rule.**

94 *Except as otherwise provided in this chapter, no person shall be prosecuted under Chapter 7*
95 *(§ 18.2-247 et seq.) of Title 18.2 for acting in accordance with § 54.1-3421 or for prescribing,*
96 *administering, dispensing, or possessing pursuant to a valid prescription issued by a prescriber any*
97 *substance that has been approved as a prescription drug by the U.S. Food and Drug Administration*
98 *pursuant to 21 U.S.C. § 360bb and 21 U.S.C. § 355 on or after July 1, 2017, in accordance with any*
99 *final or interim final order or rule issued pursuant to 21 U.S.C. § 811(j). Such immunity from*
100 *prosecution for a particular substance shall remain in effect until the earlier of (i) nine months as*
101 *calculated from the latter of the date of the publication in the Federal Register of the interim final order*
102 *or rule scheduling such substance or the final order or rule scheduling such substance, provided that a*
103 *final order or rule is issued within nine months of the interim final order or rule, or (ii) such substance*
104 *being added to a schedule in Article 5 (§ 54.1-3443 et seq.) pursuant to § 54.1-3443 or by enactment*
105 *into law.*

106 **§ 54.1-3443. Board to administer article.**

107 A. The Board shall administer this article and may add substances to or deschedule or reschedule all
108 substances enumerated in the schedules in this article pursuant to the procedures of the Administrative
109 Process Act (§ 2.2-4000 et seq.). In making a determination regarding a substance, the Board shall
110 consider the following:

- 111 1. The actual or relative potential for abuse;
- 112 2. The scientific evidence of its pharmacological effect, if known;
- 113 3. The state of current scientific knowledge regarding the substance;
- 114 4. The history and current pattern of abuse;
- 115 5. The scope, duration, and significance of abuse;
- 116 6. The risk to the public health;
- 117 7. The potential of the substance to produce psychic or physical dependence; and
- 118 8. Whether the substance is an immediate precursor of a substance already controlled under this
119 article.

120 B. After considering the factors enumerated in subsection A, the Board shall make findings and issue
121 a regulation controlling the substance if it finds the substance has a potential for abuse.

C. If the Board designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

D. If the Board, in consultation with the Department of Forensic Science, determines the substance shall be placed into Schedule I or II pursuant to § 54.1-3445 or 54.1-3447, the Board may amend its regulations pursuant to Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. Prior to making such amendments, the Board shall conduct a public hearing. At least 30 days prior to conducting such hearing, it shall post notice of the hearing on the Virginia Regulatory Town Hall and shall send notice of the hearing to any persons requesting to be notified of a regulatory action. In the notice, the Board shall include a list of all substances it intends to schedule by regulation. The Board shall notify the House Courts of Justice and Senate Courts of Justice Committees of any new substance added to Schedule I or II pursuant to this subsection. Any substance added to Schedule I or II pursuant to this subsection shall remain on Schedule I or II for a period of 18 months. Upon expiration of such 18-month period, such substance shall be descheduled unless a general law is enacted adding such substance to or descheduling or rescheduling all substances enumerated in the schedules pursuant to the provisions of subsections A, B, and E.

E. If any substance is designated, rescheduled, or descheduled as a controlled substance under federal law and notice of such action is given to the Board, the Board may similarly control the substance under this chapter after the expiration of ~~420~~ 30 days from publication in the Federal Register of ~~the~~ a final or interim final order or rule designating a substance as a controlled substance or rescheduling or descheduling a substance without following the provisions specified in subsections A and B by amending its regulations in accordance with the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. Prior to making such amendments, the Board shall post notice of the hearing on the Virginia Regulatory Town Hall and shall send notice of the hearing to any persons requesting to be notified of a regulatory action. The Board shall include a list of all substances it intends to schedule by regulation in such notice.

F. Authority to control under this section does not extend to distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 4.1.

G. The Board shall exempt any nonnarcotic substance from a schedule if such substance may, under the provisions of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) or state law, be lawfully sold over the counter without a prescription.