

WEST VIRGINIA LEGISLATURE

2016 REGULAR SESSION

Introduced

Senate Bill 651

BY SENATOR TRUMP

[Introduced February 20, 2016;

Referred to the Committee on Health and Human
Resources; and then to the Committee on the Judiciary.]

1 A BILL to amend and reenact §60A-9-4 and §60A-9-5 of the Code of West Virginia, 1931, as
2 amended, all relating to controlled substance monitoring; expanding access to confidential
3 information; requiring information on reports of emergency department overdose visits;
4 authorizing reporting certain information to law enforcement, the Drug Enforcement
5 Administration, licensing boards of the prescribers and dispensers whose activity is called
6 into question; modifying duties of the West Virginia Controlled Substances Monitoring
7 Program Database Review Committee; and imposing duties on licensing agencies having
8 jurisdiction over certain prescribers and dispensers.

Be it enacted by the Legislature of West Virginia:

1 That §60A-9-4 and §60A-9-5 of the Code of West Virginia, 1931, as amended, be
2 amended and reenacted, all to read as follows:

ARTICLE 9. CONTROLLED SUBSTANCES MONITORING.

§60A-9-4. Required information.

1 (a) Whenever a medical services provider dispenses a controlled substance listed in
2 Schedule II, III or IV as established under the provisions of article two of this chapter or whenever
3 a prescription for the controlled substance is filled by: (i) A pharmacist or pharmacy in this state;
4 (ii) a hospital, or other health care facility, for out-patient use; or (iii) a pharmacy or pharmacist
5 licensed by the Board of Pharmacy, but situated outside this state for delivery to a person residing
6 in this state, the medical services provider, health care facility, pharmacist or pharmacy shall, in
7 a manner prescribed by rules promulgated by the board under this article, report the following
8 information, as applicable:

9 (1) The name, address, pharmacy prescription number and Drug Enforcement
10 Administration controlled substance registration number of the dispensing pharmacy or the
11 dispensing physician or dentist;

12 (2) The full legal name, address and birth date of the person for whom the prescription is
13 written;

14 (3) The name, address and Drug Enforcement Administration controlled substances
15 registration number of the practitioner writing the prescription;

16 (4) The name and national drug code number of the Schedule II, III, and IV controlled
17 substance dispensed;

18 (5) The quantity and dosage of the Schedule II, III, and IV controlled substance dispensed;

19 (6) The date the prescription was written and the date filled;

20 (7) The number of refills, if any, authorized by the prescription;

21 (8) If the prescription being dispensed is being picked up by someone other than the
22 patient on behalf of the patient, the first name, last name and middle initial, address and birth date
23 of the person picking up the prescription as set forth on the person's government-issued photo
24 identification card shall be retained in either print or electronic form until such time as otherwise
25 directed by rule promulgated by the board; ~~and~~

26 (9) The source of payment for the controlled substance dispensed; and

27 (10) Reports of emergency department overdose visits.

28 (b) The board may prescribe by rule promulgated under this article the form to be used in
29 prescribing a Schedule II, III, and IV substance if, in the determination of the board, the
30 administration of the requirements of this section would be facilitated.

31 (c) Products regulated by the provisions of article ten of this chapter shall be subject to
32 reporting pursuant to the provisions of this article to the extent set forth in said article.

33 (d) Reporting required by this section is not required for a drug administered directly to a
34 patient by a practitioner. Reporting is, however, required by this section for a drug dispensed to a
35 patient by a practitioner: *Provided*, That the quantity dispensed may not exceed an amount
36 adequate to treat the patient for a maximum of seventy-two hours with no greater than two
37 seventy-two-hour cycles dispensed in any fifteen-day period of time.

**§60A-9-5. Confidentiality; limited access to records; period of retention; no civil liability
for required reporting.**

1 (a) (1) (A) The information required by this article to be kept by the board is confidential
2 and not subject to the provisions of chapter twenty-nine-b of this code or obtainable as discovery
3 in civil matters absent a court order and is open to inspection only by:

4 (i) Inspectors and agents of the board;

5 (ii) Members of the West Virginia State Police expressly authorized by the Superintendent
6 of the West Virginia State Police to have access to the information;

7 (iii) Authorized agents of local law-enforcement agencies as members of a federally
8 affiliated drug task force;

9 (iv) Authorized agents of the federal Drug Enforcement Administration;

10 (v) Duly authorized agents of the Bureau for Medical Services;

11 (vi) Duly authorized agents of the Office of the Chief Medical Examiner for use in post-
12 mortem examinations;

13 (vii) Duly authorized agents of licensing boards of practitioners in this state and other
14 states authorized to prescribe Schedules II, III, and IV controlled substances;

15 (viii) Prescribing practitioners and pharmacists and persons with an enforceable court
16 order or regulatory agency administrative subpoena; and

17 (ix) The dean of a medical school or chief medical officer of a hospital, an employee of the
18 medical school, hospital as designated by the dean or chief medical officer and who is working
19 under his or her specific direction, or a physician designee if the hospital has no chief medical
20 officer, if the officer, employee, or designee certifies that the requested information is for the
21 purpose of providing medical or pharmaceutical treatment to a bona fide current or prospective
22 patient of any clinic operated by the medical school or it's practice plan or of the hospital for
23 assessing and evaluating through the peer review process, the prescribing practices of
24 prescribers who are on the adjunct, volunteer, part time or full time faculty or resident physicians
25 of the medical school or have privileges or are resident physicians at the hospital.

26 ~~Provided, That~~ (B) All law-enforcement personnel who have access to the Controlled

27 Substances Monitoring Program database shall be granted access in accordance with applicable
28 state laws and the board's legislative rules, shall be certified as a West Virginia law-enforcement
29 officer and shall have successfully completed training approved by the board. All information
30 released by the board must be related to a specific patient or a specific individual or entity under
31 investigation by any of the above parties except that practitioners who prescribe or dispense
32 controlled substances may request specific data related to their Drug Enforcement Administration
33 controlled substance registration number or for the purpose of providing treatment to a patient:
34 ~~Provided, however, That~~ (C) The West Virginia Controlled Substances Monitoring Program
35 Database Review Committee established in subsection (b) of this section is authorized to query
36 the database to comply with ~~said~~ that subsection.

37 (2) Subject to the provisions of subdivision (1) of this subsection, the board shall also
38 review the West Virginia Controlled Substance Monitoring Program database and issue reports
39 that identify abnormal or unusual practices of patients, prescribers and dispensers who exceed
40 parameters as determined by the advisory committee established in this section. The board shall
41 communicate with prescribers and dispensers to more effectively manage the medications of their
42 patients in the manner recommended by the advisory committee and/or report that information to
43 law enforcement, the Drug Enforcement Administration and/or the licensing board of the
44 prescribers and dispensers whose activity is called into question. Reports made to the licensing
45 boards, and all other reports produced by the board, shall be kept confidential except as otherwise
46 provided in this section. The board shall maintain the information required by this article for a
47 period of not less than five years. Notwithstanding any other provisions of this code to the contrary,
48 data obtained under the provisions of this article may be used for compilation of educational,
49 scholarly or statistical purposes, and may be shared with the West Virginia Department of Health
50 and Human Resources for those purposes, as long as the identities of persons or entities and any
51 personally identifiable information, including protected health information, contained therein shall
52 be redacted, scrubbed or otherwise irreversibly destroyed in a manner that will preserve the

53 confidential nature of the information. No individual or entity required to report under section four
54 of this article may be subject to a claim for civil damages or other civil relief for the reporting of
55 information to the board as required under and in accordance with the provisions of this article.

56 (3) The board shall establish an advisory committee to develop, implement and
57 recommend parameters to be used in identifying abnormal or unusual usage patterns of patients
58 in this state. This advisory committee shall:

59 (A) Consist of the following members: A physician licensed by the West Virginia Board of
60 Medicine, a dentist licensed by the West Virginia Board of Dental Examiners, a physician licensed
61 by the West Virginia Board of Osteopathy, a licensed physician certified by the American Board
62 of Pain Medicine, a licensed physician board certified in medical oncology recommended by the
63 West Virginia State Medical Association, a licensed physician board certified in palliative care
64 recommended by the West Virginia Center on End of Life Care, a pharmacist licensed by the
65 West Virginia Board of Pharmacy, a licensed physician member of the West Virginia Academy of
66 Family Physicians, an expert in drug diversion and such other members as determined by the
67 board.

68 (B) Recommend parameters to identify abnormal or unusual usage patterns of controlled
69 substances for patients in order to prepare reports as requested in accordance with subsection
70 (a), subdivision (2) of this section.

71 (C) Make recommendations for training, research and other areas that are determined by
72 the committee to have the potential to reduce inappropriate use of prescription drugs in this state,
73 including, but not limited to, studying issues related to diversion of controlled substances used for
74 the management of opioid addiction.

75 (D) Monitor the ability of medical services providers, health care facilities, pharmacists and
76 pharmacies to meet the twenty-four hour reporting requirement for the Controlled Substances
77 Monitoring Program set forth in section three of this article, and report on the feasibility of requiring
78 real-time reporting.

79 (E) Establish outreach programs with local law enforcement to provide education to local
80 law enforcement on the requirements and use of the Controlled Substances Monitoring Program
81 database established in this article.

82 (b) The board shall create a West Virginia Controlled Substances Monitoring Program
83 Database Review Committee of individuals consisting of two prosecuting attorneys from West
84 Virginia counties, two physicians with specialties which require extensive use of controlled
85 substances and a pharmacist who is trained in the use and abuse of controlled substances. The
86 review committee may determine that an additional physician who is an expert in the field under
87 investigation be added to the team when the facts of a case indicate that the additional expertise
88 is required. The review committee, working independently, ~~may~~ shall query the database monthly
89 based on parameters established by the advisory committee. The review committee ~~may~~ shall
90 make determinations on a case-by-case basis on specific unusual prescribing or dispensing
91 patterns indicated by outliers in the system or abnormal or unusual usage patterns of controlled
92 substances by patients which the review committee has reasonable cause to believe necessitates
93 further action by law enforcement or the licensing board having jurisdiction over the prescribers
94 or dispensers under consideration. The review committee shall also review notices provided by
95 the chief medical examiner pursuant to subsection (h), section ten, article twelve, chapter sixty-
96 one of this code and determine on a case-by-case basis whether a practitioner who prescribed or
97 dispensed a controlled substance resulting in or contributing to the drug overdose may have
98 breached professional or occupational standards or committed a criminal act when prescribing
99 the controlled substance at issue to the decedent. Only in those cases in which there is
100 reasonable cause to believe a breach of professional or occupational standards or a criminal act
101 may have occurred, the review committee shall notify the appropriate professional licensing
102 agency having jurisdiction over the applicable prescriber or dispenser and appropriate law-
103 enforcement agencies and provide pertinent information from the database for their consideration.
104 The licensing agency having jurisdiction over the applicable prescriber or dispenser shall review

105 each case referred to them on a monthly basis and shall report to the Board of Pharmacy the
106 dispensation of each case that was made by the licensing agency. Each month, the licensing
107 agency shall de-identify the reports and aggregate them by type of dispensation and make public
108 the number of reports received and the total number of cases by each type of dispensation. The
109 number of cases identified shall be determined by the review committee based on a number that
110 can be adequately reviewed by the review committee. The information obtained and developed
111 may not be shared except as provided in this article and is not subject to the provisions of chapter
112 twenty-nine-b of this code or obtainable as discovering in civil matters absent a court order.

113 (c) The board is responsible for establishing and providing administrative support for the
114 advisory committee and the West Virginia Controlled Substances Monitoring Program Database
115 Review Committee. The advisory committee and the review committee shall elect a chair by
116 majority vote. Members of the advisory committee and the review committee may not be
117 compensated in their capacity as members but shall be reimbursed for reasonable expenses
118 incurred in the performance of their duties.

119 (d) The board shall promulgate rules with advice and consent of the advisory committee,
120 in accordance with the provisions of article three, chapter twenty-nine-a of this code. The
121 legislative rules must include, but shall not be limited to, the following matters:

122 (1) Identifying parameters used in identifying abnormal or unusual prescribing or
123 dispensing patterns;

124 (2) Processing parameters and developing reports of abnormal or unusual prescribing or
125 dispensing patterns for patients, practitioners and dispensers;

126 (3) Establishing the information to be contained in reports and the process by which the
127 reports will be generated and disseminated; and

128 (4) Setting up processes and procedures to ensure that the privacy, confidentiality, and
129 security of information collected, recorded, transmitted and maintained by the review committee
130 is not disclosed except as provided in this section.

131 (e) All practitioners, as that term is defined in section one hundred-one, article two of this
132 chapter who prescribe or dispense schedule II, III, or IV controlled substances shall have online
133 or other form of electronic access to the West Virginia Controlled Substances Monitoring Program
134 database;

135 (f) Persons or entities with access to the West Virginia Controlled Substances Monitoring
136 Program database pursuant to this section may, pursuant to rules promulgated by the board,
137 delegate appropriate personnel to have access to said database;

138 (g) Good faith reliance by a practitioner on information contained in the West Virginia
139 Controlled Substances Monitoring Program database in prescribing or dispensing or refusing or
140 declining to prescribe or dispense a schedule II, III, or IV controlled substance shall constitute an
141 absolute defense in any civil or criminal action brought due to prescribing or dispensing or refusing
142 or declining to prescribe or dispense; and

143 (h) A prescribing or dispensing practitioner may notify law enforcement of a patient who,
144 in the prescribing or dispensing practitioner's judgment, may be in violation of section four
145 hundred ten, article four of this chapter, based on information obtained and reviewed from the
146 controlled substances monitoring database. A prescribing or dispensing practitioner who makes
147 a notification pursuant to this subsection is immune from any civil, administrative or criminal
148 liability that otherwise might be incurred or imposed because of the notification if the notification
149 is made in good faith.

150 (i) Nothing in the article may be construed to require a practitioner to access the West
151 Virginia Controlled Substances Monitoring Program database except as provided in section five-
152 a of this article.

153 (j) The board shall provide an annual report on the West Virginia Controlled Substance
154 Monitoring Program to the Legislative Oversight Commission on Health and Human Resources
155 Accountability with recommendations for needed legislation no later than January 1 of each year.

NOTE: The purpose of this bill is to modify the state's controlled substance monitoring program. It expands access to confidential information; requires information on reports of emergency department overdose visits; authorizes reporting of certain information to law enforcement, the Drug Enforcement Administration, licensing boards of the prescribers and dispensers whose activity is called into question; modifies duties of the West Virginia Controlled Substances Monitoring Program Database Review Committee; and imposes additional duties on licensing agencies having jurisdiction over certain prescribers and dispensers.

Strike-throughs indicate language that would be stricken from a heading or the present law and underscoring indicates new language that would be added.