

WEST VIRGINIA LEGISLATURE

2016 REGULAR SESSION

Introduced

Senate Bill 454

BY SENATOR KESSLER

(BY REQUEST OF THE EXECUTIVE)

[Introduced January 1, 2016;

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

1 A BILL to amend and reenact §60A-9-4, §60A-9-5, §60A-9-5a, §60A-9-7 and §60A-9-8 of the
2 Code of West Virginia, 1931, as amended, all relating to West Virginia Controlled
3 Substances Monitoring Program database; requiring reporting when an opioid antagonist
4 is dispensed by certain persons; clarifying code language related to seventy-two hour
5 prescriptions; prohibiting licensing boards from issuing or reissuing licenses to
6 practitioners who have not registered for West Virginia Controlled Substances Monitoring
7 Programs database; establishing fine for failure to register for West Virginia Controlled
8 Substances Monitoring Program database; establishing fine for failure to access West
9 Virginia Controlled Substances Monitoring Program as mandated by the code; clarifying
10 language related to Fight Substance Abuse Fund; placing administrative authority over
11 Fight Substance Abuse Fund with the Bureau for Public Health; revising code language
12 to use defined terms; and reorganizing existing code language.

Be it enacted by the Legislature of West Virginia:

1 That §60A-9-4, §60A-9-5, §60A-9-5a, §60A-9-7 and §60A-9-8 of the Code of West
2 Virginia, 1931, as amended, be amended and reenacted, all to read as follows:

ARTICLE 1. DEFINITIONS.

§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 an opioid
3 antagonist, or whenever a prescription for the controlled substance or opioid antagonist is filled
4 by: (i) A pharmacist or pharmacy in this state; (ii) a hospital, or other health care facility, for out-
5 patient use; or (iii) a pharmacy or pharmacist licensed by the Board of Pharmacy, but situated
6 outside this state for delivery to a person residing in this state, the medical services provider,
7 health care facility, pharmacist or pharmacy shall, in a manner prescribed by rules promulgated
8 by the board under this article, report the following 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 or opioid antagonist dispensed;

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

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

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

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

27 (9) The source of payment for the controlled substance dispensed.

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 or opioid antagonist if, in the determination of the
30 board, the 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 by a prescribing practitioner to his

36 or her own patient may not exceed an amount adequate to treat the patient for a maximum of
37 seventy-two hours with no greater than two seventy-two-hour cycles dispensed in any fifteen-day
38 period of time.

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

1 (a) (1) The information required by this article to be kept by the board is confidential and
2 not *subject* to the provisions of chapter twenty-nine-b of this code or obtainable as discovery in
3 civil matters absent a court order and is open to inspection only by inspectors and agents of the
4 board, members of the West Virginia State Police expressly authorized by the superintendent of
5 the West Virginia State Police to have access to the information, authorized agents of local law-
6 enforcement agencies as members of a federally affiliated drug task force, authorized agents of
7 the federal Drug Enforcement Administration, duly authorized agents of the Bureau for Medical
8 Services, duly authorized agents of the Office of the Chief Medical Examiner for use in post-
9 mortem examinations, duly authorized agents of licensing boards of practitioners in this state and
10 other states authorized to prescribe Schedules II, III, and IV controlled substances, prescribing
11 practitioners and pharmacists and persons with an enforceable court order or regulatory agency
12 administrative subpoena: *Provided*, That all law-enforcement personnel who have access to the
13 Controlled Substances Monitoring Program database shall be granted access in accordance with
14 applicable state laws and the board's legislative rules, shall be certified as a West Virginia law-
15 enforcement officer and shall have successfully completed training approved by the board. All
16 information released by the board must be related to a specific patient or a specific individual or
17 entity under investigation by any of the above parties except that practitioners who prescribe or
18 dispense controlled substances may request specific data related to their Drug Enforcement
19 Administration controlled substance registration number or for the purpose of providing treatment
20 to a patient: *Provided however*, That the West Virginia Controlled Substances Monitoring Program
21 Database Review Committee established in subsection (b) of this section is authorized to query

22 the database to comply with said subsection.

23 (2) Subject to the provisions of subdivision (1) of this subsection, the board shall also
24 review the West Virginia Controlled Substance Monitoring Program database and issue reports
25 that identify abnormal or unusual practices of patients who exceed parameters as determined by
26 the advisory committee established in this section. The board shall communicate with ~~prescribers~~
27 practitioners and dispensers to more effectively manage the medications of their patients in the
28 manner recommended by the advisory committee. All other reports produced by the board shall
29 be kept confidential. The board shall maintain the information required by this article for a period
30 of not less than five years. Notwithstanding any other provisions of this code to the contrary, data
31 obtained under the provisions of this article may be used for compilation of educational, scholarly
32 or statistical purposes, and may be shared with the West Virginia Department of Health and
33 Human Resources for those purposes, as long as the identities of persons or entities and any
34 personally identifiable information, including protected health information, contained therein shall
35 be redacted, scrubbed or otherwise irreversibly destroyed in a manner that will preserve the
36 confidential nature of the information. No individual or entity required to report under section four
37 of this article may be subject to a claim for civil damages or other civil relief for the reporting of
38 information to the board as required under and in accordance with the provisions of this article.

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

42 (A) Consist of the following members: A physician licensed by the West Virginia Board of
43 Medicine, a dentist licensed by the West Virginia Board of Dental Examiners, a physician licensed
44 by the West Virginia Board of ~~Osteopathy~~ Osteopathic Medicine, a licensed physician certified by
45 the American Board of Pain Medicine, a licensed physician board certified in medical oncology
46 recommended by the West Virginia State Medical Association, a licensed physician board
47 certified in palliative care recommended by the West Virginia Center on End of Life Care, a

48 pharmacist licensed by the West Virginia Board of Pharmacy, a licensed physician member of the
49 West Virginia Academy of Family Physicians, an expert in drug diversion and such other members
50 as determined by the board.

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

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

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

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

65 (b) The board shall create a West Virginia Controlled Substances Monitoring Program
66 Database Review Committee of individuals consisting of two prosecuting attorneys from West
67 Virginia counties, two physicians with specialties which require extensive use of controlled
68 substances and a pharmacist who is trained in the use and abuse of controlled substances. The
69 review committee may determine that an additional physician who is an expert in the field under
70 investigation be added to the team when the facts of a case indicate that the additional expertise
71 is required. The review committee, working independently, may query the database based on
72 parameters established by the advisory committee. The review committee may make
73 determinations on a case-by-case basis on specific unusual prescribing or dispensing patterns

74 indicated by outliers in the system or abnormal or unusual usage patterns of controlled
75 substances by patients which the review committee has reasonable cause to believe necessitates
76 further action by law enforcement or the licensing board having jurisdiction over the ~~prescribers~~
77 practitioners or dispensers under consideration. The review committee shall also review notices
78 provided by the chief medical examiner pursuant to subsection (h), section ten, article twelve,
79 chapter sixty-one of this code and determine on a case-by-case basis whether a practitioner who
80 prescribed or dispensed a controlled substance resulting in or contributing to the drug overdose
81 may have breached professional or occupational standards or committed a criminal act when
82 prescribing the controlled substance at issue to the decedent. Only in those cases in which there
83 is reasonable cause to believe a breach of professional or occupational standards or a criminal
84 act may have occurred, the review committee shall notify the appropriate professional licensing
85 agency having jurisdiction over the applicable ~~prescriber~~ practitioner or dispenser and appropriate
86 law-enforcement agencies and provide pertinent information from the database for their
87 consideration. The number of cases identified shall be determined by the review committee based
88 on a number that can be adequately reviewed by the review committee. The information obtained
89 and developed may not be shared except as provided in this article and is not subject to the
90 provisions of chapter twenty-nine-b of this code or obtainable as discovering in civil matters
91 absent a court order.

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

98 (d) The board shall promulgate rules with advice and consent of the advisory committee,
99 in accordance with the provisions of article three, chapter twenty-nine-a of this code. The

100 legislative rules must include, but shall not be limited to, the following matters:

101 (1) Identifying parameters used in identifying abnormal or unusual prescribing or
102 dispensing patterns;

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

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

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

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

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

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

122 ~~(h)~~ (g) A prescribing or dispensing practitioner may notify law enforcement of a patient
123 who, in the prescribing or dispensing practitioner's judgment, may be in violation of section four
124 hundred ten, article four of this chapter, based on information obtained and reviewed from the
125 controlled substances monitoring database. A prescribing or dispensing practitioner who makes

126 a notification pursuant to this subsection is immune from any civil, administrative or criminal
127 liability that otherwise might be incurred or imposed because of the notification if the notification
128 is made in good faith.

129 ~~(f)~~ (h) Nothing in the article may be construed to require a practitioner to access the West
130 Virginia Controlled Substances Monitoring Program database except as provided in section five-
131 a of this article.

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

**§60A-9-5a. Practitioner requirements to access database and conduct annual search of the
database; required rulemaking.**

1 (a) All practitioners, as that term is defined in section one hundred-one, article two of this
2 chapter who prescribe or dispense schedule II, III, or IV controlled substances shall register for
3 and have online or other form of electronic access to the West Virginia Controlled Substances
4 Monitoring Program database.

5 ~~(a)~~ (b) Upon initially prescribing or dispensing any pain-relieving controlled substance for
6 a patient and at least annually thereafter should the ~~prescriber~~ practitioner or dispenser continue
7 to treat the patient with controlled substances, all persons with prescriptive or dispensing authority
8 and in possession of a valid Drug Enforcement Administration registration identification number
9 and, who are licensed by the board of Medicine as set forth in article three, chapter thirty of this
10 code, the Board of Registered Professional Nurses as set forth in article seven, chapter thirty of
11 this code, the Board of Dental Examiners as set forth in article four, chapter thirty of this code and
12 the board of Osteopathy as set forth in article fourteen, chapter thirty of this code shall access the
13 West Virginia Controlled Substances Monitoring Program database for information regarding
14 specific patients for whom they are providing pain-relieving controlled substances as part of a
15 course of treatment for chronic, nonmalignant pain but who are not suffering from a terminal

16 illness. The information obtained from accessing the West Virginia Controlled Substances
17 Monitoring Program database for the patient shall be documented in the patient's medical record.
18 A pain-relieving controlled substance shall be defined as set forth in section one, article three-a,
19 chapter thirty of this code.

20 ~~(b)~~ (c) The various boards mentioned in subsection (a) above shall promulgate both
21 emergency and legislative rules pursuant to the provisions of article three, chapter twenty-nine-a
22 of this code to effectuate the provisions of this section.

§60A-9-7. Criminal penalties.

1 (a) Any person who is required to submit information to the State Board of Pharmacy
2 pursuant to the provisions of this article who fails to do so as directed by the board is guilty of a
3 misdemeanor and, upon conviction thereof, shall be fined not less than \$100 nor more than \$500.

4 (b) Any person who is required to submit information to the State Board of Pharmacy
5 pursuant to the provisions of this article who knowingly and willfully refuses to submit the
6 information required by this article is guilty of a misdemeanor and, upon conviction thereof, shall
7 be confined in a county or regional jail not more than six months or fined not more than \$1,000,
8 or both confined or fined.

9 (c) Any person who is required by the provisions of this article to submit information to the
10 State Board of Pharmacy who knowingly submits thereto information known to that person to be
11 false or fraudulent is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a
12 regional jail not more than one year or fined not more than \$5,000, or both confined or fined.

13 (d) No practitioner required to register and access the West Virginia Controlled
14 Substances Monitoring Program database under subsection (a), section five-a, article nine of this
15 chapter, shall be granted a license to practice in his or her respective field or be granted a renewal
16 of an existing license by the applicable state licensing board without first certifying that the
17 practitioner has registered for and has access to the West Virginia Controlled Substances
18 Monitoring Program database.

19 (e) Any practitioner who fails to register for and have access to the West Virginia
20 Controlled Substances Monitoring Program database as required in subsection (a), section five-
21 a, article nine of this chapter, shall, beginning July 1, 2015, be fined \$1,000 by the applicable
22 licensing board. All such fines collected pursuant to this subsection shall be transferred by the
23 applicable licensing board to the Fight Substance Abuse Fund created under section eight of this
24 article.

25 ~~(d)~~ (f) Any prescriber practitioner or dispenser who is required to access the information
26 contained in the West Virginia Controlled Substances Monitoring Program database as set forth
27 in subsection (a) of section five-a of this article and fails to do so as directed by the rules of their
28 licensing board shall be subject to such discipline as the licensing board deems appropriate and
29 beginning July 1, 2016, subject to a \$500 fine per violation by the applicable licensing board. All
30 such fines collected pursuant to this subsection shall be transferred by the applicable licensing
31 board to the Fight Substance Abuse Fund created under section eight of this article.

32 ~~(e)~~ (g) Any person granted access to the information required by the provisions of this
33 article to be maintained by the State Board of Pharmacy, who shall willfully disclose the
34 information required to be maintained by this article in a manner inconsistent with a legitimate
35 law-enforcement purpose, a legitimate professional regulatory purpose, the terms of a court order
36 or as otherwise expressly authorized by the provisions of this article is guilty of a misdemeanor
37 and, upon conviction thereof, shall be confined in a regional jail for not more than six months or
38 fined not more than \$1,000, or both confined or fined.

39 ~~(f)~~ (h) Unauthorized access or use or unauthorized disclosure for reasons unrelated to the
40 purposes of this article of the information in the database is a felony punishable by imprisonment
41 in a state correctional facility for not less than one year nor more than five years or fined not less
42 than \$3,000 nor more than \$10,000, or both imprisoned or fined.

§60A-9-8. Creation of Fight Substance Abuse Fund.

1 There is hereby created a special revenue account in the State Treasury, designated the

2 Fight Substance Abuse Fund, which shall be an interest-bearing account ~~and may be invested in~~
3 ~~accordance with the provisions of article six, chapter twelve of this code, with interest income a~~
4 ~~proper credit to the fund.~~ The fund shall consist of all moneys received from whatever source to
5 further the purpose of this article. ~~appropriations by the Legislature, gifts, donations or any other~~
6 ~~source~~ The fund shall be administered by the West Virginia Bureau for Public Health ~~Expenditures~~
7 ~~from the fund shall be for the following purposes~~ to provide funding for substance abuse
8 prevention, treatment, treatment coordination, recovery and education. Any moneys remaining in
9 the fund at the close of a fiscal year shall be carried forward for use in the next fiscal year. Fund
10 balances shall be invested with the state's Consolidated Investment Fund and any and all interest
11 earnings on these investments shall be used solely for the purposes that moneys deposited in
12 the fund may be used pursuant to this article.

NOTE: The purpose of this bill is to require prescriptions for opioid antagonists to be logged into the Controlled Substances Monitoring Program and to impose penalties and fines for failure to register for and access the Controlled Substances Monitoring Program as required by code.

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