

WEST VIRGINIA LEGISLATURE

2017 REGULAR SESSION

Committee Substitute

for

Senate Bill 333

BY SENATORS TAKUBO, PALUMBO, STOLLINGS, ROMANO,

CLINE AND MARONEY

[Originating in the Committee on Health and Human

Resources; reported on March 8, 2017]

1 A BILL to amend and reenact §60-A-9-4 of the Code of West Virginia, 1931, as amended; to
2 amend and reenact §60A-9-5 and §60A-9-5a of said code; and to amend said code by
3 adding thereto a new section, designated §60A-9-9, all relating the Controlled Substances
4 Monitoring Program database; requiring reporting instances of an overdose or a
5 suspected overdose to the database; setting out elements to be reported; allowing access
6 to the database to deans of the state's medical schools to monitoring prescribing practices
7 of residents; allowing the Board of Pharmacy to require that drugs of concern be reported
8 to the database; exempting reporting requirements for drugs of concern from criminal
9 penalties; allowing the Board of Pharmacy to develop administrative penalties for not
10 reporting drugs of concern; providing for rulemaking; requiring the licensing boards to
11 report to the Board of Pharmacy when notified of unusual prescribing habits of a licensee;
12 and making technical corrections.

Be it enacted by the Legislature of West Virginia:

1 That §60A-9-4 of the Code of West Virginia, 1931, as amended, be amended and
2 reenacted; that §60A-9-5 and §60A-9-5a of said code be amended and reenacted; that said code
3 be amended by adding thereto a new section, designated §60A-9-9, 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 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~~ Board of Pharmacy pursuant to this article, report the following information,

9 as applicable:

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

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

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

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

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

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

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

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

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

29 (b) Whenever a medical services provider treats a patient and an overdose has occurred
30 or is suspected as a result of illicit or prescribed medication the medical service provider shall
31 report the full legal name, address and birth date of the person for whom treatments for an
32 overdose or suspected overdose is provided including any known ancillary evidence of the
33 overdose or suspected overdose including, but not limited to, the source of the overdose or
34 potential overdose, if known, any family history of substance use, positive drugs screens and any

35 other evidence of the overdose or suspected overdose.

36 ~~(b)~~ (c) The ~~board~~ Board of Pharmacy may prescribe by rule promulgated ~~under this~~
37 pursuant to this article the form to be used in prescribing a Schedule II, III, and IV substance or
38 opioid antagonist if, in the determination of the ~~board~~ Board of Pharmacy, the administration of
39 the requirements of this section would be facilitated.

40 ~~(e)~~ (d) Products regulated by the provisions of article ten of this chapter shall be subject
41 to reporting pursuant to the provisions of this article to the extent set forth in said article.

42 ~~(d)~~ (e) Reporting required by this section is not required for a drug administered directly
43 to a patient by a practitioner. Reporting is, however, required by this section for a drug dispensed
44 to a patient by a practitioner. ~~Provided, That the~~ The quantity dispensed by a prescribing
45 practitioner to his or her own patient may not exceed an amount adequate to treat the patient for
46 a maximum of seventy-two hours with no greater than two seventy-two-hour cycles dispensed in
47 any fifteen-day period of time.

48 ~~(e)~~ (f) The Board of Pharmacy shall notify a physician prescribing buprenorphine or
49 buprenorphine/naloxone within sixty days of the availability of ~~the~~ an abuse deterrent form of
50 buprenorphine or buprenorphine/naloxone ~~is~~ if approved by the Food and Drug Administration
51 as provided in FDA Guidance to Industry. Upon receipt of the notice, a physician may switch
52 their patients using buprenorphine or buprenorphine/naloxone to the abuse deterrent form of the
53 drug.

**§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~~ Board of Pharmacy
2 is confidential and not subject to the provisions of chapter twenty-nine-b of this code or obtainable
3 as discovery in civil matters absent a court order and is open to inspection only by inspectors and
4 agents of the ~~board~~ Board of Pharmacy, members of the West Virginia State Police expressly
5 authorized by the Superintendent of the West Virginia State Police to have access to the

6 information, authorized agents of local law-enforcement agencies as members of a federally
7 affiliated drug task force, authorized agents of the federal Drug Enforcement Administration, duly
8 authorized agents of the Bureau for Medical Services, duly authorized agents of the Office of the
9 Chief Medical Examiner for use in post-mortem examinations, duly authorized agents of licensing
10 boards of practitioners in this state and other states authorized to prescribe Schedules II, III and
11 IV controlled substances, prescribing practitioners and pharmacists, a dean of any medical school
12 located in this state to monitor prescribing practices of residents enrolled in a medical degree
13 program at the school where they are dean and persons with an enforceable court order or
14 regulatory agency administrative subpoena. ~~Provided, That all~~ All law-enforcement personnel
15 who have access to the Controlled Substances Monitoring Program database shall be granted
16 access in accordance with applicable state laws and the ~~board's legislative~~ Board of Pharmacy's
17 rules, shall be certified as a West Virginia law-enforcement officer and shall have successfully
18 completed training approved by the ~~board~~ Board of Pharmacy. All information released by the
19 ~~board~~ Board of Pharmacy must be related to a specific patient or a specific individual or entity
20 under investigation by any of the above parties except that practitioners who prescribe or
21 dispense controlled substances may request specific data related to their Drug Enforcement
22 Administration controlled substance registration number or for the purpose of providing treatment
23 to a patient: *Provided, however,* That the West Virginia Controlled Substances Monitoring
24 Program Database Review Committee established in subsection (b) of this section is authorized
25 to query the database to comply with said subsection.

26 (2) Subject to the provisions of subdivision (1) of this subsection, the ~~board~~ Board of
27 Pharmacy shall also review the West Virginia Controlled Substance Monitoring Program database
28 and issue reports that identify abnormal or unusual practices of patients who exceed parameters
29 as determined by the advisory committee established in this section. The ~~board~~ Board of
30 Pharmacy shall communicate with practitioners and dispensers to more effectively manage the
31 medications of their patients in the manner recommended by the advisory committee. All other

32 reports produced by the ~~board~~ Board of Pharmacy shall be kept confidential. The ~~board~~ Board of
33 Pharmacy shall maintain the information required by this article for a period of not less than five
34 years. Notwithstanding any other provisions of this code to the contrary, data obtained under the
35 provisions of this article may be used for compilation of educational, scholarly or statistical
36 purposes, and may be shared with the West Virginia Department of Health and Human Resources
37 for those purposes, as long as the identities of persons or entities and any personally identifiable
38 information, including protected health information, contained therein shall be redacted, scrubbed
39 or otherwise irreversibly destroyed in a manner that will preserve the confidential nature of the
40 information. No individual or entity required to report under section four of this article may be
41 subject to a claim for civil damages or other civil relief for the reporting of information to the ~~board~~
42 Board of Pharmacy as required under and in accordance with the provisions of this article.

43 (3) The ~~board~~ Board of Pharmacy shall establish an advisory committee to develop,
44 implement and recommend parameters to be used in identifying abnormal or unusual usage
45 patterns of patients in this state. This advisory committee shall:

46 (A) Consist of the following members: A physician licensed by the West Virginia Board of
47 Medicine, a dentist licensed by the West Virginia Board of Dental Examiners, a physician licensed
48 by the West Virginia Board of Osteopathic Medicine, a licensed physician certified by the
49 American Board of Pain Medicine, a licensed physician board certified in medical oncology
50 recommended by the West Virginia State Medical Association, a licensed physician board
51 certified in palliative care recommended by the West Virginia Center on End of Life Care, a
52 pharmacist licensed by the West Virginia Board of Pharmacy, a licensed physician member of the
53 West Virginia Academy of Family Physicians, an expert in drug diversion and such other members
54 as determined by the ~~board~~ Board of Pharmacy.

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

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

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

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

69 (b) The ~~board~~ Board of Pharmacy shall create a West Virginia Controlled Substances
70 Monitoring Program Database Review Committee of individuals consisting of two prosecuting
71 attorneys from West Virginia counties, two physicians with specialties which require extensive
72 use of controlled substances and a pharmacist who is trained in the use and abuse of controlled
73 substances. The review committee may determine that an additional physician who is an expert
74 in the field under investigation be added to the team when the facts of a case indicate that the
75 additional expertise is required. The review committee, working independently, may query the
76 database based on parameters established by the advisory committee. The review committee
77 may make determinations on a case-by-case basis on specific unusual prescribing or dispensing
78 patterns indicated by outliers in the system or abnormal or unusual usage patterns of controlled
79 substances by patients which the review committee has reasonable cause to believe necessitates
80 further action by law enforcement or the licensing board having jurisdiction over the practitioners
81 or dispensers under consideration. The licensing board having jurisdiction over the practitioner or
82 dispenser under consideration shall report back to the Board of Pharmacy regarding any findings,
83 investigation or discipline resulting from the findings of the review committee within thirty days of

84 resolution of any action taken by the licensing board resulting from the information provided by
85 the Board of Pharmacy. The review committee shall also review notices provided by the chief
86 medical examiner pursuant to subsection (h), section ten, article twelve, chapter sixty-one of this
87 code and determine on a case-by-case basis whether a practitioner who prescribed or dispensed
88 a controlled substance resulting in or contributing to the drug overdose may have breached
89 professional or occupational standards or committed a criminal act when prescribing the
90 controlled substance at issue to the decedent. Only in those cases in which there is reasonable
91 cause to believe a breach of professional or occupational standards or a criminal act may have
92 occurred, the review committee shall notify the appropriate professional licensing agency having
93 jurisdiction over the applicable practitioner or dispenser and appropriate law-enforcement
94 agencies and provide pertinent information from the database for their consideration. The number
95 of cases identified shall be determined by the review committee based on a number that can be
96 adequately reviewed by the review committee. The information obtained and developed may not
97 be shared except as provided in this article and is not subject to the provisions of chapter twenty-
98 nine-b of this code or obtainable as discovering in civil matters absent a court order.

99 (c) The ~~board~~ Board of Pharmacy is responsible for establishing and providing
100 administrative support for the advisory committee and the West Virginia Controlled Substances
101 Monitoring Program Database Review Committee. The advisory committee and the review
102 committee shall elect a chair by majority vote. Members of the advisory committee and the review
103 committee may not be compensated in their capacity as members but shall be reimbursed for
104 reasonable expenses incurred in the performance of their duties.

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

108 (1) Identifying parameters used in identifying abnormal or unusual prescribing or
109 dispensing patterns;

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

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

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

117 (e) Persons or entities with access to the West Virginia Controlled Substances Monitoring
118 Program database pursuant to this section may, pursuant to rules promulgated by the ~~board~~
119 Board of Pharmacy, delegate appropriate personnel to have access to said database.

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

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

132 (h) Nothing in the article may be construed to require a practitioner to access the West
133 Virginia Controlled Substances Monitoring Program database except as provided in section five-
134 a of this article.

135 (i) The ~~board~~ Board of Pharmacy shall provide an annual report on the West Virginia
136 Controlled Substance Monitoring Program to the Legislative Oversight Commission on Health
137 and Human Resources Accountability with recommendations for needed legislation no later
138 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 with
3 the West Virginia Controlled Substances Monitoring Program and obtain and maintain online or
4 other electronic access to the program database: *Provided*, That compliance with the provisions
5 of this subsection must be accomplished within thirty days of the practitioner obtaining a new
6 license: *Provided, however*, That no licensing ~~board~~ Board of Pharmacy may renew a
7 practitioner's license without proof that the practitioner meet the requirements of this subsection.

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

21 ~~illness~~. The information obtained from accessing the West Virginia Controlled Substances
22 Monitoring Program database for the patient shall be documented in the patient's medical record
23 maintained by a private prescriber or any inpatient facility licensed pursuant to the provisions of
24 chapter sixteen of this code. A pain-relieving controlled substance shall be defined as set forth in
25 section one, article three-a, chapter thirty of this code.

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

§60A-9-9. Drugs of concern designation.

1 (a) The Board of Pharmacy may designate certain drugs as drugs of concern which
2 must be reported to the database established pursuant to this article. Drugs of concern shall
3 consist of drugs which have a high potential for abuse. Whenever a medical services provider
4 dispenses a drug which is listed as a drug of concern as established pursuant to this section
5 and any rules promulgated pursuant to this section, or whenever a prescription for a drugs listed
6 as a drug of concern is filled by: (i) A pharmacist or pharmacy in this state; (ii) a hospital, or
7 other health care facility, for out-patient use; or (iii) a pharmacy or pharmacist licensed by the
8 Board of Pharmacy, but situated outside this state for delivery to a person residing in this state,
9 the medical services provider, health care facility, pharmacist or pharmacy shall, in a manner
10 prescribed by rules promulgated by the Board of Pharmacy under this article, report the
11 following information, as applicable:

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

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

17 (3) The name, address and Drug Enforcement Administration controlled substances

- 18 registration number of the practitioner writing the prescription;
- 19 (4) The name and national drug number of the drug of concern dispensed;
- 20 (5) The quantity and dosage of the drug of concern dispensed;
- 21 (6) The date the prescription was written and the date filled;
- 22 (7) The number of refills, if any, authorized by the prescription;
- 23 (8) If the prescription being dispensed is being picked up by someone other than the
24 patient on behalf of the patient, the first name, last name and middle initial, address and birth date
25 of the person picking up the prescription as set forth on the person's government-issued photo
26 identification card shall be retained in either print or electronic form until such time as otherwise
27 directed by rule promulgated by the Board of Pharmacy; and
- 28 (9) The source of payment for the controlled substance dispensed.
- 29 (b) The penalties set forth in section seven of this article shall not apply to drugs listed
30 as drugs of concern. Failure to report may be considered a violation of the practice act of the
31 prescriber and may result in discipline by the appropriate licensing board.
- 32 (c) The Board of Pharmacy may promulgate emergency rules pursuant to the provisions
33 of section fifteen, article three, chapter twenty-nine-a of this code to effectuate the provisions of
34 this section.