

WEST VIRGINIA LEGISLATURE

2017 REGULAR SESSION

ENROLLED

Committee Substitute

for

Committee Substitute

for

Senate Bill 333

SENATORS TAKUBO, PALUMBO, STOLLINGS, ROMANO,

CLINE AND MARONEY, *original sponsors*

[Passed April 8, 2017; in effect 90 days from passage]

1 AN ACT to amend and reenact §60A-9-4, §60A-9-5 and §60A-9-5a of the Code of West Virginia,
2 1931, as amended; and to amend said code by adding thereto a new section, designated
3 §60A-9-9, all relating to the Controlled Substances Monitoring Program database;
4 requiring reporting instances of an overdose or a suspected overdose to the database;
5 setting out elements to be reported; allowing access to the database to deans of the state's
6 medical schools or their designees for monitoring prescribing practices of prescribing
7 faculty members, prescribers and residents enrolled in a degree program at the school
8 where the dean serves; allowing access to designated physician reviewers for medical
9 provider employers; providing access to a physician reviewer designated by an employer
10 of medical providers for monitoring prescribing practices of physicians, advance practice
11 registered nurses or physician assistants in their employ; providing access to chief medical
12 officers of a hospital or a physician designated by the chief executive officer of a hospital
13 who does not have a chief medical officer for monitoring prescribing practices of
14 prescribers who have admitting privileges to the hospital; providing that information
15 obtained from accessing the West Virginia Controlled Substances Monitoring Program
16 database shall be documented in a patient's medical record maintained by a private
17 prescriber or any inpatient facility licensed pursuant to public health; allowing the Board of
18 Pharmacy to require that drugs of concern be reported to the database; clarifying identity
19 information required to be retained by dispensers of controlled substances regarding
20 persons picking up prescriptions other than the patient; exempting reporting requirements
21 for drugs of concern from criminal penalties; allowing duly authorized agents of the Office
22 of Health Facility Licensure and Certification to access the database for use in certification,
23 licensure and regulation of health facilities; providing that a failure to report drugs of
24 concern may be considered a violation of the practice act of the prescriber and may result
25 in discipline by the appropriate licensing board; providing for rulemaking; requiring the

26 licensing boards to report to the Board of Pharmacy when notified of unusual prescribing
27 habits of a licensee; and making technical corrections.

Be it enacted by the Legislature of West Virginia:

1 That §60A-9-4, §60A-9-5 and §60A-9-5a of the Code of West Virginia, 1931, as amended,
2 be amended and reenacted; and that said code be amended by adding thereto a new section,
3 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
5 outpatient 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 of Pharmacy pursuant to 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, information about the person picking up the prescription as set
24 forth on the person's government-issued photo identification card shall be retained in either print
25 or electronic form until such time as otherwise directed by rule promulgated by the Board of
26 Pharmacy; and

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

28 (b) Whenever a medical services provider treats a patient for an overdose that has
29 occurred as a result of illicit or prescribed medication, the medical service provider shall report
30 the full legal name, address and birth date of the person who is being treated, including any known
31 ancillary evidence of the overdose. The Board of Pharmacy shall coordinate with the Division of
32 Justice and Community Services and the Office of Drug Control Policy regarding the collection of
33 overdose data.

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

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

40 (e) Reporting required by this section is not required for a drug administered directly to a
41 patient by a practitioner. Reporting is, however, required by this section for a drug dispensed to a
42 patient by a practitioner. The quantity dispensed by a prescribing practitioner to his or her own

43 patient may not exceed an amount adequate to treat the patient for a maximum of seventy-two
44 hours with no greater than two 72-hour cycles dispensed in any fifteen-day period of time.

45 (f) The Board of Pharmacy shall notify a physician prescribing buprenorphine or
46 buprenorphine/naloxone within sixty days of the availability of an abuse deterrent form of
47 buprenorphine or buprenorphine/naloxone if approved by the Food and Drug Administration as
48 provided in FDA Guidance to Industry. Upon receipt of the notice, a physician may switch their
49 patients using buprenorphine or buprenorphine/naloxone to the abuse deterrent form of the
50 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 of Pharmacy is
2 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 of Pharmacy, members of the West Virginia State Police expressly authorized
5 by the Superintendent of the West Virginia State Police to have access to the information,
6 authorized agents of local law-enforcement agencies as members of a federally affiliated drug
7 task force, authorized agents of the federal Drug Enforcement Administration, duly authorized
8 agents of the Bureau for Medical Services, duly authorized agents of the Office of the Chief
9 Medical Examiner for use in post-mortem examinations, duly authorized agents of the Office of
10 Health Facility Licensure and Certification for use in certification, licensure and regulation of health
11 facilities, duly authorized agents of licensing boards of practitioners in this state and other states
12 authorized to prescribe Schedules II, III and IV controlled substances, prescribing practitioners
13 and pharmacists, a dean of any medical school or his or her designee located in this state to
14 access prescriber level data to monitor prescribing practices of faculty members, prescribers and
15 residents enrolled in a degree program at the school where he or she serves as dean, a physician
16 reviewer designated by an employer of medical providers to monitor prescriber level information

17 of prescribing practices of physicians, advance practice registered nurses or physician assistant
18 in their employ, and a chief medical officer of a hospital or a physician designated by the chief
19 executive officer of a hospital who does not have a chief medical officer, for prescribers who have
20 admitting privileges to the hospital or prescriber level information, and persons with an
21 enforceable court order or regulatory agency administrative subpoena. All law-enforcement
22 personnel who have access to the Controlled Substances Monitoring Program database shall be
23 granted access in accordance with applicable state laws and the Board of Pharmacy's rules, shall
24 be certified as a West Virginia law-enforcement officer and shall have successfully completed
25 training approved by the Board of Pharmacy. All information released by the Board of Pharmacy
26 must be related to a specific patient or a specific individual or entity under investigation by any of
27 the above parties except that practitioners who prescribe or dispense controlled substances may
28 request specific data related to their Drug Enforcement Administration controlled substance
29 registration number or for the purpose of providing treatment to a patient: *Provided*, That the West
30 Virginia Controlled Substances Monitoring Program Database Review Committee established in
31 subsection (b) of this section is authorized to query the database to comply with said subsection.

32 (2) Subject to the provisions of subdivision (1) of this subsection, the Board of Pharmacy
33 shall also review the West Virginia Controlled Substance Monitoring Program database and issue
34 reports that identify abnormal or unusual practices of patients who exceed parameters as
35 determined by the advisory committee established in this section. The Board of Pharmacy shall
36 communicate with practitioners and dispensers to more effectively manage the medications of
37 their patients in the manner recommended by the advisory committee. All other reports produced
38 by the Board of Pharmacy shall be kept confidential. The Board of Pharmacy shall maintain the
39 information required by this article for a period of not less than five years. Notwithstanding any
40 other provisions of this code to the contrary, data obtained under the provisions of this article may
41 be used for compilation of educational, scholarly or statistical purposes, and may be shared with
42 the West Virginia Department of Health and Human Resources for those purposes, as long as

43 the identities of persons or entities and any personally identifiable information, including protected
44 health information, contained therein shall be redacted, scrubbed or otherwise irreversibly
45 destroyed in a manner that will preserve the confidential nature of the information. No individual
46 or entity required to report under section four of this article may be subject to a claim for civil
47 damages or other civil relief for the reporting of information to the Board of Pharmacy as required
48 under and in accordance with the provisions of this article.

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

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

61 (B) Recommend parameters to identify abnormal or unusual usage patterns of controlled
62 substances for patients in order to prepare reports as requested in accordance with subdivision
63 (2) of this subsection.

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

68 (D) Monitor the ability of medical services providers, health care facilities, pharmacists and
69 pharmacies to meet the 24-hour reporting requirement for the Controlled Substances Monitoring
70 Program set forth in section three of this article, and report on the feasibility of requiring real-time
71 reporting.

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

75 (b) The Board of Pharmacy shall create a West Virginia Controlled Substances Monitoring
76 Program Database Review Committee of individuals consisting of two prosecuting attorneys from
77 West Virginia counties, two physicians with specialties which require extensive use of controlled
78 substances and a pharmacist who is trained in the use and abuse of controlled substances. The
79 review committee may determine that an additional physician who is an expert in the field under
80 investigation be added to the team when the facts of a case indicate that the additional expertise
81 is required. The review committee, working independently, may query the database based on
82 parameters established by the advisory committee. The review committee may make
83 determinations on a case-by-case basis on specific unusual prescribing or dispensing patterns
84 indicated by outliers in the system or abnormal or unusual usage patterns of controlled
85 substances by patients which the review committee has reasonable cause to believe necessitates
86 further action by law enforcement or the licensing board having jurisdiction over the practitioners
87 or dispensers under consideration. The licensing board having jurisdiction over the practitioner or
88 dispenser under consideration shall report back to the Board of Pharmacy regarding any findings,
89 investigation or discipline resulting from the findings of the review committee within thirty days of
90 resolution of any action taken by the licensing board resulting from the information provided by
91 the Board of Pharmacy. The review committee shall also review notices provided by the chief
92 medical examiner pursuant to subsection (h), section ten, article twelve, chapter sixty-one of this
93 code and determine on a case-by-case basis whether a practitioner who prescribed or dispensed

94 a controlled substance resulting in or contributing to the drug overdose may have breached
95 professional or occupational standards or committed a criminal act when prescribing the
96 controlled substance at issue to the decedent. Only in those cases in which there is reasonable
97 cause to believe a breach of professional or occupational standards or a criminal act may have
98 occurred, the review committee shall notify the appropriate professional licensing agency having
99 jurisdiction over the applicable practitioner or dispenser and appropriate law-enforcement
100 agencies and provide pertinent information from the database for their consideration. The number
101 of cases identified shall be determined by the review committee based on a number that can be
102 adequately reviewed by the review committee. The information obtained and developed may not
103 be shared except as provided in this article and is not subject to the provisions of chapter
104 twenty-nine-b of this code or obtainable as discovering in civil matters absent a court order.

105 (c) The Board of Pharmacy is responsible for establishing and providing administrative
106 support for the advisory committee and the West Virginia Controlled Substances Monitoring
107 Program Database Review Committee. The advisory committee and the review committee shall
108 elect a chair by majority vote. Members of the advisory committee and the review committee may
109 not be compensated in their capacity as members but shall be reimbursed for reasonable
110 expenses incurred in the performance of their duties.

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

114 (1) Identifying parameters used in identifying abnormal or unusual prescribing or
115 dispensing patterns;

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

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

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

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

126 (f) Good faith reliance by a practitioner on information contained in the West Virginia
127 Controlled Substances Monitoring Program database in prescribing or dispensing or refusing or
128 declining to prescribe or dispense a Schedule II, III or IV controlled substance shall constitute an
129 absolute defense in any civil or criminal action brought due to prescribing or dispensing or refusing
130 or declining to prescribe or dispense.

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

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

141 (i) The Board of Pharmacy shall provide an annual report on the West Virginia Controlled
142 Substance Monitoring Program to the Legislative Oversight Commission on Health and Human
143 Resources Accountability with recommendations for needed legislation no later than January 1 of
144 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 the Board of Pharmacy may renew a practitioner's license
7 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 of said chapter, the Board of Dental
16 Examiners as set forth in article four of said chapter and the Board of Osteopathic Medicine as
17 set forth in article fourteen of said chapter shall access the West Virginia Controlled Substances
18 Monitoring Program database for information regarding specific patients. The information
19 obtained from accessing the West Virginia Controlled Substances Monitoring Program database
20 for the patient shall be documented in the patient's medical record maintained by a private
21 prescriber or any inpatient facility licensed pursuant to the provisions of chapter sixteen of this
22 code. A pain-relieving controlled substance shall be defined as set forth in section one, article
23 three-a, chapter thirty of this code.

24 (c) The various boards mentioned in subsection (b) of this section shall promulgate both
25 emergency and legislative rules pursuant to the provisions of article three, chapter twenty-nine-a
26 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 must
2 be reported to the database established pursuant to this article. The designation of a drug of
3 concern shall be reserved for drugs which have a high potential for abuse. Whenever a medical
4 services provider dispenses a drug of concern or whenever a prescription for a drug of concern
5 is filled by: (i) A pharmacist or pharmacy in this state; (ii) a hospital, or other health care facility,
6 for outpatient use; or (iii) a pharmacy or pharmacist licensed by the Board of Pharmacy, but
7 situated outside this state for delivery to a person residing in this state, the medical services
8 provider, health care facility, pharmacist or pharmacy shall, in a manner prescribed by rules
9 promulgated by the Board of Pharmacy under this article, report the following information, as
10 applicable:

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

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

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

18 (4) The name and national drug number of the drug of concern dispensed;

19 (5) The quantity and dosage of the drug of concern 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, information about the person picking up the prescription as set
24 forth on the person's government-issued photo identification card shall be retained in either print
25 or electronic form until such time as otherwise directed by rule promulgated by the Board of
26 Pharmacy; and

27 (9) The source of payment for the drug of concern dispensed.

28 (b) The penalties set forth in section seven of this article shall not apply to drugs listed as
29 drugs of concern. Failure to report may be considered a violation of the practice act of the
30 prescriber and may result in discipline by the appropriate licensing board.

31 (c) The Board of Pharmacy may promulgate emergency rules pursuant to the provisions
32 of section fifteen, article three, chapter twenty-nine-a of this code to effectuate the provisions of
33 this section.

The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.

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Chairman, Senate Committee

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Chairman, House Committee

Originated in the Senate.

In effect 90 days from passage.

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Clerk of the Senate

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Clerk of the House of Delegates

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President of the Senate

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Speaker of the House of Delegates

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Day of, 2017.

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Governor