

WEST VIRGINIA LEGISLATURE

2020 REGULAR SESSION

ENROLLED

Committee Substitute

for

House Bill 4395

BY DELEGATES SUMMERS, LONGSTRETH AND

PORTERFIELD

[Passed March 7, 2020; in effect ninety days from
passage.]

1 AN ACT to amend and reenact §60A-1-101 of the Code of West Virginia, 1931, as amended,
2 relating to the controlled substances monitoring database; removing the requirement that
3 a veterinarian monitor the controlled substance monitoring database; adding the
4 requirement that a pharmacist licensed by the West Virginia Board of Pharmacy monitor
5 the controlled substance database; and updating the code to reflect previous changes.

Be it enacted by the Legislature of West Virginia:

ARTICLE 9. CONTROLLED SUBSTANCES MONITORING.

**§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 §29B-1-1 *et seq.* of this code or obtainable as
3 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
11 health facilities, duly authorized agents of licensing boards of practitioners in this state and other
12 states authorized to prescribe Schedules II, III, IV, and V controlled substances, prescribing
13 practitioners and pharmacists, a dean of any medical school or his or her designee located in this
14 state to access prescriber level data to monitor prescribing practices of faculty members,
15 prescribers, and residents enrolled in a degree program at the school where he or she serves as
16 dean, a physician reviewer designated by an employer of medical providers to monitor prescriber
17 level information of prescribing practices of physicians, advance practice registered nurses, or

18 physician assistants in their employ, and a chief medical officer of a hospital or a physician
19 designated by the chief executive officer of a hospital who does not have a chief medical officer,
20 for prescribers who have admitting privileges to the hospital or prescriber level information, and
21 persons with an enforceable court order or regulatory agency administrative subpoena. All law-
22 enforcement personnel who have access to the Controlled Substances Monitoring Program
23 Database shall be granted access in accordance with applicable state laws and the Board of
24 Pharmacy's rules, shall be certified as a West Virginia law-enforcement officer and shall have
25 successfully completed training approved by the Board of Pharmacy. All information released by
26 the Board of Pharmacy must be related to a specific patient or a specific individual or entity under
27 investigation by any of the above parties except that practitioners who prescribe or dispense
28 controlled substances may request specific data related to their Drug Enforcement Administration
29 controlled substance registration number or for the purpose of providing treatment to a patient:
30 *Provided, That the West Virginia Controlled Substances Monitoring Program Database Review*
31 *Committee established in §30A-9-5(b) of this code is authorized to query the database to comply*
32 *with §30A-9-5(b) of this code.*

33 (2) Subject to the provisions of §60A-9-5(a)(1) of this code, the Board of Pharmacy shall
34 also review the West Virginia Controlled Substances Monitoring Program Database and issue
35 reports that identify abnormal or unusual practices of patients and practitioners with prescriptive
36 authority who exceed parameters as determined by the advisory committee established in this
37 section. The Board of Pharmacy shall communicate with practitioners and dispensers to more
38 effectively manage the medications of their patients in the manner recommended by the advisory
39 committee. All other reports produced by the Board of Pharmacy shall be kept confidential. The
40 Board of Pharmacy shall maintain the information required by this article for a period of not less
41 than five years. Notwithstanding any other provisions of this code to the contrary, data obtained
42 under the provisions of this article may be used for compilation of educational, scholarly, or
43 statistical purposes, and may be shared with the West Virginia Department of Health and Human

44 Resources for those purposes, as long as the identities of persons or entities and any personally
45 identifiable information, including protected health information, contained therein shall be
46 redacted, scrubbed, or otherwise irreversibly destroyed in a manner that will preserve the
47 confidential nature of the information. No individual or entity required to report under §60A-9-4 of
48 this code may be subject to a claim for civil damages or other civil relief for the reporting of
49 information to the Board of Pharmacy as required under and in accordance with the provisions of
50 this article.

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

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

63 (B) Recommend parameters to identify abnormal or unusual usage patterns of controlled
64 substances for patients in order to prepare reports as requested in accordance with §60A-9-
65 5(a)(2) of this code.

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

70 (D) Monitor the ability of medical services providers, health care facilities, pharmacists,
71 and pharmacies to meet the 24-hour reporting requirement for the Controlled Substances
72 Monitoring Program set forth in §60A-9-3 of this code, and report on the feasibility of requiring
73 real-time reporting.

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

77 (b) The Board of Pharmacy shall create a West Virginia Controlled Substances Monitoring
78 Program Database Review Committee of individuals consisting of two prosecuting attorneys from
79 West Virginia counties, two physicians with specialties which require extensive use of controlled
80 substances and a pharmacist who is trained in the use and abuse of controlled substances. The
81 review committee may determine that an additional physician who is an expert in the field under
82 investigation be added to the team when the facts of a case indicate that the additional expertise
83 is required. The review committee, working independently, may query the database based on
84 parameters established by the advisory committee. The review committee may make
85 determinations on a case-by-case basis on specific unusual prescribing or dispensing patterns
86 indicated by outliers in the system or abnormal or unusual usage patterns of controlled
87 substances by patients which the review committee has reasonable cause to believe necessitates
88 further action by law enforcement or the licensing board having jurisdiction over the practitioners
89 or dispensers under consideration. The licensing board having jurisdiction over the practitioner or
90 dispenser under consideration shall report back to the Board of Pharmacy regarding any findings,
91 investigation, or discipline resulting from the findings of the review committee within 30 days of
92 resolution of any action taken by the licensing board resulting from the information provided by
93 the Board of Pharmacy. The review committee shall also review notices provided by the chief
94 medical examiner pursuant to §61-12-10(h) of this code and determine on a case-by-case basis
95 whether a practitioner who prescribed or dispensed a controlled substance resulting in or

96 contributing to the drug overdose may have breached professional or occupational standards or
97 committed a criminal act when prescribing the controlled substance at issue to the decedent. Only
98 in those cases in which there is reasonable cause to believe a breach of professional or
99 occupational standards or a criminal act may have occurred, the review committee shall notify the
100 appropriate professional licensing agency having jurisdiction over the applicable practitioner or
101 dispenser and appropriate law-enforcement agencies and provide pertinent information from the
102 database for their consideration. The number of cases identified shall be determined by the review
103 committee based on a number that can be adequately reviewed by the review committee. The
104 information obtained and developed may not be shared except as provided in this article and is
105 not subject to the provisions of §29B-1-1 *et seq.* of this code or obtainable as discovering in civil
106 matters absent a court order.

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

113 (d) The Board of Pharmacy shall promulgate rules with advice and consent of the advisory
114 committee, after consultation with the licensing boards set forth in §60A-9-5(d)(4) of this code and
115 in accordance with the provisions of §29A-3-1 *et seq.* of this code. The legislative rules must
116 include, but shall not be limited to, the following matters:

117 (1) Identifying parameters used in identifying abnormal or unusual prescribing or
118 dispensing patterns;

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

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

123 (4) Dissemination of these reports at least quarterly to:

124 (A) The West Virginia Board of Medicine codified in §30-3-1 *et seq.* of this code;

125 (B) The West Virginia Board of Osteopathic Medicine codified in §30-14-1 *et seq.* of this
126 code;

127 (C) The West Virginia Board of Examiners for Registered Professional Nurses codified in
128 §30-7-1 *et seq.* of this code;

129 (D) The West Virginia Board of Dentistry codified in §30-4-1 *et seq.* of this code; and

130 (E) The West Virginia Board of Optometry codified in §30-8-1 *et seq.* of this code; and

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

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

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

142 (g) A prescribing or dispensing practitioner may notify law enforcement of a patient who,
143 in the prescribing or dispensing practitioner's judgment, may be in violation of §60A-4-410 of this
144 code, based on information obtained and reviewed from the Controlled Substances Monitoring
145 Program Database. A prescribing or dispensing practitioner who makes a notification pursuant to

146 this subsection is immune from any civil, administrative, or criminal liability that otherwise might
147 be incurred or imposed because of the notification if the notification is made in good faith.

148 (h) Nothing in the article may be construed to require a practitioner to access the West
149 Virginia Controlled Substances Monitoring Program Database except as provided in §60A-9-5 of
150 this code.

151 (i) The Board of Pharmacy shall provide an annual report on the West Virginia Controlled
152 Substances Monitoring Program to the Legislative Oversight Commission on Health and Human
153 Resources Accountability with recommendations for needed legislation no later than January 1 of
154 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 §60A-2-101 of this code who prescribe or
2 dispense Schedule II, III, IV or V controlled substances shall register with the West Virginia
3 Controlled Substances Monitoring Program and obtain and maintain online or other electronic
4 access to the program database: *Provided*, That compliance with the provisions of this subsection
5 must be accomplished within 30 days of the practitioner obtaining a new license: *Provided*,
6 *however*, That the Board of Pharmacy may renew a practitioner's license without proof that the
7 practitioner meet the requirements of this subsection.

8 (b) All persons with prescriptive or dispensing authority and in possession of a valid Drug
9 Enforcement Administration registration identification number and who are licensed by the Board
10 of Medicine as set forth in §30-3-1 *et seq.* of this code, the Board of Registered Professional
11 Nurses as set forth in §30-7-1 *et seq.* of this code, the Board of Dental Examiners as set forth in
12 §30-4-1 *et seq.* of this code, the Board of Osteopathic Medicine as set forth in §30-14-1 *et seq.*
13 of this code, the West Virginia Board of Optometrists as set forth in §30-8-1 *et seq.* of this code,
14 and a pharmacist licensed by the West Virginia Board of Pharmacy as set forth in §30-5-1 *et seq.*
15 of this code, upon initially prescribing or dispensing any Schedule II controlled substance, any

16 opioid or any benzodiazepine to a patient who is not suffering from a terminal illness, and at least
17 annually thereafter should the practitioner or dispenser continue to treat the patient with a
18 controlled substance, shall access the West Virginia Controlled Substances Monitoring Program
19 Database for information regarding specific patients. The information obtained from accessing the
20 West Virginia Controlled Substances Monitoring Program Database for the patient shall be
21 documented in the patient's medical record maintained by a private prescriber or any inpatient
22 facility licensed pursuant to the provisions of Chapter 16 of this code. A pain-relieving controlled
23 substance shall be defined as set forth in §30-3A-1 of this code.

24 (c) The various boards mentioned in §60A-9-5(b) of this code shall promulgate both
25 emergency and legislative rules pursuant to the provisions of §29A-3-1 *et seq.* of this code to
26 effectuate the provisions of this article.

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

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Chairman, House Committee

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Chairman, Senate Committee

Originating in the House.

In effect ninety days from passage.

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Clerk of the House of Delegates

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Clerk of the Senate

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Speaker of the House of Delegates

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President of the Senate

The within this the.....
day of, 2020.

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Governor