FILED

2015 APR -1 P 1:53

OFFICE WEST VIRGINIA SECRETARY OF STATE

WEST VIRGINIA LEGISLATÜRE

FIRST REGULAR SESSION, 2015

ENROLLED

House Bill No. 2733

(By Delegate(s) Ellington and Householder)



Passed March 12, 2015

In effect ninety days from passage.

FILED 2015 APR - 1 P 1:53 ENROLLED OFFICE WEST VIRGINIA SECRETARY OF STATE

H. B. 2733

(BY DELEGATE(S) ELLINGTON AND HOUSEHOLDER)

[Passed March 12, 2015; in effect ninety days from passage.]

AN ACT to amend and reenact §60A-2-208 of the Code of West Virginia, 1931, as amended; to amend and reenact §60A-9-3, §60A-9-4, §60A-9-4a and §60A-9-5 of said code; and to amend and reenact §60A-10-16 of said code, all relating to removing certain combinations of drugs containing hydrocodone from Schedule III of the controlled substances law; updating the controlled substances monitoring law and extending the expiration date of provisions relating to the Multi-/State Real-Time Tracking System.

Be it enacted by the Legislature of West Virginia:

That §60A-2-208 of the Code of West Virginia, 1931, as amended, be amended and reenacted; that §60A-9-3, §60A-9-4, §60A-9-4a and §60A-9-5 of said code be amended and reenacted; and that §60A-10-16 of said code be amended and reenacted, all to read as follows:

ARTICLE 2. STANDARDS AND SCHEDULES.

§60A-2-208. Schedule III.

- 1 (a) Schedule III consists of the drugs and other substances,
- 2 by whatever official name, common or usual name, chemical
- 3 name or brand name designated, listed in this section.

4 (b) Stimulants. — Unless specifically excepted or unless 5 listed in another schedule, any material, compound, mixture or 6 preparation which contains any quantity of the following substances having a stimulant effect on the central nervous 7 8 system, including its salts, isomers (whether optical, position or 9 geometric) and salts of such isomers whenever the existence of 10 the salts, isomers and salts of isomers is possible within the 11 specific chemical designation:

12 (1) Those compounds, mixtures or preparations in dosage 13 unit form containing any stimulant substances listed in Schedule 14 II which compounds, mixtures or preparations were listed on 15 August 25, 1971, as excepted compounds under 21 C.F.R. 16 §C.F.R. §1308.32, and any other drug of the quantitative 17 composition shown in that list for those drugs or which is the 18 same except that it contains a lesser quantity of controlled 19 substances;

- 20 (2) Benzphetamine;
- 21 (3) Chlorphentermine;
- 22 (4) Clortermine;
- 23 (5) Phendimetrazine.

(c) *Depressants.* — Unless specifically excepted or unless
listed in another schedule, any material, compound, mixture or
preparation which contains any quantity of the following

substances having a depressant effect on the central nervoussystem:

- 29 (1) Any compound, mixture or preparation containing:
- 30 (A) Amobarbital;

31 (B) Secobarbital;

32 (C) Pentobarbital; or any salt of pentobarbital and one or
33 more other active medicinal ingredients which are not listed in
34 any schedule;

35 (2) Any suppository dosage form containing:

36 (A) Amobarbital;

37 (B) Secobarbital;

38 (C) Pentobarbital; or any salt of any of these drugs and
39 approved by the food and drug administration for marketing only
40 as a suppository;

41 (3) Any substance which contains any quantity of a42 derivative of barbituric acid or any salt of barbituric acid;

43 (4) Aprobarbital;

44 (5) Butabarbital (secbutabarbital);

45 (6) Butalbital (including, but not limited to, Fioricet);

- 46 (7) Butobarbital (butethal);
- 47 (8) Chlorhexadol;
- 48 (9) Embutramide;
- 49 (10) Gamma Hydroxybutryic Acid preparations;

50 (11) Ketamine, its salts, isomers and salts of isomers [Some 51 other names for ketamine: (+-)-2-(2-chlorophenyl)-2-52 (methylamino)-cyclohexanone];

•

4

- 53 (12) Lysergic acid;
- 54 (13) Lysergic acid amide;
- 55 (14) Methyprylon;
- 56 (15) Sulfondiethylmethane;
- 57 (16) Sulfonethylmethane;
- 58 (17) Sulfonmethane;
- 59 (18) Thiamylal;
- 60 (19) Thiopental;

61 (20) Tiletamine and zolazepam or any salt of tiletamine and 62 trade or other zolazepam; some names for a 63 tiletamine-zolazepam combination product: Telazol; some trade names for tiletamine: 2-(ethylamino)-2-64 or other 65 (2-thienyl)-cyclohexanone; some trade or other names for zolazepam: 4-(2-flurophenyl)-6, 66 8-dihydro-1, 3. 8-trimethylpyrazolo-[3,4-e] [1,4]-diazepin-7(1H)-one, 67 68 flupyrazapon; and

- 69 (21) Vinbarbital.
- 70 (d) Nalorphine.

(e) *Narcotic drugs.* — Unless specifically excepted or unless
listed in another schedule:

(1) Any material, compound, mixture or preparationcontaining any of the following narcotic drugs, or their salts

calculated as the free anhydrous base or alkaloid, in limitedquantities as set forth below:

(A) Not more than 1.8 grams of codeine per 100 milliliters
and not more than 90 milligrams per dosage unit, with an equal
or greater quantity of an isoquinoline alkaloid of opium;

(B) Not more than 1.8 grams of codeine per 100 milliliters
or not more than 90 milligrams per dosage unit, with one or
more active, nonnarcotic ingredients in recognized therapeutic
amounts;

(C) Not more than 1.8 grams of dihydrocodeine per 100
milliliters and not more than 90 milligrams per dosage unit, with
one or more active, nonnarcotic ingredients in recognized
therapeutic amounts;

(D) Not more than 300 milligrams of ethylmorphine per 100
milliliters or not more than 15 milligrams per dosage unit, with
one or more active, nonnarcotic ingredients in recognized
therapeutic amounts;

92 (E) Not more than 500 milligrams of opium per 100
93 milliliters or per 100 grams or not more than 25 milligrams per
94 dosage unit, with one or more active, nonnarcotic ingredients in
95 recognized therapeutic amounts;

96 (F) Not more than 50 milligrams of morphine per 100
97 milliliters or per 100 grams, with one or more active,
98 nonnarcotic ingredients in recognized therapeutic amounts.

99 (2) Any material, compound, mixture or preparation
100 containing buprenorphine or its salts (including, but not limited
101 to, Suboxone).

102 (f) Anabolic steroids. — Unless specifically excepted or 103 unless listed in another schedule, any material, compound,

104 mixture, or preparation containing any quantity of anabolic
105 steroids, including its salts, isomers and salts of isomers
106 whenever the existence of the salts of isomers is possible within
107 the specific chemical designation.

6

108 (g) Human growth hormones.

109 (h) Dronabinol (synthetic) in sesame oil and encapsulated in 110 a soft gelatin capsule in a United States food and drug 111 administration approved drug product. (Some other names for dronabinol: (6aR-trans)-6a, 7, 8, 10a- tetrahydro-6, 112 6. 113 9-trimethyl-3-pentyl-6H-dibenzo [b,d]pyran-1- ol or (-)-delta-9-(trans)-tetrahydrocannabinol). 114

ARTICLE 9. CONTROLLED SUBSTANCES MONITORING.

§60A-9-3. Reporting system requirements; implementation; central repository requirement.

(a) The Board of Pharmacy shall implement a program 1 2 wherein a central repository is established and maintained which shall contain such information as is required by the provisions of 3 4 this article regarding Schedule II, III, and IV controlled substance prescriptions written or filled in this state. In 5 implementing this program, the Board of Pharmacy shall consult 6 with the West Virginia State Police, the licensing boards of 7 practitioners affected by this article and affected practitioners. 8

9 (b) The program authorized by subsection (a) of this section shall be designed to minimize inconvenience to patients, 10 11 prescribing practitioners and pharmacists while effectuating the collection and storage of the required information. The board 12 shall allow reporting of the required information by electronic 13 data transfer where feasible, and where not feasible, on reporting 14 forms promulgated by the board. The information required to be 15 16 submitted by the provisions of this article shall be required to be filed no more frequently than within twenty-four hours. 17

mixture, or preparation containing any quantity of anabolic
steroids, including its salts, isomers and salts of isomers
whenever the existence of the salts of isomers is possible within
the specific chemical designation.

108 (g) Human growth hormones.

(h) Dronabinol (synthetic) in sesame oil and encapsulated in
a soft gelatin capsule in a United States food and drug
administration approved drug product. (Some other names for
dronabinol: (6aR-trans)-6a, 7, 8, 10a- tetrahydro-6, 6,
9-trimethyl-3-pentyl-6H-dibenzo [b,d] pyran-1- ol or
(-)-delta-9-(trans)-tetrahydrocannabinol).

ARTICLE 9. CONTROLLED SUBSTANCES MONITORING.

§60A-9-3. Reporting system requirements; implementation; central repository requirement.

1 (a) The Board of Pharmacy shall implement a program 2 wherein a central repository is established and maintained which shall contain such information as is required by the provisions of 3 4 this article regarding Schedule II, III, and IV controlled 5 substance prescriptions written or filled in this state. In 6 implementing this program, the Board of Pharmacy shall consult 7 with the West Virginia State Police, the licensing boards of practitioners affected by this article and affected practitioners. 8

9 (b) The program authorized by subsection (a) of this section 10 shall be designed to minimize inconvenience to patients, 11 prescribing practitioners and pharmacists while effectuating the 12 collection and storage of the required information. The board 13 shall allow reporting of the required information by electronic 14 data transfer where feasible, and where not feasible, on reporting 15 forms promulgated by the board. The information required to be 16 submitted by the provisions of this article shall be required to be filed no more frequently than within twenty-four hours. 17

18 (c) (1) The board shall provide for the electronic
19 transmission of the information required to be provided by this
20 article by and through the use of a toll-free telephone line.

(2) A dispenser, who does not have an automated
record-keeping system capable of producing an electronic report
in the established format may request a waiver from electronic
reporting. The request for a waiver shall be made to the board in
writing and shall be granted if the dispenser agrees in writing to
report the data by submitting a completed "Pharmacy Universal
Claim Form" as defined by legislative rule.

§60A-9-4. Required information.

1 (a) Whenever a medical services provider dispenses a 2 controlled substance listed in Schedule II. III or IV as established 3 under the provisions of article two of this chapter or whenever 4 a prescription for the controlled substance is filled by: (i) A 5 pharmacist or pharmacy in this state; (ii) a hospital, or other 6 health care facility, for out-patient use; or (iii) a pharmacy or 7 pharmacist licensed by the Board of Pharmacy, but situated 8 outside this state for delivery to a person residing in this state, the medical services provider, health care facility, pharmacist or 9 pharmacy shall, in a manner prescribed by rules promulgated by 10 11 the board under this article, report the following information, as 12 applicable:

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

17 (2) The full legal name, address and birth date of the person18 for whom the prescription is written;

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

(4) The name and national drug code number of the ScheduleII, III, and IV controlled substance dispensed;

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

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

(7) The number of refills, if any, authorized by theprescription;

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

36 (9) The source of payment for the controlled substance37 dispensed.

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

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

(d) Reporting required by this section is not required for a
drug administered directly to a patient by a practitioner.
Reporting is, however, required by this section for a drug
dispensed to a patient by a practitioner: *Provided*, That the
quantity dispensed may not exceed an amount adequate to treat

- 51 the patient for a maximum of seventy-two hours with no greater
- 52 than two seventy-two-hour cycles dispensed in any fifteen-day
- 53 period of time.

§60A-9-4a. Verification of identity.

Prior to releasing a Schedule II, III, or IV controlled substance sold at retail, a pharmacist or pharmacy shall verify the full legal name, address and birth date of the person picking up the controlled substance dispensed by requiring the presentation of a valid government-issued photo identification card. This information shall be reported in accordance with the provisions of this article.

§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 $(a) = a^{2} a^{2} b^{2}$ 2 the board is confidential and not subject to the provisions of 3 chapter twenty-nine-b of this code or obtainable as discovery in 4 civil matters absent a court order and is open to inspection only 5 by inspectors and agents of the board members of the West 6 Virginia State Police expressly authorized by the Superintendent 7 of the West Virginia State Police to have access to the 8 information, authorized agents of local law-enforcement 9 agencies as members of a federally affiliated drug task force, 10 authorized agents of the federal Drug Enforcement 11 Administration, duly authorized agents of the Bureau for 12 Medical Services, duly authorized agents of the Office of the 13 Chief Medical Examiner for use in post-mortem examinations, 14 duly authorized agents of licensing boards of practitioners in this 15 state and other states authorized to prescribe Schedules II, III, 16 and IV controlled substances, prescribing practitioners and 17 pharmacists and persons with an enforceable court order or 18 regulatory agency administrative subpoena: Provided, That all 19 law-enforcement personnel who have access to the Controlled 20 Substances Monitoring Program database shall be granted access 21 in accordance with applicable state laws and the board's 22 legislative rules, shall be certified as a West Virginia 23 law-enforcement officer and shall have successfully completed 24 training approved by the board. All information released by the board must be related to a specific patient or a specific 25 26 individual or entity under investigation by any of the above 27 parties except that practitioners who prescribe or dispense 28 controlled substances may request specific data related to their 29 Drug Enforcement Administration controlled substance 30 registration number or for the purpose of providing treatment to 31 a patient: Provided, however, That the West Virginia Controlled 32 Substances Monitoring Program Database Review Committee 33 established in subsection (b) of this section is authorized to 34 query the database to comply with said subsection.

10

35 (2) Subject to the provisions of subdivision (1) of this 36 subsection, the board shall also review the West Virginia 37 Controlled Substance Monitoring Program database and issue 38 reports that identify abnormal or unusual practices of patients 39 who exceed parameters as determined by the advisory committee 40 established in this section. The board shall communicate with 41 prescribers and dispensers to more effectively manage the 42 medications of their patients in the manner recommended by the 43 advisory committee. All other reports produced by the board 44 shall be kept confidential. The board shall maintain the 45 information required by this article for a period of not less than 46 five years. Notwithstanding any other provisions of this code to 47 the contrary, data obtained under the provisions of this article 48 may be used for compilation of educational, scholarly or 49 statistical purposes, and may be shared with the West Virginia 50 Department of Health and Human Resources for those purposes, 51 as long as the identities of persons or entities and any personally 52 identifiable information, including protected health information, 53 contained therein shall be redacted, scrubbed or otherwise

54 irreversibly destroyed in a manner that will preserve the 55 confidential nature of the information. No individual or entity 56 required to report under section four of this article may be 57 subject to a claim for civil damages or other civil relief for the 58 reporting of information to the board as required under and in 59 accordance with the provisions of this article.

60 (3) The board shall establish an advisory committee to 61 develop, implement and recommend parameters to be used in 62 identifying abnormal or unusual usage patterns of patients in this 63 state. This advisory committee shall:

64 (A) Consist of the following members: A physician licensed 65 by the West Virginia Board of Medicine, a dentist licensed by 66 the West Virginia Board of Dental Examiners, a physician 67 licensed by the West Virginia Board of Osteopathy, a licensed 68 physician certified by the American Board of Pain Medicine, a 69 licensed physician board certified in medical oncology 70 recommended by the West Virginia State Medical Association, 71 a licensed physician board certified in palliative care 72 recommended by the West Virginia Center on End of Life Care, 73 a pharmacist licensed by the West Virginia Board of Pharmacy, 74 a licensed physician member of the West Virginia Academy of 75 Family Physicians, an expert in drug diversion and such other 76 members as determined by the board.

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

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

87 (D) Monitor the ability of medical services providers, health 88 care facilities, pharmacists and pharmacies to meet the 89 twenty-four hour reporting requirement for the Controlled 90 Substances Monitoring Program set forth in section three of this 91 article, and report on the feasibility of requiring real-time 92 reporting.

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

97 (b) The board shall create a West Virginia Controlled 98 Substances Monitoring Program Database Review Committee of 99 individuals consisting of two prosecuting attorneys from West 100 Virginia counties, two physicians with specialties which require 101 extensive use of controlled substances and a pharmacist who is 102 trained in the use and abuse of controlled substances. The review 103 committee may determine that an additional physician who is an 104 expert in the field under investigation be added to the team when 105 the facts of a case indicate that the additional expertise is 106 required. The review committee, working independently, may 107 query the database based on parameters established by the 108 advisory committee. The review committee may make 109 determinations on a case-by-case basis on specific unusual 110 prescribing or dispensing patterns indicated by outliers in the 111 system or abnormal or unusual usage patterns of controlled 112 substances by patients which the review committee has 113 reasonable cause to believe necessitates further action by law 114 enforcement or the licensing board having jurisdiction over the 115 prescribers or dispensers under consideration. The review 116 committee shall also review notices provided by the chief 117 medical examiner pursuant to subsection (h), section ten, article 118 twelve, chapter sixty-one of this code and determine on a 119 case-by-case basis whether a practitioner who prescribed or 120 dispensed a controlled substance resulting in or contributing to

the drug overdose may have breached professional or 121 122 occupational standards or committed a criminal act when 123 prescribing the controlled substance at issue to the decedent. 124 Only in those cases in which there is reasonable cause to believe a breach of professional or occupational standards or a criminal 125 126 act may have occurred, the review committee shall notify the 127 appropriate professional licensing agency having jurisdiction 128 over the applicable prescriber or dispenser and appropriate 129 law-enforcement agencies and provide pertinent information 130 from the database for their consideration. The number of cases 131 identified shall be determined by the review committee based on 132 a number that can be adequately reviewed by the review 133 committee. The information obtained and developed may not be 134 shared except as provided in this article and is not subject to the 135 provisions of chapter twenty-nine-b of this code or obtainable as 136 discovering in civil matters absent a court order.

137 (c) The board is responsible for establishing and providing 138 administrative support for the advisory committee and the West 139 Virginia Controlled Substances Monitoring Program Database 140 Review Committee. The advisory committee and the review 141 committee shall elect a chair by majority vote. Members of the 142 advisory committee and the review committee may not be 143 compensated in their capacity as members but shall be 144 reimbursed for reasonable expenses incurred in the performance 145 of their duties.

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

(1) Identifying parameters used in identifying abnormal orunusual prescribing or dispensing patterns;

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

(3) Establishing the information to be contained in reportsand the process by which the reports will be generated anddisseminated; and

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

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

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

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

(h) A prescribing or dispensing practitioner may notify law
enforcement of a patient who, in the prescribing or dispensing
practitioner's judgment, may be in violation of section four
hundred ten, article four of this chapter, based on information

obtained and reviewed from the controlled substances
monitoring database. A prescribing or dispensing practitioner
who makes a notification pursuant to this subsection is immune
from any civil, administrative or criminal liability that otherwise
might be incurred or imposed because of the notification if the
notification is made in good faith.

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

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

ARTICLE 10. METHAMPHETAMINELABORATORY ERADICATION ACT.

§60A-10-16. Expiration of enactments made during 2012 regular session.

- 1 The provisions of this article enacted during the 2012 regular
- 2 legislative session establishing the Multi-State Real-Time
- 3 Tracking System shall expire on June 30,2017.

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

17

Chairman, House Committee Chairman, Senate Committee

Originating in the House.

In effect ninety days from passage.

Clerk of the House of Delegates AN Clerk of the Senate Speaker of the House of Delegates President of the Senate

18unit this the The within. _, 2015. day of _ Emilli nor

PRESENTED TO THE GOVERNOR

MAR 1 8 2015

Time 5:30 pm

5

,