H. B. 2733

(By Delegates Ellington and Householder)

[Introduced February 13, 2015; referred to the
Committee on Health and Human Resources then the Judiciary.]

A BILL 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.

(a) Schedule III consists of the drugs and other substances, by whatever official name,

common or usual name, chemical name or brand name designated, listed in this section.

(b) *Stimulants*. -- 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 stimulant effect on the central nervous system, including its salts, isomers (whether optical, position or geometric) and salts of such isomers whenever the existence of the salts, isomers and salts of isomers is possible within the specific chemical designation:

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

(2) Benzphetamine;

(3) Chlorphentermine;

(4) Clortermine;

(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 nervous system:

(1) Any compound, mixture or preparation containing:

(A) Amobarbital;

(B) Secobarbital;

(C) Pentobarbital; or any salt of pentobarbital and one or more other active medicinal

ingredients which are not listed in any schedule;

(2) Any suppository dosage form containing:

(A) Amobarbital;

(B) Secobarbital;

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

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

(4) Aprobarbital;

(5) Butabarbital (secbutabarbital);

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

(7) Butobarbital (butethal);

(8) Chlorhexadol;

(9) Embutramide;

(10) Gamma Hydroxybutryic Acid preparations;

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

(12) Lysergic acid;

(13) Lysergic acid amide;

(14) Methyprylon;

(15) Sulfondiethylmethane;

(16) Sulfonethylmethane;

(17) Sulfonmethane;

(18) Thiamylal;

(19) Thiopental;

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

(21) Vinbarbital.

(d) Nalorphine.

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

(1) Any material, compound, mixture or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities 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;

~~(3) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium: *Provided, That* a prescription for this may not be filled for more than a one month supply or filled or refilled more than three moths after the date of the original prescription. Such~~

~~prescription may not be refilled more than twice;~~

~~(4) Not more than 300 milligrams of dihydrocodeinone (hydrocodone) per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts: *Provided, That* a prescription for this product may not be filled for more than a one month supply or filled or refilled more than three moths after the date of the original prescription. Such prescription may not be refilled more than twice;~~

(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;

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

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

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

(f) *Anabolic steroids*. -- Unless specifically excepted or unless listed in another schedule, any material, compound, 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.

(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.

(a) ~~On or before September 1, 2002,~~ The Board of Pharmacy shall implement a program wherein a central repository is established and maintained which shall contain such information as is required by the provisions of this article regarding Schedule II, III, and IV controlled substance prescriptions written or filled in this state. In implementing this program, the Board of Pharmacy shall consult with the West Virginia State Police, the licensing boards of practitioners affected by this article and affected practitioners.

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

(c) (1) The ~~State~~ board ~~of Pharmacy~~ shall provide for the electronic transmission of the

information required to be provided by this 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 ~~State~~ board ~~of Pharmacy~~ 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.

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

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

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

registration number of the practitioner writing the prescription;

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

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

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

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

(8) If the prescription being dispensed is being picked up by someone other than the patient on behalf of the patient, ~~the full legal name~~ 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; ~~of pharmacy~~ and

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

(b) The board ~~of Pharmacy~~ 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.

(c) Products regulated by the provisions of article ten of this chapter shall be subject to reporting pursuant to the provisions of 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 the patient for a maximum of seventy-two hours with no greater than two seventy-two-hour cycles dispensed in any fifteen-day 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 ~~receiving or otherwise acquiring~~ 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. ~~information shall be retained in either print or electronic form until such time as otherwise directed by rule promulgated by the board of pharmacy.~~

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

(a) (1) The information required by this article to be kept by the ~~State~~ board ~~of Pharmacy~~ is confidential and not subject to the provisions of chapter twenty-nine-b of this code or obtainable as discovery in civil matters absent a court order and is open to inspection only by inspectors and agents of the ~~State~~ board ~~of Pharmacy~~, members of the West Virginia State Police expressly authorized by the Superintendent of the West Virginia State Police to have access to the information, authorized agents of local law-enforcement agencies as members of a federally affiliated drug task force, authorized agents of the federal Drug Enforcement Administration, duly authorized agents of the Bureau for Medical Services, duly authorized agents of the Office of the Chief Medical Examiner for use in post-mortem examinations, duly authorized agents of licensing boards of practitioners in this state and other states authorized to prescribe Schedules II, III, and IV controlled substances, prescribing practitioners and pharmacists and persons with an enforceable court order or regulatory agency administrative subpoena: *Provided*, That all law-enforcement personnel who have access to the Controlled Substances Monitoring Program database shall be granted access in accordance

with applicable state laws and the board's ~~Board of Pharmacy~~ legislative rules, shall be certified as a West Virginia law-enforcement officer and shall have successfully completed ~~United States Drug Enforcement Administration Diversion Training and National Association of Drug Diversion Investigation Training~~ training approved by the board. All information released by the ~~State Board of Pharmacy~~ board must be related to a specific patient or a specific individual or entity under investigation by any of the above parties except that practitioners who prescribe or dispense controlled substances may request specific data related to their Drug Enforcement Administration controlled substance registration number or for the purpose of providing treatment to a patient: *Provided*, *however*, That the West Virginia Controlled Substances Monitoring Program Database Review Committee established in subsection (b) of this section is authorized to query the database to comply with said subsection.

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

protected health information, contained therein shall be redacted, scrubbed or otherwise irreversibly destroyed in a manner that will preserve the confidential nature of the information. No individual or entity required to report under section four of this article may be subject to a claim for civil damages or other civil relief for the reporting of information to the ~~Board of Pharmacy~~ board as required under and in accordance with the provisions of this article.

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

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

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

(b) The ~~Board of Pharmacy~~ board shall create a West Virginia Controlled Substances Monitoring Program Database Review Committee of individuals consisting of two prosecuting attorneys from West Virginia counties, two physicians with specialties which require extensive use of controlled substances and a pharmacist who is trained in the use and abuse of controlled substances. The review committee may determine that an additional physician who is an expert in the field under investigation be added to the team when the facts of a case indicate that the additional expertise is required. The review committee, working independently, may query the database based on parameters established by the advisory committee. The review committee may make determinations on a case-by-case basis on specific unusual prescribing or dispensing patterns indicated by outliers in the system or abnormal or unusual usage patterns of controlled substances by patients which the review committee has reasonable cause to believe necessitates further action by law enforcement or the licensing board having jurisdiction over the prescribers or dispensers under consideration. The review committee shall also review notices provided by the chief medical examiner pursuant to subsection (h), section ten, article twelve, chapter sixty-one of this code and

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

(c) The ~~Board of Pharmacy~~ board is responsible for establishing and providing administrative support for the advisory committee and the West Virginia Controlled Substances Monitoring Program Database Review Committee. The advisory committee and the review committee shall elect a chair by majority vote. Members of the advisory committee and the review committee may not be compensated in their capacity as members but shall be reimbursed for reasonable expenses incurred in the performance 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. ~~on or before June 1, 2013.~~ The legislative rules must include, but shall not be limited to, the following matters:

(1) Identifying parameters used in identifying abnormal or unusual 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 reports and the process by which the reports will be generated and disseminated; 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 ~~on or before July 1, 2011,~~ 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 of Pharmacy~~ 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 or V 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 of Pharmacy~~ 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. METHAMPHETAMINE LABORATORY ERADICATION ACT.

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

The provisions of this article enacted during the 2012 regular legislative session establishing the Multi–State Real-Time Tracking System shall expire on ~~June 30, 2015.~~ June 30,2017.

NOTE: The purpose of this bill is to remove certain drugs from Schedule III of the controlled substances law; update the requirements of the Control Substance Monitoring Program and extend the expiration date of law relating to the Multi-State Real-Time Tracking System.

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