Prescription Monitoring Program State Profiles – West Virginia

Research current through December 2014.

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WEST VIRGINIA

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- Status of Program – operational
- Housing Entity – Board of Pharmacy
- Advisory Commission – yes
- Funding – grants, public and private assistance, and licensure fees
- Drugs Monitored – Schedules II – V
- Who's Required to Report Dispensing Information – medical services providers, health care facilities, pharmacists, pharmacies
- Exemptions from Reporting – direct administration of drug to patient
- Nonresident Pharmacies Required to Report – yes
- Veterinarians Required to Report – yes
- Data Collection Interval – daily/24 hours
- Notice to Consumers – yes
- Interstate Sharing – with other PMPs and authorized users in other states
- Persons Authorized to Receive Information – Office of the Chief Medical Examiner; law enforcement and judicial/prosecutorial officials; licensing/regulatory boards; authorized agents of the Bureau for Medical Services; prescribers; dispensers
- Delegates Allowed – yes
- De-identified Data Provided – yes
- Unsolicited Reports – to law enforcement and licensing boards
- Training Required – yes; law enforcement only
- Mandatory Enrollment – yes; dentists, practitioners, registered nurses, and osteopaths
- Mandatory Access – yes; multiple circumstances; see States that Require Prescribers and/or Dispensers to Access PMP in Certain Circumstances, compilation of statutes, on NAMSDL's website for further information

West's Annotated Code of West Virginia (2014)
Chapter 16. Public Health
Article 1. State Public Health System

§ 16-1-4. Proposal of rules by the secretary

(a) The secretary may propose rules in accordance with the provisions of article three, chapter twenty-nine-a of this code that are necessary and proper to effectuate the purposes of this chapter. The secretary may appoint or designate advisory councils of professionals in the areas of hospitals, nursing homes, barbers and beauticians, postmortem examinations, mental health and intellectual disability centers and any other areas necessary to advise the secretary on rules.

(b) The rules may include, but are not limited to, the regulation of:

(1) Land usage endangering the public health: Provided, That no rules may be promulgated or enforced restricting the subdivision or development of any parcel of land within which the individual tracts, lots or parcels exceed two acres each in total surface area and which individual tracts, lots or parcels have an average frontage of not less than one hundred fifty feet even though the total surface area of the tract, lot or parcel equals or exceeds two acres in total surface area, and which tracts are sold, leased or utilized only as single-family dwelling units. Notwithstanding the provisions of this subsection, nothing in this section may be construed to abate the authority of the department to:

(A) Restrict the subdivision or development of a tract for any more intense or higher density occupancy than a single-family dwelling unit;

(B) Propose or enforce rules applicable to single-family dwelling units for single-family dwelling unit sanitary sewerage disposal systems; or

(C) Restrict any subdivision or development which might endanger the public health, the sanitary condition of streams or sources of water supply;

(2) The sanitary condition of all institutions and schools, whether public or private, public conveyances, dairies, slaughterhouses, workshops, factories, labor camps, all other places open to the general public and inviting public patronage or public assembly, or tendering to the public any item for human consumption and places where trades or industries are conducted;

(3) Occupational and industrial health hazards, the sanitary conditions of streams, sources of water supply, sewerage facilities and plumbing systems and the qualifications of personnel connected with any of those facilities, without regard to whether the supplies or systems are publicly or privately owned; and the design of all water systems, plumbing systems, sewerage systems, sewage treatment plants, excreta disposal methods and swimming pools in this state, whether publicly or privately owned;

(4) Safe drinking water, including:

(A) The maximum contaminant levels to which all public water systems must conform in order to prevent adverse effects on the health of individuals and, if appropriate, treatment techniques that reduce the contaminant or contaminants to a level which will not adversely affect the health of the consumer. The rule shall contain provisions to protect and prevent contamination of wellheads and well fields used by public water supplies so that contaminants do not reach a level that would adversely affect the health of the consumer;

(B) The minimum requirements for: Sampling and testing; system operation; public notification by a public water system on being granted a variance or exemption or upon failure to comply with specific requirements of this section and rules promulgated under this section; record keeping; laboratory certification; as well as procedures and conditions for granting variances and exemptions to public water systems from state public water systems rules; and

(C) The requirements covering the production and distribution of bottled drinking water and may establish requirements governing the taste, odor, appearance and other consumer acceptability parameters of drinking water;

(5) Food and drug standards, including cleanliness, proscription of additives, proscription of sale and other requirements in accordance with article seven of this chapter as are necessary to protect the health of the citizens of this state;

(6) The training and examination requirements for emergency medical service attendants and emergency medical care technician- paramedics; the designation of the health care facilities, health care services and the industries and occupations in the state that must have emergency medical service attendants and emergency medical care technician-paramedics employed and the availability, communications and equipment requirements with respect to emergency medical service attendants and to emergency medical care technician-paramedics. Any regulation of emergency medical service attendants and emergency medical care technician- paramedics may not exceed the provisions of article four-c of this chapter;

(7) The health and sanitary conditions of establishments commonly referred to as bed and breakfast inns. For purposes of this article, "bed and breakfast inn" means an establishment providing sleeping accommodations and, at a minimum, a breakfast for a fee. The secretary may not require an owner of a bed and breakfast providing sleeping accommodations of six or fewer rooms to install a restaurant-style or commercial food service facility. The secretary may not require an owner of a bed and breakfast providing sleeping accommodations of more than six rooms to install a restaurant-type or commercial food service facility if the entire bed and breakfast inn or those rooms numbering above six are used on an aggregate of two weeks or less per year;

(8) Fees for services provided by the Bureau for Public Health including, but not limited to, laboratory service fees, environmental health service fees, health facility fees and permit fees;

(9) The collection of data on health status, the health system and the costs of health care;

(10) Opioid treatment programs duly licensed and operating under the requirements of chapter twenty-seven of this code.

(A) The Health Care Authority shall develop new certificate of need standards, pursuant to the provisions of article two-d of this chapter, that are specific for opioid treatment program facilities.

(B) No applications for a certificate of need for opioid treatment programs may be approved by the Health Care Authority as of the effective date of the 2007 amendments to this subsection.

(C) There is a moratorium on the licensure of new opioid treatment programs that do not have a certificate of need as of the effective date of the 2007 amendments to this subsection, which shall continue until the Legislature determines that there is a necessity for additional opioid treatment facilities in West Virginia.

(D) The secretary shall file revised emergency rules with the Secretary of State to regulate opioid treatment programs in compliance with the provisions of this section. Any opioid treatment program facility that has received a certificate of need pursuant to article two-d, of this chapter by the Health Care Authority shall be permitted to proceed to license and operate the facility.

(E) All existing opioid treatment programs shall be subject to monitoring by the secretary. All staff working or volunteering at opioid treatment programs shall complete the minimum education, reporting and safety training criteria established by the secretary. All existing opioid treatment programs shall be in compliance within one hundred eighty days of the effective date of the revised emergency rules as required herein. The revised emergency rules shall provide at a minimum:

(i) That the initial assessment prior to admission for entry into the opioid treatment program shall include an initial drug test to determine whether an individual is either opioid addicted or presently receiving methadone for an opioid addiction from another opioid treatment program.

(ii) The patient may be admitted to the opioid treatment program if there is a positive test for either opioids or methadone or there are objective symptoms of withdrawal, or both, and all other criteria set forth in the rule for admission into an opioid treatment program are met. Admission to the program may be allowed to the following groups with a high risk of relapse without the necessity of a positive test or the presence of objective symptoms: Pregnant women with a history of opioid abuse, prisoners or parolees recently released from correctional facilities, former clinic patients who have successfully completed treatment but who believe themselves to be at risk of imminent relapse and HIV patients with a history of intravenous drug use.

(iii) That within seven days of the admission of a patient, the opioid treatment program shall complete an initial assessment and an initial plan of care.

(iv) That within thirty days after admission of a patient, the opioid treatment program shall develop an individualized treatment plan of care and attach the plan to the patient's chart no later

than five days after the plan is developed. The opioid treatment program shall follow guidelines established by a nationally recognized authority approved by the secretary and include a recovery model in the individualized treatment plan of care. The treatment plan is to reflect that detoxification is an option for treatment and supported by the program; that under the detoxification protocol the strength of maintenance doses of methadone should decrease over time, the treatment should be limited to a defined period of time, and participants are required to work toward a drug-free lifestyle.

(v) That each opioid treatment program shall report and provide statistics to the Department of Health and Human Resources at least semiannually which includes the total number of patients; the number of patients who have been continually receiving methadone treatment in excess of two years, including the total number of months of treatment for each such patient; the state residency of each patient; the number of patients discharged from the program, including the total months in the treatment program prior to discharge and whether the discharge was for:

(A) Termination or disqualification;

(B) Completion of a program of detoxification;

(C) Voluntary withdrawal prior to completion of all requirements of detoxification as determined by the opioid treatment program;

(D) Successful completion of the individualized treatment care plan; or

(E) An unexplained reason.

(vi) That random drug testing of all patients shall be conducted during the course of treatment at least monthly. For purposes of these rules, "random drug testing" means that each patient of an opioid treatment program facility has a statistically equal chance of being selected for testing at random and at unscheduled times. Any refusal to participate in a random drug test shall be considered a positive test. Nothing contained in this section or the legislative rules promulgated in conformity herewith will preclude any opioid treatment program from administering such additional drug tests as determined necessary by the opioid treatment program.

(vii) That all random drug tests conducted by an opioid treatment program shall, at a minimum, test for the following:

(A) Opiates, including oxycodone at common levels of dosing;

(B) Methadone and any other medication used by the program as an intervention;

(C) Benzodiazepine including diazepam, lorazepan, clonazepam and alprazolam;

(D) Cocaine;

(E) Methamphetamine or amphetamine;

(F) Tetrahydrocannabinol, delta-9-tetrahydrocannabinol or dronabinol or other similar substances; or

(G) Other drugs determined by community standards, regional variation or clinical indication.

(viii) That a positive drug test is a test that results in the presence of any drug or substance listed in this schedule and any other drug or substance prohibited by the opioid treatment program. A positive drug test result after the first six months in an opioid treatment program shall result in the following:

(A) Upon the first positive drug test result, the opioid treatment program shall:

(1) Provide mandatory and documented weekly counseling of no less than thirty minutes to the patient, which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules and on staff at the opioid treatment program;

(2) Immediately revoke the take home methadone privilege for a minimum of thirty days; and

(B) Upon a second positive drug test result within six months of a previous positive drug test result, the opioid treatment program shall:

(1) Provide mandatory and documented weekly counseling of no less than thirty minutes, which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules and on staff at the opioid treatment program;

(2) Immediately revoke the take-home methadone privilege for a minimum of sixty days; and

(3) Provide mandatory documented treatment team meetings with the patient.

(C) Upon a third positive drug test result within a period of six months the opioid treatment program shall:

(1) Provide mandatory and documented weekly counseling of no less than thirty minutes, which shall include weekly meetings with a counselor who is licensed, certified or enrolled in the process of obtaining licensure or certification in compliance with the rules and on staff at the opioid treatment program;

(2) Immediately revoke the take-home methadone privilege for a minimum of one hundred twenty days; and

(3) Provide mandatory and documented treatment team meetings with the patient which will include, at a minimum: The need for continuing treatment; a discussion of other treatment alternatives; and the execution of a contract with the patient advising the patient of discharge for continued positive drug tests.

(D) Upon a fourth positive drug test within a six-month period, the patient shall be immediately discharged from the opioid treatment program or, at the option of the patient, shall immediately be provided the opportunity to participate in a twenty- one day detoxification plan, followed by immediate discharge from the opioid treatment program: Provided, That testing positive solely for tetrahydrocannabinol, delta-9-tetrahydrocannabinol or dronabinol or similar substances shall not serve as a basis for discharge from the program.

(ix) That the opioid treatment program must report and provide statistics to the Department of Health and Human Resources demonstrating compliance with the random drug test rules, including:

(A) Confirmation that the random drug tests were truly random in regard to both the patients tested and to the times random drug tests were administered by lottery or some other objective standard so as not to prejudice or protect any particular patient;

(B) Confirmation that the random drug tests were performed at least monthly for all program participants;

(C) The total number and the number of positive results; and

(D) The number of expulsions from the program.

(x) That all opioid treatment facilities be open for business seven days per week; however, the opioid treatment center may be closed for eight holidays and two training days per year. During all operating hours, every opioid treatment program shall have a health care professional as defined by rule promulgated by the secretary actively licensed in this state present and on duty at the treatment center and a physician actively licensed in this state available for consultation.

(xi) That the Office of Health Facility Licensure and Certification develop policies and procedures in conjunction with the Board of Pharmacy that will allow physicians treating patients through an opioid treatment program access to the Controlled Substances Monitoring Program database maintained by the Board of Pharmacy at the patient's intake, before administration of methadone or other treatment in an opioid treatment program, after the initial thirty days of treatment, prior to any take-home medication being granted, after any positive drug test, and at each ninety-day treatment review to ensure the patient is not seeking prescription medication from multiple sources. The results obtained from the Controlled Substances Monitoring Program database shall be maintained with the patient records.

(xii) That each opioid treatment program shall establish a peer review committee, with at least one physician member, to review whether the program is following guidelines established by a

nationally recognized authority approved by the secretary. The secretary shall prescribe the procedure for evaluation by the peer review. Each opioid treatment program shall submit a report of the peer review results to the secretary on a quarterly basis.

(xiii) The secretary shall propose a rule for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code for the distribution of state aid to local health departments and basic public health services funds.

The rule shall include the following provisions:

Base allocation amount for each county;

Establishment and administration of an emergency fund of no more than two percent of the total annual funds of which unused amounts are to be distributed back to local boards of health at the end of each fiscal year;

A calculation of funds utilized for state support of local health departments;

Distribution of remaining funds on a per capita weighted population approach which factors coefficients for poverty, health status, population density and health department interventions for each county and a coefficient which encourages counties to merge in the provision of public health services;

A hold-harmless provision to provide that each local health department receives no less in state support for a period of four years beginning in the 2009 budget year.

The Legislature finds that an emergency exists and, therefore, the secretary shall file an emergency rule to implement the provisions of this section pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code. The emergency rule is subject to the prior approval of the Legislative Oversight Commission on Health and Human Resources Accountability prior to filing with the Secretary of State.

(xiv) Other health-related matters which the department is authorized to supervise and for which the rule-making authority has not been otherwise assigned.

West's Annotated Code of West Virginia (2014)
Chapter 16. Public Health
Article 5H. Chronic Pain Clinic Licensing Act

§ 16-5H-4. Operational requirements

(a) Any person, partnership, association or corporation that desires to operate a pain management clinic in this state must submit to the director documentation that the facility meets all of the following requirements:

(1) The clinic shall be licensed in this state with the secretary, the Secretary of State, the State Tax Department and all other applicable business or license entities.

(2) The application shall list all owners of the clinic. At least one owner shall be a physician actively licensed to practice medicine, surgery or osteopathic medicine or surgery in this state. The clinic shall notify the secretary of any change in ownership within ten days of the change and must submit a new application within the time frame prescribed by the secretary.

(3) Each pain management clinic shall designate a physician owner who shall practice at the clinic and who will be responsible for the operation of the clinic. Within ten days after termination of a designated physician, the clinic shall notify the director of the identity of another designated physician for that clinic. Failing to have a licensed designated physician practicing at the location of the clinic may be the basis for a suspension or revocation of the clinic license. The designated physician shall:

(A) Have a full, active and unencumbered license to practice medicine, surgery or osteopathic medicine or surgery in this state:

(B) Meet one of the following training requirements:

(i) Complete a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education or such other similar program as may be approved by the secretary; or

(ii) Hold current board certification by the American Board of Pain Medicine or current board certification by the American Board of Anesthesiology or such other board certification as may be approved by the secretary.

(C) Practice at the licensed clinic location for which the physician has assumed responsibility;

(D) Be responsible for complying with all requirements related to the licensing and operation of the clinic;

(E) Supervise, control and direct the activities of each individual working or operating at the facility, including any employee, volunteer or individual under contract, who provides treatment

of chronic pain at the clinic or is associated with the provision of that treatment. The supervision, control and direction shall be provided in accordance with rules promulgated by the secretary.

(4) All persons employed by the facility shall comply with the requirements for the operation of a pain management clinic established by this article or by any rule adopted pursuant to this article.

(5) No person may own or be employed by or associated with a pain management clinic who has previously been convicted of, or pleaded guilty to, any felony in this state or another state or territory of the United States. All owners, employees, volunteers or associates of the clinic shall undergo a criminal records check prior to operation of the clinic or engaging in any work, paid or otherwise. The application for license shall include copies of the background check for each anticipated owner, physician, employee, volunteer or associate. The secretary shall review the results of the criminal records check and may deny licensure for any violation of this requirement. The facility shall complete a criminal records check on any subsequent owner, physician, employee, volunteer or associate of the clinic and submit the results to the secretary for continued review.

(6) The clinic may not be owned by, nor may it employ or associate with, any physician or prescriber:

(A) Whose Drug Enforcement Administration number has ever been revoked;

(B) Whose application for a license to prescribe, dispense or administer a controlled substance has been denied by any jurisdiction; or

(C) Who, in any jurisdiction of this state or any other state or territory of the United States, has been convicted of or plead guilty or nolo contendere to an offense that constitutes a felony for receipt of illicit and diverted drugs, including controlled substances, as defined by section one hundred one, article one, chapter sixty-a of this code.

(7) A person may not dispense any medication, including a controlled substance, as defined by section one hundred one, article one, chapter sixty-a of this code, on the premises of a licensed pain management clinic unless he or she is a physician or pharmacist licensed in this state. Prior to dispensing or prescribing controlled substances, as defined by section one hundred one, article one, chapter sixty-a of this code, at a pain management clinic, the treating physician must access the Controlled Substances Monitoring Program database maintained by the Board of Pharmacy to ensure the patient is not seeking controlled substances from multiple sources. If the patient receives ongoing treatment, the physician shall also review the Controlled Substances Monitoring Program database at each patient examination or at least every ninety days. The results obtained from the Controlled Substances Monitoring Program database shall be maintained with the patient's medical records.

(8) Each clinic location shall be licensed separately, regardless of whether the clinic is operated under the same business name or management as another clinic.

(9) A pain management clinic shall not dispense to any patient more than a seventy-two-hour supply of a controlled substance, as defined by section one hundred one, article one, chapter sixty-a of this code.

(10) The pain management clinic shall develop patient protocols, treatment plans and profiles, as prescribed by the secretary by rule, and which shall include, but not be limited by, the following guidelines:

(A) When a physician diagnoses an individual as having chronic pain, the physician may treat the pain by managing it with medications in amounts or combinations that may not be appropriate when treating other medical conditions. The physician's diagnosis shall be made after having the individual evaluated by one or more other physicians who specialize in the treatment of the area, system or organ of the body perceived as the source of the pain unless the individual has been previously diagnosed as suffering from chronic pain and is referred to the pain management clinic by such diagnosing physician. The physician's diagnosis and treatment decisions shall be made according to accepted and prevailing standards for medical care.

(B) The physician shall maintain a record of all of the following:

(i) Medical history and physical examination of the individual;

(ii) The diagnosis of chronic pain, including signs, symptoms and causes;

(iii) The plan of treatment proposed, the patient's response to the treatment and any modification to the plan of treatment;

(iv) The dates on which any medications were prescribed, dispensed or administered, the name and address of the individual to or for whom the medications were prescribed, dispensed or administered and the amounts and dosage forms for the drugs prescribed, dispensed or administered;

(v) A copy of the report made by the physician to whom referral for evaluation was made.

(C) A physician, physician assistant, certified registered nurse anesthetist or advanced nurse practitioner shall perform a physical examination of a patient on the same day that the physician initially prescribes, dispenses or administers a controlled substance to a patient and at least four times a year thereafter at a pain management clinic according to accepted and prevailing standards for medical care.

(D) A physician authorized to prescribe controlled substances who practices at a pain management clinic is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing controlled substance pain medication. The physician shall comply with all state and federal requirements for tamper-resistant prescription paper. In addition to any other requirements imposed by statute or rule, the

physician shall notify the secretary in writing within twenty-four hours following any theft or loss of a prescription blank or breach of any other method for prescribing pain medication.

(c) Upon satisfaction that an applicant has met all of the requirements of this article, the secretary may issue a license to operate a pain management clinic. An entity that obtains this license may possess, have custody or control of, and dispense drugs designated as Schedule II or Schedule III in sections two hundred six or two hundred eight, article two, chapter sixty-a of this code.

West's Annotated Code of West Virginia (2014)
Chapter 60A. Uniform Controlled Substances Act
Article 8. Wholesale Drug Distribution Licensing Act of 1991

§ 60A-8-7. Wholesale drug distributor licensing requirements

(a) Every applicant for a license under this article shall provide the board with the following as part of the application for a license and as part of any renewal of such license:

(1) The name, full business address and telephone number of the licensee;

(2) All trade or business names used by the licensee;

(3) Addresses, telephone numbers and the names of contact persons for all facilities used by the licensee for the storage, handling and distribution of prescription drugs;

(4) The type of ownership or operation (i.e., partnership, corporation or sole proprietorship);

(5) The name(s) of the owner and operator, or both, of the licensee, including:

(A) If a person, the name of the person;

(B) If a partnership, the name of each partner and the name of the partnership;

(C) If a corporation, the name and title of each corporate officer and director, the corporate names and the name of the state of incorporation; and

(D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity; and

(6) Any other information or documentation that the board may require.

(b) All wholesale distributors and pharmacy distributors shall be subject to the following requirements:

(1) No person or distribution outlet may act as a wholesale drug distributor without first obtaining a license to do so from the Board of Pharmacy and paying any reasonable fee required by the Board of Pharmacy, such fee not to exceed four hundred dollars per year: Provided, That for licenses that are effective on and after July 1, 2012, the annual fee shall be $750 per license until modified by legislative rule. All fees collected pursuant to this section shall be used for the operation and implementation of the West Virginia Controlled Substances Monitoring Program database or in the same manner as those fees governed by article five, chapter thirty of this code.

(2) The Board of Pharmacy may grant a temporary license when a wholesale drug distributor first applies to the board for a wholesale drug distributor's license and the temporary license shall

remain valid until the Board of Pharmacy finds that the applicant meets or fails to meet the requirements for regular licensure, except that no temporary license shall be valid for more than ninety days from the date of issuance. Any temporary license issued pursuant to this subdivision shall be renewable for a similar period of time not to exceed ninety days pursuant to policies and procedures to be prescribed by the Board of Pharmacy.

(3) No license may be issued or renewed for a wholesale drug distributor to operate unless the distributor operates in a manner prescribed by law and according to the rules promulgated by the Board of Pharmacy with respect thereto.

(4) The Board of Pharmacy may require a separate license for each facility directly or indirectly owned or operated by the same business entity within this state, or for a parent entity with divisions, subsidiaries, or affiliate companies within this state when operations are conducted at more than one location and there exists joint ownership and control among all the entities.

(c) The minimum qualifications for licensure are set forth in this section as follows:

(1) As a condition for receiving and retaining any wholesale drug distributor license issued pursuant to this article, each applicant shall satisfy the Board of Pharmacy that it has and will continuously maintain:

(A) Acceptable storage and handling conditions plus facilities standards;

(B) Minimum liability and other insurance as may be required under any applicable federal or state law;

(C) A security system which includes after hours central alarm or comparable entry detection capability, restricted premises access, adequate outside perimeter lighting, comprehensive employment applicant screening and safeguards against employee theft;

(D) An electronic, manual or any other reasonable system of records describing all wholesale distributor activities governed by this article for the two-year period following disposition of each product and being reasonably accessible as defined by Board of Pharmacy regulations during any inspection authorized by the Board of Pharmacy;

(E) Officers, directors, managers and other persons in charge of wholesale drug distribution, storage and handling, who must at all times demonstrate and maintain their capability of conducting business according to sound financial practices as well as state and federal law;

(F) Complete, updated information to be provided to the Board of Pharmacy as a condition for obtaining and retaining a license about each wholesale distributor to be licensed under this article including all pertinent licensee ownership and other key personnel and facilities information determined necessary for enforcement of this article;

(G) Written policies and procedures which assure reasonable wholesale distributor preparation for protection against and handling of any facility security or operation problems, including, but not limited to, those caused by natural disaster or government emergency, inventory inaccuracies or product shipping and receiving, outdated product or other unauthorized product control, appropriate disposition of returned goods and product recalls;

(H) Sufficient inspection procedures for all incoming and outgoing product shipments; and

(I) Operations in compliance with all federal legal requirements applicable to wholesale drug distribution.

(2) The board of pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who apply for a wholesale distributor license under this section or for renewal of that license:

(A) Any conviction of the applicant under any federal, state or local laws relating to drug samples, wholesale or retail drug distribution or distribution of controlled substances;

(B) Any felony convictions of the applicant or any key person under federal, state or local laws;

(C) The applicant's past experience in the manufacture or distribution of prescription drugs, including, but not limited to, controlled substances;

(D) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(E) Suspension or revocation by federal, state or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drug, including, but not limited to, controlled substances;

(F) Compliance with licensing requirements under previously granted licenses, if any;

(G) Whether personnel employed by the applicant in wholesale drug distribution have appropriate education or experience, or both education and experience, to assume responsibility for positions related to compliance with the requirements of this article;

(H) Compliance with requirements to maintain and make available to the Board of Pharmacy or to federal, state or local law-enforcement officials those records required by this article; and

(I) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with the public health and safety, including whether the granting of the license would not be in the public interest.

(3) All requirements set forth in this subsection shall conform to wholesale drug distributor licensing guidelines formally adopted by the United States Food and Drug Administration

(FDA); and in case of conflict between any wholesale drug distributor licensing requirement imposed by the Board of Pharmacy pursuant to this subsection and any food and drug administration wholesale drug distributor licensing guideline, the latter shall control.

(d) An employee of any licensed wholesale drug distributor need not seek licensure under this section and may lawfully possess pharmaceutical drugs when the employee is acting in the usual course of business or employment.

(e) The issuance of a license pursuant to this article does not change or affect tax liability imposed by this state's Department of Tax and Revenue on any wholesale drug distributor.

(f) An applicant who is awarded a license or renewal of a license shall give the board written notification of any material change in the information previously submitted in, or with the application for the license or for renewal thereof, whichever is the most recent document filed with the board, within thirty days after the material change occurs or the licensee becomes aware of the material change, whichever event occurs last. Material changes include, but are not limited to:

(1) A change of the physical address or mailing address;

(2) A change of the responsible individual, compliance officer or other executive officers or board members;

(3) A change of the licensee's name or trade name;

(4) A change in the location where the records of the licensee are retained;

(5) The felony conviction of a key person of the licensee; and

(6) Any other material change that the board may specify by rule.

(g) Before denial of a license or application for renewal of a license, the applicant shall be entitled to a hearing in accordance with subsection (h), section eight, article one, chapter thirty of this code.

(h) The licensing of any person as a wholesale drug distributor subjects the person and the person's agents and employees to the jurisdiction of the board and to the laws of this state for the purpose of the enforcement of this article, article five, chapter thirty of this code and the rules of the board. However, the filing of an application for a license as a wholesale drug distributor by, or on behalf of, any person or the licensing of any person as a wholesale drug distributor may not, of itself, constitute evidence that the person is doing business within this state.

(i) The Board of Pharmacy may adopt rules pursuant to section nine of this article which permit out-of-state wholesale drug distributors to obtain any license required by this article on the basis of reciprocity to the extent that: (1) An out-of-state wholesale drug distributor possesses a valid

license granted by another state pursuant to legal standards comparable to those which must be met by a wholesale drug distributor of this state as prerequisites for obtaining a license under the laws of this state; and (2) such other state would extend reciprocal treatment under its own laws to a wholesale drug distributor of this state.

West's Annotated Code of West Virginia (2014)
Chapter 60A. Uniform Controlled Substances Act
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.

West's Annotated Code of West Virginia (2014)
Chapter 60A. Uniform Controlled Substances Act
Article 9. Controlled Substances Monitoring

§ 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, 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.

West's Annotated Code of West Virginia (2014)
Chapter 60A. Uniform Controlled Substances Act
Article 9. Controlled Substances Monitoring

§ 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 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. All information released by the State Board of Pharmacy 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 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 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 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, 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 of Pharmacy 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.

West's Annotated Code of West Virginia (2014)
Chapter 60A. Uniform Controlled Substances Act
Article 9. Controlled Substances Monitoring

§ 60A-9-5a. Practitioner requirements to conduct annual search of the database; required rulemaking

(a) Upon initially prescribing or dispensing any pain-relieving controlled substance for a patient and at least annually thereafter should the prescriber or dispenser continue to treat the patient with controlled substances, all persons with prescriptive or dispensing authority and in possession of a valid Drug Enforcement Administration registration identification number and, who are licensed by the Board of Medicine as set forth in article three, chapter thirty of this code, the Board of Registered Professional Nurses as set forth in article seven, chapter thirty of this code, the Board of Dental Examiners as set forth in article four, chapter thirty of this code and the Board of Osteopathy as set forth in article fourteen, chapter thirty of this code shall access the West Virginia Controlled Substances Monitoring Program database for information regarding specific patients for whom they are providing pain-relieving controlled substances as part of a course of treatment for chronic, nonmalignant pain but who are not suffering from a terminal illness. The information obtained from accessing the West Virginia Controlled Substances Monitoring Program database for the patient shall be documented in the patient's medical record. A pain-relieving controlled substance shall be defined as set forth in section one, article three-a, chapter thirty of this code.

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

West's Annotated Code of West Virginia (2014)
Chapter 60A. Uniform Controlled Substances Act
Article 9. Controlled Substances Monitoring

§ 60A-9-8. Creation of Fight Substance Abuse Fund

There is hereby created a special revenue account in the state treasury, designated the Fight Substance Abuse Fund, which shall be an interest-bearing account and may be invested in accordance with the provisions of article six, chapter twelve of this code, with interest income a proper credit to the fund. The fund shall consist of appropriations by the Legislature, gifts, donations or any other source. Expenditures from the fund shall be for the following purposes: to provide funding for substance abuse prevention, treatment, treatment coordination, recovery and education.

West Virginia Code of State Rules (2014)
Title 5. West Virginia Board of Dental Examiners
Legislative Rule (Ser. 10)
Series 10. Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

§ 5-10-3. General Rules for Practitioners for Patients Not Suffering from a Terminal Illness.

3.1. Prior to the initial provision of any pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain to any patient not considered by a practitioner to be suffering from a terminal illness, a practitioner shall apply for and receive capability to access the CSMP for purposes of compliance with this rule.

3.2. Prior to the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain to a patient not considered by the current practitioner to be suffering from a terminal illness, a current practitioner, or the practitioner's authorized agent, is required to access the CSMP to determine whether the patient has obtained any controlled substance reported to the CSMP from any source other than the current practitioner within the 12 month period immediately preceding the visit of the patient to the current practitioner.

3.3. Upon accessing the CSMP prior to the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain, the access and any controlled substances reported to the CSMP within the 12 month period immediately preceding the visit of the patient shall be then promptly documented in the patient's medical record, with rationale for provision of the pain-relieving controlled substance by the current practitioner, with a copy of the CSMP accessed report signed and dated by the current practitioner.

3.4. After the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain, should the patient continue as a patient with the current practitioner, and the current practitioner continues to provide pain-relieving controlled substances as part of a course of treatment for chronic, nonmalignant pain, the CSMP shall be accessed by the current practitioner, or the practitioner's authorized agent, at least annually to determine whether the patient has obtained any controlled substances reported to the CSMP from any source other than the current practitioner within the 12 month period immediately preceding the access. The access and any controlled substances from any other source other than the current practitioner reported to the CSMP within such 12 month immediately preceding the access shall be then promptly documented in the patient's medical record, with rationale for continuing provision of the pain-relieving substance by the current practitioner, with a copy of the CSMP accessed report signed and dated by the current practitioner.

3.5. Nothing herein prohibits the CSMP from being accessed for a specific patient more frequently than annually by the current practitioner, or the practitioner's authorized agent, however, upon any such additional access of the CSMP, controlled substances reported to the CSMP from any source other than the current practitioner shall be promptly documented in the patient's medical record, with rationale for provision of the pain-relieving controlled substance

by the current practitioner, with a copy of the CSMP accessed report signed and dated by the current practitioner.

3.6. Accessing the CSMP must occur prior to the provision of the controlled substance Provided, that if there is an equipment failure, electricity outage or other disaster or prevent that renders review of the CSMP impossible prior to provision of the required controlled substances and it is determined by the practitioner that providing a controlled substance is medically necessary, this determination of medical necessity shall be documented in the medical record and the controlled substance may be provided in a limited amount. The circumstances preventing the access to the CSMP prior to provision of the controlled substance shall be documented in the patient's medical record, and immediately upon having access restored the CSMP report shall be accessed, documented as described in this rule and the practitioner shall adjust patient care as needed, Provided further, that if a practitioner is unable to access the CSMP due to the unavailability of commercially affordable broadband coverage in a practitioner's area and it is determined by the practitioner that providing a controlled substances is medically necessary, this determination shall be documented in the medical record and the controlled substance may be provided in a limited amount. The practitioner shall access the CSMP through alternate means and document the treatment rendered and the practitioner shall adjust patient care as needed.

West Virginia Code of State Rules (2014)
Title 11. West Virginia Board of Medicine
Legislative Rule (Ser. 10)
Series 10. Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

§ 11-10-3. General Rules for Practitioners for Patients Not Suffering from a Terminal Illness.

3.1.Prior to the initial provision of any pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain to any patient not considered by a practitioner to be suffering from a terminal illness, a practitioner shall apply for and receive capability to access the CSMP for purposes of compliance with this rule.

3.2.Prior to the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain to a patient not considered by the current practitioner to be suffering from a terminal illness, a current practitioner is required to access the CSMP to determine whether the patient has obtained any controlled substance reported to the CSMP from any source other than the current practitioner within the twelve (12) month period immediately preceding the visit of the patient to the current practitioner.

3.3. Upon accessing the CSMP prior to the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain, the date of access and any controlled substances reported to the CSMP within the twelve (12) month period immediately preceding the visit of the patient shall be then promptly documented in the patient's medical record by the current practitioner, with rationale for provision of the pain-relieving controlled substance by the current practitioner.

3.4.After the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain, should the patient continue as a patient with the current practitioner, and the current practitioner continues to provide pain-relieving controlled substances as part of a course of treatment for chronic, nonmalignant pain, the CSMP shall be accessed by the current practitioner at least annually to determine whether the patient has obtained any controlled substances reported to the CSMP from any source other than the current practitioner within the twelve (12) month period immediately preceding the date of access.The date of access and any controlled substances from any other source other than the current practitioner reported to the CSMP within such twelve (12) month period immediately preceding the date of access shall be then promptly documented in the patient's medical record by the current practitioner, with rationale for continuing provision of the pain-relieving substance by the current practitioner.

3.5. Nothing herein prohibits the CSMP from being accessed for a specific patient more frequently than annually by the current practitioner, however, upon any such additional access of the CSMP, controlled substances reported to the CSMP from any source other than the current practitioner shall be promptly documented in the patient's medical record by the current

practitioner, with the date of access and rationale for provision of the pain-relieving controlled substance by the current practitioner.

West Virginia Code of State Rules (2014)
Title 15. West Virginia Board of Pharmacy
Legislative Rule (Ser. 8)
Series 8. Controlled Substances Monitoring

§ 15-8-4. Information To Be Transmitted Within 24 Hours.

4.1. The information required to be submitted by the provisions of this rule may be transmitted at any time, but shall be transmitted at least within twenty-four (24) hours of the dispensing, Provided that, if the dispensing is done by mail or other postal, courier, or logistics services such as United Parcel Service or Federal Express, then the information shall be submitted at least within forty-eight (48) hours of the time the dispensing is placed in the mail for delivery. If there was no dispensing of any Schedule II, III, or IV controlled substances within up to seven days of the last report, the reporter shall submit a "zero" report no later than seven days after the last date and time reported on the previous report. If a reporter is closed for a holiday, or week-end day, the reporter shall make the required report as soon as is practicable upon reopening, or within forty-eight (48) hours, whichever occurs first. If a reporter is unable to make the required reporting in a timely manner due to an emergency, the reporter shall inform the board of the emergency and provide the board with information on when the reporter believes it will return to full compliance. Such notification may be taken into consideration by any agency, licensing board, or court, when determining if the reporter is in compliance with reporting requirements of West Virginia Code Section 60A-9-3 and Section 3 of this Series, and any penalties that may attach for any violation thereof.

4.2. If a reporter does not possess for the purpose of dispensing any Schedule II, III, or IV controlled substances, the dispenser may notify the board in writing by requesting a waiver from reporting on a form supplied by the board. If the waiver is properly filed with and granted by the board, the reporter is not required to submit a zero report unless and until the reporter possesses a Schedule II, III, or IV controlled substance for the purpose of dispensing.

4.3. The board may not penalize a reporter for failure to comply with the program if the board or the central repository cannot secure adequate funding to implement the program and recover the cost.

West Virginia Code of State Rules (2014)
Title 15. West Virginia Board of Pharmacy
Legislative Rule (Ser. 8)
Series 8. Controlled Substances Monitoring

§ 15-8-3. Prescription Monitoring Program.

3.1. Each time a Schedule II, III, or IV Controlled Substance is dispensed for out-patient use, the medical services provider, health care facility, or pharmacy that dispensed the controlled substance shall transmit to the central repository the information required by West Virginia Code § 60A-9-4. This includes the following:

3.1.a. The name, address, pharmacy prescription number and Drug Enforcement Administration controlled substance registration number of the dispensing pharmacy or the dispensing medical services provider;

3.1.b. The full legal name, address and birth date of the recipient. When reporting the full legal name, address, and date of birth of the recipient, the reporter shall include any middle name or initial and any suffix (e.g., Jr., II, III) as listed on the patient's government-issued photo identification card, Provided that, if the patient does not have such an identification card, such as a minor, then the reporter shall obtain and input the information to the best of its knowledge and ability based upon the information available to it from the prescription, the patient profile or record, and any other information known to the reporter. Examples of acceptable forms of ID include, but are not limited to: driver's licenses, non-driver identification cards, passports, and military IDs;

3.1.c. The Drug Enforcement Administration controlled substances registration number of the practitioner writing the prescription. By providing this registration number, the Controlled Substances Monitoring Program database will extract the prescriber's name and address required by statute; therefore, the reporters do not need to additionally supply the prescriber's name and address in addition to the prescriber's DEA number;

3.1.d. The national drug code number of the Schedule II, III and IV controlled substance dispensed. By providing this NDC number, the Controlled Substances Monitoring Program database will extract the name and dosage or (strength) of the controlled substance required by the statute such that the reporters do not need to additionally supply the name and dosage;

3.1.e. The quantity of the Schedule II, III and IV controlled substance dispensed;

3.1.f. The date the prescription was written and the date filled;

3.1.g. The number of refills, if any, authorized by the prescription;

3.1.h. If the prescription being dispensed is being picked up by a recipient representative on behalf of the recipient, the full legal name, address and birth date of the recipient representative

as set forth on the person's government-issued photo identification card. When reporting the full legal name, address, and date of birth of the person picking up the prescription on behalf of the patient, the reporter shall include any middle name or initial and any suffix (e.g., Jr., II, III) as listed on the person's government-issued photo identification card. If the reporter is unable to input this information to the central repository at the time of reporting, this information shall be retained in either print or electronic form. If the reporter electronically reports the individual's first name, last name, official government-issued photo identification card number and the card's issuing authority or jurisdiction (e.g. United States military, State driver's license, Passport, Green Card, etc.) into the central repository, the reporter shall retain the additional information in print or electronic form for a period of ninety (90) days. If the reporter does not file the listed information into the central repository, the information shall be retained in print or electronic form for a period of at least two (2) years; and

3.1.i. The source of payment for the controlled substance dispensed.

3.2. Any person reporting more than 20 controlled substance prescriptions in any given month shall transmit to the central repository the information outlined in section 4 of this rule using one of the following methods:

3.2.a. An electronic device compatible with the receiving device of the central repository;

3.2.b. A computer compact disc; or

3.2. .c. A magnetic tape.

3.3. Any person reporting less than 20 Schedule II, III, or IV controlled substance dispensings in any given month may submit data using a Universal Claim Form or transmit the information using the methods outlined in subsection 3.2 of this section.

3.4. The board may grant a waiver to a reporter who does not have an automated recordkeeping system capable of producing an electronic report in the established format. A reporter requesting a waiver shall make the request to the board in writing and the board shall grant the request if the reporter agrees to report the data by submitting a completed Universal Claim Form.

3.5. The board and the central repository shall provide for the electronic transmission of the information required to be provided by and through the use of a toll-free telephone line or other Internet connection.

West Virginia Code of State Rules (2014)
Title 19. West Virginia Board of Examiners for Registered Professional Nurses
Legislative Rule (Ser. 14)
Series 14. Practitioner Requirements for Accessing the West Virginia Controlled Substances Monitoring Program Database

§ 19-14-3. General Rules for Practitioners for Patients Not Suffering From a Terminal Illness.

3.1. Prior to the initial provision of any pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain to any patient not considered by a practitioner to be suffering from a terminal illness, a practitioner shall apply for and receive capability to access the CSMP for purposes of compliance with this rule.

3.2. Prior to the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain to a patient not considered by the current practitioner to be suffering from a terminal illness, a current practitioner, or the practitioner's authorized agent, is required to access the CSMP to determine whether the patient has obtained any controlled substance reported to the CSMP from any source other than the current practitioner within the 12 month period immediately preceding the visit of the patient to the current practitioner.

3.3. Upon accessing the CSMP prior to the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain, the access and any controlled substances reported to the CSMP within the 12 month period immediately preceding the visit of the patient shall be then promptly documented in the patient's medical record, with rationale for provision of the pain-relieving controlled substance by the current practitioner with a paper or electronic copy of the CSMP accessed report maintained in the patient medical record.

3.4. After the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain, should the patient continue as a patient with the current practitioner, and the current practitioner continues to provide pain-relieving controlled substances as part of a course of treatment for chronic, nonmalignant pain, the CSMP shall be accessed by the current practitioner, or the practitioner's authorized agent, at least annually to determine whether the patient has obtained any controlled substances reported to the CSMP from any source other than the current practitioner within the 12 month period immediately preceding the access. The access and any controlled substances from any other source other than the current practitioner reported to the CSMP -within such 12 months immediately preceding the access shall be then promptly documented in the patient's medical record, with rationale for continuing provision of the pain-relieving substance by the current practitioner, with a paper or electronic copy of the CSMP accessed report maintained in the patient medical record.

3.5. Nothing herein prohibits the CSMP from being accessed for a specific patient more frequently than annually by the current practitioner, or the practitioner's authorized agent; however, upon any such additional access of the CSMP, controlled substances reported to the CSMP from any source other than the current practitioner shall be promptly documented in the patient's medical record, with rationale for provision of the pain-relieving controlled substance

by the current practitioner, with a paper or electronic copy of the CSMP accessed report maintained in the patient medical record.

3.6. Accessing the CSMP must occur prior to the provision of the controlled substance Provided, that if there is an equipment failure, electricity outage or other disaster or event that renders review of the CSMP impossible prior to provision of the required controlled substances and it is determined by the practitioner that providing a controlled substance is medically necessary, this determination of medical necessity shall be documented in the medical record and the controlled substance may be provided in a limited amount. The circumstances preventing the access to the CSMP prior to provision of the controlled substance shall be documented in the patient's medical record, and immediately upon having access restored the CSMP report shall be accessed, documented as described in this rule and the practitioner shall adjust patient care as needed.

West Virginia Code of State Rules (2014)
Title 24. West Virginia Board of Osteopathic Medicine
Legislative Rule (Ser. 7)
Series 7. Practitioner Requirements for Controlled Substances Licensure and Accessing the West Virginia Controlled Substances Monitoring Program Database

§ 24-7-3. General Rules for Practitioners for Patients Not Suffering from a Terminal Illness.

3.1. Prior to the initial provision of any pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain to any patient not considered by a practitioner to be suffering from a terminal illness, a practitioner shall apply for and receive capability to access the CSMP for purposes of compliance with this rule.

3.2. Prior to the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain to a patient not considered by the current practitioner to be suffering from a terminal illness, a current practitioner is required to access the CSMP to determine whether the patient has obtained any controlled substance reported to the CSMP from any source other than the current practitioner within the twelve-month period immediately preceding the visit of the patient to the current practitioner.

3.3. Upon accessing the CSMP prior to the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain, the access and any controlled substances reported to the CSMP within the twelve-month period immediately preceding the visit of the patient shall be then promptly documented in the patient's medical record with rationale for provision of the pain-relieving controlled substance by the current practitioner, with a copy of the CSMP accessed report signed and dated by the current practitioner.

3.4. After the initial provision of a pain-relieving controlled substance as part of a course of treatment for chronic nonmalignant pain, should the patient continue as a patient with the current practitioner, and the current practitioner continues to provide pain-relieving controlled substances as part of a course of treatment for chronic nonmalignant pain, the CSMP shall be accessed by the current practitioner at least annually to determine whether the patient has obtained any controlled substances reported to the CSMP from any source other than the current practitioner within the twelve-month period immediately preceding the access. The access and any controlled substances from any other source other than the current practitioner, reported to the CSMP within such twelve-month period immediately preceding the access shall be then promptly documented in the patient's medical record, with rationale for continuing provision of the pain-relieving substance by the current practitioner, with a copy of the CSMP accessed report signed and dated by the current practitioner.

3.5. Nothing herein prohibits the CSMP from being accessed for a specific patient more frequently than annually by the current practitioner, however, upon any such additional access of the CSMP, controlled substances reported to the CSMP from any source other than the current practitioner shall be promptly documented in the patient's medical record, with rationale for

provision of the pain-relieving controlled substance by the current practitioner, with a copy of the CSMP accessed report signed and dated by the current practitioner.

West Virginia Code of State Rules (2014)
Title 69. Department of Health and Human Resources
Legislative Rule (Ser. 7)
Series 7. Regulation of Opioid Treatment Programs

§ 69-7-27. Pre-Admission Assessment; Admission Criteria.

27.1. Each opioid treatment program shall maintain current procedures designed to ensure that patients are admitted to maintenance treatment only after assessment by qualified personnel who have determined that the person meets the qualifications for admission.

27.2. Any person seeking admittance to the opioid treatment program shall undergo a pre-admission initial assessment in order to determine whether the person meets the criteria for admission to an opioid treatment program. The initial assessment, consisting of a physical examination and an intake screening, shall be conducted by the medical director, an approved program physician or a supervised physician extender. The initial assessment shall focus on the individual's eligibility and need for treatment and shall provide indicators for initial dosage level, if required and if admission is determined appropriate. The determination of admission eligibility shall be made using accepted medical criteria such as those listed in the Diagnostic and Statistical Manual for Mental disorders (DSM-IV).

27.3. The initial physical examination shall include documentation of:

27.3.a. A brief physical examination;

27.3.b. The patient's immediately relevant health history (e.g., determination of chronic or acute medical conditions such as diabetes, renal disease, hepatitis, sickle cell anemia, tuberculosis, HIV exposure, sexually transmitted disease, chronic cardiopulmonary disease and pregnancy);

27.3.c. A determination of currently prescribed medications;

27.3.d. An evaluation of other substances of abuse;

27.3.e. Determination of current opioid dependence;

27.3.f. Determination of length of addiction;

27.3.g. A toxicology screen to determine immediate use of opiates;

27.3.h. An initial drug test and full toxicology screen to identify whether the patient is using other drugs, including opiates, methadone, amphetamines, cocaine, barbiturates, benzodiazepines, marijuana, or other drugs or substances as determined by community standards, regional variation or clinical indication (e.g., carispodol); to determine whether the individual is opioid addicted; and to determine whether the patient is presently receiving methadone for an opioid addiction from another opioid treatment program;

27.3.i. An inquiry to and report from the Controlled Substances Monitoring Program; and.

27.3.j. An inquiry whether the patient is enrolled in any other opioid treatment program.

27.4. The person desiring admission for treatment through the use of an opioid treatment medication must be at least eighteen years of age. Exceptions may be made on extremely rare occasions by application to the state authority.

27.5. All admissions shall include documentation regarding medical necessity and program eligibility for opioid treatment that includes:

27.5.a. Objective evidence, such as a positive drug test, of current physical dependence or tolerance to opioids or methadone; or

27.5.b. Objective symptoms of withdrawal, with documentation of the signs and symptoms of withdrawal; or both; or

27.5.b. Evidence of an onset of opioid physical dependence of at least one year prior to admission with continuous use the greater part of the year; and

27.5.c. Evidence of multiple and daily self-administration of an opioid.

27.6. The following behavioral signs which support the diagnosis of opioid addiction shall be discussed and documented, although none are considered required for admission:

27.6.a. Unsuccessful efforts to control use;

27.6.b. Time spent obtaining drugs or recovering from the effects of abuse;

27.6.c. Continual use despite harmful consequences;

27.6.d. Obtaining opiates illegally;

27.6.e. Inappropriate use of prescribed opiates;

27.6.f. Giving up or reducing important social, occupational or recreational activities;

27.6.g. Continuing use of the opiate despite known adverse consequences to self, family or society; and

27.6.h. One or more unsuccessful attempts at gradual removal of physical dependence on opioids (detoxification) using methadone or other appropriate medications.

27.7. The absence of physiological dependence should not be an exclusion criterion, and admission may be clinically justified. The initial assessment may recognize that individuals in

some populations may be susceptible to relapse to opioid addiction, leading to high-risk behaviors with potentially life threatening consequences.

27.8. After thorough review of the information acquired through the initial assessment, an individual may be admitted to the opioid treatment program if, using accepted medical criteria, a determination is made that one or more of the following factors are met:

27.9.a. The person is currently addicted to an opioid drug, as evidenced by a positive test for either opioids or methadone, and the person became addicted at least one year before admission for treatment; or

27.9.b. There are objective symptoms of withdrawal, or both; or

27.9.c. There is objective evidence that the individual qualifies under the provisions of § 27.9 of this rule.

27.9. Admission to the opioid treatment program may be allowed to the following groups with a high risk of relapse without the necessity of a positive test or the presence of objective symptoms:

27.9.a. The person is a pregnant woman with a history of opioid abuse.

27.9.b. The person is a prisoner or has been released from a correctional facility within six months.

27.9.c. The person is a former clinic patient who successfully completed treatment but believes that he or she is at risk of imminent relapse.

27.9.d. The person is an HIV patient with a history of intravenous drug use.

27.10. A patient enrolled in an opioid treatment program shall not be permitted to obtain treatment in any other opioid treatment program except in exceptional circumstances and only as provided in § 28 of these rules.

27.11. The admission and initial dosing of the patient may take place only after the patient is seen by a program physician, or an experienced medical professional working within the scope of his or her license who:

27.11.a. Has consulted by telephone or in person with the program physician;

27.11.b. Is approved by the medical director; and

27.11.c. Has completed a plan of development.

27.12. Whenever possible, the patient shall be admitted only after observation by and an interview with the program physician. Under unusual circumstances, an experienced medical professional working within the scope of his or her license may conduct the interview and observation and obtain telephone or fax orders from the physician to initiate treatment. Any patient admitted under those circumstances must be seen by the physician within three working days of admission for verification of appropriate admission and treatment. All unusual circumstances and their outcomes shall be reviewed by the admissions committee.

27.13. The program physician or physician extender shall review the accumulated data directly with the individual and confirm a diagnosis of opioid addiction of sufficient severity to warrant admission to the opioid treatment program. The program physician shall document that treatment is medically necessary. The admission and initial dosing decisions ultimately rest with the medical director or the designated program physician.

27.14. The program physician shall ensure that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of opioid treatment drugs are clearly and adequately explained to the patient. The program physician shall ensure that each newly admitted patient provides informed written consent to treatment.

27.15. Every individual shall be given the opportunity to enter into a detoxification program and shall be fully informed of the protocol, goals and procedures for detoxification. The individual shall specifically consent to participation in the detoxification program in writing. The consent form shall be maintained in the patient chart and with the patient's individualized treatment plan of care.

27.16. Admission of individuals with no opioid tolerance shall require careful monitoring during the induction phase of treatment.

27.17. The physician or physician extender and patient shall each sign and date verification that the initial assessment and review occurred and that the patient received all applicable information, policies and procedures.

27.18. Exceptions to admission policy shall be reviewed and tracked by the admissions committee and be made available to regulatory bodies.

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§ 69-7-29. Orientation.

29.1. Every person admitted to an opioid treatment program shall receive program orientation. The orientation shall be made verbally at the earliest opportunity at which the patient is stable and capable of understanding and retaining the information presented. Information provided in the orientation shall be given to the patient at the time the decision is made to admit the patient, regardless of his or her condition.

29.2. Orientation shall include the following:

29.2.a. An explanation of the rights and responsibilities of the patient.

29.2.b. An explanation of the patient's right to file a grievance and applicable appeal procedures.

29.2.c. An explanation of the services and activities provided by the opioid treatment program, including:

29.2.c.1. Expectations and rules;

29.2.c.2. Hours of operation;

29.2.c.3. Access to after-hour services;

29.2.c.4. Confidentiality policy;

29.2.c.5. Toxicological screening and random testing policies;

29.2.c.6. Sanctions, restrictions and other penalties;

29.2.c.7. Interventions;

29.2.c.8. Incentives; and

29.2.c.9. Various discharge criteria.

29.2.d. An explanation about obtaining reports from the Controlled Substances Monitoring Program database; how the reports are used to treat and monitor the patient and the requirement that the reports be maintained in the patient files.

29.2.e. An explanation of any and all financial obligations of the patient; all fees charged by the opioid treatment program; and any financial arrangements for services provided by the opioid treatment program.

29.2.f. Familiarization with the opioid treatment programs facility and premises.

29.2.g. A description of the opioid treatment program's policies regarding:

29.2.g.1. Use of alcohol on or prior to entering the premises;

29.2.g.2. Smoking;

29.2.g.3. Illicit or licit drugs brought into the program; and

29.2.g.4. Weapons brought into the program.

29.2.h. Identification of the counselor assigned to the patient and contact information for that counselor.

29.2.i. A copy of the opioid treatment program rules identifying the following:

29.2.i.1. Any restrictions the program may place on the patient;

29.2.i.2. Events, behaviors, or attitudes that may lead to the loss of rights or privileges for the patient; and

29.2.i.3. Means by which the patient may regain rights or privileges that have been restricted.

29.2.j. An explanation of the purpose and process of the initial and subsequent medical and psychological assessments; and

29.2.k. A description of how the individualized treatment plan of care will be developed and the patient's expected participation in the plan of care.

29.2.l. An explanation of alternative methods that are available for treatment of opioid addiction, whether offered by the program or not, and the potential benefits, risks and costs of each treatment.

29.3. Upon admission, each patient shall receive the following written information:

29.3.a. Signs and symptoms of overdose and when, where and how to seek emergency assistance;

29.3.b. A formal agreement of informed consent to be signed by the patient and a copy retained by him or her;

29.3.c. Patient's rights;

29.3.d. Confidentiality policies; and

29.3.e. The program's processes for dispensing medication.

29.3.f. Information on alternative methods available for treatment of opioid addiction and the potential benefits, risks and costs of each treatment. The state authority is responsible for providing informational materials to be used in discussing alternative treatments.

29.4. As soon as the individual is stable and capable of understanding, the patient shall receive group or individual education on the following:

29.4.a. Medication administration, including methods of dispensing and dosage restrictions;

29.4.b. The nature of addictive disorders including the great likelihood that addiction is a relapsing disease and is likely to have grave medical and social consequences if not treated on an ongoing basis;

29.4.c. The anticipated benefits of treatment;

29.4.d. The nature of the recovery process;

29.4.e. HIV spectrum and other infectious diseases;

29.4.f. Potential drug interactions;

29.4.g. Self-help groups, if any are available;

29.4.h. Medical issues related to detoxification from opioid treatment medications;

29.4.i. The special risk of withdrawal from methadone and detoxification to pregnant women and the fetus (as appropriate);

29.4.j. Characteristics of the medications administered and/or prescribed by the program;

29.4.k. Drug safety issues;

29.4.l. Dispensing procedures; and

29.4.m. Side effects of medications administered or prescribed by the program.

29.5. Documentation that the patient has completed the orientation training shall be completed and signed by the program physician and the patient and maintained in the patient's chart and individualized treatment plan of care.

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§ 69-7-42. Controlled Substances Monitoring Program Database.

42.1. Each opioid treatment program shall comply with policies and procedures developed by the designated state oversight agency and the West Virginia Board of Pharmacy to allow physicians treating patients through an opioid treatment program access to the Controlled Substances Monitoring Program database maintained by the West Virginia Board of Pharmacy.

42.2. Program physicians shall access the database:

42.2.a. At the patient's intake;

42.2.b. Before the administration of methadone or other treatment in an opioid treatment program;

42.2.c. After the initial thirty days of treatment;

42.2.d. Prior to any take-home medication being granted;

42.2.e. After any positive drug test; and

4.2.f. At each ninety-day treatment review.

42.3. The physician shall access the Controlled Substances Monitoring Program database in order to ensure that the patient is not seeking prescription medication from multiple sources. The results obtained from the database shall be maintained with the patient records.