H. B. 4336

(By Mr. Speaker, (Mr. Thompson) and Delegate Armstead)

[By Request of the Executive]

[Introduced January 27, 2012; referred to the Committee on Health and Human Resources then the Judiciary.]

A BILL to amend and reenact §16-1-4 of the Code of West Virginia, 1931, as amended; to amend said code by adding thereto a new section, designated §16-1-19; to amend said code by adding thereto a new article, designated §16-5H-1, §16-5H-2, §16-5H-3, §16-5H-4, §16-5H-5, §16-5H-6, §16-5H-7, §16-5H-8, and §16-5H-9; to amend and reenact §30-1-7a of said code; to amend and reenact §30-5-3 of said code; to amend and reenact §60A-9-3, §60A-9-4, and §60A-9-5; to amend and reenact §60A-10-3, §60A-10-4, §60A-10-5, §60A-10-7, and §60A-10-8 of said code; and to amend and reenact §61-12-10 of said code, all relating to substance abuse, generally; addressing the regulation of opioid treatment programs in this state; updating rules for opioid treatment program facilities to require clinical guidelines, recovery models, education and

training requirements for treatment facility staff and treatment limitations and requirements; requiring clinical monitoring of opioid treatment programs; creating an advisory council for opioid treatment programs; addressing the licensing and oversight of chronic pain management clinics; creating the Chronic Pain Clinic Licensing Act; providing definitions; establishing requirements for ownership, licensure, operation and management of pain management clinics; establishing limitations on the dispensing of controlled substances at a pain management clinic; requiring annual inspections of pain management clinics; providing for suspension or revocation of a pain management clinic license and setting forth due process requirements; providing for prohibitions on practicing at or operating a pain management clinic under certain circumstances; providing civil penalties regarding pain management clinics; requiring rules for the licensure of pain management clinics; requiring certain licensing boards to establish drug diversion training and best practice prescribing of controlled substances training; requiring certain licensed or certified healthcare professionals to complete drug diversion training and best practice prescribing of controlled substances training; requiring a valid practitioner-patient relationship to exist

prior to compounding or dispensing prescriptions; defining valid practitioner-patient relationship; requiring certain persons to submit information to the controlled substances reporting system within twenty-four hours; requiring additional information to be submitted to the controlled substances reporting system; clarifying that reporting is required for certain amounts of drugs dispensed to patients; providing certain requirements and training for law-enforcement officials in order to access the controlled substance monitoring database; permitting the Controlled Substance Monitoring Program Database Review Committee to query the substance monitoring database; requiring the Board of Pharmacy to review the substance monitoring system in order to issue certain reports; permitting the Board of Pharmacy to share certain information contained in the substance monitoring system with the Department of Health and Human Resources; requiring the Board of Pharmacy to establish an advisory committee; outlining the advisory committee's scope and duties; requiring the Board of Pharmacy to create a Controlled Substances Monitoring Program Database Review Committee; outlining the review committee's scope, powers and duties; requiring the Board of Pharmacy to promulgate certain legislative rules; permitting prescribing practitioners to

notify law enforcement of certain violations with immunity; establishing a felony offense and penalties for unauthorized access, use or disclosure of information contained in the substance monitoring database; requiring the Board of Pharmacy to provide annual reports to the Legislature; defining and removing definitions in the Methamphetamine Laboratory Eradication Act; establishing restrictions on the sale, transfer, or dispensing of ephedrine, pseudoephedrine and phenylpropanolamine by pharmacies; establishing criminal penalties for purchasing, receiving, or possessing certain quantities of ephedrine, pseudoephedrine and phenylpropanolamine; establishing criminal penalties for pharmacies, wholesalers or other entities which sells, transfers or dispenses a product under certain circumstances; amending the restrictions on the sale, transfer or delivery of certain designated precursors to the manufacture of methamphetamine or other controlled substances; requiring certain processing requirements of pharmacists, pharmacy interns, and pharmacy technicians; establishing use and requirements of the Multi-State Real-Time Tracking System; requiring pharmacies and retail establishments to electronically submit certain information to the Multi-State Real-Time Tracking System; requiring pharmacies and retail

establishments to stop pending sales under certain circumstances; limiting liability of retailers utilizing the Multi-State Real-Time Tracking System under certain circumstances; requiring pharmacies or retail establishments to maintain written logs or electronic record keeping databases under certain circumstances; providing supersession and preemption of all local laws, ordinances, and regulations pertaining to the sale of certain substances; amending reporting requirements and requiring real time electronic reporting of certain information; requiring that reported information is subject to random and warrantless inspection by certain persons; requiring the National Association of Drug Diversion Investigators to forward certain records to the West Virginia State Police and provide real-time access to the Multi-State Real-Time Tracking System; and requiring the chief medical officer to provide notice to the Database Review Committee in the case of a death caused by overdose.

Be it enacted by the Legislature of West Virginia:

That §16-1-4 of the code of West Virginia, 1931, as amended, be amended and re-enacted; that said code be amended by adding thereto a new section, designated §16-1-19; that said code be amended by adding thereto a new article, designated §16-5H-1, §16-5H-2, §16-5H-3, §16-5H-4, §16-5H-5, §16-5H-6, §16-5H-7,

§16-5H-8 and §16-5H-9; that §30-1-7a of said code be amended and reenacted; that §30-5-3 of said code be amended and reenacted; that §60A-9-3, §60A-9-4, and §60A-9-5 of said code be amended and reenacted; that §60A-10-3, §60A-10-4, §60A-10-5, §60A-10-7, and §60A-10-8 of said code be amended and reenacted; and that §61-12-10 of said code be amended and reenacted, all to read as follows:

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:

~~(a)~~ (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:

~~(1)~~ (A) Restrict the subdivision or development of a tract for any more intense or higher density occupancy than a single-family dwelling unit;

~~(2)~~ (B) Propose or enforce rules applicable to single-family dwelling units for single-family dwelling unit sanitary sewerage disposal systems; or

~~(3)~~ (C) Restrict any subdivision or development which might endanger the public health, the sanitary condition of streams or sources of water supply;

~~(b)~~ (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;

~~(c)~~ (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;

~~(d)~~ (4) Safe drinking water, including:

~~(1)~~ (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;

~~(2)~~ (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

~~(3)~~ (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;

~~(e)~~ (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;

~~(f)~~ (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. ~~Provided, That~~ 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;

~~(g)~~ (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. ~~Provided, That~~ 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. ~~Provided, however, That~~ 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;

~~(h)~~ (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;

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

~~(j)~~ (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 ~~shall~~ may be approved by the Health Care Authority as of the effective date of the 2007 amendments to this subsection. ~~The secretary shall promulgate revised emergency rules to govern licensed programs: Provided, That~~

(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 ~~subsections (1) through (9), inclusive, of~~ the provisions of this section. ~~Provided, however, That~~ 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 or by a designated advisory council, or

both. 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.~~: Provided, That~~ 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. All other patients must test positive for the presence of an opioid in the system before treatment through the use of methadone.

~~(2)~~ (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, ~~Subsequently,~~ the opioid treatment program shall develop an individualized treatment plan of care ~~by the thirtieth day after admission~~ and attach the plan to the patient's chart no later than five days after ~~such~~ 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 the strength of maintenance doses of methadone should decrease over time; that the treatment is limited to a defined period of time; and that participants are required to work toward a drug-free lifestyle.

~~(3)~~ (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; ~~or~~

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

(E) An unexplained reason.

~~(4)~~ (vi) That random drug testing as well as scheduled drug testing of all patients shall be conducted during the course of treatment. For purposes of these rules, "random drug testing" ~~shall~~ 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. Scheduled drug testing of all patients shall be done no less than monthly. ~~Provided, That~~ 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.

~~(5)~~ (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; ~~and~~

(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 and that ~~(6) That~~ 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.

~~(7)~~ (ix) That the opioid treatment program must report and provide statistics to the Department of Health and Human Resources demonstrating compliance with the random and scheduled drug test rules, including: ~~confirmation that:~~

(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 scheduled drug tests were performed at least monthly for all program participants;

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

~~(C)~~ (D) The number of expulsions from the program.

~~(8)~~ (x) That all opioid treatment facilities be open for business seven days per week; however, ~~Provided, That~~ the opioid treatment center may be closed for eight holidays and two training days per year. Every opioid treatment program shall have a physician actively licensed in this state present and on duty during all operating hours.

~~(9)~~ (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 Prescription Drug Registry maintained by the Board of Pharmacy before administration of methadone or other treatment in an opioid treatment program, after any positive drug test, and at each ~~ninety~~ thirty-day treatment review to ensure the patient is not seeking prescription medication from multiple sources. The results obtained from the Prescription Drug Registry shall be maintained with the patient records.

~~(k)~~ (11) 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.

~~(1)~~ (A) The rule shall include the following provisions:

~~(A)~~ (I) Base allocation amount for each county;

~~(B)~~ (ii) 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;

~~(C)~~ (iii) A calculation of funds utilized for state support of local health departments;

~~(D)~~ (iv) 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;

~~(E)~~ (v) 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.

~~(2)~~ (B) 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.

~~(1)~~ (12) Other health-related matters which the department is authorized to supervise and for which the rule-making authority has not been otherwise assigned.

§16-1-19. Advisory Council for Opioid Treatment Programs.

(a) The Advisory Council for Opioid Treatment Programs is hereby created as an advisory body to the Secretary of the Department of Health and Human Resources for the purpose of reporting to the secretary as to the regulation, monitoring and review of opioid treatment programs throughout the state.

(b) The council may perform clinical monitoring of all opioid treatment programs in this state and report to the secretary on all matters pertaining to the operation, management, monitoring and success of all opioid treatment programs. The council may review all state public health rules and advise the secretary on necessary revisions. The council may advise the secretary on the need for additional or special advisory committees to assist the council in matters concerning opioid treatment programs. The council shall review all performance based standards and assist the secretary in

the development and implementation of a coordinated, prevention oriented opioid treatment program that addresses the issues surrounding opioid addiction throughout the state.

(c) The council shall be composed of seventeen members appointed by the Governor by and with the advice and consent of the Senate. The state insurance commissioner or his or her designated representative, the Single State Methadone Authority or his or her designated representative, and the Commissioner of the Bureau for Public Health shall serve as members ex officio. The Governor shall appoint two persons to represent the general public, and twelve individuals selected from a list of nominees submitted to serve on the council. One person shall be selected from the following twelve areas, as nominated by:

(1) The West Virginia Association of Local Health Departments, which shall submit to the governor a list of three names of members of local boards of health;

(2) The West Virginia Association of County Commissioners, which shall submit to the Governor a list of three names of representatives from its association;

(3) The West Virginia Association of Social Workers, which shall submit to the Governor a list of three names of representatives from its association;

(4) The West Virginia Association of Pharmacists, which shall

submit to the Governor a list of three names of representatives from its association;

(5) The West Virginia Hospital Association, which shall submit to the Governor a list of three names of representatives from its association;

(6) The West Virginia Medical Association, which shall submit to the Governor a list of three names of representatives from its association;

(7) The West Virginia Emergency Medical Services Coalition, which shall submit to the Governor a list of three names of representatives from its association;

(8) The West Virginia Primary Care Association, which shall submit to the Governor a list of three names of representatives from its association;

(9) The Nursing Section of the West Virginia Public Health Association, which shall submit to the Governor a list of three names of public health nurses;

(10) The state college and university systems of West Virginia, which shall submit to the Governor a list of three names of representatives from its members;

(11) The State Health Education Council, which shall submit to the Governor a list of three names of individuals from the prevention and wellness community; and

(12) The West Virginia State Police, which shall submit to the Governor a list of three names of representatives from the law-enforcement community.

(d) Pursuant to the provisions of this section, the Governor shall appoint an advisory council on July 1, 2012. Of those first members appointed, one-third shall serve for one year, one-third shall serve for two years and one-third shall serve for three years. Each subsequent term shall be a three-year term and no member may serve more than four consecutive terms.

(e) The advisory council shall choose its own chairperson and meet at the call of the Single State Methadone Authority at least twice a year.

(f) The members of the council shall receive compensation and expense reimbursement in an amount not to exceed the same compensation and expense reimbursement that is paid to members of the Legislature for their interim duties as recommended by the citizens legislative compensation commission and authorized by law, for each day or substantial portion of a day engaged in the performance of official duties.

(g) Pursuant to the provisions of article ten, chapter four of this code, the State Advisory Council on Public Health shall continue to exist until July 1, 2020.

(h) The Secretary of the Department of Health and Human

Resources shall promulgate emergency rules pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code in order to establish the duties and responsibilities of the advisory council.

ARTICLE 5H. CHRONIC PAIN CLINIC LICENSING ACT.

§16-5H-1. Purpose and short title.

This article shall be known as the Chronic Pain Clinic Licensing Act. The purpose of this act is to establish licensing requirements for facilities that treat patients for chronic pain management in order to ensure that patients may be lawfully treated for chronic pain by physicians in facilities that comply with oversight requirements developed by the Department of Health and Human Resources.

§16-5H-2. Definitions.

(a) "Chronic pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three continuous months. For purposes of this article, "chronic pain" does not include pain associated with a terminal condition or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition.

(b) "Director" means the Director of the Office of Health

Facility Licensure and Certification within the Bureau of the Inspector General.

(c) "Owner" means any person, partnership, association or corporation listed as the owner of a pain management clinic on the licensing forms required by this article.

(d) "Pain management clinic" means all privately owned pain management clinics, facilities or offices not otherwise exempted from this article and which meet one or more of the following criteria:

(1) The facility advertises in any medium for any type of pain management services;

(2) The facility employs a physician who is primarily engaged in the treatment of pain by prescribing or dispensing controlled substance medications;

(3) The treatment of pain or chronic pain is the primary component of the facility's practice;

(4) The majority of patients of the prescribers at the facility are provided treatment for pain or chronic pain that includes the use of controlled substances, tramadol, carisoprodol or other drugs specified in rules adopted pursuant to this article;

(5) The facility meets any other identifying criteria established by the secretary by rule.

(e) "Physician" means an individual authorized to practice

medicine or surgery or osteopathic medicine or surgery in this state.

(f) "Prescriber" means an individual who is authorized by law to prescribe drugs or drug therapy related devices in the course of the individual's professional practice, including only a medical or osteopathic physician authorized to practice medicine or surgery; a physician assistant who holds a certificate to prescribe drugs; or a certified nurse practitioner who holds a certificate to prescribe.

(g) "Secretary" means the Secretary of the West Virginia Department of Health and Human Resources. The secretary may define in rules any term or phrase used in this article which is not expressly defined.

§16-5H-3. Pain management clinics to obtain license; application; fees and inspections.

(a) No person, partnership, association or corporation may operate a pain management clinic without first obtaining a license from the secretary in accordance with the provisions of this article and the rules lawfully promulgated hereunder.

(b) Any person, partnership, association or corporation desiring a license to operate a pain management clinic in this state shall file with the Office of Health Facility Licensure and Certification an application in such form as the secretary shall

prescribe and furnish accompanied by a fee to be determined by the secretary.

(c) The Director of the Office of Health Facility Licensure and Certification or his or her designee shall inspect each facility prior to issuing a license and review all documentation submitted with the application. The secretary shall issue a license if the facility is in compliance with the provisions of this article and with the rules lawfully promulgated hereunder.

(d) A license shall expire one year from the date of issuance. Sixty days prior to the expiration date, an application for renewal shall be submitted on forms furnished by the secretary. A license shall be renewed if the secretary determines that the applicant is in compliance with this article and with all rules promulgated hereunder. A license issued to one facility pursuant to this article is not transferable or assignable. A change of ownership of a licensed pain management clinic requires submission of a new application.

(e) The secretary or his or her designee shall inspect on a periodic basis all pain management clinics that are subject to this article and all rules adopted pursuant to this article to ensure continued compliance.

§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.

(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) Complete a pain medicine fellowship that is accredited by the Accreditation Council for Graduate Medical Education or a pain

medicine residency that is accredited by the Accreditation Council for Graduate Medical Education, or such other similar program as may be approved by the secretary. Any physician who qualifies to practice medicine in a pain management clinic pursuant to rules adopted by the West Virginia Board of Medicine or the West Virginia Board of Osteopathic Medicine as of July 1, 2012, may continue to practice medicine in a pain management clinic so long as the physician continues to meet the qualifications set forth in the board rules, meets all other requirements of this article; and practices at a pain management clinic licensed and 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) Directly 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 pain or 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 thereto.

(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 or employee 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:

(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 a controlled substance listed as Schedule I, Schedule II, Schedule III, Schedule IV or Schedule V drugs in sections two hundred four, two hundred six, two hundred eight, two hundred ten or two hundred twelve, article two, chapter sixty-a of this code.

(7) A person may not dispense any medication, including a controlled substance, on the premises of a licensed pain management clinic unless he or she is a physician licensed in this state. Prior to dispensing or prescribing any medication at a pain management clinic, the treating physician must access the Prescription Drug Registry maintained by the Board of Pharmacy to ensure the patient is not seeking prescription medications from multiple sources. The results obtained from the Prescription Drug Registry shall be maintained with the patient medical records. If the patient receives ongoing treatment, the physician shall review the Prescription Drug Registry every thirty days and maintain the reports in the patient files.

(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 listed as a Schedule II, Schedule III, Schedule IV or Schedule V drug in sections two hundred six, two hundred eight, two hundred ten or two hundred twelve, article two, 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 dangerous drugs 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. 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 drugs were prescribed, furnished or administered, the name and address of the individual to or for whom the dangerous drugs were prescribed, dispensed or administered, and the amounts and dosage forms for the drugs prescribed, furnished or administered;

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

(C) A physician shall perform a physical examination of a patient on the same day that he or she dispenses or prescribes a controlled substance to a patient at a pain management clinic.

(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 counterfeit-resistant prescription blanks. 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.

(b) 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 distribute drugs designated as Schedule I, Schedule II or Schedule III in sections two hundred four, two hundred six or two hundred eight, article two, chapter sixty-a of this code.

§16-5H-5. Exemptions.

(a) The following facilities are not pain management clinics subject to the requirements of this article:

(1) A facility that is affiliated with an accredited medical school at which training is provided for medical or osteopathic students, residents or fellows, podiatrists, dentists, nurses, physician assistants, optometrists, veterinarians or any affiliated facility to the extent that it participates in the provision of the instruction.

(2) A facility that does not prescribe or dispense controlled substances for the treatment of pain.

(3) A hospital licensed in this state.

(4) A hospice program licensed in this state.

(5) An ambulatory surgical facility licensed in this state.

(b) Any facility that is not included in this section may petition to the secretary for an exemption from the requirements of this article. All such petitions are subject to the administrative procedures requirements of chapter twenty-nine-a of this code.

§16-5H-6. Inspection.

(a) The Office of Health Facility Licensure and Certification shall inspect each pain management clinic annually, including a review of the patient records, to ensure that it complies with this article and the applicable rules.

(b) During an onsite inspection, the inspector shall make a reasonable attempt to discuss each violation with the owner or designated physician of the pain management clinic before issuing a formal written notification.

(c) Any action taken to correct a violation shall be documented in writing by the owner or designated physician of the pain management clinic and verified by follow-up visits by departmental personnel.

§16-5H-7. Suspension; revocation.

(a) The secretary may suspend or revoke a license issued hereunder if the provisions of this article or of the rules are violated. The secretary may revoke a clinic's license and prohibit all physicians associated with that pain management clinic from practicing at the clinic location based upon an annual or periodic

inspection and evaluation.

(b) Before any such license is suspended or revoked, however, written notice shall be given the licensee, stating the grounds of the complaint, and the date, time and place set for the hearing on the complaint, which date shall not be less than thirty days from the time notice is given. The notice shall be sent by registered mail to the licensee at the address where the pain management clinic concerned is located. The licensee shall be entitled to be represented by legal counsel at the hearing.

(c) If a license is revoked as herein provided, a new application for a license shall be considered by the secretary if, when and after the conditions upon which revocation was based have been corrected and evidence of this fact has been furnished. A new license shall then be granted after proper inspection has been made and all provisions of this article and rules promulgated hereunder have been satisfied.

(d) All of the pertinent provisions of article five, chapter twenty-nine-a of this code shall apply to and govern any hearing authorized and required by the provisions of this article and the administrative procedure in connection therewith.

(e) Any applicant or licensee who is dissatisfied with the decision of the secretary as a result of the hearing provided in this section may, within thirty days after receiving notice of the

decision, appeal the decision to the Circuit Court of Kanawha County, in term or in vacation, for judicial review of the decision.

(f) The court may affirm, modify or reverse the decision of the secretary and either the applicant or licensee or the secretary may appeal from the court's decision to the Supreme Court of Appeals.

(g) If the license of a pain management clinic is revoked or suspended, the designated physician of the clinic, the owner or lessor of the clinic property, the manager and the proprietor shall cease to operate the facility as a pain management clinic as of the effective date of the suspension or revocation. The owner or lessor of the clinic property, the manager or the proprietor is responsible for removing all signs and symbols identifying the premises as a pain management clinic.

(h) Upon the effective date of the suspension or revocation, the designated physician of the pain management clinic shall advise the secretary and the Board of Pharmacy of the disposition of all drugs located on the premises. The disposition is subject to the supervision and approval of the secretary. Drugs that are purchased or held by a pain management clinic that is not licensed may be deemed adulterated.

(I) If the license of a pain management clinic is suspended or

revoked, any person named in the licensing documents of the clinic, including persons owning or operating the pain management clinic, may not, as an individual or as part of a group, apply to operate another pain management clinic for five years after the date of suspension or revocation.

(j) The period of suspension for the license of a pain management clinic shall be prescribed by the secretary, but may not exceed one year.

§16-5H-8. Violations; penalties; injunction.

(a) Any person, partnership, association or corporation which establishes, conducts, manages or operates a pain management clinic without first obtaining a license therefor as herein provided, or which violates any provisions of this article or any rule lawfully promulgated thereunder, shall be assessed a civil penalty by the secretary in accordance with this subsection. Each day of continuing violation after conviction shall be considered a separate violation:

(1) If a pain management clinic or any owner or designated physician is found to be in violation of any provision of this article, unless otherwise noted herein, the secretary may suspend or revoke the clinic's license.

(2) If the clinic's designated physician knowingly and intentionally misrepresents actions taken to correct a violation,

the secretary may impose a civil penalty not to exceed $10,000, and, in the case of an owner-operated pain management clinic, revoke or deny a pain management clinic's license.

(3) If an owner or designated physician of a pain management clinic concurrently operates an unlicensed pain management clinic, the secretary may impose a civil penalty upon the owner or physician, or both, not to exceed $5,000 per day.

(4) If the owner of a pain management clinic that requires a license under this article fails to apply for a new license for the clinic upon a change-of-ownership and operates the clinic under the new ownership, the secretary may impose a civil penalty not to exceed $5,000.

(5) If a physician knowingly operates, owns or manages an unlicensed pain management clinic that is required to be licensed pursuant to this article; knowingly prescribes or dispenses or causes to be prescribed or dispensed, controlled substances in an unlicensed pain management clinic that is required to be licensed; or licenses a pain management clinic through misrepresentation or fraud; procures or attempts to procure a license for a pain management clinic for any other person by making or causing to be made any false representation, the secretary may assess a civil penalty of not more than $20,000. The penalty may be in addition to or in lieu of any other action that may be taken by the

secretary or any other board, court or entity.

(b) Notwithstanding the existence or pursuit of any other remedy, the secretary may, in the manner provided by law, maintain an action in the name of the state for an injunction against any person, partnership, association, or corporation to restrain or prevent the establishment, conduct, management or operation of any pain management clinic or violation of any provisions of this article or any rule or regulation lawfully promulgated thereunder without first obtaining a license therefor in the manner hereinbefore provided.

(c) In determining whether a penalty is to be imposed and in fixing the amount of the penalty, the secretary shall consider the following factors:

(1) The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the pain management clinic's actions or the actions of the designated or practicing physician, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated.

(2) What actions, if any, the owner or designated physician took to correct the violations.

(3) Whether there were any previous violations at the pain management clinic.

(4) The financial benefits that the pain management clinic derived from committing or continuing to commit the violation.

§16-5H-9. Rules.

(a) The Secretary of the Department of Health and Human Resources shall promulgate rules in accordance with the provisions of chapter twenty-nine-a of this code for the licensure of pain management clinics to ensure adequate care, treatment, health, safety, welfare and comfort of patients at these facilities. These rules shall include, but not be limited to:

(1) The qualifications and supervision of licensed and non-licensed personnel at pain management clinics and training requirements for all facility health care practitioners who are not regulated by another board;

(2) The provision and coordination of patient care, including the development of a written plan of care;

(3) The management, operation, staffing and equipping of the pain management clinic;

(4) The clinical, medical, patient and business records kept by the pain management clinic;

(5) The procedures for inspections and for the review of utilization and quality of patient care;

(6) The standards and procedures for the general operation of a pain management clinic, including facility operations, physical

operations, infection control requirements, health and safety requirements, and quality assurance;

(7) A list of drugs that may be used to treat pain or chronic pain that identify a facility as a pain management clinic;

(8) Any other criteria that identify a facility as a pain management clinic;

(9) The standards and procedures to be followed by an owner in providing supervision, direction and control of individuals employed by or associated with a pain management clinic;

(10) Data collection and reporting requirements; and

(11) Such other standards or requirements as the secretary determines are appropriate.

(b) The West Virginia Board of Medicine and the West Virginia Board of Osteopathic Medicine shall promulgate rules in accordance with the provisions of chapter twenty-nine-a of this code that establish standards and procedures for physicians who operate or provide care at pain management clinics, including standards and procedures to be followed in the diagnosis and treatment of chronic pain and managing chronic pain by prescribing, personally furnishing or administering drugs in amounts or combinations that may not be appropriate when treating other medical conditions.

(c) The rules authorized by this section may be filed as emergency rules if deemed necessary to promptly effectuate the

purposes of this article.

CHAPTER 30. PROFESSIONS AND OCCUPATIONS.

ARTICLE 1. GENERAL PROVISIONS APPLICABLE TO STATE BOARDS.

§30-1-7a. Continuing education.

(a) Each board referred to in this chapter shall establish continuing education requirements as a prerequisite to license renewal. Each board shall develop continuing education criteria appropriate to its discipline, which shall include, but not be limited to, course content, course approval, hours required and reporting periods.

(b) (1) Notwithstanding any other provision of this code or the provision of any rule to the contrary, each person issued a license to practice medicine and surgery or a license to practice podiatry or a license as a physician assistant by the West Virginia Board of Medicine, each person licensed as a pharmacist by the West Virginia Board of Pharmacy, each person licensed to practice registered professional nursing or licensed as an advanced nurse practitioner by the West Virginia Board of Examiners for Registered Professional Nurses, each person licensed as a licensed practical nurse by the West Virginia State Board of Examiners for licensed Practical Nurses and each person licensed to practice medicine and surgery as an osteopathic physician and surgeon or certified as an osteopathic physician assistant by the West Virginia Board of

Osteopathy shall complete two hours of continuing education coursework in the subject of end-of-life care including pain management during each continuing education reporting period through the reporting period ending June 30, 2005. The two hours shall be part of the total hours of continuing education required by each board by rule and not two additional hours.

(2) Effective as of the reporting period beginning July 1, 2005, the coursework requirement imposed by this subsection will become a one-time requirement, and all licensees who have not completed the coursework requirement shall complete the coursework requirement prior to his or her first license renewal.

(c) Notwithstanding any other provision of this code or the provision of any rule to the contrary, each person issued a license to practice medicine and surgery or a license to practice podiatry or a license as a physician assistant by the West Virginia Board of Medicine, each person issued a license to practice dentistry by the West Virginia Board of Dental Examiners, each person issued a license to practice optometry by the West Virginia Board of Optometry, each person licensed as a pharmacist by the West Virginia Board of Pharmacy, each person licensed to practice registered professional nursing or licensed as an advanced nurse practitioner by the West Virginia Board of Examiners for Registered Professional Nurses, each person licensed as a licensed practical

nurse by the West Virginia State Board of Examiners for Licensed Practical Nurses and each person licensed to practice medicine and surgery as an osteopathic physician and surgeon or licensed or certified as an osteopathic physician assistant by the West Virginia Board of Osteopathy shall complete drug diversion training and best practice prescribing of controlled substances training, as the trainings are established by his or her respective licensing board, if that person prescribes, administers, or dispenses a controlled substance, as that term is defined in section one hundred one, article one, chapter sixty-a of this code.

(1) Notwithstanding any other provision of this code or the provision of any rule to the contrary, the West Virginia Board of Medicine, the West Virginia Board of Dental Examiners, the West Virginia Board of Pharmacy, the West Virginia Board of Examiners for Registered Professional Nurses, the West Virginia State Board of Examiners for Licensed Practical Nurses, and the West Virginia Board of Osteopathy shall establish continuing education requirements and criteria appropriate to their respective discipline in the subject of drug diversion training and best practice prescribing of controlled substances training for each person issued a license or certificate by their respective board who prescribes, administers, or dispenses a controlled substance, as that term is defined in section one hundred one, article one,

chapter sixty-a of this code, and shall develop a certification form pursuant to subsection (c)(4) of this section.

(2) Each person who receives his or her initial license or certificate from any of the boards set forth in subsection (c)(1) of this section shall complete the continuing education requirements set forth in subsection (c) of this section within one year of receiving his or her initial license from that board.

(3) Each person licensed or certified by any of the boards set forth in subsection (c)(1) of this section who has held his or her license or certificate for longer than one year shall complete the continuing education requirements set forth in subsection (c) of this section as a prerequisite to each license renewal.

(4) A person subject to subsection (c)(3) of this section may waive the continuing education requirements for license renewal set forth in subsection (c) of this section if he or she completes and submits to his or her licensing board a certification developed by his or her licensing board stating that he or she has not prescribed, administered, or dispensed a controlled substance, as that term is defined in section one hundred one, article one, chapter sixty-a of this code, during the entire applicable reporting period.

ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS AND PHARMACIES.

§30-5-3. When licensed pharmacist required; person not licensed pharmacist, pharmacy technician or licensed intern not to compound prescriptions or dispense poisons or narcotics; licensure of interns; prohibiting the dispensing of prescription orders in absence of practitioner-patient relationship.

(a) It is unlawful for any person not a pharmacist, or who does not employ a pharmacist, to conduct any pharmacy or store for the purpose of retailing, compounding or dispensing prescription drugs or prescription devices.

(b) It is unlawful for the proprietor of any store or pharmacy, any ambulatory health care facility, as that term is defined in section one, article five-b, chapter sixteen of this code, that offers pharmaceutical care, or a facility operated to provide health care or mental health care services free of charge or at a reduced rate and that operates a charitable clinic pharmacy to permit any person not a pharmacist to compound or dispense prescriptions or prescription refills or to retail or dispense the poisons and narcotic drugs named in sections two, three and six, article eight, chapter sixteen of this code: *Provided,* That a licensed intern may compound and dispense prescriptions or prescription refills under the direct supervision of a pharmacist:

Provided, however, That registered pharmacy technicians may assist in the preparation and dispensing of prescriptions or prescription refills, including, but not limited to, reconstitution of liquid medications, typing and affixing labels under the direct supervision of a licensed pharmacist.

(c) It is the duty of a pharmacist or employer who employs an intern to license the intern with the board within ninety days after employment. The board shall furnish proper forms for this purpose and shall issue a certificate to the intern upon licensure.

(d) The experience requirement for licensure as a pharmacist shall be computed from the date certified by the supervising pharmacist as the date of entering the internship. If the internship is not registered with the Board of Pharmacy, then the intern shall receive no credit for ~~such~~ the experience when he or she makes application for examination for licensure as a pharmacist: *Provided,* That credit may be given for ~~such~~ the unregistered experience if an appeal is made and evidence produced showing experience was obtained but not registered and that failure to register the internship experience was not the fault of the intern.

(e) An intern having served part or all of his or her internship in a pharmacy in another state or foreign country shall

be given credit for the same when the affidavit of his or her internship is signed by the pharmacist under whom he or she served, and it shows the dates and number of hours served in the internship and when the affidavit is attested by the secretary of the State Board of Pharmacy of the state or country where the internship was served.

(f) Up to one third of the experience requirement for licensure as a pharmacist may be fulfilled by an internship in a foreign country.

(g) No pharmacist may compound or dispense any prescription order when he or she has knowledge that the prescription was issued by a practitioner without establishing ~~an ongoing~~ valid practitioner-patient relationship. For purposes of this section, a "valid practitioner-patient relationship" means the following have been established:

(1) A patient has a medical complaint;

(2) A medical history has been taken;

(3) A face-to-face physical examination adequate to establish the medical complaint has been performed by the prescribing practitioner or in the instances of telemedicine through telemedicine practice approved by the appropriate practitioner board; and

(4) Some logical connection exists between the medical complaint, the medical history, the physical examination and the drug prescribed.

An online or telephonic evaluation by questionnaire, or an online or telephonic consultation is inadequate to establish an appropriate practitioner-patient relationship: *Provided,* That this prohibition does not apply:

(1) In a documented emergency;

(2) In an on-call or cross-coverage situation; or

(3) Where patient care is rendered in consultation with another practitioner who has an ongoing relationship with the patient and who has agreed to supervise the patient's treatment, including the use of any prescribed medications.

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 once ~~a week~~ every twenty-four hours.

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

(2) A dispenser, who does not have an automated record-keeping system capable of producing an electronic report in the established format may request a waiver from electronic reporting. The request

for a waiver shall be made to the State Board of Pharmacy in writing and shall be granted if the dispenser agrees in writing to report the data by submitting a completed "Pharmacy Universal Claim Form" as defined by legislative rule.

§60A-9-4. Required information.

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

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

(2) The <u>legal</u> name, address and birth date of the person for whom the prescription is written <u>as set forth on the patient's</u>

government issued photo identification card;

(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; ~~and~~

(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 legal name, address and date of birth of the person picking up the prescription as set forth on the person's government issued photo identification card; 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. ~~or a drug dispensed~~ by a practitioner ~~at a facility licensed by the state.~~ Reporting is, however, required by this section for a drug dispensed to a patient by a practitioner: *Provided,* That the quantity dispensed ~~is limited to~~ may not exceed an amount adequate to treat the patient for a maximum of seventy-two hours with no greater than two seventy-two-hour cycles dispensed in any fifteen-day period of time.

§60A-9-5. 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 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 ~~a member~~ 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 ~~and the Workers' Compensation Commission~~, 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 database shall be granted access in accordance with applicable state laws and Board of Pharmacy legislative rules and shall be certified as a West Virginia law-enforcement officer, shall have successfully completed U. S. Drug Enforcement Administration Diversion Training and National Association of Drug Diversion Investigation Training. ~~*Provided*, That all~~ 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 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. ~~remain confidential.~~ 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 licensed physician member of the West Virginia Board of Medicine, a licensed dentist member of the West Virginia Board of Dental Examiners, a licensed physician member of 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 member of 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.

(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 established in section three of 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 knowledgeable about 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, shall query the database based on parameters established by the review committee. The review committee shall make determinations on a case-by-case basis on specific unusual prescribing patterns indicated by outliers in the system that could determine a need for 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 make determinations on a case-by-case basis whether the practitioner who prescribed or dispensed the controlled substance resulting in 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.

(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. 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; and (3) establishing the information to be contained in reports and the process by which the reports will be generated and disseminated.

~~(b)~~ (d) 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;

~~(c)~~ (e) 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;

~~(d)~~ (f) 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

~~(e) The Board of Pharmacy is hereby authorized to promulgate an emergency rule under chapter twenty-nine-a to effectuate the amendments to this section enacted during the 2010 Regular Session of the Legislature.~~

(g) A prescribing practitioner may notify law enforcement of a patient who, in the prescribing 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 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.

~~(f)~~ (h) Nothing in the article ~~shall~~ may be construed to ~~requirea~~ require a practitioner to access the West Virginia Controlled Substances Monitoring Program database.

(I) Unauthorized access or use or unauthorized disclosure of the information in the database is a felony punishable by imprisonment in a state correctional facility for not less than one year nor more than five years or fined not less than $3,000 nor more than $10,000, or both fined and imprisoned.

(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.

ARTICLE 10. METHAMPHETAMINE LABORATORY ERADICATION ACT.

§60A-10-3. Definitions.

In this article:

(a) "Board of Pharmacy" or "board" means the West Virginia Board of Pharmacy established by the provisions of article five, chapter thirty of this code.

(b) "Designated precursor" means any drug product made subject to the requirements of this article by the provisions of section seven of this article.

(c) "Distributor" means any person within this state or another state, other than a manufacturer or wholesaler, who sells, delivers, transfers or in any manner furnishes a drug product to any person who is not the ultimate user or consumer of the product.

(d) "Drug product" means a pharmaceutical product that contains ~~as its single active ingredient~~ ephedrine, pseudoephedrine or phenylpropanolamine or a substance identified on the supplemental list provided ~~for~~ in section seven of this article which may be sold without a prescription and which is labeled for use by a consumer in accordance with the requirements of the laws and rules of this state and the federal government.

(e) "Ephedrine " means ephedrine, its salts or optical isomers

or salts of optical isomers.

(f) "Manufacturer" means any person within this state who produces, compounds, packages or in any manner initially prepares for sale or use any drug product or any such person in another state if they cause the products to be compounded, packaged or transported into this state.

(g) "National Association of Drug Diversion Investigators" or "NADDI" means the non-profit 501(c)(3) organization established in 1989, made up of members who are responsible for investigating and prosecuting pharmaceutical drug diversion, and that facilitates cooperation between law enforcement, healthcare professionals, state regulatory agencies, and pharmaceutical manufacturers in the investigation and prevention of prescription drug abuse and diversion.

(h) "Multi-State Real-Time Tracking System" or "MSRTTS" means the real-time electronic logging system provided by NADDI at no cost to states that have legislation requiring real-time electronic monitoring of precursor purchases, and agree to use the system. MSRTTS is used by pharmacies and law enforcement to track sales of over-the-counter (OTC) cold and allergy medications containing precursors to the illegal drug, methamphetamine.

~~(g)~~ (I) "Phenylpropanolamine" means phenylpropanolamine, its

salts, optical isomers and salts of optical isomers.

~~(h)~~ (j) "Pseudoephedrine" means pseudoephedrine, its salts, optical isomers and salts of optical isomers.

~~(i)~~ (k) "Precursor" means any substance which may be used along with other substances as a component in the production and distribution of illegal methamphetamine.

~~(j)~~ (l) "Pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy and pharmaceutical care as defined in subsection (t), section one-b, article fifty, chapter thirty of this code.

~~(k)~~ (m) "Pharmacy intern" has the same meaning as the term "intern" as set forth in section one-b, article five, chapter thirty of this code.

~~(l)~~ (n) "Pharmacy" means any drugstore, apothecary or place within this state where drugs are dispensed and sold at retail or display for sale at retail and pharmaceutical care is provided outside of this state where drugs are dispensed and pharmaceutical care is provided to residents of this state.

~~(m)~~ (o) "Pharmacy counter" means an area in the pharmacy restricted to the public where controlled substances are stored and housed and where controlled substances may only be sold, transferred or dispensed by a pharmacist, pharmacy intern or

pharmacy technician.

~~(n)~~ (p) "Pharmacy technician" means a registered technician who meets the requirements for registration as set forth in article five, chapter thirty of this code.

~~(o)~~ (q) "Retail establishment" means any entity or person within this state who sells, transfers or distributes goods, including over-the-counter drug products, to an ultimate consumer.

~~(p)~~ (r) "Schedule V" means the schedule of controlled substances set out in section two hundred twelve, section two of this chapter.

~~(q) "Single active ingredient" means those ingredients listed on a drug product package as the only active ingredient in over the counter medication or identified on the Schedule maintained by the Board of Pharmacy as being primarily used in the illegal production and distribution of methamphetamine.~~

~~(r)~~ (s) "Superintendent of the State Police" or "Superintendent" means the Superintendent of the West Virginia State Police as set forth in section five, article two, chapter fifteen of this code.

~~(s)~~ (t) "Wholesaler" means any person within this state or another state, other than a manufacturer, who sells, transfers or in any manner furnishes a drug product to any other person in this

state for the purpose of being resold.

§60A-10-4. Purchase, receipt, acquisition and possession of substances to be used as precursor to manufacture of methamphetamine or another controlled substance; offenses; exceptions; penalties.

(a) A pharmacy may not sell, transfer or dispense to the same person, and a person may not purchase, more than three and six-tenths grams per day or more than seven and five-tenths grams per thirty-day period of ephedrine, pseudoephedrine or phenylpropanolamine. The limits shall apply to the total amount of ephedrine, pseudoephedrine and phenylpropanolamine contained in the products, and not the overall weight of the products.

(1) Any person who knowingly purchases, receives, or otherwise possesses more than three and six-tenths grams per day ~~within any thirty day period knowingly purchases, receives or otherwise possesses more than three packages of a drug product containing as its single active ingredient ephedrine, pseudoephedrine or phenylpropanolamine~~ or more than ~~nine~~ seven and five-tenths grams per thirty-day period of ephedrine, pseudoephedrine or phenylpropanolamine in any form ~~shall be~~ is guilty of a misdemeanor and, upon conviction, shall be confined in a jail for not more than one year, fined not more than $1,000, or both fined and confined.

(2) Any pharmacy, wholesaler or other entity operating the retail establishment which sells, transfers or dispenses a product in violation of this section is guilty of a misdemeanor and, upon conviction, shall be fined not more than $1,000 for the first offense, or more than $10,000 for each subsequent offense.

(b) Notwithstanding the provisions of subsection (a)(1) of this section, any person convicted of a second or subsequent violation of the provisions of said subsection or a statute or ordinance of the United States or another state which contains the same essential elements ~~shall be~~ is guilty of a felony and, upon conviction, shall be ~~confined~~ imprisoned in a state correctional facility for not less than one nor more than five years, fined not more than $25,000, or both imprisoned and fined.

(c) The provisions of subsection (a) of this section shall not apply to:

(1) Products dispensed pursuant to a valid prescription;

~~(1)~~(2) Drug products which are for pediatric use primarily intended for administration to children under the age of twelve;

~~(2)~~ (3) Drug products which have been determined by the Board of Pharmacy to be in a form which is ~~unamenable~~ not amenable to being used for the manufacture of methamphetamine; or

~~(3)~~ (4) Persons lawfully possessing drug products in their

capacities as distributors, wholesalers, manufacturers, pharmacists, pharmacy interns, pharmacy technicians, or health care professionals. ~~or persons possessing such drug products pursuant to a valid prescription~~

(d) Notwithstanding any provision of this code to the contrary, any person who knowingly possesses any amount of ephedrine, pseudoephedrine, phenylpropanolamine or other designated precursor with the intent to use it in the manufacture of methamphetamine or who knowingly possesses a substance containing ephedrine, pseudoephedrine or phenylpropanolamine or their salts, optical isomers or salts of optical isomers in a state or form which is, or has been altered or converted from the state or form in which these chemicals are, or were, commercially distributed ~~shall be~~ is guilty of a felony and, upon conviction, shall be ~~confined~~ imprisoned in a state correctional facility for not less than two nor more than ten years, fined not more than $25,000, or both imprisoned and fined.

(e) (1) Any pharmacy, wholesaler, manufacturer or distributor of drug products containing ~~as their single active ingredient~~ ephedrine, pseudoephedrine, phenylpropanolamine, their salts or optical isomers or salts of optical isomers or other designated precursor shall obtain a registration annually from the State Board

of Pharmacy as described in section six of this article. Any such pharmacy, wholesaler, manufacturer or distributor shall keep complete records of all sales and transactions as provided in section eight of this article. The records shall be gathered and maintained pursuant to legislative rule promulgated by the Board of Pharmacy.

(2) Any drug products possessed without a registration as provided in this section are subject to forfeiture upon conviction for a violation of this section.

(3) In addition to any administrative penalties provided by law, any violation of this subsection is a misdemeanor, punishable upon conviction by a fine in an amount not more than $10,000.

§60A-10-5. Restrictions on the sale, transfer or delivery of certain drug products; penalties.

(a) No pharmacy or individual may display, offer for sale or place a drug product containing ~~as its single active ingredient~~ ephedrine, pseudoephedrine or phenylpropanolamine or other designated precursor where the public may freely access the drug product. All such drug products or designated precursors shall be placed behind a pharmacy counter where access is restricted to a pharmacist, a pharmacy intern, a pharmacy technician or other pharmacy employee.

(b) All storage of drug products regulated by the provisions of this section shall be in a controlled and locked access location that is not accessible by the general public and shall maintain strict inventory control standards and complete records of quantity of the product maintained in bulk form.

(c) No pharmacy ~~shall~~ may sell, deliver or provide any drug product regulated by the provisions of this section to any person who is under the age of eighteen.

(d) If a drug product regulated by the provisions of this section is transferred, sold or delivered, the individual, pharmacy or retail establishment transferring, selling or delivering the drug product shall require the person purchasing, receiving or otherwise acquiring the drug product to:

(1) Produce a government-issued photo identification showing his or her date of birth; and

(2) Sign a ~~form~~ logbook containing the information set forth in subsection (b), section eight of this article and attesting to the validity of ~~such~~ the information.

(e) Any person who knowingly makes a false representation or statement pursuant to the requirements of this section ~~shall be~~ is guilty of a misdemeanor and, upon conviction, be confined in a jail for not more than six months, fined not more than $5,000, or both

fined and confined.

(f) (1) The pharmacist, pharmacy intern or pharmacy technician processing the transaction shall determine that the name entered in the logbook corresponds to the name provided on the identification.

(2) Beginning January 1, 2013, a pharmacy or retail establishment shall, before completing a sale under this section, electronically submit the information required by section eight of this article to the Multi-State Real-Time Tracking System (MSRTTS) administered by the National Association of Drug Diversion Investigators (NADDI): *Provided,* That the system is available to retailers in the state without a charge for accessing the system. This system shall be capable of generating a stop sale alert, which shall be a notification that completion of the sale would result in the seller or purchaser violating the quantity limits set forth in this section. The seller may not complete the sale if the system generates a stop sale alert. The system shall contain an override function that may be used by a dispenser of a drug product who has a reasonable fear of imminent bodily harm if he or she does not complete a sale. Each instance in which the override function is utilized shall be logged by the system. Absent negligence, wantonness, recklessness or deliberate misconduct, any retailer utilizing the Multi-State Real-Time Tracking System in accordance

with this subdivision may not be civilly liable as a result of any act or omission in carrying out the duties required by this subsection and is immune from liability to any third party unless the retailer has violated any provision of this subsection in relation to a claim brought for the violation.

(3) If a pharmacy or retail establishment selling a nonprescription product containing pseudoephedrine or ephedrine experiences mechanical or electronic failure of the Multi-State Real-Time Tracking System and is unable to comply with the electronic sales tracking requirement, the pharmacy or retail establishment shall maintain a written log or an alternative electronic record keeping mechanism until such time as the pharmacy or retail establishment is able to comply with the electronic sales tracking requirement.

~~(e)~~ (g) This section does not apply to drug products that are dispensed pursuant to a prescription, are pediatric products primarily intended for administration, according to label instructions, to children under twelve years of age.

~~(f)~~ (h) Any violation of this section is a misdemeanor, punishable upon conviction by a fine in an amount not more than $10,000.

(I) The provisions of this section supersede and preempt all

local laws, ordinances, rules and regulations pertaining to the sale of any compounds, mixtures, or preparation containing ephedrine, pseudoephedrine, or phenylpropanolamine.

§60A-10-7. Restricted products; rule-making authority.

(a) On or before July 1, 2005, the Board of Pharmacy shall promulgate emergency and legislative rules pursuant to the provision of article three, chapter twenty-nine-a of this code to implement a program wherein the Board of Pharmacy shall consult with the Superintendent of the State Police in identifying drug products which are a designated precursor, in addition to those that contain ~~as their single active ingredient~~ ephedrine, pseudoephedrine or phenylpropanolamine, that are commonly being used in the production and distribution of methamphetamine. Those drug products which the Superintendent of the State Police have demonstrated by empirical evidence are commonly used in the manufacture of methamphetamine shall be added to a supplemental list and shall be subject to all of the restrictions of this article. These rules established pursuant to this section shall include:

(1) A process whereby pharmacies are made aware of all drug products that contain ~~as their single active ingredient~~ ephedrine, pseudoephedrine and phenylpropanolamine that will be listed as a

Schedule V substance and must be sold, transferred or dispensed from behind a pharmacy counter;

(2) A process whereby pharmacies and retail establishments are made aware of additional drug products added to Schedule V that are required to be placed behind the pharmacy counter for sale, transfer or distribution can be periodically reviewed and updated.

(b) At any time after July 1, 2005, the Board of Pharmacy, upon the recommendation of the Superintendent of the State Police, shall promulgate emergency and legislative rules pursuant to the provision of article three, chapter twenty-nine-a of this code to implement an updated supplemental list of products containing the controlled substances ephedrine, pseudoephedrine or phenylpropanolamine as an active ingredient or any other drug used as a precursor in the manufacture of methamphetamine, which the Superintendent of the State Police has demonstrated by empirical evidence is being used in the manufacture of methamphetamine. This listing process shall comport with the requirements of subsection (a) of this section.

§60A-10-8. Reporting requirements; confidentiality.

(a) ~~Whenever~~ Until January 1, 2013, upon each ~~there is a~~ sale, retail, transfer or distribution of any drug product referred to in section seven of this article or another designated precursor, the

pharmacist, pharmacy intern, or pharmacy technician making the sale, transfer or distribution shall report the following information for inclusion in ~~a~~ the central repository established and maintained by the Board of Pharmacy:

(1) The date of the transaction;

(2) The name, address and driver's license or state-issued identification number of the person; and

(3) The name, quantity of packages and total gram weight of the product or products purchased, received or otherwise acquired.

(b) The information required to be reported by this section shall be reported by paper log maintained at the point of sale: Provided, That, beginning on January 1, 2007, reporting shall be by electronic transmission to the Board of Pharmacy no more frequently than once a week. Beginning on January 1, 2013, the electronic transmission of the information required to be reported in subsection (a) of this section shall be reported to the MSRTTS, and shall be made in real time at the time of the transaction.

(c) The information required by this section shall be the property of the state, and is subject to random and warrantless inspection by city, county, or state law-enforcement officers, or members of the federal Drug Enforcement Administration ~~and a pharmacy shall have no duty to retain a copy of the information in~~

~~any format once the information has been reported to the Board of Pharmacy as required by this section~~. NADDI shall forward state transaction records in the MSRTTS to the West Virginia State Police weekly, and provide real-time access to MSRTTS information through the MSRTTS online portal to authorized agents of the federal Drug Enforcement Administration and certified law enforcement in this and other states for use in the detection of violations of this article or of federal laws designed to prevent the illegal use, production, or distribution of methamphetamine.

CHAPTER 61. CRIMES AND OTHER PUNISHMENT.

ARTICLE 12. POSTMORTEM EXAMINATIONS.

§61-12-10. When autopsies made and by whom performed; records of date investigated; copies of records and information; reporting requirements.

(a) If in the opinion of the chief medical examiner, or of the county medical examiner of the county in which the death in question occurred, it is advisable and in the public interest that an autopsy be made, or if an autopsy is requested by either the prosecuting attorney or the judge of the circuit court or other court of record having criminal jurisdiction in that county, an autopsy shall be conducted by the chief medical examiner or his or her designee, by a member of his or her staff, or by a competent

pathologist designated and employed by the chief medical examiner under the provisions of this article. For this purpose, the chief medical examiner may employ any county medical examiner who is a pathologist who holds board certification or board eligibility in forensic pathology or has completed an American Board of Pathology fellowship in forensic pathology to make the autopsies, and the fees to be paid for autopsies under this section shall be in addition to the fee provided for investigations pursuant to section eight of this article. A full record and report of the findings developed by the autopsy shall be filed with the office of the chief medical examiner by the person making the autopsy.

(b) Within the discretion of the chief medical examiner, or of the person making the autopsy, or if requested by the prosecuting attorney of the county, or of the county where any injury contributing to or causing the death was sustained, a copy of the report of the autopsy shall be furnished to the prosecuting attorney.

(c) The office of the chief medical examiner shall keep full, complete and properly indexed records of all deaths investigated, containing all relevant information concerning the death and the autopsy report if ~~such be~~ an autopsy report is made. Any prosecuting attorney or law-enforcement officer may secure copies

of these records or information necessary for the performance of his or her official duties.

(d) Copies of these records or information shall be furnished, upon request, to any court of law, or to the parties therein to whom the cause of death is a material issue, except where the court determines that interests in a civil matter conflict with the interests in a criminal proceeding, in which case the interests in the criminal proceeding shall take precedence. The office of chief medical examiner shall be reimbursed a reasonable rate by the requesting party for costs incurred in the production of records under this subsection and subsection (c) of this section.

(e) The chief medical examiner is authorized to release investigation records and autopsy reports to the multidisciplinary team authorized by section three, article five-d, chapter forty-nine of this code and as authorized in subsection (h) of this section. At the direction of the Secretary of the Department of Health and Human Resources the chief medical examiner may release records and information to other state agencies when considered to be in the public interest.

(f) Any person performing an autopsy under this section is empowered to keep and retain, for and on behalf of the chief medical examiner, any tissue from the body upon which the autopsy

was performed which may be necessary for further study or consideration.

(g) In cases of the death of any infant in the State of West Virginia where sudden infant death syndrome is the suspected cause of death and the chief medical examiner or the medical examiner of the county in which the death in question occurred considers it advisable to perform an autopsy, it is the duty of the chief medical examiner or the medical examiner of the county in which the death occurred to notify the sudden infant death syndrome program within the division of maternal and child health and to inform the program of all information to be given to the infant's parents.

(h) If the chief medical officer determines that a drug overdose is the cause of death of a person, the chief medical examiner shall provide notice of the death to the West Virginia Controlled Substances Monitoring Program Database Review Committee established pursuant to subsection (b), section five, article nine, chapter sixty-a of this code and shall include in the notice any information relating to the drug that resulted in the overdose, including the name of the licensed practitioner who prescribed or dispensed the controlled substance to the decedent.

NOTE: The purpose of this bill is to address the growing

substance abuse issues in this state. This bill addresses the regulation of opioid treatment programs in this state; updates rules for opioid treatment program facilities to require clinical guidelines, recovery models, education and training requirements for treatment facility staff and treatment limitations and requirements; requires clinical monitoring of opioid treatment programs; creates an advisory council for opioid treatment programs; addresses the licensing and oversight of chronic pain management clinics; creates the Chronic Pain Clinic Licensing Act; provides definitions; establishes requirements for ownership, licensure, operation and management of pain management clinics; establishes limitations on the dispensing of controlled substances at a pain management clinic; requires annual inspections of pain management clinics; provides for suspension or revocation of a pain management clinic license and setting forth due process requirements; provides for prohibitions on practicing at or operating a pain management clinic under certain circumstances; provides civil penalties regarding pain management clinics; requires rules for the licensure of pain management clinics; requires certain licensing boards to establish drug diversion training and best practice prescribing of controlled substances training; requires certain licensed or certified healthcare professionals to complete drug diversion training and best practice prescribing of controlled substances training; requires a valid practitioner-patient relationship to exist prior to compounding or dispensing prescriptions; defines valid practitioner-patient relationship; requires certain persons to submit information to the controlled substances reporting system within twenty-four hours; requires additional information to be submitted to the controlled substances reporting system; clarifies that reporting is required for certain amounts of drugs dispensed to patients; provides certain requirements and training for law-enforcement officials in order to access the controlled substance monitoring database; permits the Controlled Substance Monitoring Program Database Review Committee to query the substance monitoring database; requires the Board of Pharmacy to review the substance monitoring system in order to issue certain reports; permits the Board of Pharmacy to share certain information contained in the substance monitoring system with the Department of Health and Human Resources; requires the Board of Pharmacy to establish an advisory committee; outlines the advisory committee's scope and duties; requires the Board of Pharmacy to create a Controlled Substances Monitoring Program Database Review Committee; outlines the review committee's scope, powers and duties; requires the Board of Pharmacy to promulgate certain legislative rules; permits prescribing practitioners to

notify law enforcement of certain violations with immunity; establishes a felony offense and penalties for unauthorized access, use or disclosure of information contained in the substance monitoring database; requires the Board of Pharmacy to provide annual reports to the Legislature; defines and removing definitions in the Methamphetamine Laboratory Eradication Act; establishes restrictions on the sale, transfer, or dispensing of ephedrine, pseudoephedrine and phenylpropanolamine by pharmacies; establishes criminal penalties for purchasing, receiving, or possessing certain quantities of ephedrine, pseudoephedrine and phenylpropanolamine; establishes criminal penalties for pharmacies, wholesalers or other entities which sell, transfers or dispense a product under certain circumstances; amends the restrictions on the sale, transfer or delivery of certain designated precursors to the manufacture of methamphetamine or other controlled substances; requires certain processing requirements of pharmacists, pharmacy interns, and pharmacy technicians; establishes use and requirements of the Multi-State Real-Time Tracking System; requires pharmacies and retail establishments to electronically submit certain information to the Multi-State Real-Time Tracking System; requires pharmacies and retail establishments to stop pending sales under certain circumstances; limits liability of retailers utilizing the Multi-State Real-Time Tracking System under certain circumstances; requires pharmacies or retail establishments to maintain written logs or electronic record keeping databases under certain circumstances; provides supersession and preemption of all local laws, ordinances, and regulations pertaining to the sale of certain substances; amends reporting requirements and requiring real time electronic reporting of certain information; requires that reported information is subject to random and warrantless inspection by certain persons; requires the National Association of Drug Diversion Investigators to forward certain records to the West Virginia State Police and provide real-time access to the Multi-State Real-Time Tracking System; and requires the chief medical officer to provide notice to the Database Review Committee in the case of a death caused by overdose.

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

This article is new; §16-5H-1, §16-5H-2, §16-5H-3, §16-5H-4, §16-5H-5, §16-5H-6, §16-5H-7, §16-5H-8 and §16-5H-9; therefore, it has been completely underscored.

§16-1-19 is new; therefore, it has been completely underscored.