

1 **ENROLLED**

2 COMMITTEE SUBSTITUTE

3 FOR

4 **Senate Bill No. 437**

5 (BY SENATORS KESSLER (MR. PRESIDENT) AND HALL,

6 BY REQUEST OF THE EXECUTIVE)

7 _____
8 [Passed March 10, 2012; in effect ninety days from passage.]
9 _____

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11
12 AN ACT to amend and reenact §16-1-4 of the Code of West Virginia,
13 1931, as amended; to amend said code by adding thereto a new
14 article, designated §16-5H-1, §16-5H-2, §16-5H-3, §16-5H-4,
15 §16-5H-5, §16-5H-6, §16-5H-7, §16-5H-8, §16-5H-9 and
16 §16-5H-10; to amend and reenact §30-1-7a of said code; to
17 amend and reenact §30-5-3 of said code; to amend and reenact
18 §60A-3-308 of said code; to amend and reenact §60A-9-3,
19 §60A-9-4, §60A-9-5 and §60A-9-7 of said code; to amend said
20 code by adding thereto three new sections, designated
21 §60A-9-4a, §60A-9-5a and §60A-9-8; to amend and reenact
22 §60A-10-3, §60A-10-4, §60A-10-5, §60A-10-7, §60A-10-8 and
23 §60A-10-11 of said code; to amend said code by adding thereto
24 a new section, designated §60A-10-16; and to amend and reenact
25 §61-12-10 of said code, all relating to substance abuse
26 generally; addressing the regulation of opioid treatment

1 programs in this state; updating rules for opioid treatment
2 program facilities to require clinical guidelines, recovery
3 models, education and training requirements for treatment
4 facility staff and treatment limitations and requirements;
5 addressing the licensing and oversight of chronic pain
6 management clinics; creating the Chronic Pain Clinic Licensing
7 Act; providing definitions; establishing requirements for
8 ownership, licensure, operation and management of pain
9 management clinics; establishing limitations on the dispensing
10 of controlled substances at a pain management clinic;
11 requiring annual inspections of pain management clinics;
12 setting forth exemptions from the act; providing for
13 suspension or revocation of a pain management clinic license
14 and setting forth due process requirements; providing for
15 prohibitions on practicing at or operating a pain management
16 clinic under certain circumstances; providing civil penalties
17 regarding pain management clinics; providing for notice
18 requirements to applicable licensing boards; requiring rules
19 for the licensure of pain management clinics; removing
20 requirement of certain licensed or certified health care
21 professionals to complete continuing education course work on
22 the subject of end-of-life care; requiring certain licensed or
23 certified health care professionals to complete drug diversion
24 training and best practice prescribing of controlled
25 substances training; requiring certain licensing boards to
26 establish drug diversion training and best practice

1 prescribing of controlled substances training; requiring a
2 valid practitioner-patient relationship to exist prior to
3 compounding or dispensing prescriptions; requiring that
4 buprenorphine combined with naloxone prescribed or dispensed
5 for treatment for opioid addiction be in the form of
6 sublingual film unless medically contraindicated as of
7 September 1, 2012; clarifying certain circumstances that do
8 not establish a valid practitioner-patient relationship;
9 requiring certain persons to submit information to the
10 Controlled Substances Monitoring Program database within
11 twenty-four hours; requiring additional information to be
12 submitted to the Controlled Substances Monitoring Program
13 database; clarifying that reporting is required for certain
14 amounts of drugs dispensed to patients; requiring verification
15 of certain information reported to the Controlled Substances
16 Monitoring Program database; providing certain requirements
17 and training for law-enforcement officials in order to access
18 the Controlled Substances Monitoring Program database;
19 permitting the Controlled Substances Monitoring Program
20 Database Review Committee to query the Controlled Substances
21 Monitoring Program database; requiring the Board of Pharmacy
22 to review the Controlled Substances Monitoring Program
23 database in order to issue certain reports; permitting the
24 Board of Pharmacy to share certain information contained in
25 the Controlled Substances Monitoring Program database with the
26 Department of Health and Human Resources; requiring the Board

1 of Pharmacy to establish an advisory committee; setting forth
2 the membership of the advisory committee; outlining the
3 advisory committee's scope and duties; requiring the Board of
4 Pharmacy to create a Controlled Substances Monitoring Program
5 Database Review Committee; setting forth the membership of the
6 review committee; outlining the review committee's scope,
7 powers and duties; requiring the Board of Pharmacy to
8 promulgate certain legislative rules; permitting prescribing
9 practitioners to notify law enforcement of certain violations
10 with immunity; requiring the Board of Pharmacy to provide
11 annual reports to the Legislature; requiring various boards
12 that regulate professions with prescriptive authority to
13 require persons licensed by the board to conduct an initial
14 search of the Controlled Substances Monitoring Program
15 database when prescribing a course of treatment that includes
16 prescribing of pain-relieving controlled substances and an
17 annual search of the Controlled Substances Monitoring Program
18 database for certain patients; setting forth penalties for
19 failing to search the Controlled Substances Monitoring Program
20 database in certain circumstances; establishing a felony
21 offense and penalties for unauthorized access, use or
22 disclosure of information contained in the Controlled
23 Substances Monitoring Program database; creating Fight
24 Substance Abuse Fund and setting forth permissible uses for
25 fund; defining terms and updating definitions in the
26 Methamphetamine Laboratory Eradication Act; establishing

1 reduced daily, monthly and annual amount restrictions on the
2 sale, transfer, dispensing or possession of ephedrine,
3 pseudoephedrine and phenylpropanolamine by pharmacies;
4 establishing criminal penalties for purchasing, receiving or
5 possessing certain quantities of ephedrine, pseudoephedrine
6 and phenylpropanolamine; establishing criminal penalties for
7 pharmacies, wholesalers or other entities which sell, transfer
8 or dispense a product under certain circumstances; amending
9 the restrictions on the sale, transfer or delivery of certain
10 designated precursors to the manufacture of methamphetamine or
11 other controlled substances; requiring offer of patient
12 counseling by a pharmacist upon the sale, transfer or delivery
13 of certain designated precursors to the manufacture of
14 methamphetamine or other controlled substances; requiring
15 certain processing requirements of pharmacists, pharmacy
16 intern and pharmacy technicians; establishing use and
17 requirements of the Multi-State Real-Time Tracking System;
18 requiring pharmacies and retail establishments to
19 electronically submit certain information to the Multi-State
20 Real-Time Tracking System; requiring pharmacies and retail
21 establishments to stop pending sales under certain
22 circumstances; limiting liability of retailers utilizing the
23 Multi-State Real-Time Tracking System under certain
24 circumstances; requiring pharmacies or retail establishments
25 to maintain written logs or electronic record-keeping
26 databases under certain circumstances; providing supersession

1 and preemption of all local laws, ordinances and regulations
2 pertaining to the sale of certain substances; amending
3 reporting requirements and requiring real-time electronic
4 reporting of certain information; providing for law
5 enforcement access to information pertaining to the sale of
6 certain substances; establishing an expiration date for Multi-
7 State Real-Time Tracking System; requiring the National
8 Association of Drug Diversion Investigators to forward certain
9 records to the West Virginia State Police and provide
10 real-time access to the Multi-State Real-Time Tracking System
11 to law enforcement; requiring the West Virginia State Police
12 to submit an annual report with data and statistics on
13 methamphetamine use, production and distribution; and
14 requiring the chief medical officer to provide notice to the
15 Controlled Substances Monitoring Program Database Review
16 Committee in the case of a death caused by overdose.

17 *Be it enacted by the Legislature of West Virginia:*

18 That §16-1-4 of the Code of West Virginia, 1931, as amended,
19 be amended and reenacted; that said code be amended by adding
20 thereto a new article, designated §16-5H-1, §16-5H-2, §16-5H-3,
21 §16-5H-4, §16-5H-5, §16-5H-6, §16-5H-7, §16-5H-8, §16-5H-9 and §16-
22 5H-10; that §30-1-7a of said code be amended and reenacted; that
23 §30-5-3 of said code be amended and reenacted; that §60A-3-308 of
24 said code be amended and reenacted; that §60A-9-3, §60A-9-4,
25 §60A-9-5 and §60A-9-7 of said code be amended and reenacted; that
26 said code be amended by adding thereto three new sections,

1 designated §60A-9-4a, §60A-9-5a and §60A-9-8; that §60A-10-3,
2 §60A-10-4, §60A-10-5, §60A-10-7, §60A-10-8 and §60A-10-11 of said
3 code be amended and reenacted; that said code be amended by adding
4 thereto a new section, designated §60A-10-16; and that §61-12-10 of
5 said code be amended and reenacted, all to read as follows:

6 **CHAPTER 16. PUBLIC HEALTH.**

7 **ARTICLE 1. STATE PUBLIC HEALTH SYSTEM.**

8 **§16-1-4. Proposal of rules by the secretary.**

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

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

19 (1) Land usage endangering the public health: *Provided*, That
20 no rules may be promulgated or enforced restricting the subdivision
21 or development of any parcel of land within which the individual
22 tracts, lots or parcels exceed two acres each in total surface area
23 and which individual tracts, lots or parcels have an average
24 frontage of not less than one hundred fifty feet even though the
25 total surface area of the tract, lot or parcel equals or exceeds

1 two acres in total surface area, and which tracts are sold, leased
2 or utilized only as single-family dwelling units. Notwithstanding
3 the provisions of this subsection, nothing in this section may be
4 construed to abate the authority of the department to:

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

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

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

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

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

1 this state, whether publicly or privately owned;

2 (4) Safe drinking water, including:

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

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

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

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

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

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

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

1 fees;

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

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

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

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

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

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

25 (E) All existing opioid treatment programs shall be subject to
26 monitoring by the secretary. All staff working or volunteering at

1 opioid treatment programs shall complete the minimum education,
2 reporting and safety training criteria established by the
3 secretary. All existing opioid treatment programs shall be in
4 compliance within one hundred eighty days of the effective date of
5 the revised emergency rules as required herein. The revised
6 emergency rules shall provide at a minimum:

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

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

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

1 (iv) That within thirty days after admission of a patient, the
2 opioid treatment program shall develop an individualized treatment
3 plan of care and attach the plan to the patient's chart no later
4 than five days after the plan is developed. The opioid treatment
5 program shall follow guidelines established by a nationally
6 recognized authority approved by the secretary and include a
7 recovery model in the individualized treatment plan of care. The
8 treatment plan is to reflect that detoxification is an option for
9 treatment and supported by the program; that under the
10 detoxification protocol the strength of maintenance doses of
11 methadone should decrease over time, the treatment should be
12 limited to a defined period of time, and participants are required
13 to work toward a drug-free lifestyle.

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

23 (A) Termination or disqualification;

24 (B) Completion of a program of detoxification;

25 (C) Voluntary withdrawal prior to completion of all
26 requirements of detoxification as determined by the opioid

1 treatment program;

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

4 (E) An unexplained reason.

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

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

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

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

21 (C) Benzodiazepine including diazepam, lorazepam, clonazepam
22 and alprazolam;

23 (D) Cocaine;

24 (E) Methamphetamine or amphetamine;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

26 (ix) That the opioid treatment program must report and provide

1 statistics to the Department of Health and Human Resources
2 demonstrating compliance with the random drug test rules,
3 including:

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

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

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

11 (D) The number of expulsions from the program.

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

20 (xi) That the Office of Health Facility Licensure and
21 Certification develop policies and procedures in conjunction with
22 the Board of Pharmacy that will allow physicians treating patients
23 through an opioid treatment program access to the Controlled
24 Substances Monitoring Program database maintained by the Board of
25 Pharmacy at the patient's intake, before administration of
26 methadone or other treatment in an opioid treatment program, after

1 the initial thirty days of treatment, prior to any take-home
2 medication being granted, after any positive drug test, and at each
3 ninety-day treatment review to ensure the patient is not seeking
4 prescription medication from multiple sources. The results
5 obtained from the Controlled Substances Monitoring Program database
6 shall be maintained with the patient records.

7 (xii) That each opioid treatment program shall establish a
8 peer review committee, with at least one physician member, to
9 review whether the program is following guidelines established by
10 a nationally recognized authority approved by the secretary. The
11 secretary shall prescribe the procedure for evaluation by the peer
12 review. Each opioid treatment program shall submit a report of the
13 peer review results to the secretary on a quarterly basis.

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

19 The rule shall include the following provisions:

20 Base allocation amount for each county;

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

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

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

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

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

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

19 **ARTICLE 5H. CHRONIC PAIN CLINIC LICENSING ACT.**

20 **§16-5H-1. Purpose and short title.**

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

1 Human Resources.

2 **§16-5H-2. Definitions.**

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

11 (b) "Director" means the Director of the Office of Health
12 Facility Licensure and Certification within the Office of the
13 Inspector General.

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

17 (d) "Pain management clinic" means all privately owned pain
18 management clinics, facilities or offices not otherwise exempted
19 from this article and which meets both of the following criteria:

20 (1) Where in any month more than fifty percent of patients of
21 the prescribers or dispensers are prescribed or dispensed opioids
22 or other controlled substances specified in rules promulgated
23 pursuant to this article for chronic pain resulting from non-
24 malignant conditions;

25 (2) The facility meets any other identifying criteria
26 established by the secretary by rule.

1 (e) "Physician" means an individual authorized to practice
2 medicine or surgery or osteopathic medicine or surgery in this
3 state.

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

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

15 **§16-5H-3. Pain management clinics to obtain license; application;**
16 **fees and inspections.**

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

22 (b) Any person, partnership, association or corporation
23 desiring a license to operate a pain management clinic in this
24 state shall file with the Office of Health Facility Licensure and
25 Certification an application in such form as the secretary shall
26 prescribe and furnish accompanied by a fee to be determined by the

1 secretary.

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

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

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

22 **§16-5H-4. Operational requirements.**

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

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

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

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

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

20 (B) Meet one of the following training requirements:

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

24 (ii) Hold current board certification by the American Board of
25 Pain Medicine or current board certification by the American Board
26 of Anesthesiology or such other board certification as may be

1 approved by the secretary.

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

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

6 (E) Supervise, control and direct the activities of each
7 individual working or operating at the facility, including any
8 employee, volunteer or individual under contract, who provides
9 treatment of chronic pain at the clinic or is associated with the
10 provision of that treatment. The supervision, control and
11 direction shall be provided in accordance with rules promulgated by
12 the secretary.

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

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

1 of this requirement. The facility shall complete a criminal
2 records check on any subsequent owner, physician, employee,
3 volunteer or associate of the clinic and submit the results to the
4 secretary for continued review.

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

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

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

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

18 (7) A person may not dispense any medication, including a
19 controlled substance, as defined by section one hundred one,
20 article one, chapter sixty-a of this code, on the premises of a
21 licensed pain management clinic unless he or she is a physician or
22 pharmacist licensed in this state. Prior to dispensing or
23 prescribing controlled substances, as defined by section one
24 hundred one, article one, chapter sixty-a of this code, at a pain
25 management clinic, the treating physician must access the
26 Controlled Substances Monitoring Program database maintained by the

1 Board of Pharmacy to ensure the patient is not seeking controlled
2 substances from multiple sources. If the patient receives ongoing
3 treatment, the physician shall also review the Controlled
4 Substances Monitoring Program database at each patient examination
5 or at least every ninety days. The results obtained from the
6 Controlled Substances Monitoring Program database shall be
7 maintained with the patient's medical records.

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

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

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

19 (A) When a physician diagnoses an individual as having chronic
20 pain, the physician may treat the pain by managing it with
21 medications in amounts or combinations that may not be appropriate
22 when treating other medical conditions. The physician's diagnosis
23 shall be made after having the individual evaluated by one or more
24 other physicians who specialize in the treatment of the area,
25 system or organ of the body perceived as the source of the pain
26 unless the individual has been previously diagnosed as suffering

1 from chronic pain and is referred to the pain management clinic by
2 such diagnosing physician. The physician's diagnosis and treatment
3 decisions shall be made according to accepted and prevailing
4 standards for medical care.

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

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

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

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

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

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

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

1 (D) A physician authorized to prescribe controlled substances
2 who practices at a pain management clinic is responsible for
3 maintaining the control and security of his or her prescription
4 blanks and any other method used for prescribing controlled
5 substance pain medication. The physician shall comply with all
6 state and federal requirements for tamper-resistant prescription
7 paper. In addition to any other requirements imposed by statute or
8 rule, the physician shall notify the secretary in writing within
9 twenty-four hours following any theft or loss of a prescription
10 blank or breach of any other method for prescribing pain
11 medication.

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

19 **§16-5H-5. Exemptions.**

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

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

1 instruction;

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

4 (3) A hospital licensed in this state, a facility located on
5 the campus of a licensed hospital that is owned, operated or
6 controlled by that licensed hospital, and an ambulatory health care
7 facility as defined by section two, article two-d, chapter sixteen
8 of this code that is owned, operated or controlled by a licensed
9 hospital;

10 (4) A physician practice owned or controlled, in whole or in
11 part, by a licensed hospital or by an entity that owns or controls,
12 in whole or in part, one or more licensed hospitals;

13 (5) A hospice program licensed in this state;

14 (6) A nursing home licensed in this state;

15 (7) An ambulatory surgical facility as defined by section two,
16 article two-d, chapter sixteen of this code; and

17 (8) A facility conducting clinical research that may use
18 controlled substances in studies approved by a hospital-based
19 institutional review board or an institutional review board
20 accredited by the association for the accreditation of human
21 research protection programs.

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

26 **§16-5H-6. Inspection.**

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

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

9 (c) Any action taken to correct a violation shall be
10 documented in writing by the designated physician or other owners
11 of the pain management clinic and verified by follow-up visits by
12 the Office of Health Facility Licensure and Certification.

13 **§16-5H-7. Suspension; revocation.**

14 (a) The secretary may suspend or revoke a license issued
15 pursuant to this article if the provisions of this article or of
16 the rules promulgated pursuant to this article are violated. The
17 secretary may revoke a clinic's license and prohibit all physicians
18 associated with that pain management clinic from practicing at the
19 clinic location based upon an annual or periodic inspection and
20 evaluation.

21 (b) Before any such license is suspended or revoked, however,
22 written notice shall be given the licensee, stating the grounds of
23 the complaint, and the date, time and place set for the hearing on
24 the complaint, which date shall not be less than thirty days from
25 the time notice is given. The notice shall be sent by certified
26 mail to the licensee at the address where the pain management

1 clinic concerned is located. The licensee shall be entitled to be
2 represented by legal counsel at the hearing.

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

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

14 (e) Any applicant or licensee who is dissatisfied with the
15 decision of the secretary as a result of the hearing provided in
16 this section may, within thirty days after receiving notice of the
17 decision, appeal the decision to the Circuit Court of Kanawha
18 County, in term or in vacation, for judicial review of the
19 decision.

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

24 (g) If the license of a pain management clinic is revoked or
25 suspended, the designated physician of the clinic, any other owner
26 of the clinic or the owner or lessor of the clinic property shall

1 cease to operate the facility as a pain management clinic as of the
2 effective date of the suspension or revocation. The owner or
3 lessor of the clinic property is responsible for removing all signs
4 and symbols identifying the premises as a pain management clinic
5 within thirty days.

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

13 (i) If the license of a pain management clinic is suspended or
14 revoked, any person named in the licensing documents of the clinic,
15 including persons owning or operating the pain management clinic,
16 may not, as an individual or as part of a group, apply to operate
17 another pain management clinic for five years after the date of
18 suspension or revocation.

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

22 **§16-5H-8. Violations; penalties; injunction.**

23 (a) Any person, partnership, association or corporation which
24 establishes, conducts, manages or operates a pain management clinic
25 without first obtaining a license therefor as herein provided, or
26 which violates any provisions of this article or any rule lawfully

1 promulgated pursuant to this article, shall be assessed a civil
2 penalty by the secretary in accordance with this subsection. Each
3 day of continuing violation after conviction shall be considered a
4 separate violation:

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

9 (2) If the clinic's designated physician knowingly and
10 intentionally misrepresents actions taken to correct a violation,
11 the secretary may impose a civil penalty not to exceed \$10,000,
12 and, in the case of an owner-operated pain management clinic,
13 revoke or deny a pain management clinic's license.

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

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

23 (5) If a physician knowingly operates, owns or manages an
24 unlicensed pain management clinic that is required to be licensed
25 pursuant to this article; knowingly prescribes or dispenses or
26 causes to be prescribed or dispensed, controlled substances in an

1 unlicensed pain management clinic that is required to be licensed;
2 or licenses a pain management clinic through misrepresentation or
3 fraud; procures or attempts to procure a license for a pain
4 management clinic for any other person by making or causing to be
5 made any false representation, the secretary may assess a civil
6 penalty of not more than \$20,000. The penalty may be in addition
7 to or in lieu of any other action that may be taken by the
8 secretary or any other board, court or entity.

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

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

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

26 (2) What actions, if any, the owner or designated physician

1 took to correct the violations;

2 (3) Whether there were any previous violations at the pain
3 management clinic; and

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

6 (d) Upon finding that a physician has violated the provisions
7 of this article or rules adopted pursuant to this article, the
8 secretary shall provide notice of the violation to the applicable
9 licensing board.

10 **§16-5H-9. Rules.**

11 (a) The Secretary of the Department of Health and Human
12 Resources, in collaboration with the West Virginia Board of
13 Medicine and the West Virginia Board of Osteopathy, shall
14 promulgate rules in accordance with the provisions of chapter
15 twenty-nine-a of this code for the licensure of pain management
16 clinics to ensure adequate care, treatment, health, safety, welfare
17 and comfort of patients at these facilities. These rules shall
18 include, at a minimum:

19 (1) The process to be followed by applicants seeking a
20 license;

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

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

1 (4) The management, operation, staffing and equipping of the
2 pain management clinic;

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

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

7 (7) The standards and procedures for the general operation of
8 a pain management clinic, including facility operations, physical
9 operations, infection control requirements, health and safety
10 requirements and quality assurance;

11 (8) Identification of drugs that may be used to treat chronic
12 pain that identify a facility as a pain management clinic,
13 including, at a minimum, tramadol and carisoprodol;

14 (9) Any other criteria that identify a facility as a pain
15 management clinic;

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

19 (11) Data collection and reporting requirements; and

20 (12) Such other standards or requirements as the secretary
21 determines are appropriate.

22 (b) The rules authorized by this section may be filed as
23 emergency rules if deemed necessary to promptly effectuate the
24 purposes of this article.

25 **§16-5H-10. Advertisement disclosure.**

26 Any advertisement made by or on behalf of a pain management

1 clinic through public media, such as a telephone directory, medical
2 directory, newspaper or other periodical, outdoor advertising,
3 radio or television, or through written or recorded communication,
4 concerning the treatment of chronic pain, as defined in section two
5 of this article, shall include the name of, at a minimum, one
6 physician owner responsible for the content of the advertisement.

7 **CHAPTER 30. PROFESSIONS AND OCCUPATIONS.**

8 **ARTICLE 1. GENERAL PROVISIONS APPLICABLE TO STATE BOARDS.**

9 **§30-1-7a. Continuing education.**

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

16 (b) Notwithstanding any other provision of this code or the
17 provision of any rule to the contrary, each person issued a license
18 to practice medicine and surgery or a license to practice podiatry
19 or licensed as a physician assistant by the West Virginia Board of
20 Medicine, each person issued a license to practice dentistry by the
21 West Virginia Board of Dental Examiners, each person issued a
22 license to practice optometry by the West Virginia Board of
23 Optometry, each person licensed as a pharmacist by the West
24 Virginia Board of Pharmacy, each person licensed to practice
25 registered professional nursing or licensed as an advanced nurse

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

13 (1) Notwithstanding any other provision of this code or the
14 provision of any rule to the contrary, the West Virginia Board of
15 Medicine, the West Virginia Board of Dental Examiners, the West
16 Virginia Board of Optometry, the West Virginia Board of Pharmacy,
17 the West Virginia Board of Examiners for Registered Professional
18 Nurses, the West Virginia State Board of Examiners for Licensed
19 Practical Nurses and the West Virginia Board of Osteopathy shall
20 establish continuing education requirements and criteria
21 appropriate to their respective discipline on the subject of drug
22 diversion training and best practice prescribing of controlled
23 substances training for each person issued a license or certificate
24 by their respective board who prescribes, administers or dispenses
25 a controlled substance, as that term is defined in section one
26 hundred one, article one, chapter sixty-a of this code, and shall

1 develop a certification form pursuant to subdivision (b) (2) of this
2 section.

3 (2) Each person who receives his or her initial license or
4 certificate from any of the boards set forth in subsection (b)
5 shall complete the continuing education requirements set forth in
6 subsection (b) within one year of receiving his or her initial
7 license from that board and each person licensed or certified by
8 any of the boards set forth in subsection (b) who has held his or
9 her license or certificate for longer than one year shall complete
10 the continuing education requirements set forth in subsection (b)
11 as a prerequisite to each license renewal: *Provided*, That a person
12 subject to subsection (b) may waive the continuing education
13 requirements for license renewal set forth in subsection (b) if he
14 or she completes and submits to his or her licensing board a
15 certification form developed by his or her licensing board
16 attesting that he or she has not prescribed, administered, or
17 dispensed a controlled substance, as that term is defined in
18 section one hundred one, article one, chapter sixty-a of this code,
19 during the entire applicable reporting period.

20 **ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS AND**
21 **PHARMACIES.**

22 **§30-5-3. When licensed pharmacist required; person not licensed**
23 **pharmacist, pharmacy technician or licensed intern not**
24 **to compound prescriptions or dispense poisons or**
25 **narcotics; licensure of interns; prohibiting the**

1 **dispensing of prescription orders in absence of**
2 **practitioner-patient relationship.**

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

7 (b) It is unlawful for the proprietor of any store or
8 pharmacy, any ambulatory health care facility, as that term is
9 defined in section one, article five-b, chapter sixteen of this
10 code, that offers pharmaceutical care, or a facility operated to
11 provide health care or mental health care services free of charge
12 or at a reduced rate and that operates a charitable clinic pharmacy
13 to permit any person not a pharmacist to compound or dispense
14 prescriptions or prescription refills or to retail or dispense the
15 poisons and narcotic drugs named in sections two, three and six,
16 article eight, chapter sixteen of this code: *Provided*, That a
17 licensed intern may compound and dispense prescriptions or
18 prescription refills under the direct supervision of a pharmacist:
19 *Provided, however*, That registered pharmacy technicians may assist
20 in the preparation and dispensing of prescriptions or prescription
21 refills, including, but not limited to, reconstitution of liquid
22 medications, typing and affixing labels under the direct
23 supervision of a licensed pharmacist.

24 (c) It is the duty of a pharmacist or employer who employs an
25 intern to license the intern with the board within ninety days

1 after employment. The board shall furnish proper forms for this
2 purpose and shall issue a certificate to the intern upon licensure.

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

13 (e) An intern having served part or all of his or her
14 internship in a pharmacy in another state or foreign country shall
15 be given credit for the same when the affidavit of his or her
16 internship is signed by the pharmacist under whom he or she served,
17 and it shows the dates and number of hours served in the internship
18 and when the affidavit is attested by the secretary of the State
19 Board of Pharmacy of the state or country where the internship was
20 served.

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

24 (g) No pharmacist may compound or dispense any prescription
25 order when he or she has knowledge that the prescription was issued
26 by a practitioner without establishing a valid practitioner-patient

1 relationship. An online or telephonic evaluation by questionnaire,
2 or an online or telephonic consultation, is inadequate to establish
3 a valid practitioner-patient relationship: *Provided*, That this
4 prohibition does not apply:

5 (1) In a documented emergency;

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

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

11 **CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.**

12 **ARTICLE 3. REGULATION OF MANUFACTURE, DISTRIBUTION AND DISPENSING**
13 **OF CONTROLLED SUBSTANCES.**

14 **§60A-3-308. Prescriptions.**

15 (a) Except when dispensed directly by a practitioner, other
16 than a pharmacy, to an ultimate user, no controlled substance in
17 Schedule II may be dispensed without the lawful prescription of a
18 practitioner.

19 (b) In emergency situations, as defined by rule of the said
20 appropriate department, board or agency, Schedule II drugs may be
21 dispensed upon oral prescription of a practitioner, reduced
22 promptly to writing and filed by the pharmacy. Prescription shall
23 be retained in conformity with the requirements of section three
24 hundred six of this article. No prescription for a Schedule II
25 substance may be refilled.

1 (c) Except when dispensed directly by a practitioner, other
2 than a pharmacy, to an ultimate user, a controlled substance
3 included in Schedule III or IV, which is a prescription drug as
4 determined under appropriate state or federal statute, shall not be
5 dispensed without a lawful prescription of a practitioner. The
6 prescription shall not be filled or refilled more than six months
7 after the date thereof or be refilled more than five times unless
8 renewed by the practitioner.

9 (d) (1) A controlled substance included in Schedule V shall
10 not be distributed or dispensed other than for a medicinal purpose:
11 *Provided*, That buprenorphine shall be dispensed only by
12 prescription pursuant to subsections (a), (b) and (c) of this
13 section: *Provided, however*, That the controlled substances included
14 in subsection (e), section two hundred twelve, article two of this
15 chapter shall be dispensed, sold or distributed only by a
16 physician, in a pharmacy by a pharmacist or pharmacy technician, or
17 health care professional.

18 (2) If the substance described in subsection (e), section two
19 hundred twelve, article two of this chapter is dispensed, sold or
20 distributed in a pharmacy:

21 (A) The substance shall be dispensed, sold or distributed only
22 by a pharmacist or a pharmacy technician; and

23 (B) Any person purchasing, receiving or otherwise acquiring
24 any such substance shall produce a photographic identification
25 issued by a state or federal governmental entity reflecting his or
26 her date of birth.

1 (e) Notwithstanding any provision of this code to the
2 contrary, on or after September 1, 2012, any practitioner or entity
3 prescribing or dispensing a combination of buprenorphine and
4 naloxone to treat opioid addiction shall only prescribe or dispense
5 said product in the form of sublingual film unless the sublingual
6 film is clinically contraindicated. If the prescriber or dispenser
7 determines that sublingual film is contraindicated he or she shall
8 document the reasons for not dispensing sublingual film in the
9 patient's file or chart.

10 **ARTICLE 9. CONTROLLED SUBSTANCES MONITORING.**

11 **§60A-9-3. Reporting system requirements; implementation; central**
12 **repository requirement.**

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

22 (b) The program authorized by subsection (a) of this section
23 shall be designed to minimize inconvenience to patients,
24 prescribing practitioners and pharmacists while effectuating the
25 collection and storage of the required information. The State

1 Board of Pharmacy shall allow reporting of the required information
2 by electronic data transfer where feasible, and where not feasible,
3 on reporting forms promulgated by the Board of Pharmacy. The
4 information required to be submitted by the provisions of this
5 article shall be required to be filed no more frequently than
6 within twenty-four hours.

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

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

18 **§60A-9-4. Required information.**

19 (a) Whenever a medical services provider dispenses a
20 controlled substance listed in Schedule II, III or IV, as
21 established under the provisions of article two of this chapter or
22 whenever a prescription for the controlled substance is filled by:
23 (i) A pharmacist or pharmacy in this state; (ii) a hospital, or
24 other health care facility, for out-patient use; or (iii) a
25 pharmacy or pharmacist licensed by the Board of Pharmacy, but
26 situated outside this state for delivery to a person residing in

1 this state, the medical services provider, health care facility,
2 pharmacist or pharmacy shall, in a manner prescribed by rules
3 promulgated by the Board of Pharmacy under this article, report the
4 following information, as applicable:

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

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

10 (3) The name, address and Drug Enforcement Administration
11 controlled substances registration number of the practitioner
12 writing the prescription;

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

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

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

18 (7) The number of refills, if any, authorized by the
19 prescription; (8) If the prescription being dispensed is being
20 picked up by someone other than the patient on behalf of the
21 patient, the full legal name, address and birth date of the person
22 picking up the prescription as set forth on the person's
23 government-issued photo identification card shall be retained in
24 either print or electronic form until such time as otherwise
25 directed by rule promulgated by the board of pharmacy; and

26 (9) The source of payment for the controlled substance

1 dispensed.

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

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

10 (d) Reporting required by this section is not required for a
11 drug administered directly to a patient by a practitioner.
12 Reporting is, however, required by this section for a drug
13 dispensed to a patient by a practitioner: *Provided*, That the
14 quantity dispensed may not exceed an amount adequate to treat the
15 patient for a maximum of seventy-two hours with no greater than two
16 seventy-two-hour cycles dispensed in any fifteen-day period of
17 time.

18 **§60A-9-4a. Verification of identity.**

19 Prior to releasing a Schedule II, III or IV controlled
20 substance sold at retail, a pharmacist or pharmacy shall verify the
21 full legal name, address and birth date of the person receiving or
22 otherwise acquiring the controlled substance by requiring the
23 presentation of a valid government-issued photo identification
24 card. This information shall be reported in accordance with the
25 provisions of this article information shall be retained in either
26 print or electronic form until such time as otherwise directed by

1 rule promulgated by the board of pharmacy.

2 **§60A-9-5. Confidentiality; limited access to records; period of**
3 **retention; no civil liability for required reporting.**

4 (a) (1) The information required by this article to be kept by
5 the State Board of Pharmacy is confidential and not subject to the
6 provisions of chapter twenty-nine-b of this code or obtainable as
7 discovery in civil matters absent a court order and is open to
8 inspection only by inspectors and agents of the State Board of
9 Pharmacy, members of the West Virginia State Police expressly
10 authorized by the Superintendent of the West Virginia State Police
11 to have access to the information, authorized agents of local
12 law-enforcement agencies as members of a federally affiliated drug
13 task force, authorized agents of the federal Drug Enforcement
14 Administration, duly authorized agents of the Bureau for Medical
15 Services, duly authorized agents of the Office of the Chief Medical
16 Examiner for use in post-mortem examinations, duly authorized
17 agents of licensing boards of practitioners in this state and other
18 states authorized to prescribe Schedules II, III and IV controlled
19 substances, prescribing practitioners and pharmacists and persons
20 with an enforceable court order or regulatory agency administrative
21 subpoena: *Provided*, That all law-enforcement personnel who have
22 access to the Controlled Substances Monitoring Program database
23 shall be granted access in accordance with applicable state laws
24 and Board of Pharmacy legislative rules, shall be certified as a
25 West Virginia law-enforcement officer and shall have successfully
26 completed United States Drug Enforcement Administration Diversion

1 Training and National Association of Drug Diversion Investigation
2 Training. All information released by the State Board of Pharmacy
3 must be related to a specific patient or a specific individual or
4 entity under investigation by any of the above parties except that
5 practitioners who prescribe or dispense controlled substances may
6 request specific data related to their Drug Enforcement
7 Administration controlled substance registration number or for the
8 purpose of providing treatment to a patient: *Provided, however,*
9 That the West Virginia Controlled Substances Monitoring Program
10 Database Review Committee established in subsection (b) of this
11 section is authorized to query the database to comply with said
12 subsection.

13 (2) Subject to the provisions of subdivision (1) of this
14 subsection, the board shall also review the West Virginia
15 Controlled Substance Monitoring Program database and issue reports
16 that identify abnormal or unusual practices of patients who exceed
17 parameters as determined by the advisory committee established in
18 this section. The board shall communicate with prescribers and
19 dispensers to more effectively manage the medications of their
20 patients in the manner recommended by the advisory committee. All
21 other reports produced by the board shall be kept confidential.
22 The board shall maintain the information required by this article
23 for a period of not less than five years. Notwithstanding any
24 other provisions of this code to the contrary, data obtained under
25 the provisions of this article may be used for compilation of
26 educational, scholarly or statistical purposes, and may be shared

1 with the West Virginia Department of Health and Human Resources for
2 those purposes, as long as the identities of persons or entities
3 and any personally identifiable information, including protected
4 health information, contained therein shall be redacted, scrubbed
5 or otherwise irreversibly destroyed in a manner that will preserve
6 the confidential nature of the information. No individual or
7 entity required to report under section four of this article may be
8 subject to a claim for civil damages or other civil relief for the
9 reporting of information to the Board of Pharmacy as required under
10 and in accordance with the provisions of this article.

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

15 (A) Consist of the following members: A physician licensed by
16 the West Virginia Board of Medicine, a dentist licensed by the West
17 Virginia Board of Dental Examiners, a physician licensed by the
18 West Virginia Board of Osteopathy, a licensed physician certified
19 by the American Board of Pain Medicine, a licensed physician board
20 certified in medical oncology recommended by the West Virginia
21 State Medical Association, a licensed physician board certified in
22 palliative care recommended by the West Virginia Center on End of
23 Life Care, a pharmacist licensed by the West Virginia Board of
24 Pharmacy, a licensed physician member of the West Virginia Academy
25 of Family Physicians, an expert in drug diversion and such other
26 members as determined by the board.

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

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

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

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

20 (b) The Board of Pharmacy shall create a West Virginia
21 Controlled Substances Monitoring Program Database Review Committee
22 of individuals consisting of two prosecuting attorneys from West
23 Virginia counties, two physicians with specialties which require
24 extensive use of controlled substances and a pharmacist who is
25 trained in the use and abuse of controlled substances. The review
26 committee may determine that an additional physician who is an

1 expert in the field under investigation be added to the team when
2 the facts of a case indicate that the additional expertise is
3 required. The review committee, working independently, may query
4 the database based on parameters established by the advisory
5 committee. The review committee may make determinations on a
6 case-by-case basis on specific unusual prescribing or dispensing
7 patterns indicated by outliers in the system or abnormal or unusual
8 usage patterns of controlled substances by patients which the
9 review committee has reasonable cause to believe necessitates
10 further action by law enforcement or the licensing board having
11 jurisdiction over the prescribers or dispensers under
12 consideration. The review committee shall also review notices
13 provided by the chief medical examiner pursuant to subsection (h),
14 section ten, article twelve, chapter sixty-one of this code and
15 determine on a case-by-case basis whether a practitioner who
16 prescribed or dispensed a controlled substance resulting in or
17 contributing to the drug overdose may have breached professional or
18 occupational standards or committed a criminal act when prescribing
19 the controlled substance at issue to the decedent. Only in those
20 cases in which there is reasonable cause to believe a breach of
21 professional or occupational standards or a criminal act may have
22 occurred, the review committee shall notify the appropriate
23 professional licensing agency having jurisdiction over the
24 applicable prescriber or dispenser and appropriate law-enforcement
25 agencies and provide pertinent information from the database for
26 their consideration. The number of cases identified shall be

1 determined by the review committee based on a number that can be
2 adequately reviewed by the review committee. The information
3 obtained and developed may not be shared except as provided in this
4 article and is not subject to the provisions of chapter twenty-
5 nine-b of this code or obtainable as discovering in civil matters
6 absent a court order.

7 (c) The Board of Pharmacy is responsible for establishing and
8 providing administrative support for the advisory committee and the
9 West Virginia Controlled Substances Monitoring Program Database
10 Review Committee. The advisory committee and the review committee
11 shall elect a chair by majority vote. Members of the advisory
12 committee and the review committee may not be compensated in their
13 capacity as members but shall be reimbursed for reasonable expenses
14 incurred in the performance of their duties.

15 (d) The board shall promulgate rules with advice and consent
16 of the advisory committee, in accordance with the provisions of
17 article three, chapter twenty-nine-a of this code on or before June
18 1, 2013. The legislative rules must include, but shall not be
19 limited to, the following matters: (1) Identifying parameters used
20 in identifying abnormal or unusual prescribing or dispensing
21 patterns; (2) processing parameters and developing reports of
22 abnormal or unusual prescribing or dispensing patterns for
23 patients, practitioners and dispensers; (3) establishing the
24 information to be contained in reports and the process by which the
25 reports will be generated and disseminated; and (4) setting up
26 processes and procedures to ensure that the privacy,

1 confidentiality, and security of information collected, recorded,
2 transmitted and maintained by the review committee is not disclosed
3 except as provided in this section.

4 (e) All practitioners, as that term is defined in section one
5 hundred-one, article two of this chapter who prescribe or dispense
6 schedule II, III or IV controlled substances shall, on or before
7 July 1, 2011, have online or other form of electronic access to the
8 West Virginia Controlled Substances Monitoring Program database;

9 (f) Persons or entities with access to the West Virginia
10 Controlled Substances Monitoring Program database pursuant to this
11 section may, pursuant to rules promulgated by the Board of
12 Pharmacy, delegate appropriate personnel to have access to said
13 database;

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

21 (h) A prescribing or dispensing practitioner may notify law
22 enforcement of a patient who, in the prescribing or dispensing
23 practitioner's judgment, may be in violation of section four
24 hundred ten, article four of this chapter, based on information
25 obtained and reviewed from the controlled substances monitoring
26 database. A prescribing or dispensing practitioner who makes a

1 notification pursuant to this subsection is immune from any civil,
2 administrative or criminal liability that otherwise might be
3 incurred or imposed because of the notification if the notification
4 is made in good faith.

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

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

14 **§60A-9-5a. Practitioner requirements to conduct annual search of**
15 **the database; required rulemaking.**

16 (a) Upon initially prescribing or dispensing any
17 pain-relieving controlled substance for a patient and at least
18 annually thereafter should the prescriber or dispenser continue to
19 treat the patient with controlled substances, all persons with
20 prescriptive or dispensing authority and in possession of a valid
21 Drug Enforcement Administration registration identification number
22 and, who are licensed by the Board of Medicine as set forth in
23 article three, chapter thirty of this code, the Board of Registered
24 Professional Nurses as set forth in article seven, chapter thirty
25 of this code, the Board of Dental Examiners as set forth in article
26 four, chapter thirty of this code and the Board of Osteopathy as

1 set forth in article fourteen, chapter thirty of this code shall
2 access the West Virginia Controlled Substances Monitoring Program
3 database for information regarding specific patients for whom they
4 are providing pain-relieving controlled substances as part of a
5 course of treatment for chronic, nonmalignant pain but who are not
6 suffering from a terminal illness. The information obtained from
7 accessing the West Virginia Controlled Substances Monitoring
8 Program database for the patient shall be documented in the
9 patient's medical record. A pain-relieving controlled substance
10 shall be defined as set forth in section one, article three-a,
11 chapter thirty of this code.

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

16 **§60A-9-7. Criminal penalties.**

17 (a) Any person who is required to submit information to the
18 state Board of Pharmacy pursuant to the provisions of this article
19 who fails to do so as directed by the board is guilty of a
20 misdemeanor and, upon conviction thereof, shall be fined not less
21 than \$100 nor more than \$500.

22 (b) Any person who is required to submit information to the
23 state Board of Pharmacy pursuant to the provisions of this article
24 who knowingly and willfully refuses to submit the information
25 required by this article is guilty of a misdemeanor and, upon
26 conviction thereof, shall be confined in a county or regional jail

1 not more than six months or fined not more than \$1,000, or both
2 confined or fined.

3 (c) Any person who is required by the provisions of this
4 article to submit information to the state Board of Pharmacy who
5 knowingly submits thereto information known to that person to be
6 false or fraudulent is guilty of a misdemeanor and, upon conviction
7 thereof, shall be confined in a county or regional jail not more
8 than one year or fined not more than \$5,000, or both confined or
9 fined.

10 (d) Any prescriber or dispenser who is required to access the
11 information contained in the West Virginia Controlled Substances
12 Monitoring Program database as set forth in subsection (a) of
13 section five-a of this article and fails to do so as directed by
14 the rules of their licensing board shall be subject to such
15 discipline as the licensing board deems appropriate.

16 (e) Any person granted access to the information required by
17 the provisions of this article to be maintained by the state Board
18 of Pharmacy, who shall willfully disclose the information required
19 to be maintained by this article in a manner inconsistent with a
20 legitimate law-enforcement purpose, a legitimate professional
21 regulatory purpose, the terms of a court order or as otherwise
22 expressly authorized by the provisions of this article is guilty of
23 a misdemeanor and, upon conviction thereof, shall be confined in a
24 county or regional jail for not more than six months or fined not
25 more than \$1,000, or both confined or fined.

26 (f) Unauthorized access or use or unauthorized disclosure for

1 reasons unrelated to the purposes of this article of the
2 information in the database is a felony punishable by imprisonment
3 in a state correctional facility for not less than one year nor
4 more than five years or fined not less than \$3,000 nor more than
5 \$10,000, or both imprisoned or fined.

6 **§60A-9-8. Creation of Fight Substance Abuse Fund.**

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

17 **ARTICLE 10. METHAMPHETAMINE LABORATORY ERADICATION ACT.**

18 **§60A-10-3. Definitions.**

19 In this article:

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

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

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

5 (d) "Drug product" means a pharmaceutical product that
6 contains ephedrine, pseudoephedrine or phenylpropanolamine or a
7 substance identified on the supplemental list provided in section
8 seven of this article which may be sold without a prescription and
9 which is labeled for use by a consumer in accordance with the
10 requirements of the laws and rules of this state and the federal
11 government.

12 (e) "Ephedrine " means ephedrine, its salts or optical isomers
13 or salts of optical isomers.

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

19 (g) "National Association of Drug Diversion Investigators" or
20 "NADDI" means the non-profit 501(c)(3) organization established in
21 1989, made up of members who are responsible for investigating and
22 prosecuting pharmaceutical drug diversion, and that facilitates
23 cooperation between law enforcement, health care professionals,
24 state regulatory agencies and pharmaceutical manufacturers in the
25 investigation and prevention of prescription drug abuse and
26 diversion.

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

8 (i) "Phenylpropanolamine" means phenylpropanolamine, its
9 salts, optical isomers and salts of optical isomers.

10 (j) "Pseudoephedrine" means pseudoephedrine, its salts,
11 optical isomers and salts of optical isomers.

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

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

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

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

1 (o) "Pharmacy counter" means an area in the pharmacy
2 restricted to the public where controlled substances are stored and
3 housed and where controlled substances may only be sold,
4 transferred or dispensed by a pharmacist, pharmacy intern or
5 pharmacy technician.

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

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

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

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

17 (t) "Wholesaler" means any person within this state or another
18 state, other than a manufacturer, who sells, transfers or in any
19 manner furnishes a drug product to any other person in this state
20 for the purpose of being resold.

21 **§60A-10-4. Purchase, receipt, acquisition and possession of**
22 **substances to be used as precursor to manufacture**
23 **of methamphetamine or another controlled**
24 **substance; offenses; exceptions; penalties.**

25 (a) A pharmacy may not sell, transfer or dispense to the same

1 person, and a person may not purchase more than three and six-
2 tenths grams per day, more than seven and two-tenths grams in a
3 thirty-day period or more than forty-eight grams annually of
4 ephedrine, pseudoephedrine or phenylpropanolamine without a
5 prescription. The limits shall apply to the total amount of
6 ephedrine, pseudoephedrine and phenylpropanolamine contained in the
7 products, and not the overall weight of the products.

8 (1) Any person who or knowingly purchases, receives or
9 otherwise possesses more than seven and two-tenths grams in a
10 thirty-day period of ephedrine, pseudoephedrine or
11 phenylpropanolamine in any form without a prescription is guilty of
12 a misdemeanor and, upon conviction, shall be confined in a jail for
13 not more than one year, fined not more than \$1,000, or both fined
14 and confined.

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

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

1 both imprisoned and fined.

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

4 (1) Products dispensed pursuant to a valid prescription;

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

7 (3) Drug products containing ephedrine, pseudoephedrine or
8 phenylpropanolamine, their salts or optical isomers or salts of
9 optical isomers or other designated precursor which have been
10 determined by the Board of Pharmacy to be in a form which is not
11 feasible for being used for the manufacture of methamphetamine; or

12 (4) Persons lawfully possessing drug products in their
13 capacities as distributors, wholesalers, manufacturers,
14 pharmacists, pharmacy interns, pharmacy technicians, or health care
15 professionals.

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

1 years, fined not more than \$25,000, or both imprisoned and fined.

2 (e) (1) Any pharmacy, wholesaler, manufacturer or distributor
3 of drug products containing ephedrine, pseudoephedrine,
4 phenylpropanolamine, their salts or optical isomers or salts of
5 optical isomers or other designated precursor shall obtain a
6 registration annually from the State Board of Pharmacy as described
7 in section six of this article. Any such pharmacy, wholesaler,
8 manufacturer or distributor shall keep complete records of all
9 sales and transactions as provided in section eight of this
10 article. The records shall be gathered and maintained pursuant to
11 legislative rule promulgated by the Board of Pharmacy.

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

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

18 **§60A-10-5. Restrictions on the sale, transfer or delivery of**
19 **certain drug products; penalties.**

20 (a) No pharmacy or individual may display, offer for sale or
21 place a drug product containing ephedrine, pseudoephedrine or
22 phenylpropanolamine or other designated precursor where the public
23 may freely access the drug product. All such drug products or
24 designated precursors shall be placed behind a pharmacy counter
25 where access is restricted to a pharmacist, a pharmacy intern, a
26 pharmacy technician or other pharmacy employee.

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

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

9 (d) If a drug product regulated by the provisions of this
10 section is transferred, sold or delivered, the individual, pharmacy
11 or retail establishment transferring, selling or delivering the
12 drug product shall offer to have a pharmacist provide patient
13 counseling, as defined by section one-b, article five, chapter
14 thirty of this code and the rules of the Board of Pharmacy, to the
15 person purchasing, receiving or acquiring the drug product in order
16 to improve the proper use of the drug product and to discuss
17 contraindications.

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

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

25 (2) Sign a logbook, in either paper or electronic format,
26 containing the information set forth in subsection (b), section

1 eight of this article and attesting to the validity of the
2 information.

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

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

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

1 wantonness, recklessness or deliberate misconduct, any retailer
2 utilizing the Multi-State Real-Time Tracking System in accordance
3 with this subdivision may not be civilly liable as a result of any
4 act or omission in carrying out the duties required by this
5 subdivision and is immune from liability to any third party unless
6 the retailer has violated any provision of this subdivision in
7 relation to a claim brought for the violation.

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

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

21 (i) Any violation of this section is a misdemeanor, punishable
22 upon conviction by a fine in an amount not more than \$10,000.

23 (j) The provisions of this section supersede and preempt all
24 local laws, ordinances, rules and regulations pertaining to the
25 sale of any compounds, mixtures or preparation containing
26 ephedrine, pseudoephedrine or phenylpropanolamine.

1 **§60A-10-7. Restricted products; rule-making authority.**

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

16 (1) A process whereby pharmacies are made aware of all drug
17 products that contain ephedrine, pseudoephedrine and
18 phenylpropanolamine that will be listed as a Schedule V substance
19 and must be sold, transferred or dispensed from behind a pharmacy
20 counter;

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

25 (b) At any time after July 1, 2005, the Board of Pharmacy,
26 upon the recommendation of the Superintendent of the State Police,

1 shall promulgate emergency and legislative rules pursuant to the
2 provision of article three, chapter twenty-nine-a of this code to
3 implement an updated supplemental list of products containing the
4 controlled substances ephedrine, pseudoephedrine or
5 phenylpropanolamine as an active ingredient or any other drug used
6 as a precursor in the manufacture of methamphetamine, which the
7 Superintendent of the State Police has demonstrated by empirical
8 evidence is being used in the manufacture of methamphetamine. This
9 listing process shall comport with the requirements of subsection
10 (a) of this section.

11 **§60A-10-8. Reporting requirements; confidentiality.**

12 (a) Until January 1, 2013, upon each sale, retail, transfer or
13 distribution of any drug product referred to in section seven of
14 this article or another designated precursor, the pharmacist,
15 pharmacy intern, or pharmacy technician making the sale, transfer
16 or distribution shall report the following information for
17 inclusion in the central repository established and maintained by
18 the Board of Pharmacy:

19 (1) The date of the transaction;

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

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

24 (b) The information required to be reported by this section
25 shall be reported by paper log maintained at the point of sale:

26 Provided, That, beginning on January 1, 2007, reporting shall be by

1 electronic transmission to the Board of Pharmacy no more frequently
2 than once a week. Beginning on January 1, 2013, the electronic
3 transmission of the information required to be reported in
4 subsection (a) of this section shall be reported to the MSRTTS, and
5 shall be made in real time at the time of the transaction.

6 (c) The information required by this section shall be the
7 property of the state. The information shall be disclosed as
8 appropriate to the federal Drug Enforcement Administration and to
9 state and local law-enforcement agencies. The information shall
10 not be accessed, used or shared for any purpose other than to
11 ensure compliance with this article and federal law. NADDI shall
12 forward state transaction records in the MSRTTS to the West
13 Virginia State Police weekly, and provide real-time access to
14 MSRTTS information through the MSRTTS online portal to authorized
15 agents of the federal Drug Enforcement Administration and certified
16 law enforcement in this and other states for use in the detection
17 of violations of this article or of federal laws designed to
18 prevent the illegal use, production or distribution of
19 methamphetamine.

20 **§60A-10-11. Reporting to the Legislative Oversight Commission on**
21 **Health and Human Resources Accountability.**

22 Beginning July 1, 2013, the Superintendent of the West
23 Virginia State Police shall submit an annual report no later than
24 July 1 of each year to the Legislative Oversight Commission on
25 Health and Human Resources Accountability with data and statistics
26 related to methamphetamine use, production and distribution in this

1 state including, but not limited to, the number of clandestine
2 methamphetamine lab incidents per year.

3 **§60A-10-16. Expiration of enactments made during two thousand**
4 **eleven regular session.**

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

8 **CHAPTER 61. CRIMES AND OTHER PUNISHMENT.**

9 **ARTICLE 12. POSTMORTEM EXAMINATIONS.**

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

13 (a) If in the opinion of the chief medical examiner, or of the
14 county medical examiner of the county in which the death in
15 question occurred, it is advisable and in the public interest that
16 an autopsy be made, or if an autopsy is requested by either the
17 prosecuting attorney or the judge of the circuit court or other
18 court of record having criminal jurisdiction in that county, an
19 autopsy shall be conducted by the chief medical examiner or his or
20 her designee, by a member of his or her staff, or by a competent
21 pathologist designated and employed by the chief medical examiner
22 under the provisions of this article. For this purpose, the chief
23 medical examiner may employ any county medical examiner who is a
24 pathologist who holds board certification or board eligibility in
25 forensic pathology or has completed an American Board of Pathology

1 fellowship in forensic pathology to make the autopsies, and the
2 fees to be paid for autopsies under this section shall be in
3 addition to the fee provided for investigations pursuant to section
4 eight of this article. A full record and report of the findings
5 developed by the autopsy shall be filed with the office of the
6 chief medical examiner by the person making the autopsy.

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

13 (c) The office of the chief medical examiner shall keep full,
14 complete and properly indexed records of all deaths investigated,
15 containing all relevant information concerning the death and the
16 autopsy report if an autopsy report is made. Any prosecuting
17 attorney or law-enforcement officer may secure copies of these
18 records or information necessary for the performance of his or her
19 official duties.

20 (d) Copies of these records or information shall be furnished,
21 upon request, to any court of law, or to the parties therein to
22 whom the cause of death is a material issue, except where the court
23 determines that interests in a civil matter conflict with the
24 interests in a criminal proceeding, in which case the interests in
25 the criminal proceeding shall take precedence. The office of chief
26 medical examiner shall be reimbursed a reasonable rate by the

1 requesting party for costs incurred in the production of records
2 under this subsection and subsection (c) of this section.

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

11 (f) Any person performing an autopsy under this section is
12 empowered to keep and retain, for and on behalf of the chief
13 medical examiner, any tissue from the body upon which the autopsy
14 was performed which may be necessary for further study or
15 consideration.

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

25 (h) If the chief medical officer determines that a drug
26 overdose is the cause of death of a person, the chief medical

1 examiner shall provide notice of the death to the West Virginia
2 Controlled Substances Monitoring Program Database Review Committee
3 established pursuant to subsection (b), section five, article nine,
4 chapter sixty-a of this code and shall include in the notice any
5 information relating to the cause of the fatal overdose.