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2012 MAR 29 PM 3:35

WEST VIRGINIA LEGISLATURE
EIGHTIETH LEGISLATURE
REGULAR SESSION, 2012

WEST VIRGINIA
SECRETARY OF STATE

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ENROLLED

COMMITTEE SUBSTITUTE

FOR

Senate Bill No. 437

(BY SENATORS KESSLER (MR. PRESIDENT) AND HALL,
BY REQUEST OF THE EXECUTIVE)

[PASSED MARCH 10, 2012; IN EFFECT NINETY DAYS FROM PASSAGE.]

SB 437

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(BY SENATORS KESSLER (MR. PRESIDENT) AND HALL,
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[Passed March 10, 2012; in effect ninety days from passage.]

AN ACT to amend and reenact §16-1-4 of the Code of West Virginia, 1931, as amended; to amend said code by adding thereto a new article, designated §16-5H-1, §16-5H-2, §16-5H-3, §16-5H-4, §16-5H-5, §16-5H-6, §16-5H-7, §16-5H-8, §16-5H-9 and §16-5H-10; to amend and reenact §30-1-7a of said code; to amend and reenact §30-5-3 of said code; to amend and reenact §60A-3-308 of said code; to amend and reenact §60A-9-3, §60A-9-4, §60A-9-5 and §60A-9-7 of said code; to amend said code by adding thereto three new sections, designated §60A-9-4a, §60A-9-5a and §60A-9-8; to amend and reenact §60A-10-3, §60A-10-4, §60A-10-5, §60A-10-7, §60A-10-8 and §60A-10-11 of said code; to amend said code by adding thereto a new section, designated §60A-10-16; and to amend and reenact §61-12-10 of said code, all relating to substance abuse generally; addressing the regulation of opioid treatment programs in this state; updating rules for opioid treatment program facilities to require clinical guidelines, recovery models, education and training requirements for treatment facility staff and treatment limitations and require-

ments; addressing the licensing and oversight of chronic pain management clinics; creating the Chronic Pain Clinic Licensing Act; providing definitions; establishing requirements for ownership, licensure, operation and management of pain management clinics; establishing limitations on the dispensing of controlled substances at a pain management clinic; requiring annual inspections of pain management clinics; setting forth exemptions from the act; providing for suspension or revocation of a pain management clinic license and setting forth due process requirements; providing for prohibitions on practicing at or operating a pain management clinic under certain circumstances; providing civil penalties regarding pain management clinics; providing for notice requirements to applicable licensing boards; requiring rules for the licensure of pain management clinics; removing requirement of certain licensed or certified health care professionals to complete continuing education course work on the subject of end-of-life care; requiring certain licensed or certified health care professionals to complete drug diversion training and best practice prescribing of controlled substances training; requiring certain licensing boards to establish drug diversion training and best practice prescribing of controlled substances training; requiring a valid practitioner-patient relationship to exist prior to compounding or dispensing prescriptions; requiring that buprenorphine combined with naloxone prescribed or dispensed for treatment for opioid addiction be in the form of sublingual film unless medically contraindicated as of September 1, 2012; clarifying certain circumstances that do not establish a valid practitioner-patient relationship; requiring certain persons to submit information to the Controlled Substances Monitoring Program database within twenty-four hours; requiring additional information to be submitted to the Controlled Substances Monitoring Program database; clarifying that reporting is required for certain amounts of drugs dispensed to patients; requiring verification of certain information reported to the Controlled Substances Monitoring Program database; providing certain requirements and training for law-enforcement officials in order to access the Controlled Substances Monitoring Program database; permitting the Controlled Substances Monitoring Program Database

Review Committee to query the Controlled Substances Monitoring Program database; requiring the Board of Pharmacy to review the Controlled Substances Monitoring Program database in order to issue certain reports; permitting the Board of Pharmacy to share certain information contained in the Controlled Substances Monitoring Program database with the Department of Health and Human Resources; requiring the Board of Pharmacy to establish an advisory committee; setting forth the membership of the advisory committee; outlining the advisory committee's scope and duties; requiring the Board of Pharmacy to create a Controlled Substances Monitoring Program Database Review Committee; setting forth the membership of the review committee; outlining the review committee's scope, powers and duties; requiring the Board of Pharmacy to promulgate certain legislative rules; permitting prescribing practitioners to notify law enforcement of certain violations with immunity; requiring the Board of Pharmacy to provide annual reports to the Legislature; requiring various boards that regulate professions with prescriptive authority to require persons licensed by the board to conduct an initial search of the Controlled Substances Monitoring Program database when prescribing a course of treatment that includes prescribing of pain-relieving controlled substances and an annual search of the Controlled Substances Monitoring Program database for certain patients; setting forth penalties for failing to search the Controlled Substances Monitoring Program database in certain circumstances; establishing a felony offense and penalties for unauthorized access, use or disclosure of information contained in the Controlled Substances Monitoring Program database; creating Fight Substance Abuse Fund and setting forth permissible uses for fund; defining terms and updating definitions in the Methamphetamine Laboratory Eradication Act; establishing reduced daily, monthly and annual amount restrictions on the sale, transfer, dispensing or possession of ephedrine, pseudoephedrine and phenylpropanolamine by pharmacies; establishing criminal penalties for purchasing, receiving or possessing certain quantities of ephedrine, pseudoephedrine and phenylpropanolamine; establishing criminal penalties for pharmacies, wholesalers or other entities which sell, transfer or dispense a

product under certain circumstances; amending the restrictions on the sale, transfer or delivery of certain designated precursors to the manufacture of methamphetamine or other controlled substances; requiring offer of patient counseling by a pharmacist upon the sale, transfer or delivery of certain designated precursors to the manufacture of methamphetamine or other controlled substances; requiring certain processing requirements of pharmacists, pharmacy intern and pharmacy technicians; establishing use and requirements of the Multi-State Real-Time Tracking System; requiring pharmacies and retail establishments to electronically submit certain information to the Multi-State Real-Time Tracking System; requiring pharmacies and retail establishments to stop pending sales under certain circumstances; limiting liability of retailers utilizing the Multi-State Real-Time Tracking System under certain circumstances; requiring pharmacies or retail establishments to maintain written logs or electronic record-keeping databases under certain circumstances; providing supersession and preemption of all local laws, ordinances and regulations pertaining to the sale of certain substances; amending reporting requirements and requiring real-time electronic reporting of certain information; providing for law enforcement access to information pertaining to the sale of certain substances; establishing an expiration date for Multi-State Real-Time Tracking System; requiring the National Association of Drug Diversion Investigators to forward certain records to the West Virginia State Police and provide real-time access to the Multi-State Real-Time Tracking System to law enforcement; requiring the West Virginia State Police to submit an annual report with data and statistics on methamphetamine use, production and distribution; and requiring the chief medical officer to provide notice to the Controlled Substances Monitoring Program Database Review Committee in the case of a death caused by overdose.

Be it enacted by the Legislature of West Virginia:

That §16-1-4 of the Code of West Virginia, 1931, as amended, be amended and reenacted; that said code be amended by adding thereto a new article, designated §16-5H-1, §16-5H-2, §16-5H-3,

§16-5H-4, §16-5H-5, §16-5H-6, §16-5H-7, §16-5H-8, §16-5H-9 and §16-5H-10; that §30-1-7a of said code be amended and reenacted; that §30-5-3 of said code be amended and reenacted; that §60A-3-308 of said code be amended and reenacted; that §60A-9-3, §60A-9-4, §60A-9-5 and §60A-9-7 of said code be amended and reenacted; that said code be amended by adding thereto three new sections, designated §60A-9-4a, §60A-9-5a and §60A-9-8; that §60A-10-3, §60A-10-4, §60A-10-5, §60A-10-7, §60A-10-8 and §60A-10-11 of said code be amended and reenacted; that said code be amended by adding thereto a new section, designated 60A-10-16; and that §61-12-10 of said code be amended and reenacted, all to read as follows:

CHAPTER 16. PUBLIC HEALTH.

ARTICLE 1. STATE PUBLIC HEALTH SYSTEM.

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

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

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

12 (1) Land usage endangering the public health: *Provided*,
 13 That no rules may be promulgated or enforced restricting the
 14 subdivision or development of any parcel of land within
 15 which the individual tracts, lots or parcels exceed two acres
 16 each in total surface area and which individual tracts, lots or
 17 parcels have an average frontage of not less than one
 18 hundred fifty feet even though the total surface area of the
 19 tract, lot or parcel equals or exceeds two acres in total
 20 surface area, and which tracts are sold, leased or utilized
 21 only as single-family dwelling units. Notwithstanding the

22 provisions of this subsection, nothing in this section may be
23 construed to abate the authority of the department to:

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

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

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

33 (2) The sanitary condition of all institutions and schools,
34 whether public or private, public conveyances, dairies,
35 slaughterhouses, workshops, factories, labor camps, all other
36 places open to the general public and inviting public patron-
37 age or public assembly, or tendering to the public any item
38 for human consumption and places where trades or indus-
39 tries are conducted;

40 (3) Occupational and industrial health hazards, the
41 sanitary conditions of streams, sources of water supply,
42 sewerage facilities and plumbing systems and the qualifica-
43 tions of personnel connected with any of those facilities,
44 without regard to whether the supplies or systems are
45 publicly or privately owned; and the design of all water
46 systems, plumbing systems, sewerage systems, sewage
47 treatment plants, excreta disposal methods and swimming
48 pools in this state, whether publicly or privately owned;

49 (4) Safe drinking water, including:

50 (A) The maximum contaminant levels to which all public
51 water systems must conform in order to prevent adverse
52 effects on the health of individuals and, if appropriate,
53 treatment techniques that reduce the contaminant or
54 contaminants to a level which will not adversely affect the
55 health of the consumer. The rule shall contain provisions to
56 protect and prevent contamination of wellheads and well

57 fields used by public water supplies so that contaminants do
58 not reach a level that would adversely affect the health of the
59 consumer;

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

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

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

77 (6) The training and examination requirements for
78 emergency medical service attendants and emergency
79 medical care technician-paramedics; the designation of the
80 health care facilities, health care services and the industries
81 and occupations in the state that must have emergency
82 medical service attendants and emergency medical care
83 technician-paramedics employed and the availability,
84 communications and equipment requirements with respect
85 to emergency medical service attendants and to emergency
86 medical care technician-paramedics. Any regulation of
87 emergency medical service attendants and emergency
88 medical care technician- paramedics may not exceed the
89 provisions of article four-c of this chapter;

90 (7) The health and sanitary conditions of establishments
91 commonly referred to as bed and breakfast inns. For pur-
92 poses of this article, "bed and breakfast inn" means an

93 establishment providing sleeping accommodations and, at a
94 minimum, a breakfast for a fee. The secretary may not
95 require an owner of a bed and breakfast providing sleeping
96 accommodations of six or fewer rooms to install a restau-
97 rant-style or commercial food service facility. The secretary
98 may not require an owner of a bed and breakfast providing
99 sleeping accommodations of more than six rooms to install
100 a restaurant-type or commercial food service facility if the
101 entire bed and breakfast inn or those rooms numbering
102 above six are used on an aggregate of two weeks or less per
103 year;

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

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

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

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

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

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

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

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

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

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

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

164 (iv) That within thirty days after admission of a patient,
165 the opioid treatment program shall develop an individualized
166 treatment plan of care and attach the plan to the patient's
167 chart no later than five days after the plan is developed. The
168 opioid treatment program shall follow guidelines established
169 by a nationally recognized authority approved by the
170 secretary and include a recovery model in the individualized
171 treatment plan of care. The treatment plan is to reflect that
172 detoxification is an option for treatment and supported by
173 the program; that under the detoxification protocol the
174 strength of maintenance doses of methadone should decrease
175 over time, the treatment should be limited to a defined
176 period of time, and participants are required to work toward
177 a drug-free lifestyle.

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

188 (A) Termination or disqualification;

189 (B) Completion of a program of detoxification;

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

193 (D) Successful completion of the individualized treat-
194 ment care plan; or

195 (E) An unexplained reason.

196 (vi) That random drug testing of all patients shall be
197 conducted during the course of treatment at least monthly.
198 For purposes of these rules, "random drug testing" means

199 that each patient of an opioid treatment program facility has
200 a statistically equal chance of being selected for testing at
201 random and at unscheduled times. Any refusal to participate
202 in a random drug test shall be considered a positive test.
203 Nothing contained in this section or the legislative rules
204 promulgated in conformity herewith will preclude any opioid
205 treatment program from administering such additional drug
206 tests as determined necessary by the opioid treatment
207 program.

208 (vii) That all random drug tests conducted by an opioid
209 treatment program shall, at a minimum, test for the follow-
210 ing:

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

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

215 (C) Benzodiazepine including diazepam, lorazepam,
216 clonazepam and alprazolam;

217 (D) Cocaine;

218 (E) Methamphetamine or amphetamine;

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

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

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

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

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

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

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

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

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

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

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

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

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

262 (3) Provide mandatory and documented treatment team
263 meetings with the patient which will include, at a minimum:

264 The need for continuing treatment; a discussion of other
265 treatment alternatives; and the execution of a contract with
266 the patient advising the patient of discharge for continued
267 positive drug tests.

268 (D) Upon a fourth positive drug test within a six-month
269 period, the patient shall be immediately discharged from the
270 opioid treatment program or, at the option of the patient,
271 shall immediately be provided the opportunity to participate
272 in a twenty- one day detoxification plan, followed by
273 immediate discharge from the opioid treatment program:
274 *Provided*, That testing positive solely for tetrahydro-
275 cannabinal, delta-9-tetrahydrocannabinal or dronabinal or
276 similar substances shall not serve as a basis for discharge
277 from the program.

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

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

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

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

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

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

299 center and a physician actively licensed in this state avail-
300 able for consultation.

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

316 (xii) That each opioid treatment program shall establish
317 a peer review committee, with at least one physician mem-
318 ber, to review whether the program is following guidelines
319 established by a nationally recognized authority approved by
320 the secretary. The secretary shall prescribe the procedure for
321 evaluation by the peer review. Each opioid treatment
322 program shall submit a report of the peer review results to
323 the secretary on a quarterly basis.

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

329 The rule shall include the following provisions:

330 Base allocation amount for each county;

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

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

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

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

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

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

ARTICLE 5H. CHRONIC PAIN CLINIC LICENSING ACT.

§16-5H-1. Purpose and short title.

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

§16-5H-2. Definitions.

1 (a) "Chronic pain" means pain that has persisted after
2 reasonable medical efforts have been made to relieve the

3 pain or cure its cause and that has continued, either continu-
4 ously or episodically, for longer than three continuous
5 months. For purposes of this article, "chronic pain" does not
6 include pain associated with a terminal condition or with a
7 progressive disease that, in the normal course of progression,
8 may reasonably be expected to result in a terminal condition.

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

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

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

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

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

26 (e) "Physician" means an individual authorized to
27 practice medicine or surgery or osteopathic medicine or
28 surgery in this state.

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

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

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

1 (a) No person, partnership, association or corporation
2 may operate a pain management clinic without first obtain-
3 ing a license from the secretary in accordance with the
4 provisions of this article and the rules lawfully promulgated
5 pursuant to this article.

6 (b) Any person, partnership, association or corporation
7 desiring a license to operate a pain management clinic in this
8 state shall file with the Office of Health Facility Licensure
9 and Certification an application in such form as the secre-
10 tary shall prescribe and furnish accompanied by a fee to be
11 determined by the secretary.

12 (c) The Director of the Office of Health Facility
13 Licensure and Certification or his or her designee shall
14 inspect each facility prior to issuing a license and review all
15 documentation submitted with the application. The secretary
16 shall issue a license if the facility is in compliance with the
17 provisions of this article and with the rules lawfully promul-
18 gated pursuant to this article.

19 (d) A license shall expire one year from the date of
20 issuance. Sixty days prior to the expiration date, an applica-
21 tion for renewal shall be submitted on forms furnished by the
22 secretary. A license shall be renewed if the secretary deter-
23 mines that the applicant is in compliance with this article
24 and with all rules promulgated pursuant to this article. A
25 license issued to one facility pursuant to this article is not
26 transferable or assignable. A change of ownership of a
27 licensed pain management clinic requires submission of a
28 new application.

29 (e) The secretary or his or her designee shall inspect on
30 a periodic basis all pain management clinics that are subject

31 to this article and all rules adopted pursuant to this article
32 to ensure continued compliance.

§16-5H-4. Operational requirements.

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

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

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

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

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

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

28 (i) Complete a pain medicine fellowship that is accredited
29 by the Accreditation Council for Graduate Medical Educa-
30 tion or such other similar program as may be approved by
31 the secretary; or

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

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

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

40 (E) Supervise, control and direct the activities of each
41 individual working or operating at the facility, including any
42 employee, volunteer or individual under contract, who
43 provides treatment of chronic pain at the clinic or is associ-
44 ated with the provision of that treatment. The supervision,
45 control and direction shall be provided in accordance with
46 rules promulgated by the secretary.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

136 (C) A physician, physician assistant, certified registered
137 nurse anesthetist or advanced nurse practitioner shall
138 perform a physical examination of a patient on the same day

139 that the physician initially prescribes, dispenses or adminis-
140 ters a controlled substance to a patient and at least four
141 times a year thereafter at a pain management clinic accord-
142 ing to accepted and prevailing standards for medical care.

143 (D) A physician authorized to prescribe controlled
144 substances who practices at a pain management clinic is
145 responsible for maintaining the control and security of his or
146 her prescription blanks and any other method used for
147 prescribing controlled substance pain medication. The
148 physician shall comply with all state and federal require-
149 ments for tamper-resistant prescription paper. In addition to
150 any other requirements imposed by statute or rule, the
151 physician shall notify the secretary in writing within
152 twenty-four hours following any theft or loss of a prescrip-
153 tion blank or breach of any other method for prescribing
154 pain medication.

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

§16-5H-5. Exemptions.

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

3 (1) A facility that is affiliated with an accredited medical
4 school at which training is provided for medical or osteo-
5 pathic students, residents or fellows, podiatrists, dentists,
6 nurses, physician assistants, veterinarians or any affiliated
7 facility to the extent that it participates in the provision of
8 the instruction;

9 (2) A facility that does not prescribe or dispense con-
10 trolled substances for the treatment of chronic pain;

11 (3) A hospital licensed in this state, a facility located on
12 the campus of a licensed hospital that is owned, operated or

13 controlled by that licensed hospital, and an ambulatory
14 health care facility as defined by section two, article two-d,
15 chapter sixteen of this code that is owned, operated or
16 controlled by a licensed hospital;

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

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

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

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

24 (8) A facility conducting clinical research that may use
25 controlled substances in studies approved by a hospi-
26 tal-based institutional review board or an institutional
27 review board accredited by the association for the accredita-
28 tion of human research protection programs.

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

§16-5H-6. Inspection.

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

5 (b) During an onsite inspection, the inspector shall make
6 a reasonable attempt to discuss each violation with the
7 designated physician or other owners of the pain manage-
8 ment clinic before 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
11 owners of the pain management clinic and verified by

12 follow-up visits by the Office of Health Facility Licensure
13 and Certification.

§16-5H-7. Suspension; revocation.

1 (a) The secretary may suspend or revoke a license issued
2 pursuant to this article if the provisions of this article or of
3 the rules promulgated pursuant to this article are violated.
4 The secretary may revoke a clinic's license and prohibit all
5 physicians associated with that pain management clinic from
6 practicing at the clinic location based upon an annual or
7 periodic inspection and evaluation.

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

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

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

30 (e) Any applicant or licensee who is dissatisfied with the
31 decision of the secretary as a result of the hearing provided
32 in this section may, within thirty days after receiving notice
33 of the decision, appeal the decision to the Circuit Court of

34 Kanawha County, in term or in vacation, for judicial review
35 of the decision.

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

40 (g) If the license of a pain management clinic is revoked
41 or suspended, the designated physician of the clinic, any
42 other owner of the clinic or the owner or lessor of the clinic
43 property shall cease to operate the facility as a pain manage-
44 ment clinic as of the effective date of the suspension or
45 revocation. The owner or lessor of the clinic property is
46 responsible for removing all signs and symbols identifying
47 the premises as a pain management clinic within thirty days.

48 (h) Upon the effective date of the suspension or revoca-
49 tion, the designated physician of the pain management clinic
50 shall advise the secretary and the Board of Pharmacy of the
51 disposition of all drugs located on the premises. The disposi-
52 tion is subject to the supervision and approval of the secre-
53 tary. Drugs that are purchased or held by a pain manage-
54 ment clinic that is not licensed may be deemed adulterated.

55 (i) If the license of a pain management clinic is suspended
56 or revoked, any person named in the licensing documents of
57 the clinic, including persons owning or operating the pain
58 management clinic, may not, as an individual or as part of a
59 group, apply to operate another pain management clinic for
60 five years after the date of suspension or revocation.

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

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

1 (a) Any person, partnership, association or corporation
2 which establishes, conducts, manages or operates a pain
3 management clinic without first obtaining a license therefor
4 as herein provided, or which violates any provisions of this

5 article or any rule lawfully promulgated pursuant to this
6 article, shall be assessed a civil penalty by the secretary in
7 accordance with this subsection. Each day of continuing
8 violation after conviction shall be considered a separate
9 violation:

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

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

20 (3) If an owner or designated physician of a pain manage-
21 ment clinic concurrently operates an unlicensed pain
22 management clinic, the secretary may impose a civil penalty
23 upon the owner or physician, or both, not to exceed \$5,000
24 per day.

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

30 (5) If a physician knowingly operates, owns or manages
31 an unlicensed pain management clinic that is required to be
32 licensed pursuant to this article; knowingly prescribes or
33 dispenses or causes to be prescribed or dispensed, controlled
34 substances in an unlicensed pain management clinic that is
35 required to be licensed; or licenses a pain management clinic
36 through misrepresentation or fraud; procures or attempts to
37 procure a license for a pain management clinic for any other
38 person by making or causing to be made any false represen-
39 tation, the secretary may assess a civil penalty of not more
40 than \$20,000. The penalty may be in addition to or in lieu of

41 any other action that may be taken by the secretary or any
42 other board, court or entity.

43 (b) Notwithstanding the existence or pursuit of any other
44 remedy, the secretary may, in the manner provided by law,
45 maintain an action in the name of the state for an injunction
46 against any person, partnership, association, or corporation
47 to restrain or prevent the establishment, conduct, manage-
48 ment or operation of any pain management clinic or viola-
49 tion of any provisions of this article or any rule lawfully
50 promulgated thereunder without first obtaining a license
51 therefor in the manner hereinbefore provided.

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

55 (1) The gravity of the violation, including the probability
56 that death or serious physical or emotional harm to a patient
57 has resulted, or could have resulted, from the pain manage-
58 ment clinic's actions or the actions of the designated or
59 practicing physician, the severity of the action or potential
60 harm, and the extent to which the provisions of the applica-
61 ble laws or rules were violated;

62 (2) What actions, if any, the owner or designated physi-
63 cian took to correct the violations;

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

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

69 (d) Upon finding that a physician has violated the
70 provisions of this article or rules adopted pursuant to this
71 article, the secretary shall provide notice of the violation to
72 the applicable licensing board.

§16-5H-9. Rules. ↵

1 (a) The Secretary of the Department of Health and
2 Human Resources, in collaboration with the West Virginia

3 Board of Medicine and the West Virginia Board of Osteopa-
4 thy, shall promulgate rules in accordance with the provisions
5 of chapter twenty-nine-a of this code for the licensure of
6 pain management clinics to ensure adequate care, treatment,
7 health, safety, welfare and comfort of patients at these
8 facilities. These rules shall include, at a minimum:

9 (1) The process to be followed by applicants seeking a
10 license;

11 (2) The qualifications and supervision of licensed and
12 non-licensed personnel at pain management clinics and
13 training requirements for all facility health care practitio-
14 ners who are not regulated by another board;

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

17 (4) The management, operation, staffing and equipping
18 of the pain management clinic;

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

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

23 (7) The standards and procedures for the general opera-
24 tion of a pain management clinic, including facility opera-
25 tions, physical operations, infection control requirements,
26 health and safety requirements and quality assurance;

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

30 (9) Any other criteria that identify a facility as a pain
31 management clinic;

32 (10) The standards and procedures to be followed by an
33 owner in providing supervision, direction and control of
34 individuals employed by or associated with a pain manage-
35 ment clinic;

36 (11) Data collection and reporting requirements; and

37 (12) Such other standards or requirements as the secre-
38 tary determines are appropriate.

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

§16-5h-10. Advertisement disclosure.

1 Any advertisement made by or on behalf of a pain
2 management clinic through public media, such as a tele-
3 phone directory, medical directory, newspaper or other
4 periodical, outdoor advertising, radio or television, or
5 through written or recorded communication, concerning the
6 treatment of chronic pain, as defined in section two of this
7 article, shall include the name of, at a minimum, one physi-
8 cian owner responsible for the content of the advertisement.

CHAPTER 30. PROFESSIONS AND OCCUPATIONS.

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

§30-1-7a. Continuing education.

1 (a) Each board referred to in this chapter shall establish
2 continuing education requirements as a prerequisite to
3 license renewal. Each board shall develop continuing
4 education criteria appropriate to its discipline, which shall
5 include, but not be limited to, course content, course ap-
6 proval, hours required and reporting periods.

7 (b) Notwithstanding any other provision of this code or
8 the provision of any rule to the contrary, each person issued
9 a license to practice medicine and surgery or a license to
10 practice podiatry or licensed as a physician assistant by the
11 West Virginia Board of Medicine, each person issued a
12 license to practice dentistry by the West Virginia Board of
13 Dental Examiners, each person issued a license to practice
14 optometry by the West Virginia Board of Optometry, each
15 person licensed as a pharmacist by the West Virginia Board

16 of Pharmacy, each person licensed to practice registered
17 professional nursing or licensed as an advanced nurse
18 practitioner by the West Virginia Board of Examiners for
19 Registered Professional Nurses, each person licensed as a
20 licensed practical nurse by the West Virginia State Board of
21 Examiners for Licensed Practical Nurses and each person
22 licensed to practice medicine and surgery as an osteopathic
23 physician and surgeon or licensed or certified as an osteo-
24 pathic physician assistant by the West Virginia Board of
25 Osteopathy shall complete drug diversion training and best
26 practice prescribing of controlled substances training, as the
27 trainings are established by his or her respective licensing
28 board, if that person prescribes, administers, or dispenses a
29 controlled substance, as that term is defined in section one
30 hundred one, article one, chapter sixty-a of this code.

31 (1) Notwithstanding any other provision of this code or
32 the provision of any rule to the contrary, the West Virginia
33 Board of Medicine, the West Virginia Board of Dental
34 Examiners, the West Virginia Board of Optometry, the West
35 Virginia Board of Pharmacy, the West Virginia Board of
36 Examiners for Registered Professional Nurses, the West
37 Virginia State Board of Examiners for Licensed Practical
38 Nurses and the West Virginia Board of Osteopathy shall
39 establish continuing education requirements and criteria
40 appropriate to their respective discipline on the subject of
41 drug diversion training and best practice prescribing of
42 controlled substances training for each person issued a
43 license or certificate by their respective board who pre-
44 scribes, administers or dispenses a controlled substance, as
45 that term is defined in section one hundred one, article one,
46 chapter sixty-a of this code, and shall develop a certification
47 form pursuant to subdivision (b)(2) of this section.

48 (2) Each person who receives his or her initial license or
49 certificate from any of the boards set forth in subsection (b)
50 shall complete the continuing education requirements set
51 forth in subsection (b) within one year of receiving his or her
52 initial license from that board and each person licensed or
53 certified by any of the boards set forth in subsection (b) who
54 has held his or her license or certificate for longer than one

55 year shall complete the continuing education requirements
56 set forth in subsection (b) as a prerequisite to each license
57 renewal: *Provided*, That a person subject to subsection (b)
58 may waive the continuing education requirements for license
59 renewal set forth in subsection (b) if he or she completes and
60 submits to his or her licensing board a certification form
61 developed by his or her licensing board attesting that he or
62 she has not prescribed, administered, or dispensed a con-
63 trolled substance, as that term is defined in section one
64 hundred one, article one, chapter sixty-a of this code, during
65 the entire applicable reporting period.

**ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHAR-
MACY INTERNS AND PHARMACIES.**

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

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

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

20 or prescription refills, including, but not limited to, reconsti-
21 tution of liquid medications, typing and affixing labels under
22 the direct supervision of a licensed pharmacist.

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

28 (d) The experience requirement for licensure as a
29 pharmacist shall be computed from the date certified by the
30 supervising pharmacist as the date of entering the intern-
31 ship. If the internship is not registered with the Board of
32 Pharmacy, then the intern shall receive no credit for the
33 experience when he or she makes application for examina-
34 tion for licensure as a pharmacist: *Provided*, That credit may
35 be given for the unregistered experience if an appeal is made
36 and evidence produced showing experience was obtained but
37 not registered and that failure to register the internship
38 experience was not the fault of the intern.

39 (e) An intern having served part or all of his or her
40 internship in a pharmacy in another state or foreign country
41 shall be given credit for the same when the affidavit of his or
42 her internship is signed by the pharmacist under whom he or
43 she served, and it shows the dates and number of hours
44 served in the internship and when the affidavit is attested by
45 the secretary of the State Board of Pharmacy of the state or
46 country where the internship was served.

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

50 (g) No pharmacist may compound or dispense any
51 prescription order when he or she has knowledge that the
52 prescription was issued by a practitioner without establish-
53 ing a valid practitioner-patient relationship. An online or
54 telephonic evaluation by questionnaire, or an online or
55 telephonic consultation, is inadequate to establish a valid

56 practitioner-patient relationship: *Provided*, That this
57 prohibition does not apply:

58 (1) In a documented emergency;

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

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

CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.

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

§60A-3-308. Prescriptions.

1 (a) Except when dispensed directly by a practitioner,
2 other than a pharmacy, to an ultimate user, no controlled
3 substance in Schedule II may be dispensed without the
4 lawful prescription of a practitioner.

5 (b) In emergency situations, as defined by rule of the said
6 appropriate department, board or agency, Schedule II drugs
7 may be dispensed upon oral prescription of a practitioner,
8 reduced promptly to writing and filed by the pharmacy.
9 Prescription shall be retained in conformity with the re-
10 quirements of section three hundred six of this article. No
11 prescription for a Schedule II substance may be refilled.

12 (c) Except when dispensed directly by a practitioner,
13 other than a pharmacy, to an ultimate user, a controlled
14 substance included in Schedule III or IV, which is a prescrip-
15 tion drug as determined under appropriate state or federal
16 statute, shall not be dispensed without a lawful prescription
17 of a practitioner. The prescription shall not be filled or
18 refilled more than six months after the date thereof or be
19 refilled more than five times unless renewed by the practitio-
20 ner.

21 (d) (1) A controlled substance included in Schedule V
22 shall not be distributed or dispensed other than for a medici-
23 nal purpose: *Provided*, That buprenorphine shall be dis-
24 pensed only by prescription pursuant to subsections (a), (b)
25 and (c) of this section: *Provided, however*, That the con-
26 trolled substances included in subsection (e), section two
27 hundred twelve, article two of this chapter shall be dis-
28 pensed, sold or distributed only by a physician, in a phar-
29 macy by a pharmacist or pharmacy technician, or health care
30 professional.

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

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

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

40 (e) Notwithstanding any provision of this code to the
41 contrary, on or after September 1, 2012, any practitioner or
42 entity prescribing or dispensing a combination of
43 buprenorphine and naloxone to treat opioid addiction shall
44 only prescribe or dispense said product in the form of
45 sublingual film unless the sublingual film is clinically
46 contraindicated. If the prescriber or dispenser determines
47 that sublingual film is contraindicated he or she shall
48 document the reasons for not dispensing sublingual film in
49 the patient's file or chart.

ARTICLE 9. CONTROLLED SUBSTANCES MONITORING.

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

1 (a) On or before September 1, 2002, the Board of Phar-
2 macy shall implement a program wherein a central reposi-
3 tory is established and maintained which shall contain such

4 information as is required by the provisions of this article
5 regarding Schedule II, III and IV controlled substance
6 prescriptions written or filled in this state. In implementing
7 this program, the Board of Pharmacy shall consult with the
8 West Virginia State Police, the licensing boards of practitio-
9 ners affected by this article and affected practitioners.

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

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

25 (2) A dispenser, who does not have an automated re-
26 cord-keeping system capable of producing an electronic
27 report in the established format may request a waiver from
28 electronic reporting. The request for a waiver shall be made
29 to the State Board of Pharmacy in writing and shall be
30 granted if the dispenser agrees in writing to report the data
31 by submitting a completed "Pharmacy Universal Claim
32 Form" as defined by legislative rule.

§60A-9-4. Required information.

1 (a) Whenever a medical services provider dispenses a
2 controlled substance listed in Schedule II, III or IV, as
3 established under the provisions of article two of this
4 chapter or whenever a prescription for the controlled
5 substance is filled by: (i) A pharmacist or pharmacy in this
6 state; (ii) a hospital, or other health care facility, for

7 out-patient use; or (iii) a pharmacy or pharmacist licensed by
8 the Board of Pharmacy, but situated outside this state for
9 delivery to a person residing in this state, the medical
10 services provider, health care facility, pharmacist or phar-
11 macy shall, in a manner prescribed by rules promulgated by
12 the Board of Pharmacy under this article, report the follow-
13 ing information, as applicable:

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

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

20 (3) The name, address and Drug Enforcement Adminis-
21 tration controlled substances registration number of the
22 practitioner writing the prescription;

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

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

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

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

31 (8) If the prescription being dispensed is being picked up
32 by someone other than the patient on behalf of the patient,
33 the full legal name, address and birth date of the person
34 picking up the prescription as set forth on the person's
35 government-issued photo identification card shall be
36 retained in either print or electronic form until such time as
37 otherwise directed by rule promulgated by the board of
38 pharmacy; and

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

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

46 (c) Products regulated by the provisions of article ten of
47 this chapter shall be subject to reporting pursuant to the
48 provisions of this article to the extent set forth in said
49 article.

50 (d) Reporting required by this section is not required for
51 a drug administered directly to a patient by a practitioner.
52 Reporting is, however, required by this section for a drug
53 dispensed to a patient by a practitioner: *Provided*, That the
54 quantity dispensed may not exceed an amount adequate to
55 treat the patient for a maximum of seventy-two hours with
56 no greater than two seventy-two-hour cycles dispensed in
57 any fifteen-day period of time.

§60A-9-4a. Verification of identity.

1 Prior to releasing a Schedule II, III or IV controlled
2 substance sold at retail, a pharmacist or pharmacy shall
3 verify the full legal name, address and birth date of the
4 person receiving or otherwise acquiring the controlled
5 substance by requiring the presentation of a valid
6 government-issued photo identification card. This informa-
7 tion shall be reported in accordance with the provisions of
8 this article information shall be retained in either print or
9 electronic form until such time as otherwise directed by rule
10 promulgated by the board of pharmacy.

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

1 (a) (1) The information required by this article to be kept
2 by the State Board of Pharmacy is confidential and not
3 subject to the provisions of chapter twenty-nine-b of this
4 code or obtainable as discovery in civil matters absent a
5 court order and is open to inspection only by inspectors and
6 agents of the State Board of Pharmacy, members of the West

7 Virginia State Police expressly authorized by the Superin-
8 tendent of the West Virginia State Police to have access to
9 the information, authorized agents of local law-enforcement
10 agencies as members of a federally affiliated drug task force,
11 authorized agents of the federal Drug Enforcement Adminis-
12 tration, duly authorized agents of the Bureau for Medical
13 Services, duly authorized agents of the Office of the Chief
14 Medical Examiner for use in post-mortem examinations,
15 duly authorized agents of licensing boards of practitioners in
16 this state and other states authorized to prescribe Schedules
17 II, III and IV controlled substances, prescribing practitioners
18 and pharmacists and persons with an enforceable court order
19 or regulatory agency administrative subpoena: *Provided,*
20 That all law-enforcement personnel who have access to the
21 Controlled Substances Monitoring Program database shall
22 be granted access in accordance with applicable state laws
23 and Board of Pharmacy legislative rules, shall be certified as
24 a West Virginia law-enforcement officer and shall have
25 successfully completed United States Drug Enforcement
26 Administration Diversion Training and National Association
27 of Drug Diversion Investigation Training. All information
28 released by the State Board of Pharmacy must be related to
29 a specific patient or a specific individual or entity under
30 investigation by any of the above parties except that practi-
31 tioners who prescribe or dispense controlled substances may
32 request specific data related to their Drug Enforcement
33 Administration controlled substance registration number or
34 for the purpose of providing treatment to a patient: *Provided,*
35 *however,* That the West Virginia Controlled Substances
36 Monitoring Program Database Review Committee estab-
37 lished in subsection (b) of this section is authorized to query
38 the database to comply with said subsection.

39 (2) Subject to the provisions of subdivision (1) of this
40 subsection, the board shall also review the West Virginia
41 Controlled Substance Monitoring Program database and
42 issue reports that identify abnormal or unusual practices of
43 patients who exceed parameters as determined by the
44 advisory committee established in this section. The board
45 shall communicate with prescribers and dispensers to more

46 effectively manage the medications of their patients in the
47 manner recommended by the advisory committee. All other
48 reports produced by the board shall be kept confidential. The
49 board shall maintain the information required by this article
50 for a period of not less than five years. Notwithstanding any
51 other provisions of this code to the contrary, data obtained
52 under the provisions of this article may be used for compila-
53 tion of educational, scholarly or statistical purposes, and
54 may be shared with the West Virginia Department of Health
55 and Human Resources for those purposes, as long as the
56 identities of persons or entities and any personally identifi-
57 able information, including protected health information,
58 contained therein shall be redacted, scrubbed or otherwise
59 irreversibly destroyed in a manner that will preserve the
60 confidential nature of the information. No individual or
61 entity required to report under section four of this article
62 may be subject to a claim for civil damages or other civil
63 relief for the reporting of information to the Board of
64 Pharmacy as required under and in accordance with the
65 provisions of this article.

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

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

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

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

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

100 (E) Establish outreach programs with local law enforce-
101 ment to provide education to local law enforcement on the
102 requirements and use of the Controlled Substances Monitor-
103 ing Program database established in this article.

104 (b) The Board of Pharmacy shall create a West Virginia
105 Controlled Substances Monitoring Program Database
106 Review Committee of individuals consisting of two prosecut-
107 ing attorneys from West Virginia counties, two physicians
108 with specialties which require extensive use of controlled
109 substances and a pharmacist who is trained in the use and
110 abuse of controlled substances. The review committee may
111 determine that an additional physician who is an expert in
112 the field under investigation be added to the team when the
113 facts of a case indicate that the additional expertise is
114 required. The review committee, working independently,
115 may query the database based on parameters established by
116 the advisory committee. The review committee may make
117 determinations on a case-by-case basis on specific unusual
118 prescribing or dispensing patterns indicated by outliers in
119 the system or abnormal or unusual usage patterns of con-
120 trolled substances by patients which the review committee

121 has reasonable cause to believe necessitates further action by
122 law enforcement or the licensing board having jurisdiction
123 over the prescribers or dispensers under consideration. The
124 review committee shall also review notices provided by the
125 chief medical examiner pursuant to subsection (h), section
126 ten, article twelve, chapter sixty-one of this code and
127 determine on a case-by-case basis whether a practitioner
128 who prescribed or dispensed a controlled substance resulting
129 in or contributing to the drug overdose may have breached
130 professional or occupational standards or committed a
131 criminal act when prescribing the controlled substance at
132 issue to the decedent. Only in those cases in which there is
133 reasonable cause to believe a breach of professional or
134 occupational standards or a criminal act may have occurred,
135 the review committee shall notify the appropriate profes-
136 sional licensing agency having jurisdiction over the applica-
137 ble prescriber or dispenser and appropriate law-enforcement
138 agencies and provide pertinent information from the data-
139 base for their consideration. The number of cases identified
140 shall be determined by the review committee based on a
141 number that can be adequately reviewed by the review
142 committee. The information obtained and developed may not
143 be shared except as provided in this article and is not subject
144 to the provisions of chapter twenty-nine-b of this code or
145 obtainable as discovering in civil matters absent a court
146 order.

147 (c) The Board of Pharmacy is responsible for establishing
148 and providing administrative support for the advisory
149 committee and the West Virginia Controlled Substances
150 Monitoring Program Database Review Committee. The
151 advisory committee and the review committee shall elect a
152 chair by majority vote. Members of the advisory committee
153 and the review committee may not be compensated in their
154 capacity as members but shall be reimbursed for reasonable
155 expenses incurred in the performance of their duties.

156 (d) The board shall promulgate rules with advice and
157 consent of the advisory committee, in accordance with the
158 provisions of article three, chapter twenty-nine-a of this
159 code on or before June 1, 2013. The legislative rules must

160 include, but shall not be limited to, the following matters: (1)
161 Identifying parameters used in identifying abnormal or
162 unusual prescribing or dispensing patterns; (2) processing
163 parameters and developing reports of abnormal or unusual
164 prescribing or dispensing patterns for patients, practitioners
165 and dispensers; (3) establishing the information to be
166 contained in reports and the process by which the reports
167 will be generated and disseminated; and (4) setting up
168 processes and procedures to ensure that the privacy, confi-
169 dentiality, and security of information collected, recorded,
170 transmitted and maintained by the review committee is not
171 disclosed except as provided in this section.

172 (e) All practitioners, as that term is defined in section one
173 hundred-one, article two of this chapter who prescribe or
174 dispense schedule II, III or IV controlled substances shall, on
175 or before July 1, 2011, have online or other form of electronic
176 access to the West Virginia Controlled Substances Monitor-
177 ing Program database;

178 (f) Persons or entities with access to the West Virginia
179 Controlled Substances Monitoring Program database
180 pursuant to this section may, pursuant to rules promulgated
181 by the Board of Pharmacy, delegate appropriate personnel to
182 have access to said database;

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

191 (h) A prescribing or dispensing practitioner may notify
192 law enforcement of a patient who, in the prescribing or
193 dispensing practitioner's judgment, may be in violation of
194 section four hundred ten, article four of this chapter, based
195 on information obtained and reviewed from the controlled
196 substances monitoring database. A prescribing or dispensing

197 practitioner who makes a notification pursuant to this
198 subsection is immune from any civil, administrative or
199 criminal liability that otherwise might be incurred or
200 imposed because of the notification if the notification is
201 made in good faith.

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

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

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

1 (a) Upon initially prescribing or dispensing any
2 pain-relieving controlled substance for a patient and at least
3 annually thereafter should the prescriber or dispenser
4 continue to treat the patient with controlled substances, all
5 persons with prescriptive or dispensing authority and in
6 possession of a valid Drug Enforcement Administration
7 registration identification number and, who are licensed by
8 the Board of Medicine as set forth in article three, chapter
9 thirty of this code, the Board of Registered Professional
10 Nurses as set forth in article seven, chapter thirty of this
11 code, the Board of Dental Examiners as set forth in article
12 four, chapter thirty of this code and the Board of Osteopathy
13 as set forth in article fourteen, chapter thirty of this code
14 shall access the West Virginia Controlled Substances
15 Monitoring Program database for information regarding
16 specific patients for whom they are providing pain-relieving
17 controlled substances as part of a course of treatment for
18 chronic, nonmalignant pain but who are not suffering from
19 a terminal illness. The information obtained from accessing
20 the West Virginia Controlled Substances Monitoring Pro-
21 gram database for the patient shall be documented in the

22 patient's medical record. A pain-relieving controlled sub-
23 stance shall be defined as set forth in section one, article
24 three-a, chapter thirty of this code.

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

§60A-9-7. Criminal penalties.

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

6 (b) Any person who is required to submit information to
7 the state Board of Pharmacy pursuant to the provisions of
8 this article who knowingly and willfully refuses to submit
9 the information required by this article is guilty of a misde-
10 meanor and, upon conviction thereof, shall be confined in a
11 county or regional jail not more than six months or fined not
12 more than \$1,000, or both confined or fined.

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

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

27 (e) Any person granted access to the information re-
28 quired by the provisions of this article to be maintained by
29 the state Board of Pharmacy, who shall willfully disclose the
30 information required to be maintained by this article in a
31 manner inconsistent with a legitimate law-enforcement
32 purpose, a legitimate professional regulatory purpose, the
33 terms of a court order or as otherwise expressly authorized
34 by the provisions of this article is guilty of a misdemeanor
35 and, upon conviction thereof, shall be confined in a county
36 or regional jail for not more than six months or fined not
37 more than \$1,000, or both confined or fined.

38 (f) Unauthorized access or use or unauthorized disclosure
39 for reasons unrelated to the purposes of this article of the
40 information in the database is a felony punishable by
41 imprisonment in a state correctional facility for not less than
42 one year nor more than five years or fined not less than
43 \$3,000 nor more than \$10,000, or both imprisoned or fined.

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

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

ARTICLE 10. METHAMPHETAMINE LABORATORY ERADICATION ACT.

§60A-10-3. Definitions.

1 In this article:

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

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

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

13 (d) "Drug product" means a pharmaceutical product that
14 contains ephedrine, pseudoephedrine or phenylpropanol-
15 amine or a substance identified on the supplemental list
16 provided in section seven of this article which may be sold
17 without a prescription and which is labeled for use by a
18 consumer in accordance with the requirements of the laws
19 and rules of this state and the federal government.

20 (e) "Ephedrine" means ephedrine, its salts or optical
21 isomers or salts of optical isomers.

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

27 (g) "National Association of Drug Diversion Investiga-
28 tors" or "NADDI" means the non-profit 501(c)(3) organiza-
29 tion established in 1989, made up of members who are
30 responsible for investigating and prosecuting pharmaceutical
31 drug diversion, and that facilitates cooperation between law
32 enforcement, health care professionals, state regulatory
33 agencies and pharmaceutical manufacturers in the investiga-
34 tion and prevention of prescription drug abuse and diversion.

35 (h) "Multi-State Real-Time Tracking System" or
36 "MSRTTS" means the real-time electronic logging system
37 provided by NADDI at no cost to states that have legislation
38 requiring real-time electronic monitoring of precursor
39 purchases, and agree to use the system. MSRTTS is used by
40 pharmacies and law enforcement to track sales of

41 over-the-counter (OTC) cold and allergy medications
42 containing precursors to the illegal drug, methamphetamine.

43 (i) "Phenylpropanolamine" means phenylpropanolamine,
44 its salts, optical isomers and salts of optical isomers.

45 (j) "Pseudoephedrine" means pseudoephedrine, its salts,
46 optical isomers and salts of optical isomers.

47 (k) "Precursor" means any substance which may be used
48 along with other substances as a component in the produc-
49 tion and distribution of illegal methamphetamine.

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

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

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

62 (o) "Pharmacy counter" means an area in the pharmacy
63 restricted to the public where controlled substances are
64 stored and housed and where controlled substances may only
65 be sold, transferred or dispensed by a pharmacist, pharmacy
66 intern or pharmacy technician.

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

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

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

77 (s) "Superintendent of the State Police" or "Superinten-
78 dent" means the Superintendent of the West Virginia State
79 Police as set forth in section five, article two, chapter fifteen
80 of this code.

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

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

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

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

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

21 the first offense, or more than \$10,000 for each subsequent
22 offense.

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

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

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

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

38 (3) Drug products containing ephedrine, pseudoephed-
39 rine or phenylpropanolamine, their salts or optical isomers
40 or salts of optical isomers or other designated precursor
41 which have been determined by the Board of Pharmacy to be
42 in a form which is not feasible for being used for the manu-
43 facture of methamphetamine; or

44 (4) Persons lawfully possessing drug products in their
45 capacities as distributors, wholesalers, manufacturers,
46 pharmacists, pharmacy interns, pharmacy technicians, or
47 health care professionals.

48 (d) Notwithstanding any provision of this code to the
49 contrary, any person who knowingly possesses any amount
50 of ephedrine, pseudoephedrine, phenylpropanolamine or
51 other designated precursor with the intent to use it in the
52 manufacture of methamphetamine or who knowingly
53 possesses a substance containing ephedrine, pseudoephed-
54 rine or phenylpropanolamine or their salts, optical isomers
55 or salts of optical isomers in a state or form which is, or has

56 been altered or converted from the state or form in which
57 these chemicals are, or were, commercially distributed is
58 guilty of a felony and, upon conviction, shall be imprisoned
59 in a state correctional facility for not less than two nor more
60 than ten years, fined not more than \$25,000, or both impris-
61 oned and fined.

62 (e) (1) Any pharmacy, wholesaler, manufacturer or
63 distributor of drug products containing ephedrine, pseudo-
64 ephedrine, phenylpropanolamine, their salts or optical
65 isomers or salts of optical isomers or other designated
66 precursor shall obtain a registration annually from the State
67 Board of Pharmacy as described in section six of this article.
68 Any such pharmacy, wholesaler, manufacturer or distributor
69 shall keep complete records of all sales and transactions as
70 provided in section eight of this article. The records shall be
71 gathered and maintained pursuant to legislative rule promul-
72 gated by the Board of Pharmacy.

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

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

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

1 (a) No pharmacy or individual may display, offer for sale
2 or place a drug product containing ephedrine, pseudo-
3 ephedrine or phenylpropanolamine or other designated
4 precursor where the public may freely access the drug
5 product. All such drug products or designated precursors
6 shall be placed behind a pharmacy counter where access is
7 restricted to a pharmacist, a pharmacy intern, a pharmacy
8 technician or other pharmacy employee.

9 (b) All storage of drug products regulated by the provi-
10 sions of this section shall be in a controlled and locked

11 access location that is not accessible by the general public
12 and shall maintain strict inventory control standards and
13 complete records of quantity of the product maintained in
14 bulk form.

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

18 (d) If a drug product regulated by the provisions of this
19 section is transferred, sold or delivered, the individual,
20 pharmacy or retail establishment transferring, selling or
21 delivering the drug product shall offer to have a pharmacist
22 provide patient counseling, as defined by section one-b,
23 article five, chapter thirty of this code and the rules of the
24 Board of Pharmacy, to the person purchasing, receiving or
25 acquiring the drug product in order to improve the proper
26 use of the drug product and to discuss contraindications.

27 (e) If a drug product regulated by the provisions of this
28 section is transferred, sold or delivered, the individual,
29 pharmacy or retail establishment transferring, selling or
30 delivering the drug product shall require the person purchas-
31 ing, receiving or otherwise acquiring the drug product to:

32 (1) Produce a valid government-issued photo identifica-
33 tion showing his or her date of birth; and

34 (2) Sign a logbook, in either paper or electronic format,
35 containing the information set forth in subsection (b), section
36 eight of this article and attesting to the validity of the
37 information.

38 (f) Any person who knowingly makes a false representa-
39 tion or statement pursuant to the requirements of this section
40 is guilty of a misdemeanor and, upon conviction, be confined
41 in a jail for not more than six months, fined not more than
42 \$5,000, or both fined and confined.

43 (g) (1) The pharmacist, pharmacy intern or pharmacy
44 technician processing the transaction shall determine that

45 the name entered in the logbook corresponds to the name
46 provided on the identification.

47 (2) Beginning January 1, 2013, a pharmacy or retail
48 establishment shall, before completing a sale under this
49 section, electronically submit the information required by
50 section eight of this article to the Multi-State Real-Time
51 Tracking System (MSRTTS) administered by the National
52 Association of Drug Diversion Investigators (NADDI):
53 *Provided*, That the system is available to retailers in the state
54 without a charge for accessing the system. This system shall
55 be capable of generating a stop-sale alert, which shall be a
56 notification that completion of the sale would result in the
57 seller or purchaser violating the quantity limits set forth in
58 this article. The seller may not complete the sale if the
59 system generates a stop-sale alert. The system shall contain
60 an override function that may be used by a dispenser of a
61 drug product who has a reasonable fear of imminent bodily
62 harm if he or she does not complete a sale. Each instance in
63 which the override function is utilized shall be logged by the
64 system. Absent negligence, wantonness, recklessness or
65 deliberate misconduct, any retailer utilizing the Multi-State
66 Real-Time Tracking System in accordance with this subdivi-
67 sion may not be civilly liable as a result of any act or omis-
68 sion in carrying out the duties required by this subdivision
69 and is immune from liability to any third party unless the
70 retailer has violated any provision of this subdivision in
71 relation to a claim brought for the violation.

72 (3) If a pharmacy or retail establishment selling a
73 nonprescription product containing ephedrine, pseudoephed-
74 rine or phenylpropanolamine experiences mechanical or
75 electronic failure of the Multi-State Real-Time Tracking
76 System and is unable to comply with the electronic sales
77 tracking requirement, the pharmacy or retail establishment
78 shall maintain a written log or an alternative electronic
79 record keeping mechanism until such time as the pharmacy
80 or retail establishment is able to comply with the electronic
81 sales tracking requirement.

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

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

89 (j) The provisions of this section supersede and preempt
90 all local laws, ordinances, rules and regulations pertaining
91 to the sale of any compounds, mixtures or preparation
92 containing ephedrine, pseudoephedrine or phenylpropanol-
93 amine.

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

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

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

21 (2) A process whereby pharmacies and retail establish-
22 ments are made aware of additional drug products added to
23 Schedule V that are required to be placed behind the

24 pharmacy counter for sale, transfer or distribution can be
25 periodically reviewed and updated.

26 (b) At any time after July 1, 2005, the Board of Phar-
27 macy, upon the recommendation of the Superintendent of the
28 State Police, shall promulgate emergency and legislative
29 rules pursuant to the provision of article three, chapter
30 twenty-nine-a of this code to implement an updated supple-
31 mental list of products containing the controlled substances
32 ephedrine, pseudoephedrine or phenylpropanolamine as an
33 active ingredient or any other drug used as a precursor in the
34 manufacture of methamphetamine, which the Superinten-
35 dent of the State Police has demonstrated by empirical
36 evidence is being used in the manufacture of methamphet-
37 amine. This listing process shall comport with the require-
38 ments of subsection (a) of this section.

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

1 (a) Until January 1, 2013, upon each sale, retail, transfer
2 or distribution of any drug product referred to in section
3 seven of this article or another designated precursor, the
4 pharmacist, pharmacy intern, or pharmacy technician
5 making the sale, transfer or distribution shall report the
6 following information for inclusion in the central repository
7 established and maintained by the Board of Pharmacy:

8 (1) The date of the transaction;

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

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

14 (b) The information required to be reported by this
15 section shall be reported by paper log maintained at the
16 point of sale: Provided, That, beginning on January 1, 2007,
17 reporting shall be by electronic transmission to the Board of
18 Pharmacy no more frequently than once a week. Beginning
19 on January 1, 2013, the electronic transmission of the

20 information required to be reported in subsection (a) of this
21 section shall be reported to the MSRTTS, and shall be made
22 in real time at the time of the transaction.

23 (c) The information required by this section shall be the
24 property of the state. The information shall be disclosed as
25 appropriate to the federal Drug Enforcement Administration
26 and to state and local law-enforcement agencies. The
27 information shall not be accessed, used or shared for any
28 purpose other than to ensure compliance with this article
29 and federal law. NADDI shall forward state transaction
30 records in the MSRTTS to the West Virginia State Police
31 weekly, and provide real-time access to MSRTTS informa-
32 tion through the MSRTTS online portal to authorized agents
33 of the federal Drug Enforcement Administration and
34 certified law enforcement in this and other states for use in
35 the detection of violations of this article or of federal laws
36 designed to prevent the illegal use, production or distribu-
37 tion of methamphetamine.

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

1 Beginning July 1, 2013, the Superintendent of the West
2 Virginia State Police shall submit an annual report no later
3 than July 1 of each year to the Legislative Oversight Com-
4 mission on Health and Human Resources Accountability
5 with data and statistics related to methamphetamine use,
6 production and distribution in this state including, but not
7 limited to, the number of clandestine methamphetamine lab
8 incidents per year.

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

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

CHAPTER 61. CRIMES AND OTHER PUNISHMENT.

ARTICLE 12. POSTMORTEM EXAMINATIONS.

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

1 (a) If in the opinion of the chief medical examiner, or of
2 the county medical examiner of the county in which the
3 death in question occurred, it is advisable and in the public
4 interest that an autopsy be made, or if an autopsy is re-
5 quested by either the prosecuting attorney or the judge of the
6 circuit court or other court of record having criminal
7 jurisdiction in that county, an autopsy shall be conducted by
8 the chief medical examiner or his or her designee, by a
9 member of his or her staff, or by a competent pathologist
10 designated and employed by the chief medical examiner
11 under the provisions of this article. For this purpose, the
12 chief medical examiner may employ any county medical
13 examiner who is a pathologist who holds board certification
14 or board eligibility in forensic pathology or has completed an
15 American Board of Pathology fellowship in forensic pathol-
16 ogy to make the autopsies, and the fees to be paid for
17 autopsies under this section shall be in addition to the fee
18 provided for investigations pursuant to section eight of this
19 article. A full record and report of the findings developed by
20 the autopsy shall be filed with the office of the chief medical
21 examiner by the person making the autopsy.

22 (b) Within the discretion of the chief medical examiner,
23 or of the person making the autopsy, or if requested by the
24 prosecuting attorney of the county, or of the county where
25 any injury contributing to or causing the death was sus-
26 tained, a copy of the report of the autopsy shall be furnished
27 to the prosecuting attorney.

28 (c) The office of the chief medical examiner shall keep
29 full, complete and properly indexed records of all deaths
30 investigated, containing all relevant information concerning
31 the death and the autopsy report if an autopsy report is
32 made. Any prosecuting attorney or law-enforcement officer
33 may secure copies of these records or information necessary
34 for the performance of his or her official duties.

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

45 (e) The chief medical examiner is authorized to release
46 investigation records and autopsy reports to the multi-
47 disciplinary team authorized by section three, article five-d,
48 chapter forty-nine of this code and as authorized in subsec-
49 tion (h) of this section. At the direction of the Secretary of
50 the Department of Health and Human Resources the chief
51 medical examiner may release records and information to
52 other state agencies when considered to be in the public
53 interest.

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

59 (g) In cases of the death of any infant in the State of West
60 Virginia where sudden infant death syndrome is the sus-
61 pected cause of death and the chief medical examiner or the
62 medical examiner of the county in which the death in
63 question occurred considers it advisable to perform an
64 autopsy, it is the duty of the chief medical examiner or the
65 medical examiner of the county in which the death occurred
66 to notify the sudden infant death syndrome program within
67 the division of maternal and child health and to inform the
68 program of all information to be given to the infant's
69 parents.

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

72 examiner shall provide notice of the death to the West
73 Virginia Controlled Substances Monitoring Program Data-
74 base Review Committee established pursuant to subsection
75 (b), section five, article nine, chapter sixty-a of this code and
76 shall include in the notice any information relating to the
77 cause of the fatal overdose.

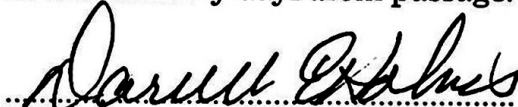
The Joint Committee on Enrolled Bills hereby certifies that the foregoing bill is correctly enrolled.


.....
Chairman Senate Committee

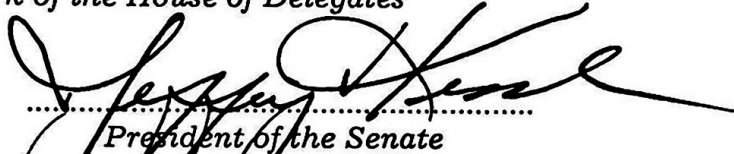

.....
Chairman House Committee

Originated in the Senate.

In effect ninety days from passage.


.....
Clerk of the Senate


.....
Clerk of the House of Delegates


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President of the Senate


.....
Speaker of the House of Delegates

The within is approved this the 29th
Day of March, 2012.


.....
Governor

PRESENTED TO THE GOVERNOR

MAR 29 2012

Time 8:40am