#### **COMMITTEE SUBSTITUTE**

**FOR** 

## H.B. 2577

(BY DELEGATE(S) PERDUE, PERRY, ELDRIDGE,
LAWRENCE AND STAGGERS)

(Originating in the House Committee on the Judiciary)
[March 29, 2013]

A BILL to repeal §30-5-1a, §30-5-1b, §30-5-2a, §30-5-3a, §30-5-5a, §30-5-5b, §30-5-6a, §30-5-7a, §30-5-7b, §30-5-7c, §30-5-9a, §30-5-10a, §30-5-12c, §30-5-14a, §30-5-14b, §30-5-16a, §30-5-16b, §30-5-16c and §30-5-22a of the Code of West Virginia, 1931, as amended; to amend and reenact §16-5A-9a of said code; to amend and reenact §30-5-1, §30-5-2, §30-5-3, §30-5-4, §30-5-5, §30-5-6, §30-5-7, §30-5-8, §30-5-9, §30-5-10, §30-5-11, §30-5-12, §30-5-13, §30-5-14, §30-5-15, §30-5-16, §30-5-17, §30-5-18,

§30-5-19, §30-5-20, §30-5-21, §30-5-22, §30-5-23, §30-5-24, §30-5-25, §30-5-26, §30-5-27, §30-5-28, §30-5-29 and §30-5-30 of said code; to amend said code by adding thereto four new sections, designated §30-5-31, §30-5-32, §30-5-33 and §30-5-34; and to amend and reenact §60A-10-3 of said code, all relating to pharmacy practice; prohibiting the practice of pharmacist care without a license; permitting a licensed practitioner to dispense in certain settings; providing other applicable sections; providing definitions; providing for board composition; setting forth the powers and duties of the board; clarifying rule-making authority; continuing a special revenue account; establishing license, registration and permit requirements; creating a scope of practice; creating a temporary permit; establishing renewal requirements; providing for exemptions from licensure; providing requirement to participate in collaborative pharmacy practice; providing requirement for dispensing generic drugs; requiring the registration of pharmacies requiring a permit for mail-order pharmacies and manufacturing of drugs; providing requirements of filling prescriptions; providing requirements for the display of a board authorization; permitting the board to file an injunction; setting forth grounds for disciplinary actions; allowing for specific disciplinary actions; providing procedures for investigation of complaints; providing for judicial review and appeals of decisions; setting forth hearing and notice requirements; providing for civil causes of action; providing criminal penalties; and updating references.

## Be it enacted by the Legislature of West Virginia:

That §30-5-1a, §30-5-1b, §30-5-2a, §30-5-3a, §30-5-5a, §30-5-5b, §30-5-6a, §30-5-7a, §30-5-7b, §30-5-7c, §30-5-9a, §30-5-10a, §30-5-12c, §30-5-14a, §30-5-14b, §30-5-16a, §30-5-16b, §30-5-16c and §30-5-22a of the Code of West Virginia, 1931, as amended, be repealed; that §30-5-1, §30-5-2, §30-5-3, §30-5-4, §30-5-5, §30-5-6, §30-5-7, §30-5-8, §30-5-9, §30-5-10, §30-5-11, §30-5-12, §30-5-13, §30-5-14, §30-5-15, §30-5-16, §30-5-17, §30-5-18, §30-5-19, §30-5-20, §30-5-21, §30-5-22, §30-5-23, §30-5-24, §30-5-25, §30-5-26, §30-5-27, §30-5-28, §30-5-29 and §30-5-30 of said code be amended and reenacted; that said code be amended by adding thereto four new sections, designated §30-5-31, §30-5-32, §30-5-33 and §30-5-34; and that §60A-10-3 of said code be amended and reenacted; all to read as follows:

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

#### §30-5-1. Short title.

- This article shall be known as and may be cited as the "The
- 2 Larry W. Border Pharmacy Practice Act".

### **§30-5-2. Unlawful acts.**

- 1 (a) It is unlawful for any person in this state to practice or
- 2 offer to practice pharmacist care without a license pursuant to
- 3 the provisions of this article; or to practice or offer to assist in
- 4 the practice of pharmacist care without being registered pursuant
- 5 to the provisions of this article. Further, it is unlawful to
- 6 advertise or use any title or description tending to convey or give
- 7 the impression that he or she is a pharmacist or pharmacy
- 8 <u>technician</u>, unless the person is licensed or registered under the
- 9 provisions of this article.
- 10 (b) A business entity may not render any service or engage
- 11 <u>in any activity which, if rendered or engaged in by an individual,</u>
- 12 would constitute the practice of pharmacist care, except through
- 13 <u>a licensee.</u>
- (c) It is unlawful for the proprietor of a pharmacy or a
- 15 <u>ambulatory health care facility to permit a person, who is not a</u>

- 16 <u>licensed pharmacist, to practice pharmacist care: Provided, That</u>
- 17 a charitable clinic pharmacy may permit a licensed prescribing
- 18 practitioner to act in place of the pharmacist when no pharmacist
- 19 is present in the charitable clinic.

#### §30-5-3. Applicable law.

- 1 The practices authorized under the provisions of this article
- 2 and the Board of Pharmacy are subject to article one of this
- 3 chapter, the provisions of this article, and any rules promulgated
- 4 pursuant this article.

#### §30-5-4. Definitions.

- 1 As used in this article:
- 2 (1) "Ambulatory health care facility" includes any facility
- 3 defined in section one, article five-b, chapter sixteen of this code,
- 4 that also has a pharmacy, offers pharmacist care, or is otherwise
- 5 engaged in the practice of pharmacist care.
- 6 (2) "Active Ingredients" means chemicals, substances, or
- 7 other components of articles intended for use in the diagnosis,
- 8 cure, mitigation, treatment, or prevention of diseases in humans
- 9 or animals or for use as nutritional supplements.

(3) "Administer" means the direct application of a drug to 10 11 the body of a patient or research subject by injection, inhalation, 12 ingestion or any other means. 13 (4) "Board" means the West Virginia Board of Pharmacy. 14 (5) "Board authorization" means a license, registration or 15 permit issued under this article. 16 (6) "Chain Pharmacy Warehouse" means a permanent 17 physical location for drugs and/or devices that acts as a central warehouse and performs intracompany sales and transfers of 18 19 prescription drugs or devices to chain pharmacies, which are members of the same affiliated group, under common ownership 20 21 and control. (7) "Charitable clinic pharmacy" means a clinic or facility 22 23 organized as a not-for-profit corporation that has a pharmacy, 24 offers pharmacist care, or is otherwise engaged in the practice of 25 pharmacist care and dispenses its prescriptions free of charge to 26 appropriately screened and qualified indigent patients. 27 (8) "Collaborative pharmacy practice" is that practice of 28 pharmacist care where one or more pharmacists have jointly 29 agreed, on a voluntary basis, to work in conjunction with one or

30 more physicians under written protocol where the pharmacist or 31 pharmacists may perform certain patient care functions 32 authorized by the physician or physicians under certain specified 33 conditions and limitations. 34 (9) "Collaborative pharmacy practice agreement" is a written 35 and signed agreement, which is a physician directed approach, 36 that is entered into between an individual physician or physician 37 group, an individual pharmacist or pharmacists and an individual 38 patient or the patient's authorized representative who has given 39 informed consent that provides for collaborative pharmacy practice for the purpose of drug therapy management of a 40 41 patient, which has been approved by the board, the Board of 42 Medicine in the case of an allopathic physician or the West 43 Virginia Board of Osteopathic Medicine in the case of an 44 osteopathic physician. 45 (10) "Common Carrier" means any person or entity who 46 undertakes, whether directly or by any other arrangement, to 47 transport property including prescription drugs for 48 compensation.

49	(11) "Component" means any active ingredient or added
50	substance intended for use in the compounding of a drug
51	product, including those that may not appear in such product.
52	(12) "Compounding" means:
53	(A) The preparation, mixing, assembling, packaging or
54	labeling of a drug or device:
55	(i) As the result of a practitioner's prescription drug order or
56	initiative based on the practitioner/patient/pharmacist
57	relationship in the course of professional practice for sale or
58	dispensing; or
59	(ii) For the purpose of, or as an incident to, research,
60	teaching or chemical analysis and not for sale or dispensing; and
61	(B) The preparation of drugs or devices in anticipation of
62	prescription drug orders based on routine, regularly observed
63	prescribing patterns.
64	(13) "Deliver" or "delivery" means the actual, constructive
65	or attempted transfer of a drug or device from one person to
66	another, whether or not for a consideration.
67	(14) "Device" means an instrument, apparatus, implement or

68 machine, contrivance, implant or other similar or related article,

- 69 including any component part or accessory, which is required
- 70 under federal law to bear the label, "Caution: Federal or state
- 71 law requires dispensing by or on the order of a physician".
- 72 (15) "Digital Signature" means an electronic signature based
- 73 upon cryptographic methods of originator authentication, and
- 74 computed by using a set of rules and a set of parameters so that
- 75 the identity of the signer and the integrity of the data can be
- 76 verified.
- 77 (16) "Dispense" or "dispensing" means the interpretation,
- 78 evaluation, and implementation of a prescription drug order,
- 79 including the preparation, verification and delivery of a drug or
- 80 device to a patient or patient's agent in a suitable container
- 81 appropriately labeled for subsequent administration to, or use by,
- 82 a patient.
- 83 (17) "Distribute" or "Distribution" means to sell, offer to
- 84 sell, deliver, offer to deliver, broker, give away, or transfer a
- 85 drug, whether by passage of title, physical movement, or both.
- 86 The term does not include:
- 87 (A) To dispense or administer;
- 88 (B) (i) Delivering or offering to deliver a drug by a common
- 89 carrier in the usual course of business as a common carrier; or

90	providing a drug sample to a patient by a practitioner licensed to
91	prescribe such drug;
92	(ii) A health care professional acting at the direction and
93	under the supervision of a practitioner; or the pharmacy of a
94	hospital or of another health care entity that is acting at the
95	direction of such a practitioner and that received such sample in
96	accordance with the Prescription Drug Marketing Act and
97	regulations to administer or dispense;
98	(iii) Intracompany sales.
99	(18) "Drop shipment" means the sale of a prescription drug
100	to a wholesale distributor by the manufacturer of the prescription
101	drug or by that manufacturer's colicensed product partner, that
102	manufacturer's third party logistics provider, that manufacturer's
103	exclusive distributor, or by an authorized distributor of record
104	that purchased the product directly from the manufacturer or
105	from one of these entities whereby:
106	(A) The wholesale distributor takes title to but not physical
107	possession of such prescription drug;
108	(B) The wholesale distributor invoices the pharmacy,
109	pharmacy warehouse, or other person authorized by law to

110	dispense or administer such drug; and
111	(C) The pharmacy, pharmacy warehouse or other person
112	authorized by law to dispense or administer such drug receives
113	delivery of the prescription drug directly from the manufacturer
114	or from that manufacturer's colicensed product partner, that
115	manufacturer's third party logistics provider, that manufacturer's
116	exclusive distributor, or from an authorized distributor of record
117	that purchased the product directly from the manufacturer or
118	from one of these entities.
119	(19) "Drug" means:
120	(A) Articles recognized as drugs by the United States Food
121	and Drug Administration, or in any official compendium, or
122	supplement;
123	(B) An article, designated by the board, for use in the
124	diagnosis, cure, mitigation, treatment, or prevention of disease
125	in humans or other animals;
126	(C) Articles, other than food, intended to affect the structure
127	or any function of the body of human or other animals; and
128	(D) Articles intended for use as a component of any articles
129	specified in paragraph (A), (B) or (C) of this subdivision.

130	(20) "Drug regimen review" includes, but is not limited to,
131	the following activities:
132	(A) Evaluation of the prescription drug orders and if
133	available, patient records for:
134	(i) Known allergies;
135	(ii) Rational therapy-contraindications;
136	(iii) Reasonable dose and route of administration; and
137	(iv) Reasonable directions for use.
138	(B) Evaluation of the prescription drug orders and patient
139	records for duplication of therapy.
140	(C) Evaluation of the prescription drug for interactions
141	and/or adverse effects which may include, but are not limited to,
142	any of the following:
143	(i) Drug-drug;
144	(ii) Drug-food;
145	(iii) Drug-disease; and
146	(iv) Adverse drug reactions.
147	(D) Evaluation of the prescription drug orders and if
148	available, patient records for proper use, including overuse and

149 underuse and optimum therapeutic outcomes.

150	(21) "Drug therapy management" means the review of drug
151	therapy regimens of patients by a pharmacist for the purpose of
152	evaluating and rendering advice to a physician regarding
153	adjustment of the regimen in accordance with the collaborative
154	pharmacy practice agreement. Decisions involving drug therapy
155	management shall be made in the best interest of the patient.
156	Drug therapy management is limited to:
157	(A) Implementing, modifying and managing drug therapy
158	according to the terms of the collaborative pharmacy practice
159	agreement;
160	(B) Collecting and reviewing patient histories;
<ul><li>160</li><li>161</li></ul>	<ul><li>(B) Collecting and reviewing patient histories;</li><li>(C) Obtaining and checking vital signs, including pulse,</li></ul>
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161	(C) Obtaining and checking vital signs, including pulse,
161 162	(C) Obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration;
<ul><li>161</li><li>162</li><li>163</li></ul>	(C) Obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration;  (D) Ordering screening laboratory tests that are dose related
<ul><li>161</li><li>162</li><li>163</li><li>164</li></ul>	(C) Obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration;  (D) Ordering screening laboratory tests that are dose related and specific to the patient's medication or are protocol driven
<ul><li>161</li><li>162</li><li>163</li><li>164</li><li>165</li></ul>	(C) Obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration;  (D) Ordering screening laboratory tests that are dose related and specific to the patient's medication or are protocol driven and are also specifically set out in the collaborative pharmacy
<ul><li>161</li><li>162</li><li>163</li><li>164</li><li>165</li><li>166</li></ul>	(C) Obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration;  (D) Ordering screening laboratory tests that are dose related and specific to the patient's medication or are protocol driven and are also specifically set out in the collaborative pharmacy practice agreement between the pharmacist and physician.

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- 170 prescribing practitioner with a computer system or other
- 171 electronic device used by a pharmacy to facilitate the secure
- transmission of:
- 173 (A) An electronic prescription order;
- (B) A refill authorization request;
- 175 (C) A communication; or
- (D) Other patient care information.
- 177 (23) "E-prescribing" means the transmission, using
- 178 electronic media, of prescription or prescription-related
- 179 information between a practitioner, pharmacist, pharmacy
- benefit manager or health plan as defined in 45 CFR §160.103,
- 181 either directly or through an electronic data intermediary.
- 182 E-prescribing includes, but is not limited to, two-way
- 183 transmissions between the point of care and the pharmacist.
- 184 E-prescribing may also be referenced by the terms "electronic
- 185 prescription" or "electronic order".
- 186 (24) "Electronic Signature" means an electronic sound,
- 187 symbol, or process attached to or logically associated with a
- 188 record and executed or adopted by a person with the intent to
- 189 sign the record.

190	(25) "Electronic transmission" means transmission of
191	information in electronic form or the transmission of the exact
192	visual image of a document by way of electronic equipment.
193	(26) "Emergency medical reasons" include, but are not
194	limited to, transfers of a prescription drug by one pharmacy to
195	another pharmacy to alleviate a temporary shortage of a
196	prescription drug; sales to nearby emergency medical services,
197	i.e., ambulance companies and firefighting organizations in the
198	same state or same marketing or service area, or nearby licensed
199	practitioners of prescription drugs for use in the treatment of
200	acutely ill or injured persons; and provision of minimal
201	emergency supplies of prescription drugs to nearby nursing
202	homes for use in emergencies or during hours of the day when
203	necessary prescription drugs cannot be obtained.
204	(27) "Exclusive distributor" means an entity that:
205	(A) Contracts with a manufacturer to provide or coordinate
206	warehousing, wholesale distribution, or other services on behalf
207	of a manufacturer and who takes title to that manufacturer's
208	prescription drug, but who does not have general responsibility
209	to direct the sale or disposition of the manufacturer's
210	prescription drug; and

211	(B) Is licensed as a wholesale distributor under this article.
212	(28) "FDA" means the Food and Drug Administration, a
213	federal agency within the United States Department of Health
214	and Human Services.
215	(29) "Health care entity" means a person that provides
216	diagnostic, medical, pharmacist care, surgical, dental treatment,
217	or rehabilitative care but does not include a wholesale
218	distributor.
219	(30) "Health information" means any information, whether
220	oral or recorded in a form or medium, that:
221	(A) Is created or received by a health care provider, health
222	plan, public health authority, employer, life insurer, school or
223	university, or health care clearinghouse, and
224	(B) Relates to the past, present, or future physical or mental
225	health or condition of an individual; or the past, present, or
226	future payment for the provision of health care to an individual.
227	(31) "HIPAA" is the federal Health Insurance Portability and
228	Accountability Act of 1996 (Public Law 104-191).
229	(32) "Immediate container" means a container and does not
230	include package liners.

231	(33) "Individually identifiable health information" is
232	information that is a subset of health information, including
233	demographic information collected from an individual and is
234	created or received by a health care provider, health plan,
235	employer, or health care clearinghouse; and relates to the past,
236	present, or future physical or mental health or condition of an
237	individual; the provision of health care to an individual; or the
238	past, present, or future payment for the provision of health care
239	to an individual; and that identifies the individual; or with
240	respect to which there is a reasonable basis to believe the
241	information can be used to identify the individual.
242	(34) "Intracompany sales" means any transaction between a
243	division, subsidiary, parent, and/or affiliated or related company
244	under the common ownership and control of a corporate or other
245	legal business entity.
246	(35) "Label" means a display of written, printed, or graphic
247	matter upon the immediate container of any drug or device.
248	(36) "Labeling" means the process of preparing and affixing
249	a label to a drug container exclusive, however, of a labeling by
250	a manufacturer, packer or distributor of a nonprescription drug
251	or commercially packaged legend drug or device.

(37) "Long-Term care facility" means a nursing home, 252 253 retirement care, mental care, or other facility or institution that 254 provides extended health care to resident patients. 255 (38) "Mail-order pharmacy" means a pharmacy, regardless 256 of its location, which dispenses greater than twenty-five percent 257 prescription drugs via the mail or other delivery services. 258 (39) "Manufacturer" means any person who is engaged in manufacturing, preparing, propagating, processing, packaging, 259 260 repackaging or labeling of a prescription drug, whether within or 261 outside this state. 262 (40) "Manufacturing" means the production, preparation, 263 propagation or processing of a drug or device, either directly or 264 indirectly, by extraction from substances of natural origin or 265 independently by means of chemical or biological synthesis and includes any packaging or repackaging of the substance or 266 267 substances or labeling or relabeling of its contents and the promotion and marketing of the drugs or devices. Manufacturing 268 also includes the preparation and promotion of commercially 269 270 available products from bulk compounds for resale by pharmacies, practitioners or other persons. 271

272	(41) "Medical order" means a lawful order of a practitioner
273	that may or may not include a prescription drug order.
274	(42) "Medication therapy management" is a distinct service
275	or group of services that optimize medication therapeutic
276	outcomes for individual patients. Medication therapy
277	management services are independent of, but can occur in
278	conjunction with, the provision of a medication or a medical
279	device. Medication therapy management encompasses a broad
280	range of professional activities and responsibilities within the
281	licensed pharmacist's scope of practice. These services may
282	include the following, according to the individual needs of the
283	patient:
284	(A) Performing or obtaining necessary assessments of the
285	patient's health status pertinent to medication therapy
286	management;
287	(B) Optimize medication use, performing medication
288	therapy, and formulating recommendations for patient
289	medication care plans;
290	(C) Developing therapeutic recommendations, to resolve
291	medication related problems;

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292	(D) Monitoring and evaluating the patient's response to
293	medication therapy, including safety and effectiveness;
294	(E) Performing a comprehensive medication review to
295	identify, resolve, and prevent medication-related problems,
296	including adverse drug events;
297	(F) Documenting the care delivered and communicating
298	essential information to the patient's primary care providers;
299	(G) Providing verbal education and training designed to
300	enhance patient understanding and appropriate use of his or her
301	medications;
302	(H) Providing information, support services and resources
303	designed to enhance patient adherence with his or her medication
304	therapeutic regimens;
305	(I) Coordinating and integrating medication therapy
306	management services within the broader health care management
307	services being provided to the patient; and
308	(J) Such other patient care services as may be allowed by
309	<u>law.</u>
310	(43) "Misbranded" means a drug or device that has a label
311	that is false or misleading in any particular; or the label does not

312	bear the name and address of the manufacturer, packer, or
313	distributor and does not have an accurate statement of the
314	quantities of the active ingredients in the case of a drug; or the
315	label does not show an accurate monograph for prescription
316	drugs.
317	(44) "Nonprescription drug" means a drug which may be
318	sold without a prescription and which is labeled for use by the
319	consumer in accordance with the requirements of the laws and
320	rules of this state and the federal government.
321	(45) "Normal distribution channel" means a chain of custody
322	for a prescription drug that goes directly or by drop shipment,
323	from a manufacturer of the prescription drug, the manufacturer's
324	third-party logistics provider, or the manufacturer's exclusive
325	distributor to:
326	(A) A wholesale distributor to a pharmacy to a patient or
327	other designated persons authorized by law to dispense or
328	administer such prescription drug to a patient;
329	(B) A wholesale distributor to a chain pharmacy warehouse
330	to that chain pharmacy warehouse's intracompany pharmacy to
331	a patient or other designated persons authorized by law to
332	dispense or administer such prescription drug to a patient;

333	(C) A chain pharmacy warehouse to that chain pharmacy
334	warehouse's intracompany pharmacy to a patient or other
335	designated persons authorized by law to dispense or administer
36	such prescription drug to a patient;
337	(D) A pharmacy or to other designated persons authorized by
338	law to dispense or administer such prescription drug to a patient;
39	<u>or</u>
340	(E) As prescribed by the board's legislative rules.
841	(46) "Patient counseling" means the communication by the
342	pharmacist of information, as prescribed further in the rules of
343	the board, to the patient to improve therapy by aiding in the
344	proper use of drugs and devices.
345	(47) "Pedigree" means a statement or record in a written
346	form or electronic form, approved by the board, that records
347	each wholesale distribution of any given prescription drug
348	(excluding veterinary prescription drugs), which leaves the
349	normal distribution channel.
350	(48) "Person" means an individual, corporation, partnership,
351	association or any other legal entity, including government.
352	(49) "Pharmacist" means an individual currently licensed by
353	this state to engage in the practice of pharmacist care.

(50) "Pharmacist Care" means the provision by a pharmacist 354 355 of patient care activities, with or without the dispensing of drugs 356 or devices, intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's 357 358 symptoms, or arresting or slowing of a disease process and as 359 provided for in section ten. 360 (51) "Pharmacist-in-charge" means a pharmacist currently 361 licensed in this state who accepts responsibility for the operation 362 of a pharmacy in conformance with all laws and legislative rules 363 pertinent to the practice of pharmacist care and the distribution 364 of drugs and who is personally in full charge of the pharmacy 365 and pharmacy personnel. 366 (52) "Pharmacist's scope of practice pursuant to the 367 collaborative pharmacy practice agreement" means those duties and limitations of duties placed upon the pharmacist by the 368 369 collaborating physician, as jointly approved by the board and the Board of Medicine or the West Virginia Board of Osteopathic 370 371 Medicine. (53) "Pharmacy" means any place within this state where 372 drugs are dispensed and pharmacist care is provided and any 373

374	place outside of this state where drugs are dispensed and
375	pharmacist care is provided to residents of this state.
376	(54) "Pharmacy Intern" or "Intern" means an individual who
377	is currently licensed to engage in the practice of pharmacist care
378	while under the supervision of a pharmacist.
379	(55) "Pharmacy related primary care" means the
380	pharmacist's activities in patient education, health promotion,
381	selection and use of over the counter drugs and appliances and
382	referral or assistance with the prevention and treatment of health
383	related issues and diseases.
384	(56) "Pharmacy Technician" means a person registered with
385	the board to practice certain tasks related to the practice of
386	pharmacist care as permitted by the board.
387	(57) "Physician" means an individual currently licensed, in
388	good standing and without restrictions, as an allopathic physician
389	by the West Virginia Board of Medicine or an osteopathic
390	physician by the West Virginia Board of Osteopathic Medicine.
391	(58) "Practice of telepharmacy" means the provision of
392	pharmacist care by properly licensed pharmacists located within
393	United States jurisdictions through the use of

394 telecommunications or other technologies to patients or their agents at a different location that are located within United 395 396 States jurisdictions. 397 (59) "Practitioner" means an individual authorized by a 398 jurisdiction of the United States to prescribe drugs in the course 399 of professional practices, as allowed by law. 400 (60) "Prescription drug" means any human drug required by 401 federal law or regulation to be dispensed only by prescription, 402 including finished dosage forms and active ingredients subject 403 to section 503(b) of the federal food, drug and cosmetic act. 404 (61) "Prescription or prescription drug order" means a lawful order from a practitioner for a drug or device for a specific 405 406 patient, including orders derived from collaborative pharmacy 407 practice, where a valid patient-practitioner relationship exists, 408 that is communicated to a pharmacist in a pharmacy. 409 (62) "Product Labeling" means all labels and other written, 410 printed, or graphic matter upon any article or any of its 411 containers or wrappers, or accompanying such article. 412 (63) "Repackage" means changing the container, wrapper, 413 quantity, or product labeling of a drug or device to further the distribution of the drug or device. 414

(64) "Repackager" means a person who repackages. 415 (65) "Therapeutic equivalence" mean drug products 416 417 classified as therapeutically equivalent can be substituted with 418 the full expectation that the substituted product will produce the 419 same clinical effect and safety profile as the prescribed product 420 which contain the same active ingredient(s); dosage form and 421 route of administration; and strength. 422 (66) "Third-party logistics provider" means a person who 423 contracts with a prescription drug manufacturer to provide or 424 coordinate warehousing, distribution or other services on behalf 425 of a manufacturer, but does not take title to the prescription drug 426 or have general responsibility to direct the prescription drug's 427 sale or disposition. A third-party logistics provider shall be 428 licensed as a wholesale distributor under this article and, in order 429 to be considered part of the normal distribution channel, shall also be an authorized distributor of record. 430 431 (67) "Valid patient-practitioner relationship" means the 432 following have been established: 433 (A) A patient has a medical complaint; (B) A medical history has been taken; 434

435	(C) A face-to-face physical examination adequate to
436	establish the medical complaint has been performed by the
437	prescribing practitioner or in the instances of telemedicine
438	through telemedicine practice approved by the appropriate
439	practitioner board; and
440	(D) Some logical connection exists between the medical
441	complaint, the medical history, and the physical examination and
442	the drug prescribed.
443	(68) "Wholesale distribution" and "wholesale distributions"
444	mean distribution of prescription drugs, including directly or
445	through the use of a third-party logistics provider or any other
446	situation in which title, ownership or control over the
447	prescription drug remains with one person or entity but the
448	prescription drug is brought into this state by another person or
449	entity on his, her or its behalf, to persons other than a consumer
450	or patient, but does not include:
451	(A) Intracompany sales, being defined as any transaction,
452	transfer or delivery into or within this state between any division,
453	subsidiary, parent and/or affiliated or related company under the
454	common ownership and control of a corporate entity;

455	(B) The purchase or other acquisition by a hospital or other
456	health care entity that is a member of a group purchasing
457	organization of a drug for its own use from the group purchasing
458	organization or from other hospitals or health care entities that
459	are members of such organizations;
460	(C) The sale, purchase or trade of a drug or an offer to sell.
461	purchase or trade a drug by a charitable organization described
462	in section 501(c)(3) of the United States Internal Revenue Code
463	of 1986 to a nonprofit affiliate of the organization to the extent
464	otherwise permitted by law;
465	(D) The sale, purchase or trade of a drug or an offer to sell.
466	purchase or trade a drug among hospitals or other health care
467	entities that are under common control. For purposes of this
468	article, "common control" means the power to direct or cause the
469	direction of the management and policies of a person or an
470	organization, whether by ownership of stock, voting rights, by
471	contract, or otherwise;
472	(E) The sale, purchase or trade of a drug or an offer to sell,
473	purchase or trade a drug for "emergency medical reasons" for
474	purposes of this article includes transfers of prescription drugs

475	by a retail pharmacy to another retail pharmacy to alleviate a
476	temporary shortage, except that the gross dollar value of such
477	transfers shall not exceed five percent of the total prescription
478	drug sales revenue of either the transferor or transferee pharmacy
479	during any twelve consecutive month period;
480	(F) The sale, purchase or trade of a drug, an offer to sell,
481	purchase, or trade a drug or the dispensing of a drug pursuant to
482	a prescription;
483	(G) The distribution of drug samples by manufacturers'
484	representatives or distributors' representatives, if the distribution
485	is permitted under federal law [21 U. S. C. 353(d)];
486	(H) Drug returns by a pharmacy or chain drug warehouse to
487	wholesale drug distributor or the drug's manufacturer; or
488	(J) The sale, purchase or trade of blood and blood
489	components intended for transfusion.
490	(K) "Wholesale drug distributor" or "wholesale distributor"
491	means any person or entity engaged in wholesale distribution of
492	prescription drugs, including, but not limited to, manufacturers,
493	repackers, own-label distributors, jobbers, private-label
494	distributors, brokers, warehouses, including manufacturers' and

495 distributors' warehouses, chain drug warehouses and wholesale 496 drug warehouses, independent wholesale drug traders, 497 prescription drug repackagers, physicians, dentists, veterinarians, 498 birth control and other clinics, individuals, hospitals, nursing 499 homes and/or their providers, health maintenance organizations 500 and other health care providers, and retail and hospital 501 pharmacies that conduct wholesale distributions, including, but 502 not limited to, any pharmacy distributor as defined in this section. A wholesale drug distributor shall not include any for 503 504 hire carrier or person or entity hired solely to transport 505 prescription drugs.

## §30-5-5. West Virginia Board of Pharmacy.

- 1 (a) The West Virginia Board of Pharmacy is continued. The
- 2 members of the board in office on July 1, 2013, shall, unless
- 3 sooner removed, continue to serve until their respective terms
- 4 expire and until their successors have been appointed and
- 5 qualified.
- 6 (b) The Governor, by and with the advice and consent of the
- 7 Senate, shall appoint:
- 8 (1) Five members who are licensed to practice pharmacist
- 9 care in this state; and

10 (2) Two citizen members, who are not licensed under the 11 provisions of this article, and who do not perform any services related to the practice of the pharmacist care regulated under the 12 13 provisions of this article. 14 (c) After the initial appointment term, the appointment term 15 is five years. A member may not serve more than two 16 consecutive terms. A member who has served two consecutive 17 full terms may not be reappointed for at least one year after 18 completion of his or her second full term. A member may 19 continue to serve until his or her successor has been appointed 20 and qualified. 21 (d) Each licensed member of the board, at the time of his or 22 her appointment, shall have held a license in this state for a 23 period of not less than three years immediately preceding the 24 appointment. 25 (e) Each member of the board shall be a resident of this state 26 during the appointment term. 27 (f) A vacancy on the board shall be filled by appointment by 28 the Governor for the unexpired term of the member whose office

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is vacant.

30	(g) The Governor may remove any member from the board
31	for neglect of duty, incompetency or official misconduct.
32	(h) A licensed member of the board immediately and
33	automatically forfeits membership to the board if his or her
34	license to practice is suspended or revoked in any jurisdiction.
35	(i) A member of the board immediately and automatically
36	forfeits membership to the board if he or she is convicted of a
37	felony under the laws of any jurisdiction or becomes a
38	nonresident of this state.
39	(j) The board shall elect annually one of its members as
40	president, one member as vice president and one member as
41	treasurer who shall serve at the will and pleasure of the board.
42	(k) Each member of the board is entitled to receive
43	compensation and expense reimbursement in accordance with
44	article one of this chapter.
45	(l) A simple majority of the membership serving on the
46	board at a given time is a quorum for the transaction of business.
47	(m) The board shall hold at least two meetings annually.
48	Other meetings shall be held at the call of the chairperson or
49	upon the written request of three members, at the time and place
50	as designated in the call or request

- (n) Prior to commencing his or her duties as a member of the
- 52 board, each member shall take and subscribe to the oath required
- 53 by section five, article four of the Constitution of this state.
- (o) The members of the board when acting in good faith and
- 55 without malice shall enjoy immunity from individual civil
- 56 liability while acting within the scope of their duties as board
- 57 members.

#### §30-5-6. Powers and duties of the board.

- 1 The board has all the powers and duties set forth in this
- 2 article, by rule, in article one of this chapter and elsewhere in
- 3 law, including:
- 4 (a) Hold meetings;
- 5 (b) Establish additional requirements for a license, permit
- 6 and registration;
- 7 (c) Establish procedures for submitting, approving and
- 8 rejecting applications for a license, permit and registration;
- 9 (d) Determine the qualifications of any applicant for a
- 10 <u>license</u>, permit and registration;
- 11 (e) Establish the fees charged under the provisions of this
- 12 article;

13	(f) Issue, renew, deny, suspend, revoke or reinstate a license,
14	permit, and registration;
15	(g) Prepare, conduct, administer and grade written, oral or
16	written and oral examinations for a license and registration;
17	(h) Contract with third parties to administer the examinations
18	required under the provisions of this article;
19	(i) Maintain records of the examinations the board or a third
20	party administers, including the number of persons taking the
21	examination and the pass and fail rate;
22	(j) Maintain an office, and hire, discharge, establish the job
23	requirements and fix the compensation of employees and
24	contract with persons necessary to enforce the provisions of this
25	article. Inspectors shall be licensed pharmacists;
26	(k) Investigate alleged violations of the provisions of this
27	article, legislative rules, orders and final decisions of the board;
28	(1) Conduct disciplinary hearings of persons regulated by the
29	board;
30	(m) Determine disciplinary action and issue orders;
31	(n) Institute appropriate legal action for the enforcement of
32	the provisions of this article;

- (o) Maintain an accurate registry of names and addresses of
- 34 all persons regulated by the board;
- 35 (p) Keep accurate and complete records of its proceedings,
- and certify the same as may be necessary and appropriate;
- 37 (q) Propose rules in accordance with the provisions of article
- 38 three, chapter twenty-nine-a of this code to implement the
- 39 provisions of this article;
- 40 (r) Sue and be sued in its official name as an agency of this
- 41 state;
- 42 (s) Confer with the Attorney General or his or her assistant
- 43 in connection with legal matters and questions; and
- 44 (t) Take all other actions necessary and proper to effectuate
- 45 the purposes of this article.

## §30-5-7. Rule-making authority.

- 1 (a) The board shall propose rules for legislative approval, in
- 2 accordance with the provisions of article three, chapter
- 3 <u>twenty-nine-a of this code, to implement the provisions of this</u>
- 4 article, and articles two, three, eight, nine and ten of chapter
- 5 <u>sixty-A including:</u>
- 6 (1) Standards and requirements for a license, permit and
- 7 <u>registration;</u>

- 8 (2) Educational and experience requirements;
- 9 (3) Procedures for examinations and reexaminations;
- 10 (4) Requirements for third parties to prepare, administer or
- 11 prepare and administer examinations and reexaminations;
- 12 (5) The passing grade on the examination;
- 13 (6) Procedures for the issuance and renewal of a license,
- 14 permit and registration;
- 15 (7) A fee schedule;
- 16 (8) Continuing education requirements;
- 17 (9) Set standards for professional conduct;
- 18 (10) Establish equipment and facility standards for
- 19 pharmacies;
- 20 (11) Approve courses and standards for training pharmacist
- 21 <u>technicians;</u>
- 22 (12) Regulation of charitable clinic pharmacies;
- 23 13) Regulation of mail order pharmacies: *Provided*, That
- 24 until the board establishes requirements that provide further
- 25 conditions for pharmacists whom consult with or who provide
- 26 pharmacist care to patients regarding prescriptions dispensed in
- 27 this state by a mail order pharmacy, the pharmacist in charge of

- 28 the out-of-state mail order pharmacy shall be licensed in West
- 29 Virginia and any other pharmacist providing pharmacist care
- 30 from the mail order pharmacy shall be licensed in the state where
- 31 the pharmacy is located.
- 32 (14) Agreements with organizations to form pharmacist
- 33 recovery networks;
- 34 (15) Create an alcohol or chemical dependency treatment
- 35 program;
- 36 (16) A ratio of pharmacy technicians to on-duty pharmacist
- 37 operating in any outpatient, mail order or institutional pharmacy;
- 38 (17) Regulation of telepharmacy;
- 39 (18) The minimum standards for a charitable clinic
- 40 pharmacy and rules regarding the applicable definition of a
- 41 pharmacist-in-charge, who may be a volunteer, at charitable
- 42 <u>clinic pharmacies: Provided, That a charitable clinic pharmacy</u>
- 43 may not be charged any applicable licensing fees and such
- 44 <u>clinics may receive donated drugs.</u>
- 45 (19) Establish standards for substituted drug products;
- 46 (20) Establish the regulations for E-prescribing;
- 47 (21) Establish the proper use of the automated data
- 48 processing system;

- 49 (22) Registration and control of the manufacture and
- 50 distribution of controlled substances within this state.
- 51 (23) Regulation of pharmacies;
- 52 (24) Sanitation and equipment requirements for wholesalers,
- 53 distributers and pharmacies.
- 54 (25) The procedures for denying, suspending, revoking,
- 55 reinstating or limiting the practice of a licensee, permittee or
- 56 registrant;
- 57 (26) Regulations on prescription paper as provided in section
- 58 five, article five-w, chapter sixteen;
- 59 (27) Regulations on controlled substances as provided in
- 60 article two, chapter sixty-a;
- 61 (28) Regulations on manufacturing, distributing, or
- 62 dispensing any controlled substance as provided in article three,
- 63 chapter sixty-a;
- 64 (29) Regulations on wholesale drug distribution as provided
- 65 <u>in article eight, chapter sixty-a;</u>
- 66 (30) Regulations on controlled substances monitoring as
- 67 provided in article nine, chapter sixty-a;
- 68 (31) Regulations on Methamphetamine Laboratory
- 69 Eradication Act as provided in article ten, chapter sixty-a; and

(32) Any other rules necessary to effectuate the provisions 70 71 of this article. 72 (b) The board may provide an exemption to the 73 pharmacist-in-charge requirement for the opening of a new retail 74 pharmacy or during a declared emergency; 75 (c) The board, the Board of Medicine and the Board of 76 Osteopathic Medicine shall jointly agree and propose rules 77 concerning collaborative pharmacy practice for legislative 78 approval in accordance with the provisions of article three, 79 chapter twenty-nine-a of the code; 80 (d) The board with the advice of the Board of Medicine and 81 the Board of Osteopathic Medicine shall propose rules for 82 legislative approval in accordance with the provisions of article 83 three, chapter twenty-nine-a of this code to perform influenza 84 and pneumonia immunizations, on a person of eighteen years of 85 age or older. These rules shall provide, at a minimum, for the 86 following: 87 (1) Establishment of a course, or provide a list of approved 88 courses, in immunization administration. The courses shall be based on the standards established for such courses by the 89

90	Centers for Disease Control and Prevention in the public health
91	service of the United States Department of Health and Human
92	Services;
93	(2) Definitive treatment guidelines which shall include, but
94	not be limited to, appropriate observation for an adverse reaction
95	of an individual following an immunization;
96	(3) Prior to administration of immunizations, a pharmacist
97	shall have completed a board approved immunization
98	administration course and completed an American Red Cross or
99	American Heart Association basic life-support training, and
100	maintain certification in the same.
101	(4) Continuing education requirements for this area of
102	practice;
103	(5) Reporting requirements for pharmacists administering
104	immunizations to report to the primary care physician or other
105	licensed health care provider as identified by the person
106	receiving the immunization;
107	(6) Reporting requirements for pharmacists administering
108	immunizations to report to the West Virginia Statewide
109	Immunization Information (WVSII);

110 (7) That a pharmacist may not delegate the authority to 111 administer immunizations to any other person; unless 112 administered by a licensed pharmacy intern under the direct 113 supervision of a pharmacist of whom both pharmacist and intern 114 have successfully completed all board required training. 115 (8) Any other provisions necessary to implement the 116 provisions of this section. 117 (e) The board, the Board of Medicine and the Board of 118 Osteopathic Medicine shall propose joint rules for legislative 119 approval in accordance with the provisions of article three, 120 chapter twenty-nine-a of this code to permit licensed pharmacists 121 to administer other immunizations such as Hepatitis A, Hepatitis 122 B, Herpes Zoster and Tetanus. These rules shall provide, at a 123 minimum, the same provisions contained in subsection (d)(1) through (d)(8) of this section. 124 125 (f) All of the board's rules in effect and not in conflict with 126 these provisions, shall remain in effect until they are amended or 127 rescinded.

## §30-5-8. Fees; special revenue account; administrative fines.

- 1 (a) All fees and other moneys, except fines, received by the
- 2 <u>board shall be deposited in a separate special revenue fund in the</u>

- 3 State Treasury designated the "Board of Pharmacy Fund", which
- 4 fund is continued. The fund is used by the board for the
- 5 administration of this article. Except as may be provided in
- 6 article one of this chapter, the board shall retain the amounts in
- 7 the special revenue account from year to year. Any
- 8 compensation or expense incurred under this article is not a
- 9 charge against the General Revenue Fund.
- 10 (b) The board shall deposit any amounts received as
- 11 administrative fines imposed pursuant to this article into the
- 12 General Revenue Fund of the State Treasury.

#### §30-5-9. Qualifications for licensure as pharmacist;

- 1 (a) To be eligible for a license to practice pharmacist care
- 2 under the provisions of this article, the applicant shall:
- 3 (1) Submit a written application to the board;
- 4 (2) Be eighteen years of age or older;
- 5 (3) Pay all applicable fees;
- 6 (4) Graduate from an accredited school of pharmacy;
- 7 (5) Complete at least fifteen hundred hours of internship in
- 8 a pharmacy under the instruction and supervision of a
- 9 pharmacist;

- 10 (6) Pass an examination or examinations approved by the 11 board; 12 (7) Not be an alcohol or drug abuser, as these terms are 13 defined in section eleven, article one-a, chapter twenty-seven of 14 this code: *Provided*, That an applicant in an active recovery 15 process, which may, in the discretion of the board, be evidenced 16 by participation in a twelve-step program or other similar group 17 or process, may be considered; 18 (8) Present to the board satisfactory evidence that he or she 19 is a person of good moral character, has not been convicted of a 20 felony involving controlled substances or violent crime; 21 (9) Not been convicted in any jurisdiction of a felony or any 22 crime which bears a rational nexus to the individual's ability to 23 practice pharmacist care; and 24 (10) Has fulfilled any other requirement specified by the
- 27 all the requirements of this article.

(b) An applicant from another jurisdiction shall comply with

### an the requirements of this article.

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board in rule.

### §30-5-10. Scope practice for licensed pharmacist;

1 (a) A licensed pharmacist may:

- 2 (1) Provide care related to the interpretation, evaluation, and
- 3 implementation of medical orders;
- 4 (2) Dispense of prescription drug orders; participate in drug
- 5 and device selection;
- 6 (3) Provide drug administration;
- 7 (4) Provide drug regimen review;
- 8 (5) Provide drug or drug-related research;
- 9 (6) Perform patient counseling;
- 10 (7) Provide pharmacy related primary care;
- 11 (8) Provide pharmacist care in all areas of patient care,
- 12 including collaborative pharmacy practice;
- 13 (9) Compound and label drugs and drug devices;
- 14 (10) Proper and safe storage of drugs and devices;
- 15 (11) Maintain proper records;
- 16 (12) Provide patient counseling concerning the therapeutic
- value and proper use of drugs and devices;
- 18 (13) Order laboratory tests in accordance with drug therapy
- 19 management; and
- 20 (14) Provide medication therapy management.
- 21 (b) A licensee meeting the requirements as promulgated by
- 22 <u>legislative rule may administer immunizations.</u>

- 23 (c) The sale of any medicine, if the contents of its container,
- 24 or any part thereof, taken at one time, are likely to prove
- 25 poisonous, deleterious, or habit-forming is prohibited by any
- 26 person other than a registered pharmacist, who shall take
- 27 precautions to acquaint the purchaser of the nature of the
- 28 medicine at the time of sale.

#### §30-5-11. Registration of pharmacy technicians;

- 1 (a) To be eligible for registration as a pharmacy technician
- 2 to assist in the practice of pharmacist care, the applicant shall:
- 3 (1) Submit a written application to the board;
- 4 (2) Pay the applicable fees;
- 5 (3) Have graduated from high school or obtained a
- 6 Certificate of General Educational Development (GED) or
- 7 equivalent;
- 8 <u>(4) Have:</u>
- 9 (A) Graduated from a competency-based pharmacy
- 10 technician education and training program as approved by
- 11 <u>legislative rule of the board; or</u>
- 12 (B) Completed a pharmacy provided, competency-based
- 13 <u>education and training program approved by the board;</u>

14	(5) Effective July 1, 2014, have successfully passed an
15	examination developed using nationally recognized and
16	validated psychometric and pharmacy practice standards
17	approved by the board;
18	(6) Not be an alcohol or drug abuser, as these terms are
19	defined in section eleven, article one-a, chapter twenty-seven of
20	this code: Provided, That an applicant in an active recovery
21	process, which may, in the discretion of the board, be evidenced
22	by participation in a twelve-step program or other similar group
23	or process, may be considered;
24	(8) Not have been convicted of a felony in any jurisdiction
25	within ten years preceding the date of application for license,
26	which conviction remains unreversed;
27	(9) Not have been convicted of a misdemeanor or felony in
28	any jurisdiction if the offense for which he or she was convicted
29	bearing a rational nexus to the practice of pharmacist care, which
30	conviction remains unreversed; and
31	(10) Have fulfilled any other requirement specified by the
32	board in rule.
33	(b) A person whose license to practice pharmacist care has

been denied, revoked, suspended, or restricted for disciplinary

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- 35 purposes in any jurisdiction is not eligible to be registered as a
- 36 pharmacy technician.
- 37 (c) A person registered to assist in the practice pharmacist
- 38 care issued by the board prior to June 30, 2014, shall for all
- 39 purposes be considered registered under this article and may
- 40 renew pursuant to the provisions of this article.

#### §30-5-12. Scope practice for registered pharmacy technician.

- 1 (a) A registered pharmacy technician shall, under the direct
- 2 supervision of the licensed pharmacist, but is not limited to,
- 3 perform the following:
- 4 (1) Assist in the dispensing process;
- 5 (2) Receive new written or electronic prescription drug
- 6 orders;
- 7 (3) Compound; and
- 8 (4) Stock of medications.
- 9 (b) A registered pharmacy technician may perform the
- 10 <u>following under indirect supervision:</u>
- 11 (1) Process medical coverage claims; and
- 12 (2) Cashier.
- 13 (c) A registered pharmacy technician may not perform the
- 14 following:

- 15 (1) Drug regimen review;
- 16 (2) Clinical conflict resolution;
- 17 (3) Contact a prescriber concerning prescription drug order
- 18 clarification or therapy modification;
- 19 (4) Patient counseling;
- 20 (5) Dispense process validation;
- 21 (6) Prescription transfer; and
- 22 (7) Receive new oral prescription drug orders.
- 23 (d) Indirect supervision of a registered pharmacy technician
- 24 is permitted to allow a pharmacist to take one break of no more

than thirty minutes during any contiguous eight-hour period. The

- 26 pharmacist may leave the pharmacy area but may not leave the
- 27 building during the break. When a pharmacist is on break, a
- 28 pharmacy technician may continue to prepare prescriptions for
- 29 the pharmacist's verification. A prescription may not be
- 30 delivered until the pharmacist has verified the accuracy of the
- 31 prescription, and counseling, if required, has been provided to or
- 32 <u>refused by the patient.</u>

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- 33 (e) A pharmacy that permits indirect supervision of a
- 34 pharmacy technician during a pharmacist's break shall have

- 35 either an interactive voice response system or a voice mail
- 36 system installed on the pharmacy phone line in order to receive
- 37 new prescription orders and refill authorizations during the
- 38 break.
- 39 (f) The pharmacy shall establish protocols that require a
- 40 registered pharmacy technician to interrupt the pharmacist's
- 41 break if an emergency arises.

#### §30-5-13. Pharmacist interns.

- 1 (a) To be eligible for a license to assist in the practice of
- 2 pharmacist care as a pharmacy intern, the applicant shall be:
- 3 (1) Enrolled and progressing to obtain a degree in a
- 4 professional degree program of a school or college of pharmacy
- 5 that has been approved by the board, and is satisfactorily
- 6 progressing toward meeting the requirements for licensure as a
- 7 pharmacist; or
- 8 (2) A graduate of an approved professional degree program
- 9 of a school or college of pharmacy or a graduate who has
- 10 established educational equivalency by obtaining a Foreign
- 11 Pharmacy Graduate Examination Committee Certificate, who is
- 12 currently licensed by the board for the purpose of obtaining

- 13 practical experience as a requirement for licensure as a
- 14 pharmacist; or
- 15 (3) A qualified applicant awaiting examination for licensure
- 16 or meeting board requirements for relicensure; or
- 17 (4) An individual participating in a pharmacy residency or
- 18 <u>fellowship program.</u>

# §30-5-14. Prohibiting the dispensing of prescription orders in absence of practitioner-patient relationship.

- 1 A pharmacist may not compound or dispense any
- 2 prescription order when he or she has knowledge that the
- 3 prescription was issued by a practitioner without establishing a
- 4 <u>valid practitioner-patient relationship. An online or telephonic</u>
- 5 evaluation by questionnaire, or an online or telephonic
- 6 consultation, is inadequate to establish a valid
- 7 practitioner-patient relationship: *Provided*, That this prohibition
- 8 does not apply:
- 9 (1) In a documented emergency;
- 10 (2) In an on-call or cross-coverage situation; or
- 11 (3) Where patient care is rendered in consultation with
- 12 <u>another practitioner who has an ongoing relationship with the</u>

- 13 patient and who has agreed to supervise the patient's treatment,
- 14 including the use of any prescribed medications.

# §30-5-15. Reciprocal licensure of pharmacists from other states or countries.

- 1 (a) The board may by reciprocity license pharmacists in this
- 2 state who have been authorized to practice pharmacist care in
- 3 another state: *Provided*, That the applicant for licensure meets
- 4 the requirements of the rules for reciprocity promulgated by the
- 5 board in accordance with the provisions of chapter twenty-nine-a
- 6 of this code: Provided, however, That reciprocity is not
- 7 authorized for pharmacists from another state where that state
- 8 does not permit reciprocity to pharmacists licensed in West
- 9 Virginia.
- 10 (b) The board may refuse reciprocity to pharmacists from
- 11 another country unless the applicant qualifies under the
- 12 legislative rules as may be promulgated by the board for
- 13 <u>licensure of foreign applicants.</u>

#### §30-5-16. Renewal requirements.

- 1 (a) All persons regulated by this article shall annually or
- 2 biannually, renew his or her board authorization by completing

- 3 a form prescribed by the board and submitting any other
- 4 <u>information required by the board.</u>
- 5 (b) The board shall charge a fee for each renewal of an board
- 6 authorization and shall charge a late fee for any renewal not paid
- 7 by the due date.
- 8 (c) The board shall require as a condition of renewal that
- 9 each licensee or registrant complete continuing education.
- 10 (d) The board may deny an application for renewal for any
- reason which would justify the denial of an original application.
- (e) After June 30, 2014, a previously registered pharmacist
- 13 technician may renew his or her current registration without
- having successfully completed subdivision six, subsection (a), of
- 15 section eleven. The previously registered pharmacist may
- 16 continue to renew his or her registration under this provision.

# §30-5-17. Special volunteer pharmacist license; civil immunity for voluntary services rendered to indigents.

- 1 (a) There is a special volunteer pharmacist license for
- 2 pharmacists retired or retiring from the active practice of
- 3 pharmacist care who wish to donate their expertise for the
- 4 pharmacist care and treatment of indigent and needy patients in
- 5 the clinic setting of clinics organized, in whole or in part, for the

- 6 delivery of health care services without charge. The special
- 7 volunteer pharmacist license shall be issued by the board to
- 8 pharmacists licensed or otherwise eligible for licensure under
- 9 this article and the legislative rules promulgated hereunder
- without the payment of an application fee, license fee or renewal
- 11 fee, and the initial license shall be issued for the remainder of the
- 12 licensing period, and renewed consistent with the boards other
- 13 licensing requirements. The board shall develop application
- 14 forms for the special license provided in this subsection which
- 15 shall contain the pharmacist's acknowledgment that:
- 16 (1) The pharmacist's practice under the special volunteer
- 17 pharmacist license shall be exclusively devoted to providing
- 18 pharmacist care to needy and indigent persons in West Virginia;
- 19 (2) The pharmacist may not receive any payment or
- 20 compensation, either direct or indirect, or have the expectation
- 21 of any payment or compensation, for any pharmacist care
- 22 rendered under the special volunteer pharmacist license;
- 23 (3) The pharmacist will supply any supporting
- 24 documentation that the board may reasonably require; and

25 (4) The pharmacist agrees to continue to participate in 26 continuing professional education as required by the board for 27 the special volunteer pharmacist license. 28 (b) Any pharmacist who renders any pharmacist care to 29 indigent and needy patients of a clinic organized, in whole or in 30 part, for the delivery of health care services without charge under 31 a special volunteer pharmacist license authorized under 32 subsection (a) of this section without payment or compensation 33 or the expectation or promise of payment or compensation is 34 immune from liability for any civil action arising out of any act 35 or omission resulting from the rendering of the pharmacist care 36 at the clinic unless the act or omission was the result of the 37 pharmacist's gross negligence or willful misconduct. In order for 38 the immunity under this subsection to apply, there shall be a 39 written agreement between the pharmacist and the clinic 40 pursuant to which the pharmacist provides voluntary 41 uncompensated pharmacist care under the control of the clinic to 42. patients of the clinic before the rendering of any services by the pharmacist at the clinic: *Provided*, That any clinic entering into 43 44 such written agreement is required to maintain liability coverage of not less than \$1 million per occurrence. 45

46 (c) Notwithstanding the provisions of subsection (b) of this 47 section, a clinic organized, in whole or in part, for the delivery 48 of health care services without charge is not relieved from 49 imputed liability for the negligent acts of a pharmacist rendering 50 voluntary pharmacist care at or for the clinic under a special 51 volunteer pharmacist license authorized under subsection (a) of 52 this section. 53 (d) For purposes of this section, "otherwise eligible for 54 licensure" means the satisfaction of all the requirements for 55 licensure as listed in section nine of this article and in the legislative rules promulgated thereunder, except the fee 56 57 requirements of that section and of the legislative rules 58 promulgated by the board relating to fees. 59 (e) Nothing in this section may be construed as requiring the 60 board to issue a special volunteer pharmacist license to any 61 pharmacist whose license is or has been subject to any 62 disciplinary action or to any pharmacist who has surrendered a 63 license or caused such license to lapse, expire and become 64 invalid in lieu of having a complaint initiated or other action taken against his or her license, or who has elected to place a 65

- 66 pharmacist license in inactive status in lieu of having a
- 67 complaint initiated or other action taken against his or her
- 68 license, or who has been denied a pharmacist license.
- 69 (f) Any policy or contract of liability insurance providing
- 70 coverage for liability sold, issued or delivered in this state to any
- 71 pharmacist covered under the provisions of this article shall be
- 72 read so as to contain a provision or endorsement whereby the
- 73 company issuing such policy waives or agrees not to assert as a
- 74 <u>defense on behalf of the policyholder or any beneficiary thereof,</u>
- 75 to any claim covered by the terms of such policy within the
- 76 policy limits, the immunity from liability of the insured by
- 77 reason of the care and treatment of needy and indigent patients
- 78 by a pharmacist who holds a special volunteer pharmacist
- 79 <u>license.</u>

# §30-5-18. Pharmacist requirements to participate in a collaborative pharmacy practice agreement.

- For a pharmacist to participate in a collaborative pharmacy
- 2 practice agreement, the pharmacist shall:
- 3 (a) Have an unrestricted and current license to practice as a
- 4 pharmacist in West Virginia;

5 (b) Personally have or have employer coverage of at least \$1 6 million of professional liability insurance coverage; 7 (c) Meet one of the following qualifications, at a minimum: 8 (1) Earned a Certification from the Board of Pharmaceutical 9 Specialties, is a Certified Geriatric Practitioner, or has completed 10 an American Society of Health System Pharmacists(ASHP) accredited residency program, which includes two years of 11 12 clinical experience approved by the board; or 13 (2) Successfully completed the course of study and holds the 14 academic degree of Doctor of Pharmacy and has three years of 15 clinical experience approved by the board and has completed an 16 Accreditation Council for Pharmacy Education (ACPE) 17 approved practice based continuing pharmacy education activity 18 in the area of practice covered by the collaborative pharmacy 19 practice agreement; or 20 (3) Successfully completed the course of study and hold the 21 academic degree of Bachelor of Science in Pharmacy and has 22 five years of clinical experience approved by the board and has 23 completed two ACPE approved practice based continuing pharmacy education activity with at least one program in the 24

- 25 area of practice covered by a collaborative pharmacy practice
- 26 agreement.

#### §30-5-19. Collaborative pharmacy practice agreement.

(a) A pharmacist engaging in collaborative pharmacy 1 2 practice shall have on file at his or her place of practice the 3 collaborative pharmacy practice agreement. The existence and subsequent termination of the agreement and any additional 4 5 information the rules may require concerning the agreement, including the agreement itself, shall be made available to the 6 appropriate licensing board for review upon request. The 7 8 agreement may allow the pharmacist, within the pharmacist's 9 scope of practice pursuant to the collaborative pharmacy practice 10 agreement, to conduct drug therapy management activities 11 approved by the collaborating physician. The collaborative 12 pharmacy practice agreement shall be a voluntary process, which 13 is a physician directed approach, that is entered into between an individual physician or physician group, an individual 14 15 pharmacist or pharmacists and an individual patient or the 16 patient's authorized representative who has given informed 17 consent as per subsection (c).

18	(b) A collaborative pharmacy practice agreement may
19	authorize a pharmacist to provide drug therapy management. In
20	instances where drug therapy is discontinued, the pharmacist
21	shall notify the treating physician of the discontinuance in the
22	time frame and in the manner established by joint legislative
23	rules. Each protocol developed, pursuant to the collaborative
24	pharmacy practice agreement, shall contain detailed direction
25	concerning the services that the pharmacists may perform for
26	that patient. The protocol shall include, but need not be limited
27	to:
28	(1) The specific drug or drugs to be managed by the
29	pharmacist;
30	(2) The terms and conditions under which drug therapy may
31	be implemented, modified or discontinued;
32	(3) The conditions and events upon which the pharmacist is
33	required to notify the physician; and
34	(4) The laboratory tests that may be ordered in accordance
35	with drug therapy management.
36	(c) All activities performed by the pharmacist in conjunction
37	with the protocol shall be documented in the patient's medical

38	record. The pharmacists shall report at least every thirty days to
39	the physician regarding the patient's drug therapy management.
40	The collaborative pharmacy practice agreement and protocols
41	shall be available for inspection by the board, the West Virginia
12	Board of Medicine, or the West Virginia Board of Osteopathic
43	Medicine, depending on the licensing board of the participating
14	physician. A copy of the protocol shall be filed in the patient's
45	medical record.
46	(d) Collaborative pharmacy agreements may not include the
47	management of controlled substances.
48	(e) A collaborative pharmacy practice agreement, meeting
19	the requirements herein established and in accordance with joint
50	rules, shall be allowed in the hospital setting, the nursing home
51	setting, the medical school setting and the hospital,
52	community-based pharmacy setting and ambulatory care clinics.
53	The pharmacist shall be employed by or under contract to
54	provide services to the hospital, pharmacy, nursing home or
55	medical school, or hold a faculty appointment with one of the
56	schools of pharmacy or medicine in this state.
57	(f) Nothing pertaining to collaborative pharmacy practice
58	shall be interpreted to permit a pharmacist to accept delegation

- 59 of a physician's authority outside the limits included in the
- appropriate board's statute and rules.

#### §30-5-20. Board authorizations shall be displayed.

- 1 (a) The board shall prescribe the form for an board
- 2 <u>authorization</u>, and may issue a duplicate upon payment of a fee.
- 3 (b) Any person regulated by the article shall conspicuously
- 4 display his or her board authorization at his or her principal
- 5 business location.

# §30-5-21. Responsibility for quality of drugs dispensed; exception; falsification of labels; deviation from prescription.

- 1 (a) All persons, whether licensed pharmacists or not, shall be
- 2 responsible for the quality of all drugs, chemicals and medicines
- 3 they may sell or dispense, with the exception of those sold in or
- 4 dispensed unchanged from the original retail package of the
- 5 manufacturer, in which event the manufacturer shall be
- 6 <u>responsible.</u>
- 7 (b) Except as provided in section twelve-b of this article, the
- 8 <u>following acts shall be prohibited:</u>
- 9 (1) The falsification of any label upon the immediate
- 10 container, box and/or package containing a drug;

11 (2) The substitution or the dispensing of a different drug in 12 lieu of any drug prescribed in a prescription without the approval of the practitioner authorizing the original prescription: 13 Provided, That this may not be construed to interfere with the art 14 15 of prescription compounding which does not alter the therapeutic 16 properties of the prescription or appropriate generic substitute; 17 (3) The filling or refilling of any prescription for a greater 18 quantity of any drug or drug product than that prescribed in the 19 original prescription without a written or electronic order or an 20 oral order reduced to writing, or the refilling of a prescription without the verbal, written or electronic consent of the 21

### §30-5-22. Pharmacies to be registered.

22

- 1 (a) A pharmacy, an ambulatory health care facility, and a
- 2 charitable clinic pharmacy shall register with the board.

practitioner authorizing the original prescription.

- 3 (b) A person desiring to operate, maintain, open or establish
- 4 <u>a pharmacy shall register with the board.</u>
- 5 (c) To be eligible for a registration to operate, maintain, open
- 6 or establish a pharmacy the applicant shall:
- 7 (1) Submit a written application to the board;

- 8 (2) Pay all applicable fees;
- 9 (3) Designate a pharmacist-in-charge;
- 10 (4) Successfully complete an inspection by the board.
- 11 (d) A separate application shall be made and separate
- 12 permits issued for each location.
- (e) Permits are not transferable.
- (f) Permits expire and shall be renewed annually.
- 15 (g) If a permit expires, the pharmacy shall be reinspected
- and an inspection fee is required.
- 17 (h) A registrant shall employ a pharmacist-in-charge and
- 18 operate in compliance with the legislative rules governing the
- 19 practice of pharmacist care and the operation of a pharmacy.
- 20 (i) The provisions of this section do not apply to the sale of
- 21 nonprescription drugs which are not required to be dispensed
- 22 pursuant to a practitioner's prescription.

### §30-5-23. Pharmacist-in-charge.

- 1 (a) A pharmacy shall be under the direction and supervision
- 2 of a licensed pharmacist who shall be designated by the owner
- 3 of the pharmacy as the pharmacist-in-charge: *Provided that*, The
- 4 Board may permit by rule for a charitable clinic pharmacy to be

- 5 supervised by a committee of pharmacists-in-charge who accept
- 6 as a group the responsibilities of the required pharmacist-
- 7 in-charge. This designation shall be filed with the board within
- 8 thirty days of the designation.
- 9 (b) The pharmacist-in-charge is responsible for the
- 10 pharmacy's compliance with state and federal pharmacy laws
- and regulations and for maintaining records and inventory.
- 12 (c) A pharmacist-in-charge may not hold such designated
- 13 position at more than one pharmacy, whether within or outside
- 14 the State of West Virginia: *Provided that*, The Board may permit
- by rule that he or she may volunteer as the pharmacist-in-charge
- 16 at a charitable clinic pharmacy while serving as a
- 17 pharmacist-in-charge in another pharmacy.
- 18 (d) An interim pharmacist-in-charge may be designated for
- 19 a period not to exceed sixty days. The request for an interim
- 20 pharmacist-in-charge shall detail the circumstances which
- 21 warrant the change. This change in designation shall be filed
- 22 with the board within thirty days of the designation.

### §30-5-24. Permits for mail-order pharmacy.

- 1 (a) A mail-order pharmacy which dispenses drugs shall
- 2 register with the board.

- 3 (b) A mail-order pharmacy shall submit an application for a
- 4 permit to the board. The application shall require the following
- 5 information:
- 6 (1) The owner of the mail-order pharmacy, whether an
- 7 <u>individual, a partnership, or a corporation.</u>
- 8 (2) The names and titles of all individual owners, partners or
- 9 corporate officers.
- 10 (3) The pharmacy manager.
- 11 (4) The pharmacist-in-charge.
- 12 (5) The complete address, telephone number and fax number
- 13 of the mail-order pharmacy.
- (c) This section does not apply to any mail-order pharmacy
- 15 which operates solely as a wholesale distributor.

# §30-5-25. Permit for manufacture and packaging of drugs, medicines, distribution of prescription drugs.

- 1 (a) Drugs may not be manufactured, made, produced,
- 2 packed, packaged or prepared within the state, except under the
- 3 personal supervision of a pharmacist or other qualified person as
- 4 may be approved by the board;
- 5 (b) A person may not manufacture, package or prepare a
- 6 drug without obtaining a permit from the board.

- 7 (c) A person, who offers for sale, sells, offers for sale
- 8 through the method of distribution any legend drugs is subject to
- 9 this article.
- 10 (d) The application for a permit shall be made on a form to
- 11 be prescribed and furnished by the board and shall be
- 12 <u>accompanied by an application fee.</u>
- 13 (e) The board shall promulgate rules on permit requirements
- 14 and sanitation requirements.
- (f) Separate applications shall be made and separate permits
- 16 issued for each place of manufacture, distribution, making,
- 17 producing, packing, packaging or preparation.

# §30-5-26. Filling of prescriptions more than one year after issuance.

- A prescription order may not be dispensed after twelve
- 2 months from the date of issuance by the practitioner. A
- 3 pharmacist may fill the prescription after twelve months if the
- 4 prescriber confirms to the pharmacist that he or she still wants
- 5 the prescription filled and the pharmacist documents upon the
- 6 prescription that the confirmation was obtained.

#### §30-5-27. Partial filling of prescriptions.

- 1 (a) The partial filling of a prescription is permissible for any
- 2 prescription if the pharmacist is unable to supply, or the patient
- 3 requests less than the full quantity called for in a written,
- 4 electronic, or oral prescription, provided the pharmacist makes
- 5 a notation of the quantity supplied on either the written
- 6 prescription or in the electronic record.
- 7 (b) The partial filling of a prescription for a controlled
- 8 substance listed in Schedule II is permissible if the pharmacist
- 9 is unable to supply or the patient requests less than the full
- 10 quantity called for in the prescription. The remaining portion of
- 11 the prescription may be filled within seventy-two hours of the
- 12 first partial filling: *Provided*, That if the remaining portion is not
- 13 or cannot be filled within the seventy-two hour period, the
- 14 pharmacist shall notify the prescribing individual practitioner.
- 15 Further quantity may not be supplied beyond seventy-two hours
- 16 without a new prescription.

# §30-5-28. Partial filling of prescriptions for long-term care facility or terminally ill patients; requirements; records; violations.

- 1 (a) As used in this section, "long-term care facility" or
- 2 "LTCF" means any nursing home, personal care home, or

- 3 residential board and care home as defined in section two, article
- 4 five-c, chapter sixteen of this code which provides extended
- 5 health care to resident patients: Provided, That the care or
- 6 treatment in a household, whether for compensation or not, of
- 7 any person related by blood or marriage, within the degree of
- 8 consanguinity of second cousin to the head of the household, or
- 9 his or her spouse, may not be deemed to constitute a nursing
- 10 home, personal care home or residential board and care home
- 11 within the meaning of this article. This section does not apply to:
- (1) Hospitals, as defined under section one, article five-b,
- 13 chapter sixteen of this code or to extended care facilities
- 14 operated in conjunction with a hospital;
- 15 (2) State institutions as defined in section six, article one,
- 16 <u>chapter twenty-seven or in section three, article one, chapter</u>
- 17 <u>twenty-five</u>, all of this code;
- 18 (3) Nursing homes operated by the federal government;
- 19 (4) Facilities owned or operated by the state government;
- 20 (5) Institutions operated for the treatment and care of
- 21 <u>alcoholic patients;</u>
- 22 (6) Offices of physicians; or

- 23 (7) Hotels, boarding homes or other similar places that
- 24 furnish to their guests only a room and board.
- 25 (b) As used in this section, "terminally ill" means that an
- 26 individual has a medical prognosis that his or her life expectancy
- 27 is six months or less.
- 28 (c) Schedule II prescriptions for patients in a LTCF and for
- 29 terminally ill patients shall be valid for a period of sixty days
- 30 from the date of issue unless terminated within a shorter period
- 31 by the discontinuance of the medication.
- 32 (d) A prescription for a Schedule II controlled substance
- 33 written for a patient in a LTCF or for a terminally ill patient may
- 34 be filled in partial quantities, including, but not limited to,
- 35 individual dosage units. The total quantity of Schedule II
- 36 controlled substances dispensed in all partial filling may not
- 37 exceed the total quantity prescribed.
- 38 (1) If there is any question whether a patient may be
- 39 classified as having a terminal illness, the pharmacist shall
- 40 contact the prescribing practitioner prior to partially filling the
- 41 prescription.
- 42 (2) Both the pharmacist and the prescribing practitioner have
- 43 <u>a corresponding responsibility to assure that the controlled</u>
- 44 <u>substance is for a terminally ill patient.</u>

45 (e) The pharmacist shall record on the prescription that the 46 patient is "terminally ill" or a "LTCF patient". A prescription 47 that is partially filled and does not contain the notation 48 "terminally ill" or "LTCF patient" shall be deemed to have been 49 filled in violation of section three hundred eight, article three, 50 chapter sixty-a of this code. 51 (f) For each partial filling, the dispensing pharmacist shall 52 record on the back of the prescription, or on another appropriate 53 record which is readily retrievable, the following information: 54 (1) The date of the partial filling; 55 (2) The quantity dispensed; 56 (3) The remaining quantity authorized to be dispensed; and 57 (4) The identification of the dispensing pharmacist. 58 Information pertaining to current Schedule 59 prescriptions for terminally ill and LTCF patients may be 60 maintained in a computerized system if such a system has the 61 capability to permit either by display or printout, for each patient 62 and each medication, all of the information required by this 63 section as well as the patient's name and address, the name of 64 each medication, original prescription number, date of issue, and

- 65 prescribing practitioner information. The system shall also allow
- 66 immediate updating of the prescription record each time a partial
- 67 filling of the prescription is performed and immediate retrieval
- 68 of all information required under this section.

#### §30-5-29. Limitations of article.

- 1 (a) This article may not be construed to prevent, restrict or
- 2 in any manner interfere with the sale of nonnarcotic
- 3 nonprescription drugs which may be lawfully sold without a
- 4 prescription in accordance with the United States Food, Drug
- 5 and Cosmetic Act or the laws of this state, nor may any
- 6 <u>legislative rule be adopted by the board which shall require the</u>
- 7 sale of nonprescription drugs by a licensed pharmacist or in a
- 8 pharmacy or which shall prevent, restrict or otherwise interfere
- 9 with the sale or distribution of such drugs by any retail merchant.
- 10 The sale or distribution of nonprescription drugs may not be
- deemed to be improperly engaging in the practice of pharmacist
- 12 care.
- 13 (b) This article may not be construed to interfere with any
- 14 legally qualified practitioner of medicine, dentistry or veterinary
- 15 medicine, who is not the proprietor of the store for the

- 16 dispensing or retailing of drugs and who is not in the employ of
- 17 such proprietor, in the compounding of his or her own
- 18 prescriptions or to prevent him or her from supplying to his or
- 19 her patients such medicines as he or she may deem proper, if
- 20 such supply is not made as a sale.
- 21 (c) The exception provided in subsection (b) of this section
- 22 does not apply to an ambulatory health care facility: *Provided*,
- 23 That a legally licensed and qualified practitioner of medicine or
- 24 dentistry may supply medicines to patients that he or she treats
- 25 in a free clinic and that he or she deems appropriate.

### §30-5-30. Actions to enjoin violations.

- 1 (a) If the board obtains information that any person has
- 2 engaged in, is engaging in or is about to engage in any act which
- 3 constitutes or will constitute a violation of the provisions of this
- 4 article, the rules promulgated pursuant to this article, or a final
- 5 order or decision of the board, it may issue a notice to the person
- 6 to cease and desist in engaging in the act and/or apply to the
- 7 circuit court in the county of the alleged violation for an order
- 8 enjoining the act.

- 9 (b) The circuit court may issue a temporary injunction
- 10 pending a decision on the merits, and may issue a permanent
- 11 injunction based on its findings in the case.
- 12 (c) The judgment of the circuit court on an application
- 13 permitted by the provisions of this section is final unless
- 14 reversed, vacated or modified on appeal to the West Virginia
- 15 Supreme Court of Appeals.

# §30-5-31. Complaints; investigations; due process procedure; grounds for disciplinary action.

- 1 (a) The board may initiate a complaint upon receipt of
- 2 credible information, and shall upon the receipt of a written
- 3 complaint of any person, cause an investigation to be made to
- 4 determine whether grounds exist for disciplinary action under
- 5 <u>this article or the legislative rules promulgated pursuant to this</u>
- 6 article.
- 7 (b) After reviewing any information obtained through an
- 8 <u>investigation</u>, the board shall determine if probable cause exists
- 9 that the licensee, registrant or permittee has violated subsection
- 10 (g) of this section or rules promulgated pursuant to this article.
- (c) Upon a finding of probable cause to go forward with a
- 12 complaint, the board shall provide a copy of the complaint to the
- 13 <u>licensee</u>, registrant or permittee.

14 (d) Upon a finding that probable cause exists that the 15 licensee, registrant or permittee has violated subsection (g) of 16 this section or rules promulgated pursuant to this article, the 17 board may enter into a consent decree or hold a hearing for 18 disciplinary action against the licensee, registrant or permittee. 19 Any hearing shall be held in accordance with the provisions of 20 this article, and shall require a violation to be proven by a 21 preponderance of the evidence. 22 (e) Any member of the board or the executive director of the 23 board may issue subpoenas and subpoenas duces tecum to obtain 24 testimony and documents to aid in the investigation of 25 allegations against any person regulated by the article. 26 (f) Any member of the board or its executive director may 27 sign a consent decree or other legal document on behalf of the 28 board. 29 (g) The board may, after notice and opportunity for hearing, 30 deny or refuse to renew, suspend, restrict or revoke the license, 31 registration or permit of, or impose probationary conditions upon 32 or take disciplinary action against, any licensee, registrant or 33 permittee for any of the following reasons:

34	(1) Obtaining a board authorization by fraud, misrepre-
35	sentation or concealment of material facts;
36	(2) Being convicted of a felony or other crime involving
37	drugs, violent crime, or moral turpitude, or engaging in any act
38	involving moral turpitude or gross immorality;
39	(3) Being guilty of unprofessional conduct which placed the
40	public at risk, as defined by legislative rule of the board;
41	(4) Intentional violation of a lawful order or legislative rule
42	of the board;
43	(5) Having had a board authorization revoked or suspended,
44	other disciplinary action taken, or an application for a board
45	authorization revoked or suspended by the proper authorities of
46	another jurisdiction;
47	(6) Aiding or abetting unlicensed practice;
48	(7) Engaging in an act while acting in a professional capacity
49	which has endangered or is likely to endanger the health, welfare
50	or safety of the public;
51	(8) Incapacity that prevents a licensee or registrant from
52	engaging in the practice of pharmacist care or assisting in the
53	practice of pharmacist care, with reasonable skill, competence,
54	and safety to the public;

55 (9) Violation of any laws, including rules pertaining thereto, of this or any other jurisdiction, relating to the practice of 56 pharmacist care, drug samples, drug manufacturing, wholesale 57 58 or retail drug or device distribution, or controlled substances; 59 (10) Committing fraud in connection with the practice of 60 pharmacist care; 61 (11) Disciplinary action taken by another state or jurisdiction 62 against a board authorization to practice pharmacist care based 63 upon conduct by the licensee, registrant or permittee similar to 64 conduct that would constitute grounds for actions as defined in 65 this section; 66 (12) Failure to report to the board any adverse action taken 67 by another licensing jurisdiction, government agency, law-68 enforcement agency, or court for conduct that would constitute 69 grounds for action as defined in this section; 70 (13) Failure to report to the board one's surrender of a 71 license or authorization to practice pharmacist care in another 72 jurisdiction while under disciplinary investigation by any of 73 those authorities or bodies for conduct that would constitute 74 grounds for action as defined in this section;

75 (14) Failure to report to the board any adverse judgment, 76 settlement, or award arising from a malpractice claim arising related to conduct that would constitute grounds for action as 77 78 defined in this section; 79 (15) Knowing or suspecting that a licensee or registrant is 80 incapable of engaging in the practice of pharmacist care or 81 assisting in the practice of pharmacist care, with reasonable skill, 82 competence, and safety to the public, and failing to report any 83 relevant information to the board; 84 (16) Illegal use or disclosure of protected health information; 85 (17) Engaging in any conduct that subverts or attempts to 86 subvert any licensing examination or the administration of any 87 licensing examination; 88 (18) Failure to furnish to the board or its representatives any information legally requested by the board, or failure to 89 90 cooperate with or engaging in any conduct which obstructs an 91 investigation being conducted by the board; 92 (19) Agree to participate in a prescription drug product 93 conversion program promoted or offered by a manufacturer, wholesaler or distributor of such product for which the 94

- 95 pharmacist or pharmacy received any form of financial
- 96 remuneration, or agreed to participate in a prescription drug
- 97 program in which the pharmacist or pharmacy is promoted or
- 98 offered as the exclusive provider of prescription drug products
- 99 or whereby in any way the public is denied, limited or influenced
- in selecting pharmacist care or counseling;
- 101 (20) Violation of any of the terms or conditions of any order
- 102 entered in any disciplinary action.
- 103 (h) For the purposes of subsection (g) of this section,
- 104 <u>effective July 1, 2013, disciplinary action may include:</u>
- 105 (1) Reprimand;
- 106 (2) Probation;
- 107 (3) Restrictions;
- 108 (4) Suspension;
- 109 (5) Revocation;
- 110 (6) Administrative fine, not to exceed \$1,000 per day per
- 111 <u>violation;</u>
- 112 (7) Mandatory attendance at continuing education seminars
- or other training;
- 114 (8) Practicing under supervision or other restriction; or

115 (9) Requiring the licensee, registrant or permittee to report 116 to the board for periodic interviews for a specified period of 117 time. 118 (i) In addition to any other sanction imposed, the board may 119 require a licensee, registrant or permittee to pay the costs of the 120 proceeding. 121 (j) The board may defer disciplinary action with regard to an 122 impaired licensee or registrant who voluntarily signs an 123 agreement, in a form satisfactory to the board, agreeing not to 124 practice pharmacist care and to enter an approved treatment and 125 monitoring program in accordance with the board's legislative 126 rule. This subsection, provided that this section should not apply 127 to a licensee or registrant who has been convicted of, pleads 128 guilty to, or enters a plea of nolo contendere or a conviction 129 relating to a controlled substance in any jurisdiction. 130 (k) Nothing shall be construed as barring criminal 131 prosecutions for violations of this article. 132 (1) A person authorized to practice under this article, who reports or otherwise provides evidence of the negligence, 133 impairment or incompetence of another member of this 134

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- profession to the board or to any peer review organization, is not
- liable to any person for making such a report if such report is
- 137 made without actual malice and in the reasonable belief that such
- 138 report is warranted by the facts known to him or her at the time.

### §30-5-32. Procedures for hearing; right of appeal.

- 1 (a) Hearings are governed by the provisions of section eight,
- 2 <u>article one of this chapter.</u>
- 3 (b) The board may conduct the hearing or elect to have an
- 4 <u>administrative law judge conduct the hearing.</u>
- 5 (c) If the hearing is conducted by an administrative law
- 6 judge, at the conclusion of a hearing he or she shall prepare a
- 7 proposed written order containing findings of fact and
- 8 conclusions of law. The proposed order may contain proposed
- 9 disciplinary actions if the board so directs. The board may
- 10 accept, reject or modify the decision of the administrative law
- 11 judge.
- 12 (d) Any member or the executive director of the board has
- 13 the authority to administer oaths, examine any person under oath
- 14 and issue subpoenas and subpoenas duces tecum.
- (e) If, after a hearing, the board determines the licensee,
- 16 registrant or permittee has violated provisions of this article or

- 17 the board's rules, a formal written decision shall be prepared
- 18 which contains findings of fact, conclusions of law and a specific
- 19 description of the disciplinary actions imposed.

#### §30-5-33. Judicial review.

- 1 Any person adversely affected by a decision of the board
- 2 entered after a hearing may obtain judicial review of the decision
- 3 in accordance with section four, article five, chapter
- 4 twenty-nine-a of this code, and may appeal any ruling resulting
- 5 from judicial review in accordance with article six, chapter
- 6 twenty-nine-a of this code.

# §30-5-34. Criminal proceedings; penalties.

- 1 (a) When, as a result of an investigation under this article or
- 2 otherwise, the board has reason to believe that a person
- 3 authorized under this article has committed a criminal offense
- 4 under this article, the board may bring its information to the
- 5 attention of an appropriate law-enforcement official.
- 6 (b) Any person, who violates any of the provisions of this
- 7 article is guilty of a misdemeanor, and, upon conviction, shall be
- 8 fined not to exceed \$50 for the first offense, and upon conviction
- 9 of a second offense shall be fined not less than \$50 nor more

- 10 than \$500, or shall be imprisoned in the county jail not to exceed
- 11 thirty days, or both fined and imprisoned. Each and every day
- 12 that the violation continues shall constitute a separate offense.

#### CHAPTER 60A. UNIFORM CONTROLLED

#### SUBSTANCES ACT.

# 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 made
- 6 subject to the requirements of this article by the provisions of
- 7 section ten of this article.
- 8 (c) "Distributor" means any person within this state or
- 9 another state, other than a manufacturer or wholesaler, who sells.
- 10 delivers, transfers or in any manner furnishes a drug product to
- 11 any person who is not the ultimate user or consumer of the
- 12 product.
- 13 (d) "Drug product" means a pharmaceutical product that
- 14 contains ephedrine, pseudoephedrine or phenylpropanolamine or

- a substance identified on the supplemental list provided in section seven of this article which may be sold without a prescription and which is labeled for use by a consumer in accordance with the requirements of the laws and rules of this state and the federal government.
- 20 (e) "Ephedrine "means ephedrine, its salts or optical isomers21 or salts of optical isomers.
- (f) "Manufacturer" means any person within this state who produces, compounds, packages or in any manner initially prepares for sale or use any drug product or any such person in another state if they cause the products to be compounded, packaged or transported into this state.
- 27 (g) "National Association of Drug Diversion Investigators" 28 or "NADDI" means the non-profit 501(c)(3) organization 29 established in 1989, made up of members who are responsible 30 for investigating and prosecuting pharmaceutical drug diversion, 31 and that facilitates cooperation between law enforcement, health 32 care professionals, state regulatory agencies and pharmaceutical 33 manufacturers in the investigation and prevention of prescription 34 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 purchases,
- 39 and agree to use the system. MSRTTS is used by pharmacies and
- 40 law enforcement to track sales of over-the-counter (OTC) cold
- 41 and allergy medications containing precursors to the illegal drug,
- 42 methamphetamine.
- 43 (i) "Phenylpropanolamine" means phenylpropanolamine, 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 production
- 49 and distribution of illegal methamphetamine.
- 50 (1) "Pharmacist" means an individual currently licensed by
- 51 this state to engage in the practice of pharmacy and
- 52 pharmaceutical care pharmacist care as defined in subsection (t),
- 53 section 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 thirty
- of this code.

- (n) "Pharmacy" means any drugstore, apothecary or place within this state where drugs are dispensed and sold at retail or display for sale at retail and pharmaceutical pharmacist care is provided outside of this state where drugs are dispensed and pharmaceutical pharmacist care is provided to residents of this state.
- 63 (o) "Pharmacy counter" means an area in the pharmacy 64 restricted to the public where controlled substances are stored 65 and housed and where controlled substances may only be sold, 66 transferred or dispensed by a pharmacist, pharmacy intern or 67 pharmacy technician.
- (p) "Pharmacy technician" means a registered technician
   who meets the requirements for registration as set forth in article
   five, chapter thirty of this code.
- (q) "Retail establishment" means any entity or person within this state who sells, transfers or distributes goods, including over-the-counter drug products, to an ultimate consumer.
- 74 (r) "Schedule V" means the schedule of controlled 75 substances set out in section two hundred twelve, section two of 76 this chapter.

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

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