

WEST VIRGINIA LEGISLATURE

2022 REGULAR SESSION

Committee Substitute

for

House Bill 4324

BY DELEGATE ROHRBACH

[Originating in the Committee on Health and Human
Resources; reported on January 25, 2022]

1 A BILL to amend and reenact §30-5-4 and §30-5-19 of the Code of West Virginia, 1931, as
2 amended, all relating to collaborative pharmacy practice; defining terms; setting forth
3 requirements for different practice settings; prohibiting certain practices; and updating the
4 terms of collaborative practice agreements.

Be it enacted by the Legislature of West Virginia:

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

§30-5-4. Definitions.

1 As used in this article:

2 ~~(1)~~ "Ambulatory health care facility" includes any facility defined in section one, article five-
3 b, chapter sixteen of this code, that also has a pharmacy, offers pharmacist care, or is otherwise
4 engaged in the practice of pharmacist care.

5 ~~(2)~~ "Active Ingredients" means chemicals, substances, or other components of articles
6 intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in humans
7 or animals or for use as nutritional supplements.

8 ~~(3)~~ "Administer" means the direct application of a drug to the body of a patient or research
9 subject by injection, inhalation, ingestion or any other means.

10 ~~(4)~~ "Board" means the West Virginia Board of Pharmacy.

11 ~~(5)~~ "Board authorization" means a license, registration or permit issued under this article.

12 ~~(6)~~ "Chain Pharmacy Warehouse" means a permanent physical location for drugs and/or
13 devices that acts as a central warehouse and performs intracompany sales and transfers of
14 prescription drugs or devices to chain pharmacies, which are members of the same affiliated
15 group, under common ownership and control.

16 ~~(7)~~ "Charitable clinic pharmacy" means a clinic or facility organized as a not-for-profit
17 corporation that has a pharmacy, offers pharmacist care, or is otherwise engaged in the practice

18 of pharmacist care and dispenses its prescriptions free of charge to appropriately screened and
19 qualified indigent patients.

20 ~~(8)~~ “Collaborative pharmacy practice” is that practice of pharmacist care where one or
21 more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or
22 more physicians under written protocol where the pharmacist or pharmacists may perform certain
23 patient care functions authorized by the physician or physicians under certain specified conditions
24 and limitations.

25 ~~(9)~~ “Collaborative pharmacy practice agreement” is a written and signed agreement,
26 which is a physician directed approach, that is entered into between an individual physician or
27 physician group, and an individual pharmacist or pharmacists ~~and an individual patient or the~~
28 ~~patient’s authorized representative who has given informed consent~~ that provides for collaborative
29 pharmacy practice for the purpose of drug therapy management of a patient, which has been
30 approved by the board, the Board of Medicine in the case of an allopathic physician or the West
31 Virginia Board of Osteopathic Medicine in the case of an osteopathic physician within 15 days of
32 submission or it deemed approved.

33 ~~(10)~~ “Common Carrier” means any person or entity who undertakes, whether directly or
34 by any other arrangement, to transport property including prescription drugs for compensation.

35 ~~(11)~~ “Component” means any active ingredient or added substance intended for use in the
36 compounding of a drug product, including those that may not appear in such product.

37 ~~(12)~~ “Compounding” means:

38 (A) The preparation, mixing, assembling, packaging or labeling of a drug or device:

39 (i) As the result of a practitioner’s prescription drug order or initiative based on the
40 practitioner/patient/pharmacist relationship in the course of professional practice for sale or
41 dispensing; or

42 (ii) For the purpose of, or as an incident to, research, teaching or chemical analysis and
43 not for sale or dispensing; and

44 (B) The preparation of drugs or devices in anticipation of prescription drug orders based
45 on routine, regularly observed prescribing patterns.

46 ~~(13)~~ “Deliver” or “delivery” means the actual, constructive or attempted transfer of a drug
47 or device from one person to another, whether or not for a consideration.

48 ~~(14)~~ “Device” means an instrument, apparatus, implement or machine, contrivance,
49 implant or other similar or related article, including any component part or accessory, which is
50 required under federal law to bear the label, “Caution: Federal or state law requires dispensing
51 by or on the order of a physician.”

52 ~~(15)~~ “Digital Signature” means an electronic signature based upon cryptographic methods
53 of originator authentication, and computed by using a set of rules and a set of parameters so that
54 the identity of the signer and the integrity of the data can be verified.

55 ~~(16)~~ “Dispense” or “dispensing” means the interpretation, evaluation, and implementation
56 of a prescription drug order, including the preparation, verification and delivery of a drug or device
57 to a patient or patient’s agent in a suitable container appropriately labeled for subsequent
58 administration to, or use by, a patient.

59 ~~(17)~~ “Distribute” or “Distribution” means to sell, offer to sell, deliver, offer to deliver, broker,
60 give away, or transfer a drug, whether by passage of title, physical movement, or both. The term
61 does not include:

62 (A) To dispense or administer;

63 (B) (i) Delivering or offering to deliver a drug by a common carrier in the usual course of
64 business as a common carrier; or providing a drug sample to a patient by a practitioner licensed
65 to prescribe such drug;

66 (ii) A health care professional acting at the direction and under the supervision of a
67 practitioner; or the pharmacy of a hospital or of another health care entity that is acting at the
68 direction of such a practitioner and that received such sample in accordance with the Prescription
69 Drug Marketing Act and regulations to administer or dispense;

70 (iii) Intracompany sales.

71 ~~(48)~~ “Drop shipment” means the sale of a prescription drug to a wholesale distributor by
72 the manufacturer of the prescription drug or by that manufacturer’s colicensed product partner,
73 that manufacturer’s third party logistics provider, that manufacturer’s exclusive distributor, or by
74 an authorized distributor of record that purchased the product directly from the manufacturer or
75 from one of these entities whereby:

76 (A) The wholesale distributor takes title to but not physical possession of such prescription
77 drug;

78 (B) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other
79 person authorized by law to dispense or administer such drug; and

80 (C) The pharmacy, pharmacy warehouse or other person authorized by law to dispense
81 or administer such drug receives delivery of the prescription drug directly from the manufacturer
82 or from that manufacturer’s colicensed product partner, that manufacturer’s third party logistics
83 provider, that manufacturer’s exclusive distributor, or from an authorized distributor of record that
84 purchased the product directly from the manufacturer or from one of these entities.

85 ~~(49)~~ “Drug” means:

86 (A) Articles recognized as drugs by the United States Food and Drug Administration, or in
87 any official compendium, or supplement;

88 (B) An article, designated by the board, for use in the diagnosis, cure, mitigation,
89 treatment, or prevention of disease in humans or other animals;

90 (C) Articles, other than food, intended to affect the structure or any function of the body of
91 human or other animals; and

92 (D) Articles intended for use as a component of any articles specified in paragraph (A),
93 (B) or (C) of this subdivision.

94 ~~(20)~~ “Drug regimen review” includes, but is not limited to, the following activities:

95 (A) Evaluation of the prescription drug orders and if available, patient records for:

- 96 (i) Known allergies;
- 97 (ii) Rational therapy-contraindications;
- 98 (iii) Reasonable dose and route of administration; and
- 99 (iv) Reasonable directions for use.

100 (B) Evaluation of the prescription drug orders and patient records for duplication of
101 therapy.

102 (C) Evaluation of the prescription drug for interactions and/or adverse effects which may
103 include, but are not limited to, any of the following:

- 104 (i) Drug-drug;
- 105 (ii) Drug-food;
- 106 (iii) Drug-disease; and
- 107 (iv) Adverse drug reactions.

108 (D) Evaluation of the prescription drug orders and if available, patient records for proper
109 use, including overuse and underuse and optimum therapeutic outcomes.

110 ~~(24)~~ "Drug therapy management" means the review of drug therapy regimens of patients
111 by a pharmacist for the purpose of evaluating and rendering advice to a physician regarding
112 adjustment of the regimen in accordance with the collaborative pharmacy practice agreement.
113 Decisions involving drug therapy management shall be made in the best interest of the patient.
114 Drug therapy management is limited to:

115 (A) Implementing, modifying and managing drug therapy according to the terms of the
116 collaborative pharmacy practice agreement;

117 (B) Collecting and reviewing patient histories;

118 ~~(C) Obtaining and checking vital signs, including pulse, temperature, blood pressure and~~
119 ~~respiration~~ Performing patient evaluations;

120 (D) Ordering screening laboratory tests that are dose related and specific to the patient's
121 medication or are protocol driven and are also specifically set out in the collaborative pharmacy
122 practice agreement between the pharmacist and physician.

123 ~~(22)~~ "Electronic data intermediary" means an entity that provides the infrastructure to
124 connect a computer system, hand-held electronic device or other electronic device used by a
125 prescribing practitioner with a computer system or other electronic device used by a pharmacy to
126 facilitate the secure transmission of:

- 127 (A) An electronic prescription order;
- 128 (B) A refill authorization request;
- 129 (C) A communication; or
- 130 (D) Other patient care information.

131 ~~(23)~~ "E-prescribing" means the transmission, using electronic media, of prescription or
132 prescription-related information between a practitioner, pharmacist, pharmacy benefit manager
133 or health plan as defined in 45 CFR §160.103, either directly or through an electronic data
134 intermediary. E-prescribing includes, but is not limited to, two-way transmissions between the
135 point of care and the pharmacist. E-prescribing may also be referenced by the terms "electronic
136 prescription" or "electronic order".

137 ~~(24)~~ "Electronic Signature" means an electronic sound, symbol, or process attached to or
138 logically associated with a record and executed or adopted by a person with the intent to sign the
139 record.

140 ~~(25)~~ "Electronic transmission" means transmission of information in electronic form or the
141 transmission of the exact visual image of a document by way of electronic equipment.

142 ~~(26)~~ "Emergency medical reasons" include, but are not limited to, transfers of a
143 prescription drug by one pharmacy to another pharmacy to alleviate a temporary shortage of a
144 prescription drug; sales to nearby emergency medical services, i.e., ambulance companies and
145 firefighting organizations in the same state or same marketing or service area, or nearby licensed

146 practitioners of prescription drugs for use in the treatment of acutely ill or injured persons; and
147 provision of minimal emergency supplies of prescription drugs to nearby nursing homes for use
148 in emergencies or during hours of the day when necessary prescription drugs cannot be obtained.

149 ~~(27)~~ “Exclusive distributor” means an entity that:

150 (A) Contracts with a manufacturer to provide or coordinate warehousing, wholesale
151 distribution, or other services on behalf of a manufacturer and who takes title to that
152 manufacturer’s prescription drug, but who does not have general responsibility to direct the sale
153 or disposition of the manufacturer’s prescription drug; and

154 (B) Is licensed as a wholesale distributor under this article.

155 ~~(28)~~ “FDA” means the Food and Drug Administration, a federal agency within the United
156 States Department of Health and Human Services.

157 ~~(29)~~ “Health care entity” means a person that provides diagnostic, medical, pharmacist
158 care, surgical, dental treatment, or rehabilitative care but does not include a wholesale distributor.

159 “Healthcare system” means an organization of people, institutions, and resources that
160 deliver health care services to meet the health needs of target populations.

161 ~~(30)~~ “Health information” means any information, whether oral or recorded in a form or
162 medium, that:

163 (A) Is created or received by a health care provider, health plan, public health authority,
164 employer, life insurer, school or university, or health care clearinghouse, and

165 (B) Relates to the past, present, or future physical or mental health or condition of an
166 individual; or the past, present, or future payment for the provision of health care to an individual.

167 ~~(34)~~ “HIPAA” is the federal Health Insurance Portability and Accountability Act of 1996
168 (Public Law 104-191).

169 ~~(32)~~ “Immediate container” means a container and does not include package liners.

170 ~~(33)~~ “Individually identifiable health information” is information that is a subset of health
171 information, including demographic information collected from an individual and is created or

172 received by a health care provider, health plan, employer, or health care clearinghouse; and
173 relates to the past, present, or future physical or mental health or condition of an individual; the
174 provision of health care to an individual; or the past, present, or future payment for the provision
175 of health care to an individual; and that identifies the individual; or with respect to which there is
176 a reasonable basis to believe the information can be used to identify the individual.

177 ~~(34)~~ “Intracompany sales” means any transaction between a division, subsidiary, parent,
178 and/or affiliated or related company under the common ownership and control of a corporate or
179 other legal business entity.

180 ~~(35)~~ “Label” means a display of written, printed, or graphic matter upon the immediate
181 container of any drug or device.

182 ~~(36)~~ “Labeling” means the process of preparing and affixing a label to a drug container
183 exclusive, however, of a labeling by a manufacturer, packer or distributor of a nonprescription
184 drug or commercially packaged prescription drug or device.

185 ~~(37)~~ “Long-Term care facility” means a nursing home, retirement care, mental care, or
186 other facility or institution that provides extended health care to resident patients.

187 ~~(38)~~ “Mail-order pharmacy” means a pharmacy, regardless of its location, which dispenses
188 greater than twenty-five percent prescription drugs via the mail or other delivery services.

189 ~~(39)~~ “Manufacturer” means any person who is engaged in manufacturing, preparing,
190 propagating, processing, packaging, repackaging or labeling of a prescription drug, whether within
191 or outside this state.

192 ~~(40)~~ “Manufacturing” means the production, preparation, propagation or processing of a
193 drug or device, either directly or indirectly, by extraction from substances of natural origin or
194 independently by means of chemical or biological synthesis and includes any packaging or
195 repackaging of the substance or substances or labeling or relabeling of its contents and the
196 promotion and marketing of the drugs or devices. Manufacturing also includes the preparation

197 and promotion of commercially available products from bulk compounds for resale by pharmacies,
198 practitioners or other persons.

199 ~~(41)~~ “Medical order” means a lawful order of a practitioner that may or may not include a
200 prescription drug order.

201 ~~(42)~~ “Medication therapy management” is a distinct service or group of services that
202 optimize medication therapeutic outcomes for individual patients. Medication therapy
203 management services are independent of, but can occur in conjunction with, the provision of a
204 medication or a medical device. Medication therapy management encompasses a broad range of
205 professional activities and responsibilities within the licensed pharmacist’s scope of practice.

206 These services may include the following, according to the individual needs of the patient:

207 (A) Performing or obtaining necessary assessments of the patient’s health status pertinent
208 to medication therapy management;

209 (B) Optimize medication use, performing medication therapy, and formulating
210 recommendations for patient medication care plans;

211 (C) Developing therapeutic recommendations, to resolve medication related problems;

212 (D) Monitoring and evaluating the patient’s response to medication therapy, including
213 safety and effectiveness;

214 (E) Performing a comprehensive medication review to identify, resolve, and prevent
215 medication-related problems, including adverse drug events;

216 (F) Documenting the care delivered and communicating essential information to the
217 patient’s primary care providers;

218 (G) Providing verbal education and training designed to enhance patient understanding
219 and appropriate use of his or her medications;

220 (H) Providing information, support services and resources designed to enhance patient
221 adherence with his or her medication therapeutic regimens;

222 (I) Coordinating and integrating medication therapy management services within the
223 broader health care management services being provided to the patient; and

224 (J) Such other patient care services as may be allowed by law.

225 ~~(43)~~ "Misbranded" means a drug or device that has a label that is false or misleading in
226 any particular; or the label does not bear the name and address of the manufacturer, packer, or
227 distributor and does not have an accurate statement of the quantities of the active ingredients in
228 the case of a drug; or the label does not show an accurate monograph for prescription drugs.

229 ~~(44)~~ "Nonprescription drug" means a drug which may be sold without a prescription and
230 which is labeled for use by the consumer in accordance with the requirements of the laws and
231 rules of this state and the federal government.

232 ~~(45)~~ "Normal distribution channel" means a chain of custody for a prescription drug that
233 goes directly or by drop shipment, from a manufacturer of the prescription drug, the
234 manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor to:

235 (A) A wholesale distributor to a pharmacy to a patient or other designated persons
236 authorized by law to dispense or administer such prescription drug to a patient;

237 (B) A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy
238 warehouse's intracompany pharmacy to a patient or other designated persons authorized by law
239 to dispense or administer such prescription drug to a patient;

240 (C) A chain pharmacy warehouse to that chain pharmacy warehouse's intracompany
241 pharmacy to a patient or other designated persons authorized by law to dispense or administer
242 such prescription drug to a patient;

243 (D) A pharmacy or to other designated persons authorized by law to dispense or
244 administer such prescription drug to a patient; or

245 (E) As prescribed by the board's legislative rules.

246 ~~(46)~~ “Patient counseling” means the communication by the pharmacist of information, as
247 prescribed further in the rules of the board, to the patient to improve therapy by aiding in the
248 proper use of drugs and devices.

249 ~~(47)~~ “Pedigree” means a statement or record in a written form or electronic form, approved
250 by the board, that records each wholesale distribution of any given prescription drug (excluding
251 veterinary prescription drugs), which leaves the normal distribution channel.

252 ~~(48)~~ “Person” means an individual, corporation, partnership, association or any other legal
253 entity, including government.

254 ~~(49)~~ “Pharmacist” means an individual currently licensed by this state to engage in the
255 practice of pharmacist care.

256 ~~(50)~~ “Pharmacist Care” means the provision by a pharmacist of patient care activities, with
257 or without the dispensing of drugs or devices, intended to achieve outcomes related to the cure
258 or prevention of a disease, elimination or reduction of a patient’s symptoms, or arresting or slowing
259 of a disease process and as provided for in section ten.

260 ~~(51)~~ “Pharmacist-in-charge” means a pharmacist currently licensed in this state who
261 accepts responsibility for the operation of a pharmacy in conformance with all laws and legislative
262 rules pertinent to the practice of pharmacist care and the distribution of drugs and who is
263 personally in full charge of the pharmacy and pharmacy personnel.

264 ~~(52)~~ “Pharmacist’s scope of practice pursuant to the collaborative pharmacy practice
265 agreement” means those duties and limitations of duties placed upon the pharmacist by the
266 collaborating physician, as jointly approved by the board and the Board of Medicine or the West
267 Virginia Board of Osteopathic Medicine.

268 ~~(53)~~ “Pharmacy” means any place within this state where drugs are dispensed and
269 pharmacist care is provided and any place outside of this state where drugs are dispensed and
270 pharmacist care is provided to residents of this state.

271 ~~(54)~~ “Pharmacy Intern” or “Intern” means an individual who is currently licensed to engage
272 in the practice of pharmacist care while under the supervision of a pharmacist.

273 ~~(55)~~ “Pharmacy related primary care” means the pharmacist’s activities in patient
274 education, health promotion, selection and use of over the counter drugs and appliances and
275 referral or assistance with the prevention and treatment of health related issues and diseases.

276 ~~(56)~~ “Pharmacy Technician” means a person registered with the board to practice certain
277 tasks related to the practice of pharmacist care as permitted by the board.

278 ~~(57)~~ “Physician” means an individual currently licensed, in good standing and without
279 restrictions, as an allopathic physician by the West Virginia Board of Medicine or an osteopathic
280 physician by the West Virginia Board of Osteopathic Medicine.

281 ~~(58)~~ “Practice of telepharmacy” means the provision of pharmacist care by properly
282 licensed pharmacists located within United States jurisdictions through the use of
283 telecommunications or other technologies to patients or their agents at a different location that
284 are located within United States jurisdictions.

285 ~~(59)~~ “Practitioner” means an individual authorized by a jurisdiction of the United States to
286 prescribe drugs in the course of professional practices, as allowed by law.

287 ~~(60)~~ “Prescription drug” means any human drug required by federal law or regulation to
288 be dispensed only by prescription, including finished dosage forms and active ingredients subject
289 to section 503(b) of the federal food, drug and cosmetic act.

290 ~~(61)~~ “Prescription or prescription drug order” means a lawful order from a practitioner for
291 a drug or device for a specific patient, including orders derived from collaborative pharmacy
292 practice, where a valid patient-practitioner relationship exists, that is communicated to a
293 pharmacist in a pharmacy.

294 ~~(62)~~ “Product Labeling” means all labels and other written, printed, or graphic matter upon
295 any article or any of its containers or wrappers, or accompanying such article.

296 ~~(63)~~ “Repackage” means changing the container, wrapper, quantity, or product labeling of
297 a drug or device to further the distribution of the drug or device.

298 ~~(64)~~ “Repackager” means a person who repackages.

299 ~~(65)~~ “Therapeutic equivalence” mean drug products classified as therapeutically
300 equivalent can be substituted with the full expectation that the substituted product will produce
301 the same clinical effect and safety profile as the prescribed product which contain the same active
302 ingredient(s); dosage form and route of administration; and strength.

303 ~~(66)~~ “Third-party logistics provider” means a person who contracts with a prescription drug
304 manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a
305 manufacturer, but does not take title to the prescription drug or have general responsibility to
306 direct the prescription drug’s sale or disposition. A third-party logistics provider shall be licensed
307 as a wholesale distributor under this article and, in order to be considered part of the normal
308 distribution channel, shall also be an authorized distributor of record.

309 ~~(67)~~ “Valid patient-practitioner relationship” means the following have been established:

310 (A) A patient has a medical complaint;

311 (B) A medical history has been taken;

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

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

317 ~~(68)~~ “Wholesale distribution” and “wholesale distributions” mean distribution of
318 prescription drugs, including directly or through the use of a third-party logistics provider or any
319 other situation in which title, ownership or control over the prescription drug remains with one
320 person or entity but the prescription drug is brought into this state by another person or entity on
321 his, her or its behalf, to persons other than a consumer or patient, but does not include:

322 (A) Intracompany sales, as defined in subdivision thirty-four of this subsection;

323 (B) The purchase or other acquisition by a hospital or other health care entity that is a
324 member of a group purchasing organization of a drug for its own use from the group purchasing
325 organization or from other hospitals or health care entities that are members of such
326 organizations;

327 (C) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug by a
328 charitable organization described in section 501(c)(3) of the United States Internal Revenue Code
329 of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

330 (D) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug
331 among hospitals or other health care entities that are under common control. For purposes of this
332 article, "common control" means the power to direct or cause the direction of the management
333 and policies of a person or an organization, whether by ownership of stock, voting rights, by
334 contract, or otherwise;

335 (E) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug for
336 "emergency medical reasons" for purposes of this article includes transfers of prescription drugs
337 by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the
338 gross dollar value of such transfers shall not exceed five percent of the total prescription drug
339 sales revenue of either the transferor or transferee pharmacy during any twelve consecutive
340 month period;

341 (F) The sale, purchase or trade of a drug, an offer to sell, purchase, or trade a drug or the
342 dispensing of a drug pursuant to a prescription;

343 (G) The distribution of drug samples by manufacturers' representatives or distributors'
344 representatives, if the distribution is permitted under federal law [21 U. S. C. 353(d)];

345 (H) Drug returns by a pharmacy or chain drug warehouse to wholesale drug distributor or
346 the drug's manufacturer; or

347 (J) The sale, purchase or trade of blood and blood components intended for transfusion.

348 ~~(69)~~ “Wholesale drug distributor” or “wholesale distributor” means any person or entity
349 engaged in wholesale distribution of prescription drugs, including, but not limited to,
350 manufacturers, repackers, own-label distributors, jobbers, private-label distributors, brokers,
351 warehouses, including manufacturers’ and distributors’ warehouses, chain drug warehouses and
352 wholesale drug warehouses, independent wholesale drug traders, prescription drug repackagers,
353 physicians, dentists, veterinarians, birth control and other clinics, individuals, hospitals, nursing
354 homes and/or their providers, health maintenance organizations and other health care providers,
355 and retail and hospital pharmacies that conduct wholesale distributions, including, but not limited
356 to, any pharmacy distributor as defined in this section. A wholesale drug distributor shall not
357 include any for hire carrier or person or entity hired solely to transport prescription drugs.

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

1 (a) A pharmacist engaging in collaborative pharmacy practice shall have on file at his or
2 her place of practice the collaborative pharmacy practice agreement. The existence and
3 subsequent termination of the agreement and any additional information the rules may require
4 concerning the agreement, including the agreement itself, shall be made available to the
5 appropriate licensing board for review upon request. The agreement may allow the pharmacist,
6 within the pharmacist’s scope of practice pursuant to the collaborative pharmacy practice
7 agreement, to conduct drug therapy management activities approved by the collaborating
8 physician. The collaborative pharmacy practice agreement shall be a voluntary process, which is
9 a physician directed approach after informed consent of the patient and noted in the patient’s
10 medical record, that is entered into between an individual physician or physician group and an
11 individual pharmacist or pharmacists. A pharmacist may not diagnose, and an individual patient
12 or the patient’s authorized representative who has given informed consent as per subsection (c).

13 (b) A collaborative pharmacy practice agreement may authorize a pharmacist to provide
14 drug therapy management. In instances where drug therapy is discontinued, the pharmacist shall
15 notify the treating physician of the discontinuance in the time frame and in the manner established

16 by joint legislative rules. Each protocol developed, pursuant to the collaborative pharmacy
17 practice agreement, shall contain detailed direction concerning the services that the pharmacists
18 may perform for that patient. The protocol shall include, but need not be limited to:

19 (1) The specific drug or drugs to be managed by the pharmacist;

20 (2) The terms and conditions under which drug therapy may be implemented, modified or
21 discontinued;

22 (3) The conditions and events upon which the pharmacist is required to notify the
23 physician; ~~and~~

24 (4) The laboratory tests that may be ordered in accordance with drug therapy
25 management; and

26 (5) The patient evaluations the pharmacist may conduct.

27 (c) All activities performed by the pharmacist in conjunction with the protocol shall be
28 documented in the patient's medical record. The pharmacists shall report at least every thirty days
29 to the physician regarding the patient's drug therapy management. The collaborative pharmacy
30 practice agreement and protocols shall be available for inspection by the board, the West Virginia
31 Board of Medicine, or the West Virginia Board of Osteopathic Medicine, depending on the
32 licensing board of the participating physician. A copy of the protocol shall be filed in the patient's
33 medical record.

34 (d) Collaborative pharmacy agreements may not include the management of controlled
35 substances.

36 (e) A collaborative pharmacy practice agreement, meeting the requirements herein
37 established and in accordance with joint rules, shall be allowed in the hospital setting, the nursing
38 home setting, the medical school setting and the hospital, ~~community-based~~ pharmacy setting
39 and ambulatory care clinics. The pharmacist shall be employed by or under contract to provide
40 services to the hospital, community pharmacy, nursing home, ambulatory care clinic, or medical

41 school, or hold a faculty appointment with one of the schools of pharmacy or medicine in this
42 state.

43 (f) Within a healthcare system, a collaborative pharmacy practice agreement approved by
44 the hospital's pharmacy and therapeutic committee or similar medical executive committee if one
45 does not exist, shall satisfy the approval requirement for collaborative pharmacy practice
46 agreements.

47 ~~(f)~~ (g) If either board rejects a collaborative practice agreement, the applicant may appeal
48 the decision pursuant to §29A-1-1 et seq. The board which rejected the application, shall obtain
49 the services of an administrative law judge to hear the appeal. The decision of the administrative
50 law judge is final.

51 (h) Nothing pertaining to collaborative pharmacy practice shall be interpreted to permit a
52 pharmacist to accept delegation of a physician's authority outside the limits included in the
53 appropriate board's statute and rules.

NOTE: The purpose of this bill is to update collaborative pharmacy practice agreements.

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