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2005 MAY -2 P 3:10

OFFICE WEST VIRGINIA
SECRETARY OF STATE

WEST VIRGINIA LEGISLATURE

FIRST REGULAR SESSION, 2005



ENROLLED

COMMITTEE SUBSTITUTE
FOR

House Bill No. 2371

(By Delegates Perdue, Amores and Anderson)



Passed April 9, 2005

In Effect Ninety Days from Passage

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COMMITTEE SUBSTITUTE

FOR

H. B. 2371

(BY DELEGATES PERDUE, AMORES AND ANDERSON)

[Passed April 9, 2005; in effect ninety days from passage.]

AN ACT to amend and reenact §30-5-1b of the Code of West Virginia, 1931, as amended, and to amend said code by adding thereto four new sections, designated §30-5-26, §30-5-27, §30-5-28, and §30-5-29, all relating to requirements for collaborative pharmacy practice agreements between physicians and pharmacists, establishing locations, sunset provisions, and granting rule-making authority.

Be it enacted by the Legislature of West Virginia:

That §30-5-1b of the Code of West Virginia, 1931, as amended, be amended and reenacted; and that said code be amended by adding thereto four new sections, designated §30-5-26, §30-5-27, §30-5-28, and §30-5-29, all to read as follows:

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

1 **§30-5-1b. Definitions.**

2 The following words and phrases, as used in this article,
3 have the following meanings, unless the context otherwise
4 requires:

5 (1) “Administer” means the direct application of a drug to
6 the body of a patient or research subject by injection, inhalation,
7 ingestion or any other means.

8 (2) “Board of pharmacy” or “board” means the West
9 Virginia State Board of Pharmacy.

10 (3) “Collaborative pharmacy practice” is that practice of
11 pharmacy where one or more pharmacists have jointly agreed,
12 on a voluntary basis, to work in conjunction with one or more
13 physicians under written protocol where the pharmacist or
14 pharmacists may perform certain patient care functions autho-
15 rized by the physician or physicians under certain specified
16 conditions and limitations.

17 (4) “Collaborative pharmacy practice agreement” is a
18 written and signed agreement between a pharmacist, a physi-
19 cian, and the individual patient or the patients’ authorized
20 representative who has granted his or her informed consent, that
21 provides for collaborative pharmacy practice for the purpose of
22 drug therapy management of a patient, which has been ap-
23 proved by the Board of Pharmacy, the Board of Medicine in the
24 case of an allopathic physician or the West Virginia Board of
25 Osteopathy in the case of an osteopathic physician.

26 (5) “Compounding” means:

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

29 (i) As the result of a practitioner's prescription drug order
30 or initiative based on the practitioner/patient/pharmacist
31 relationship in the course of professional practice for sale or
32 dispensing; or

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

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

39 (6) "Confidential information" means information main-
40 tained by the pharmacist in the patient record or which is
41 communicated to the patient as part of patient counseling or
42 which is communicated by the patient to the pharmacist. This
43 information is privileged and may be released only to the
44 patient or to other members of the health care team and other
45 pharmacists where, in the pharmacists' professional judgment,
46 the release is necessary to the patient's health and well-being;
47 to other persons or governmental agencies authorized by law to
48 receive the privileged information; as necessary for the limited
49 purpose of peer review and utilization review; as authorized by
50 the patient or required by court order.

51 (7) "Deliver" or "delivery" means the actual, constructive
52 or attempted transfer of a drug or device from one person to
53 another, whether or not for a consideration.

54 (8) "Device" means an instrument, apparatus, implement or
55 machine, contrivance, implant or other similar or related article,
56 including any component part or accessory, which is required
57 under federal law to bear the label, "Caution: Federal or state
58 law requires dispensing by or on the order of a physician."

59 (9) “Dispense” or “dispensing” means the preparation and
60 delivery of a drug or device in an appropriately labeled and
61 suitable container to a patient or patient’s representative or
62 surrogate pursuant to a lawful order of a practitioner for
63 subsequent administration to, or use by, a patient.

64 (10) “Distribute” means the delivery of a drug or device
65 other than by administering or dispensing.

66 (11) “Drug” means:

67 (A) Articles recognized as drugs in the USP-DI, facts and
68 comparisons, physicians desk reference or supplements thereto,
69 for use in the diagnosis, cure, mitigation, treatment or preven-
70 tion of disease in human or other animals;

71 (B) Articles, other than food, intended to affect the structure
72 or any function of the body of human or other animals; and

73 (C) Articles intended for use as a component of any articles
74 specified in paragraphs (A) or (B) of this subdivision.

75 (12) “Drug regimen review” includes, but is not limited to,
76 the following activities:

77 (A) Evaluation of the prescription drug orders and patient
78 records for:

79 (i) Known allergies;

80 (ii) Rational therapy-contraindications;

81 (iii) Reasonable dose and route of administration; and

82 (iv) Reasonable directions for use.

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

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

88 (i) Drug-drug;

89 (ii) Drug-food;

90 (iii) Drug-disease; and

91 (iv) Adverse drug reactions.

92 (D) Evaluation of the prescription drug orders and patient
93 records for proper use, including over use and under use and
94 optimum therapeutic outcomes.

95 (13) “Drug therapy management” means the review of drug
96 therapy regimens of patients by a pharmacist for the purpose of
97 evaluating and rendering advice to a physician regarding
98 adjustment of the regimen in accordance with the collaborative
99 pharmacy practice agreement. Decisions involving drug therapy
100 management shall be made in the best interest of the patient.
101 Drug therapy management shall be limited to:

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

105 (B) Collecting and reviewing patient histories;

106 (C) Obtaining and checking vital signs, including pulse,
107 temperature, blood pressure and respiration;

108 (D) Ordering screening laboratory tests that are dose related
109 and specific to the patient’s medication or are protocol driven
110 and are also specifically set out in the collaborative pharmacy
111 practice agreement between the pharmacist and physician.

112 (14) "Intern" means an individual who is:

113 (A) Currently registered by this state to engage in the
114 practice of pharmacy while under the supervision of a licensed
115 pharmacist and is satisfactorily progressing toward meeting the
116 requirements for licensure as a pharmacist; or

117 (B) A graduate of an approved college of pharmacy or a
118 graduate who has established educational equivalency by
119 obtaining a foreign pharmacy graduate examination committee
120 (FPGEC) certificate, who is currently licensed by the board for
121 the purpose of obtaining practical experience as a requirement
122 for licensure as a pharmacist; or

123 (C) A qualified applicant awaiting examination for
124 licensure; or

125 (D) An individual participating in a residency or fellowship
126 program.

127 (15) "Labeling" means the process of preparing and
128 affixing a label to a drug container exclusive, however, of a
129 labeling by a manufacturer, packer or distributor of a nonpre-
130 scription drug or commercially packaged legend drug or device.
131 Any label shall include all information required by federal law
132 or regulation and state law or rule.

133 (16) "Mail-order pharmacy" means a pharmacy, regardless
134 of its location, which dispenses greater than ten percent
135 prescription drugs via the mail.

136 (17) "Manufacturer" means a person engaged in the
137 manufacture of drugs or devices.

138 (18) "Manufacturing" means the production, preparation,
139 propagation or processing of a drug or device, either directly or
140 indirectly, by extraction from substances of natural origin or

141 independently by means of chemical or biological synthesis and
142 includes any packaging or repackaging of the substance or
143 substances or labeling or relabeling of its contents and the
144 promotion and marketing of the drugs or devices. Manufactur-
145 ing also includes the preparation and promotion of commer-
146 cially available products from bulk compounds for resale by
147 pharmacies, practitioners or other persons.

148 (19) “Nonprescription drug” means a drug which may be
149 sold without a prescription and which is labeled for use by the
150 consumer in accordance with the requirements of the laws and
151 rules of this state and the federal government.

152 (20) “Patient counseling” means the oral communication by
153 the pharmacist of information, as defined in the rules of the
154 board, to the patient to improve therapy by aiding in the proper
155 use of drugs and devices.

156 (21) “Person” means an individual, corporation, partner-
157 ship, association or any other legal entity, including govern-
158 ment.

159 (22) “Pharmaceutical care” is the provision of drug therapy
160 and other pharmaceutical patient care services intended to
161 achieve outcomes related to the cure or prevention of a disease,
162 elimination or reduction of a patient’s symptoms or arresting or
163 slowing of a disease process as defined in the rules of the board.

164 (23) “Pharmacist” or “registered pharmacist” means an
165 individual currently licensed by this state to engage in the
166 practice of pharmacy and pharmaceutical care.

167 (24) “Pharmacist-in-charge” means a pharmacist currently
168 licensed in this state who accepts responsibility for the opera-
169 tion of a pharmacy in conformance with all laws and rules
170 pertinent to the practice of pharmacy and the distribution of

171 drugs and who is personally in full and actual charge of the
172 pharmacy and personnel.

173 (25) "Pharmacist's scope of practice pursuant to the
174 collaborative pharmacy practice agreement" means those duties
175 and limitations of duties placed upon the pharmacist by the
176 collaborating physician, as jointly approved by the Board of
177 Pharmacy and the Board of Medicine or the Board of Osteopa-
178 thy.

179 (26) "Pharmacy" means any drugstore, apothecary or place
180 within this state where drugs are dispensed and sold at retail or
181 displayed for sale at retail and pharmaceutical care is provided
182 and any place outside of this state where drugs are dispensed
183 and pharmaceutical care is provided to residents of this state.

184 (27) "Physician" means an individual currently licensed, in
185 good standing and without restrictions, as an allopathic physi-
186 cian by the West Virginia Board of Medicine, or an osteopathic
187 physician by the West Virginia Board of Osteopathy.

188 (28) "Pharmacy technician" means registered supportive
189 personnel who work under the direct supervision of a pharma-
190 cist who have passed an approved training program as described
191 in this article.

192 (29) "Practitioner" means an individual currently licensed,
193 registered or otherwise authorized by any state, territory or
194 district of the United States to prescribe and administer drugs
195 in the course of professional practices, including allopathic and
196 osteopathic physicians, dentists, physician's assistants, optome-
197 trists, veterinarians, podiatrists and nurse practitioners as
198 allowed by law.

199 (30) "Preceptor" means an individual who is currently
200 licensed as a pharmacist by the board, meets the qualifications

201 as a preceptor under the rules of the Board and participates in
202 the instructional training of pharmacy interns.

203 (31) “Prescription drug” or “legend drug” means a drug
204 which, under federal law, is required, prior to being dispensed
205 or delivered, to be labeled with either of the following state-
206 ments:

207 (A) “Caution: Federal law prohibits dispensing without
208 prescription”; or

209 (B) “Caution: Federal law restricts this drug to use by, or on
210 the order of, a licensed veterinarian”; or a drug which is
211 required by any applicable federal or state law or rule to be
212 dispensed pursuant only to a prescription drug order or is
213 restricted to use by practitioners only.

214 (32) “Prescription drug order” means a lawful order of a
215 practitioner for a drug or device for a specific patient.

216 (33) “Prospective drug use review” means a review of the
217 patients’ drug therapy and prescription drug order, as defined
218 in the rules of the board, prior to dispensing the drug as part of
219 a drug regimen review.

220 (34) “USP-DI” means the United States pharmaco-
221 peia-dispensing information.

222 (35) “Wholesale distributor” means any person engaged in
223 wholesale distribution of drugs, including, but not limited to,
224 manufacturers’ and distributors’ warehouses, chain drug
225 warehouses and wholesale drug warehouses, independent
226 wholesale drug trader and retail pharmacies that conduct
227 wholesale distributions.

**§30-5-26. Pharmacist requirements to participate in a collabora-
tive pharmacy practice agreement.**

1 For a pharmacist to participate in a collaborative pharmacy
2 practice agreement, the pharmacist must:

3 (a) Have an unrestricted and current license to practice as
4 a pharmacist in West Virginia;

5 (b) Have at least one million dollars of professional liability
6 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 com-
10 pleted an American Society of Health System Pharma-
11 cists (ASHP) accredited residency program, which includes two
12 years of clinical experience approved by the Boards;

13 (2) Successfully completed the course of study and holds
14 the academic degree of Doctor of Pharmacy and has three years
15 of clinical experience approved by the Board and has completed
16 an Accreditation Council for Pharmacy Education (ACPE)
17 approved certificate program in the area of practice covered by
18 the collaborative pharmacy practice agreement; or

19 (3) Successfully completed the course of study and holds
20 the academic degree of Bachelor of Science in Pharmacy and
21 has five years of clinical experience approved by the Boards
22 and has completed two ACPE approved certificate programs
23 with at least one program in the area of practice covered by a
24 collaborative pharmacy practice agreement.

§30-5-27. Collaborative pharmacy practice agreement.

1 (a) A pharmacist engaging in collaborative pharmacy
2 practice shall have on file at his or her place of practice the
3 collaborative pharmacy practice agreement. The existence and
4 subsequent termination of the agreement and any additional

5 information the rules may require concerning the agreement,
6 including the agreement itself, shall be made available to the
7 appropriate licensing board for review upon request. The
8 agreement may allow the pharmacist, within the pharmacist's
9 scope of practice pursuant to the collaborative pharmacy
10 practice agreement, to conduct drug therapy management
11 activities approved by the collaborating physician. The collabo-
12 rative pharmacy practice agreement must be a voluntary
13 process, which is a physician directed approach, that is entered
14 into between an individual physician, an individual pharmacist
15 and an individual patient or the patient's authorized representa-
16 tive who has given informed consent.

17 (b) A collaborative pharmacy practice agreement may
18 authorize a pharmacist to provide drug therapy management. In
19 instances where drug therapy is discontinued, the pharmacist
20 shall notify the treating physician of such discontinuance in the
21 time frame and in the manner established by joint legislative
22 rules. Each protocol developed, pursuant to the collaborative
23 pharmacy practice agreement, shall contain detailed direction
24 concerning the services that the pharmacists may perform for
25 that patient. The protocol shall include, but need not be limited
26 to; (1) the specific drug or drugs to be managed by the pharma-
27 cist; (2) the terms and conditions under which drug therapy may
28 be implemented, modified or discontinued; (3) the conditions
29 and events upon which the pharmacist is required to notify the
30 physician; and (4) the laboratory tests that may be ordered in
31 accordance with drug therapy management. All activities
32 performed by the pharmacist in conjunction with the protocol
33 shall be documented in the patient's medical record. The
34 pharmacists shall report at least every thirty days to the
35 physician regarding the patient's drug therapy management.
36 The collaborative pharmacy practice agreement and protocols
37 shall be available for inspection by the West Virginia Board of
38 Pharmacy, the West Virginia Board of Medicine, or the West
39 Virginia Board of Osteopathy, depending on the licensing board

40 of the participating physician. A copy of the protocol shall be
41 filed in the patient's medical record.

42 (c) Collaborative pharmacy agreements shall not include
43 the management of controlled substances.

44 (d) A collaborative pharmacy practice agreement, meeting
45 the requirements herein established and in accordance with joint
46 rules, shall be allowed in the hospital setting, the nursing home
47 setting, the medical school setting and the hospital community
48 and ambulatory care clinics. The pharmacist shall be employed
49 by or under contract to provide services to such hospital,
50 nursing home or medical school, or hold a faculty appointment
51 with one of the schools of pharmacy or medicine in this state.

52 (e) Up to five pilot project sites in the community based
53 pharmacy setting which meet the requirements established in
54 rule shall be jointly selected by the Board of Pharmacy, Board
55 of Medicine and the Board of Osteopathy.

56 (f) For the purpose of proposing a legislative rule to clarify
57 and define a collaborative pharmacy practice relationship, the
58 Boards responsible for promulgating the rule shall establish an
59 advisory committee to assist them in the development and
60 implementation of the pharmacy collaborative practice act. The
61 advisory committee shall be made up of fourteen members.
62 These members shall include one representative appointed by
63 the West Virginia State Medical Association; one representative
64 appointed by the West Virginia Academy of Family Physicians;
65 one representative appointed by the West Virginia Society of
66 Osteopathic Medicine; one representative appointed by the
67 West Virginia School of Medicine; one representative ap-
68 pointed by the Marshall University School of Medicine; one
69 representative appointed by the West Virginia School of
70 Osteopathic Medicine; two representatives appointed by the
71 West Virginia Pharmacy Association, one of whom shall

72 represent chain pharmacies and one of whom shall represent
73 independent pharmacies; two representatives appointed by the
74 West Virginia Society of Health System Pharmacists, one of
75 whom shall represent long term care settings and one of whom
76 shall represent hospital pharmacists; one representative
77 appointed by the West Virginia School of Pharmacy; one
78 representative appointed by the University of Charleston School
79 of Pharmacy; one representative appointed by the West Virginia
80 Hospital Association; and one representative appointed by the
81 West Virginia Health Care Association. A representative of
82 each board with rule-making authority shall serve as an ex
83 officio member of the advisory committee.

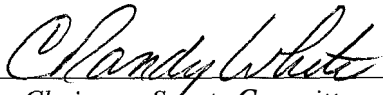
§30-5-28. Rule-making authority.

1 The Board of Pharmacy, the Board of Medicine and the
2 Board of Osteopathy shall jointly agree and propose rules for
3 legislative approval in accordance with the provisions of article
4 three, chapter twenty-nine-a of the code.

§30-5-29. Collaborative pharmacy practice continuation.

1 Pursuant to the provisions of article ten, [§§4-10-1 et seq.]
2 chapter four of this code, pharmacy collaborative agreements
3 in community settings shall continue to exist until the first day
4 of July, two thousand eight, unless sooner terminated, contin-
5 ued or reestablished pursuant to that article.


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

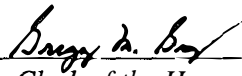

Chairman Senate Committee

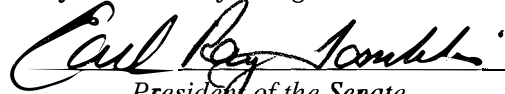

Chairman House Committee

Originating in the House.

In effect ninety days from passage.

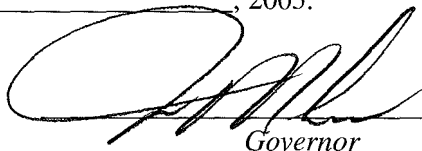

Clerk of the Senate


Clerk of the House of Delegates


President of the Senate


Speaker of the House of Delegates

The within is approved this the end
day of May, 2005.


Governor

PRESENTED TO THE
GOVERNOR

APR 26 2005

Time 4:30 pm