

WEST VIRGINIA LEGISLATURE

2019 REGULAR SESSION

Committee Substitute

for

Senate Bill 489

SENATORS MARONEY, TAKUBO, AND TARR, *original sponsors*

[Originating in the Committee on Health and Human

Resources; Reported on February 13, 2019]

1 A BILL to amend and reenact §5-16-9 of the Code of West Virginia, 1931, as amended; to amend
2 and reenact §33-51-3, §33-51-4, §33-51-7, §33-51-8, and §33-51-9 of said code; and to
3 amend said code by adding thereto a new section, designated §33-51-10, all relating
4 generally to the Pharmacy Audit Integrity Act and the regulation of pharmacy benefit
5 managers; defining terms; requiring pharmacy benefit managers to obtain a license from
6 the Insurance Commissioner before doing business in the state; setting forth terms and
7 fees for licensure of pharmacy benefit managers; authorizing the Insurance Commissioner
8 to promulgate rules for legislative approval relating to licensing, fees, application, financial
9 standards, and reporting requirements of pharmacy benefit managers; requiring pharmacy
10 benefit managers shall not provide a network comprised only of mail-order benefits;
11 requiring the Insurance Commissioner to enforce the licensure provisions relating to
12 pharmacy benefit managers; providing for the applicability of provisions to pharmacy
13 benefit managers; clarifying that requirements do not apply to certain prescription drug
14 plans; clarifying that an auditing entity may not seek a fee, charge-back, recoupment, or
15 other adjustment from a pharmacy or pharmacist except in certain circumstances;
16 prohibiting a pharmacy benefit manager or third-party entity from reimbursing an entity
17 participating in the federal 340B drug discount program for pharmacy-dispensed drugs at
18 a rate lower than that paid for the same drug to pharmacies similar in prescription volume
19 that are not 340B entities and shall not assess any fee, chargeback, or other adjustment
20 upon the 340B entity on the basis that the 340B entity participates in the 340B program;
21 and requiring the reporting of certain data relating to the payment of pharmacy claims.

Be it enacted by the Legislature of West Virginia:

**CHAPTER 5. GENERAL POWERS AND AUTHORITY OF THE
GOVERNOR, SECRETARY OF STATE, AND ATTORNEY GENERAL;
BOARD OF PUBLIC WORKS; MISCELLANEOUS AGENCIES,
COMMISSIONS, OFFICES, PROGRAMS, ETC.**

ARTICLE 16. WEST VIRGINIA PUBLIC EMPLOYEES INSURANCE ACT.

§5-16-9. Authorization to execute contracts for group hospital and surgical insurance, group major medical insurance, group prescription drug insurance, group life and accidental death insurance, and other accidental death insurance; mandated benefits; limitations; awarding of contracts; reinsurance; certificates for covered employees; discontinuance of contracts.

1 (a) The director is hereby given exclusive authorization to execute such contract or
2 contracts as are necessary to carry out the provisions of this article and to provide the plan or
3 plans of group hospital and surgical insurance coverage, group major medical insurance
4 coverage, group prescription drug insurance coverage, and group life and accidental death
5 insurance coverage selected in accordance with the provisions of this article, such contract or
6 contracts to be executed with one or more agencies, corporations, insurance companies, or
7 service organizations licensed to sell group hospital and surgical insurance, group major medical
8 insurance, group prescription drug insurance, and group life and accidental death insurance in
9 this state.

10 (b) The group hospital or surgical insurance coverage and group major medical insurance
11 coverage herein provided shall include coverages and benefits for x-ray and laboratory services
12 in connection with mammogram and pap smears when performed for cancer screening or
13 diagnostic services and annual checkups for prostate cancer in men age 50 and over. Such
14 benefits shall include, but not be limited to, the following:

15 (1) Mammograms when medically appropriate and consistent with the current guidelines
16 from the United States Preventive Services Task Force;

17 (2) A pap smear, either conventional or liquid-based cytology, whichever is medically
18 appropriate and consistent with the current guidelines from the United States Preventive Services
19 Task Force or The American College of Obstetricians and Gynecologists, for women age 18 and
20 over;

21 (3) A test for the human papilloma virus (HPV) for women age 18 or over, when medically
22 appropriate and consistent with the current guidelines from either the United States Preventive
23 Services Task Force or the American College of Obstetricians and Gynecologists for women age
24 18 and over;

25 (4) A checkup for prostate cancer annually for men age 50 or over; and

26 (5) Annual screening for kidney disease as determined to be medically necessary by a
27 physician using any combination of blood pressure testing, urine albumin or urine protein testing,
28 and serum creatinine testing as recommended by the National Kidney Foundation.

29 (6) Coverage for general anesthesia for dental procedures and associated outpatient
30 hospital or ambulatory facility charges provided by appropriately licensed healthcare individuals
31 in conjunction with dental care if the covered person is:

32 (A) Seven years of age or younger or is developmentally disabled and is either an
33 individual for whom a successful result cannot be expected from dental care provided under local
34 anesthesia because of a physical, intellectual, or other medically compromising condition of the
35 individual and for whom a superior result can be expected from dental care provided under
36 general anesthesia; or

37 (B) A child who is 12 years of age or younger with documented phobias, or with
38 documented mental illness, and with dental needs of such magnitude that treatment should not
39 be delayed or deferred and for whom lack of treatment can be expected to result in infection, loss
40 of teeth or other increased oral or dental morbidity and for whom a successful result cannot be
41 expected from dental care provided under local anesthesia because of such condition and for
42 whom a superior result can be expected from dental care provided under general anesthesia.

43 (7) (A) A policy, plan, or contract that is issued or renewed on or after January 1, 2019,
44 and that is subject to this section, shall provide coverage, through the age of 20, for amino acid-
45 based formula for the treatment of severe protein-allergic conditions or impaired absorption of
46 nutrients caused by disorders affecting the absorptive surface, function, length, and motility of the

47 gastrointestinal tract. This includes the following conditions, if diagnosed as related to the disorder
48 by a physician licensed to practice in this state pursuant to either §30-3-1 *et seq.* or §30-14-1 *et*
49 *seq.* of this code:

50 (i) Immunoglobulin E and Nonimmunoglobulin E-medicated allergies to multiple food
51 proteins;

52 (ii) Severe food protein-induced enterocolitis syndrome;

53 (iii) Eosinophilic disorders as evidenced by the results of a biopsy; and

54 (iv) Impaired absorption of nutrients caused by disorders affecting the absorptive surface,
55 function, length, and motility of the gastrointestinal tract (short bowel).

56 (B) The coverage required by §15-16-9(b)(7)(A) of this code shall include medical foods
57 for home use for which a physician has issued a prescription and has declared them to be
58 medically necessary, regardless of methodology of delivery.

59 (C) For purposes of this subdivision, “medically necessary foods” or “medical foods” shall
60 mean prescription amino acid-based elemental formulas obtained through a pharmacy: *Provided,*
61 That these foods are specifically designated and manufactured for the treatment of severe allergic
62 conditions or short bowel.

63 (D) The provisions of this subdivision shall not apply to persons with an intolerance for
64 lactose or soy.

65 (c) The group life and accidental death insurance herein provided shall be in the amount
66 of \$10,000 for every employee. The amount of the group life and accidental death insurance to
67 which an employee would otherwise be entitled shall be reduced to \$5,000 upon such employee
68 attaining age 65.

69 (d) All of the insurance coverage to be provided for under this article may be included in
70 one or more similar contracts issued by the same or different carriers.

71 (e) The provisions of §5A-3-1 *et seq.* of this code, relating to the Division of Purchasing of
72 the Department of Finance and Administration, shall not apply to any contracts for any insurance

73 coverage or professional services authorized to be executed under the provisions of this article.
74 Before entering into any contract for any insurance coverage, as authorized in this article, the
75 director shall invite competent bids from all qualified and licensed insurance companies or
76 carriers, who may wish to offer plans for the insurance coverage desired: *Provided*, That the
77 director shall negotiate and contract directly with health care providers and other entities,
78 organizations and vendors in order to secure competitive premiums, prices, and other financial
79 advantages. The director shall deal directly with insurers or health care providers and other
80 entities, organizations, and vendors in presenting specifications and receiving quotations for bid
81 purposes. No commission or finder's fee, or any combination thereof, shall be paid to any
82 individual or agent; but this shall not preclude an underwriting insurance company or companies,
83 at their own expense, from appointing a licensed resident agent, within this state, to service the
84 companies' contracts awarded under the provisions of this article. Commissions reasonably
85 related to actual service rendered for the agent or agents may be paid by the underwriting
86 company or companies: *Provided, however*, That in no event shall payment be made to any agent
87 or agents when no actual services are rendered or performed. The director shall award the
88 contract or contracts on a competitive basis. In awarding the contract or contracts the director
89 shall take into account the experience of the offering agency, corporation, insurance company, or
90 service organization in the group hospital and surgical insurance field, group major medical
91 insurance field, group prescription drug field, and group life and accidental death insurance field,
92 and its facilities for the handling of claims. In evaluating these factors, the director may employ
93 the services of impartial, professional insurance analysts or actuaries, or both. Any contract
94 executed by the director with a selected carrier shall be a contract to govern all eligible employees
95 subject to the provisions of this article. Nothing contained in this article shall prohibit any insurance
96 carrier from soliciting employees covered hereunder to purchase additional hospital and surgical,
97 major medical, or life and accidental death insurance coverage.

98 (f) The director may authorize the carrier with whom a primary contract is executed to
99 reinsure portions of the contract with other carriers which elect to be a reinsurer and who are
100 legally qualified to enter into a reinsurance agreement under the laws of this state.

101 (g) Each employee who is covered under any contract or contracts shall receive a
102 statement of benefits to which the employee, his or her spouse and his or her dependents are
103 entitled under the contract, setting forth the information as to whom the benefits are payable, to
104 whom claims shall be submitted and a summary of the provisions of the contract or contracts as
105 they affect the employee, his or her spouse and his or her dependents.

106 (h) The director may at the end of any contract period discontinue any contract or contracts
107 it has executed with any carrier and replace the same with a contract or contracts with any other
108 carrier or carriers meeting the requirements of this article.

109 (i) The director shall provide by contract or contracts entered into under the provisions of
110 this article the cost for coverage of children's immunization services from birth through age 16
111 years to provide immunization against the following illnesses: Diphtheria, polio, mumps, measles,
112 rubella, tetanus, hepatitis-b, hemophilia influenzae-b, and whooping cough. Additional
113 immunizations may be required by the Commissioner of the Bureau for Public Health for public
114 health purposes. Any contract entered into to cover these services shall require that all costs
115 associated with immunization, including the cost of the vaccine, if incurred by the health care
116 provider, and all costs of vaccine administration be exempt from any deductible, per visit charge
117 and/or copayment provisions which may be in force in these policies or contracts. This section
118 does not require that other health care services provided at the time of immunization be exempt
119 from any deductible and/or copayment provisions.

120 (j) The director shall include language in all contracts for pharmacy benefits management,
121 as defined by §33-51-3 of this code, requiring the pharmacy benefit manager to report quarterly
122 to the agency for all pharmacy claims the amount paid to the pharmacy provider per claim,
123 including, but not limited to, the following:

124 (1) The cost of drug reimbursement;
125 (2) Dispensing fees;
126 (3) Copayments; and
127 (4) The amount charged to the agency for each claim by the pharmacy benefit manager.
128 In the event there is a difference between these amounts for any claim, the pharmacy
129 benefit manager shall report an itemization of all administrative fees, rebates, or processing
130 charges associated with the claim. All data and information provided by the pharmacy benefit
131 manager shall be kept secure, and notwithstanding any other provision of this code to the
132 contrary, the agency shall maintain the confidentiality of the proprietary information and not share
133 or disclose the proprietary information contained in the report or data collected with persons
134 outside the agency. All data and information provided by the pharmacy benefit manager shall be
135 considered proprietary and confidential and exempt from disclosure under the West Virginia
136 Freedom of Information Act pursuant to §29B-1-4(a)(1) of this code. Only those agency
137 employees involved in collecting, securing, and analyzing the data for the purpose of preparing
138 the report provided for herein shall have access to the proprietary data. The director shall, using
139 aggregated, nonproprietary data only, report at least quarterly to the Joint Committee on
140 Government and Finance on the implementation of this subsection and its impact on program
141 expenditures, including any difference or spread between the amount paid by pharmacy benefit
142 managers to the pharmacy providers and the amount charged to the agency for each claim by
143 the pharmacy benefit manager.
144 (k) If the information required herein is not provided, the agency shall terminate the
145 contract with the pharmacy benefit manager.

CHAPTER 33. INSURANCE.

ARTICLE 51. PHARMACY AUDIT INTEGRITY ACT.

§33-51-3. Definitions.

1 For purposes of this article:

2 “340B entity” means an entity participating in the federal 340B drug discount program, as
3 described in 42 U.S.C. § 256b, including its pharmacy or pharmacies, or any pharmacy or
4 pharmacies, contracted with the participating entity to dispense drugs purchased through such
5 program.

6 “Affiliate” means a pharmacy, pharmacist, or pharmacy technician that directly or
7 indirectly, through one or more intermediaries, owns or controls, is owned or controlled by, or is
8 under common ownership or control with a pharmacy benefit manager.

9 “Auditing entity” means a person or company that performs a pharmacy audit, including a
10 covered entity, pharmacy benefits manager, managed care organization, or third-party
11 administrator.

12 “Business day” means any day of the week excluding Saturday, Sunday, and any legal
13 holiday as set forth in §2-2-1 of this code.

14 “Claim level information” means data submitted by a pharmacy or required by a payer or
15 claims processor to adjudicate a claim.

16 “Covered entity” means a contract holder or policy holder providing pharmacy benefits to a
17 covered individual under a health insurance policy pursuant to a contract administered by a
18 pharmacy benefits manager.

19 “Covered individual” means a member, participant, enrollee, or beneficiary of a covered
20 entity who is provided health coverage by a covered entity, including a dependent or other person
21 provided health coverage through the policy or contract of a covered individual.

22 “Extrapolation” means the practice of inferring a frequency of dollar amount of
23 overpayments, underpayments, nonvalid claims, or other errors on any portion of claims
24 submitted, based on the frequency of dollar amount of overpayments, underpayments, nonvalid
25 claims, or other errors actually measured in a sample of claims.

26 “Health care provider” has the same meaning as defined in §33-41-2 of this code.

27 “Health insurance policy” means a policy, subscriber contract, certificate, or plan that
28 provides prescription drug coverage. The term includes both comprehensive and limited benefit
29 health insurance policies.

30 “Insurance commissioner” or “commissioner” has the same meaning as defined in §33-1-
31 5 of this code.

32 “Network” means a pharmacy or group of pharmacies that agree to provide prescription
33 services to covered individuals on behalf of a covered entity or group of covered entities in
34 exchange for payment for its services by a pharmacy benefits manager or pharmacy services
35 administration organization. The term includes a pharmacy that generally dispenses outpatient
36 prescriptions to covered individuals or dispenses particular types of prescriptions, provides
37 pharmacy services to particular types of covered individuals or dispenses prescriptions in
38 particular health care settings, including networks of specialty, institutional or long-term care
39 facilities.

40 “Nonproprietary drug” means a drug containing any quantity of any controlled substance
41 or any drug which is required by any applicable federal or state law to be dispensed only by
42 prescription.

43 “Pharmacist” means an individual licensed by the West Virginia Board of Pharmacy to
44 engage in the practice of pharmacy.

45 “Pharmacy” means any place within this state where drugs are dispensed and pharmacist
46 care is provided.

47 “Pharmacy audit” means an audit, conducted on-site by or on behalf of an auditing entity
48 of any records of a pharmacy for prescription or nonproprietary drugs dispensed by a pharmacy
49 to a covered individual.

50 “Pharmacy benefits management” means the performance of any of the following:

51 (1) The procurement of prescription drugs at a negotiated contracted rate for dispensation
52 within the State of West Virginia to covered individuals;

53 (2) The administration or management of prescription drug benefits provided by a covered
54 entity for the benefit of covered individuals;

55 (3) The administration of pharmacy benefits, including:

56 (A) Operating a mail-service pharmacy;

57 (B) Claims processing;

58 (C) Managing a retail pharmacy network;

59 (D) Paying claims to a pharmacy for prescription drugs dispensed to covered individuals
60 via retail or mail-order pharmacy;

61 (E) Developing and managing a clinical formulary including utilization management and
62 quality assurance programs;

63 (F) Rebate contracting administration; and

64 (G) Managing a patient compliance, therapeutic intervention, and generic substitution
65 program.

66 "Pharmacy benefits manager" means a person, business, or other entity that performs
67 pharmacy benefits management for covered entities;

68 "Pharmacy record" means any record stored electronically or as a hard copy by a
69 pharmacy that relates to the provision of prescription or nonproprietary drugs or pharmacy
70 services or other component of pharmacist care that is included in the practice of pharmacy.

71 "Pharmacy services administration organization" means any entity that contracts with a
72 pharmacy to assist with third-party payer interactions and that may provide a variety of other
73 administrative services, including contracting with pharmacy benefits managers on behalf of
74 pharmacies and managing pharmacies' claims payments from third-party payers.

75 "Third party" means any insurer, health benefit plan for employees which provides a
76 pharmacy benefits plan, a participating public agency which provides a system of health insurance
77 for public employees, their dependents and retirees, or any other insurer or organization that
78 provides health coverage, benefits, or coverage of prescription drugs as part of workers'

79 compensation insurance in accordance with state or federal law. The term does not include an
80 insurer that provides coverage under a policy of casualty or property insurance.

§33-51-4. Procedures for conducting pharmacy audits.

1 (a) An entity conducting a pharmacy audit under this article shall conform to the following
2 rules:

3 (1) Except as otherwise provided by federal or state law, an auditing entity conducting a
4 pharmacy audit may have access to a pharmacy's previous audit report only if the report was
5 prepared by that auditing entity.

6 (2) Information collected during a pharmacy audit ~~shall be~~ is confidential by law, except
7 that the auditing entity conducting the pharmacy audit may share the information with the
8 pharmacy benefits manager and with the covered entity for which a pharmacy audit is being
9 conducted and with any regulatory agencies and law-enforcement agencies as required by law.

10 (3) The auditing entity conducting a pharmacy audit may not compensate an employee or
11 contractor with which an auditing entity contracts to conduct a pharmacy audit solely based on
12 the amount claimed or the actual amount recouped by the pharmacy being audited.

13 (4) The auditing entity shall provide the pharmacy being audited with at least 14 calendar
14 days' prior written notice before conducting a pharmacy audit unless both parties agree otherwise.
15 If a delay of the audit is requested by the pharmacy, the pharmacy shall provide notice to the
16 pharmacy benefits manager within 72 hours of receiving notice of the audit.

17 (5) The auditing entity may not initiate or schedule a pharmacy audit without the express
18 consent of the pharmacy during the first five business days of any month for any pharmacy that
19 averages in excess of 600 prescriptions filled per week.

20 (6) The auditing entity shall accept paper or electronic signature logs that document the
21 delivery of prescription or nonproprietary drugs and pharmacist services to a health plan
22 beneficiary or the beneficiary's caregiver or guardian.

23 (7) Prior to leaving the pharmacy after the on-site portion of the pharmacy audit, the
24 auditing entity shall provide to the representative of the pharmacy a complete list of pharmacy
25 records reviewed.

26 (8) A pharmacy audit that involves clinical judgment shall be conducted by, or in
27 consultation with, a pharmacist.

28 (9) A pharmacy audit may not cover:

29 (A) A period of more than 24 months after the date a claim was submitted by the pharmacy
30 to the pharmacy benefits manager or covered entity unless a longer period is required by law; or

31 (B) More than 250 prescriptions: *Provided*, That a refill does not constitute a separate
32 prescription for the purposes of this subparagraph.

33 (10) The auditing entity may not use extrapolation to calculate penalties or amounts to be
34 charged back or recouped unless otherwise required by federal requirements or federal plans.

35 (11) The auditing entity may not include dispensing fees in the calculation of overpayments
36 unless a prescription is considered a misfill. As used in this subdivision, "misfill" means a
37 prescription that was not dispensed, a prescription error, a prescription where the prescriber
38 denied the authorization request, or a prescription where an extra dispensing fee was charged.

39 (12) The auditing entity conducting a pharmacy audit or person acting on behalf of the
40 auditing entity may not seek any fee, charge-back, recoupment, or other adjustment for a
41 dispensed product, or any portion of a dispensed product, unless one of the following has
42 occurred:

43 (A) Fraud or other intentional and willful misrepresentation as evidenced by a review of
44 the claims data, statements, physical review, or other investigative methods;

45 (B) Dispensing in excess of the benefit design, as established by the plan sponsor;

46 (C) Prescriptions not filled in accordance with the prescriber's order; or

47 (D) Actual overpayment to the pharmacy.

48 (13) Any fee, charge-back, recoupment, or other adjustment is limited to the actual
49 financial harm associated with the dispensed product, or portion of the dispensed product, or the
50 actual underpayment or overpayment as set forth in the criteria in subdivision (12) of this
51 subsection.

52 ~~(12)~~ (14) A pharmacy may do any of the following when a pharmacy audit is performed:

53 (A) A pharmacy may use authentic and verifiable statements or records, including, but not
54 limited to, medication administration records of a nursing home, assisted living facility, hospital,
55 or health care provider with prescriptive authority, to validate the pharmacy record and delivery;
56 and

57 (B) A pharmacy may use any valid prescription, including, but not limited to, medication
58 administration records, facsimiles, electronic prescriptions, electronically stored images of
59 prescriptions, electronically created annotations, or documented telephone calls from the
60 prescribing health care provider or practitioner's agent, to validate claims in connection with
61 prescriptions or changes in prescriptions or refills of prescription or nonproprietary drugs.
62 Documentation of an oral prescription order that has been verified by the prescribing health care
63 provider shall meet the provisions of this subparagraph for the initial audit review.

64 (b) An auditing entity shall provide the pharmacy with a written report of the pharmacy
65 audit and comply with the following requirements:

66 (1) A preliminary pharmacy audit report ~~must~~ shall be delivered to the pharmacy or its
67 corporate parent within 60 calendar days after the completion of the pharmacy audit. The
68 preliminary report shall include contact information for the auditing entity that conducted the
69 pharmacy audit and an appropriate and accessible point of contact, including telephone number,
70 facsimile number, e-mail address, and auditing firm name and address so that audit results,
71 procedures and any discrepancies can be reviewed. The preliminary pharmacy audit report shall
72 include, but not be limited to, claim level information for any discrepancy found and total dollar
73 amounts of claims subject to recovery.

74 (2) A pharmacy ~~shall be~~ is allowed at least 30 calendar days following receipt of the
75 preliminary audit report to respond to the findings of the preliminary report.

76 (3) A final pharmacy audit report shall be delivered to the pharmacy or its corporate parent
77 no later than 90 calendar days after completion of the pharmacy audit. The final pharmacy audit
78 report shall include any response provided to the auditing entity by the pharmacy or corporate
79 parent and shall consider and address such responses.

80 (4) The final audit report may be delivered electronically.

81 (5) A pharmacy may not be subject to a charge-back or recoupment for a clerical or
82 recordkeeping error in a required document or record, including a typographical or computer error,
83 unless the error resulted in overpayment to the pharmacy.

84 (6) An auditing entity conducting a pharmacy audit or person acting on behalf of the entity
85 may not charge-back, recoup, or collect penalties from a pharmacy until the time to file an appeal
86 of a final pharmacy audit report has passed or the appeals process has been exhausted,
87 whichever is later.

88 (7) If an identified discrepancy in a pharmacy audit exceeds \$25,000, future payments to
89 the pharmacy in excess of that amount may be withheld pending adjudication of an appeal.

90 (8) No interest ~~shall accrue~~ accrues for any party during the audit period, beginning with
91 the notice of the pharmacy audit and ending with the conclusion of the appeals process.

92 (9) Except for Medicare claims, approval of drug, prescriber, or patient eligibility upon
93 adjudication of a claim ~~shall~~ may not be reversed unless the pharmacy or pharmacist obtained
94 adjudication by fraud or misrepresentation of claims elements.

§33-51-7. Pharmacy benefits manager and auditing entity registration.

1 (a) Prior to conducting business in the State of West Virginia, except as provided in
2 subsection (d) of this section, a ~~pharmacy benefits manager or~~ an auditing entity shall register
3 with the Insurance Commissioner. The commissioner shall make an application form available on
4 its publicly accessible Internet website that includes a request for the following information:

5 (1) The identity, address, and telephone number of the applicant;

6 (2) The name, business address, and telephone number of the contact person for the
7 applicant; and

8 (3) When applicable, the federal employer identification number for the applicant.

9 (b) *Term and fee.* —

10 (1) The term of registration shall be two years from the date of issuance.

11 (2) The Insurance Commissioner shall determine the amount of the initial application fee
12 and the renewal application fee for the registration. Such fee shall be submitted by the applicant
13 with an application for registration. An initial application fee ~~shall be~~ is nonrefundable. A renewal
14 application fee shall be returned if the renewal of the registration is not granted.

15 (3) The amount of the initial application fees and renewal application fees ~~shall~~ must be
16 sufficient to fund the Insurance Commissioner's duties in relation to its responsibilities under this
17 article, but a single fee may not exceed \$1,000.

18 (c) *Registration.* —

19 (1) The Insurance Commissioner shall issue a registration, as appropriate, to an applicant
20 when the Insurance Commissioner determines that the applicant has submitted a completed
21 application and paid the required registration fee.

22 (2) The registration may be in paper or electronic form, ~~shall be~~ is nontransferable, and
23 shall prominently list the expiration date of the registration.

24 (d) *Duplicate registration.* —

25 (1) A licensed insurer or other entity licensed by the commissioner pursuant to this chapter
26 shall comply with the standards and procedures of this article but ~~shall~~ is not ~~be~~ required to
27 separately register as ~~either a pharmacy benefits manager or an~~ auditing entity.

28 (2) A pharmacy benefits manager that is registered as a third-party administrator pursuant
29 to §33-46-1 *et seq.* of this code shall comply with the standards and procedures of this article but
30 ~~shall~~ is not ~~be~~ required to register separately as an auditing entity.

§33-51-8. Commissioner authorized to propose rules Licensure of pharmacy benefit managers.

31 ~~The Insurance Commissioner may propose rules for legislative approval in accordance~~
32 ~~with article three, chapter twenty-nine-a of this code that are necessary to effectuate the~~
33 ~~provisions of this article~~

34 (a) A person or organization may not establish or operate as a pharmacy benefits manager
35 in the State of West Virginia without first obtaining a license from the Insurance Commissioner
36 pursuant to this section: *Provided*, That a pharmacy benefit manager registered pursuant to §33-
37 5-7 of this code may continue to do business in the state until the Insurance Commissioner has
38 completed the legislative rule as set forth in §33-55-10 of this code: *Provided, however*, That
39 additionally the pharmacy benefit manager shall submit an application within six months of
40 completion of the final rule. The Insurance Commissioner shall make an application form
41 available on its publicly accessible Internet website that includes a request for the following
42 information:

43 (1) The identity, address, and telephone number of the applicant;

44 (2) The name, business address, and telephone number of the contact person for the
45 applicant;

46 (3) When applicable, the federal employer identification number for the applicant; and

47 (4) Any other information the Insurance Commissioner considers necessary and
48 appropriate to establish the qualifications to receive a license as a pharmacy benefit manager to
49 complete the licensure process, as set forth by legislative rule promulgated by the Insurance
50 Commissioner pursuant to §33-51-9(f) of this code.

51 (b) *Term and fee.* —

52 (1) The term of licensure shall be two years from the date of issuance.

53 (2) The Insurance Commissioner shall determine the amount of the initial application fee
54 and the renewal application fee for the registration. The fee shall be submitted by the applicant

55 with an application for registration. An initial application fee is nonrefundable. A renewal
56 application fee shall be returned if the renewal of the registration is not granted.

57 (3) The amount of the initial application fees and renewal application fees must be
58 sufficient to fund the Insurance Commissioner's duties in relation to his/her responsibilities under
59 this section, but a single fee may not exceed \$10,000.

60 (4) Each application for a license, and subsequent renewal for a license, shall be
61 accompanied by evidence of financial responsibility in an amount of \$1 million.

62 (c) Licensure. —

63 (1) The Insurance Commissioner shall propose legislative rules, in accordance with §33-
64 51-9(f) of this code, establishing the licensing, fees, application, financial standards, and reporting
65 requirements of pharmacy benefit managers.

66 (2) Upon receipt of a completed application, evidence of financial responsibility, and fee,
67 the Insurance Commissioner shall make a review of each applicant and shall issue a license if
68 the applicant is qualified in accordance with the provisions of this section and the rules
69 promulgated by the Insurance Commissioner pursuant to this section. The commissioner may
70 require additional information or submissions from an applicant and may obtain any documents
71 or information reasonably necessary to verify the information contained in the application.

72 (3) The license may be in paper or electronic form, is nontransferable, and shall
73 prominently list the expiration date of the license.

74 (d) Network adequacy. —

75 (1) A pharmacy benefit manager's network shall not be comprised only of mail-order
76 benefits but must have a mix of mail-order benefits and physical stores in this state.

77 (2) A pharmacy benefit manager shall provide a pharmacy benefit manager's network
78 report describing the pharmacy benefit manager's network and the mix of mail-order to physical
79 stores in this state in a time and manner required by rule issued by the Insurance Commissioner
80 pursuant to this section.

81 (3) Failure to provide a timely report may result in the suspension or revocation of a
82 pharmacy benefit manager's license by the Insurance Commissioner.

83 (e) Enforcement. —

84 (1) The Insurance Commissioner shall enforce this section and may examine or audit the
85 books and records of a pharmacy benefit manager providing pharmacy benefits management to
86 determine if the pharmacy benefit manager is in compliance with this section: *Provided*, That any
87 information or data acquired during the examination or audit is considered proprietary and
88 confidential and exempt from disclosure under the West Virginia Freedom of Information Act
89 pursuant to §29B-1-4(a)(1) of this code.

90 (2) The Insurance Commissioner may propose rules for legislative approval in accordance
91 with §29A-3-1 *et seq.* of this code regulating pharmacy benefit managers in a manner consistent
92 with this chapter. Rules adopted pursuant to this section shall set forth penalties or fines,
93 including, without limitation, monetary fines, suspension of licensure, and revocation of licensure
94 for violations of this chapter and the rules adopted pursuant to this section.

95 (f) Applicability. —

96 (1) This section is applicable to any contract or health benefit plan issued, renewed,
97 recredentialed, amended, or extended on or after July 1, 2019.

98 (2) The requirements of this section, and any rules promulgated by the Insurance
99 Commissioner pursuant to §33-51-9(f) of this code, do not apply to the coverage of prescription
100 drugs under a plan that is subject to the Employee Retirement Income Security Act of 1974 or
101 any information relating to such coverage.

§33-51-9. Regulation of pharmacy benefit managers.

1 (a) A pharmacy, a pharmacist, and a pharmacy technician shall have the right to provide
2 a covered individual with information related to lower cost alternatives and cost share for ~~such~~ the
3 covered individual to assist health care consumers in making informed decisions. Neither a
4 pharmacy, a pharmacist, nor a pharmacy technician ~~shall~~ may be penalized by a pharmacy

5 benefit manager for discussing information in this section or for selling a lower cost alternative to
6 a covered individual, if one is available, without using a health insurance policy.

7 (b) A pharmacy benefit manager ~~shall~~ may not collect from a pharmacy, a pharmacist, or
8 a pharmacy technician a cost share charged to a covered individual that exceeds the total
9 submitted charges by the pharmacy or pharmacist to the pharmacy benefit manager.

10 (c) A pharmacy benefit manager may only directly or indirectly charge or hold a pharmacy,
11 a pharmacist, or a pharmacy technician responsible for a fee related to the adjudication of a claim
12 if:

13 (1) The total amount of the fee is identified, reported, and specifically explained for each
14 line item on the remittance advice of the adjudicated claim; or

15 (2) The total amount of the fee is apparent at the point of sale and not adjusted between
16 the point of sale and the issuance of the remittance advice.

17 (d) A pharmacy benefit manager, or any other third party, that reimburses a 340B entity
18 for drugs that are subject to an agreement under 42 U.S.C. §256b shall not reimburse the 340B
19 entity for pharmacy-dispensed drugs at a rate lower than that paid for the same drug to
20 pharmacies similar in prescription volume that are not 340B entities, and shall not assess any fee,
21 charge-back, or other adjustment upon the 340B entity on the basis that the 340B entity
22 participates in the program set forth in 42 U.S.C. §256b.

23 (e) With respect to a patient eligible to receive drugs subject to an agreement under 42
24 U.S.C. § 256b, a pharmacy benefit manager, or any other third party that makes payment for such
25 drugs, shall not discriminate against a 340B entity in a manner that prevents or interferes with the
26 patient's choice to receive such drugs from the 340B entity: *Provided*, That for purposes of this
27 section, "third party" does not include the state Medicaid program when Medicaid is providing
28 reimbursement for covered outpatient drugs, as that term is defined in 42 U.S.C. § 1396r-8(k), on
29 a fee-for-service basis: *Provided, however*, That "third party" does include a Medicaid-managed
30 care organization as described in 42 U.S.C. § 1396b(m).

31 ~~(d)~~ (f) This section ~~shall~~ does not apply with respect to claims under an employee benefit
32 plan under the Employee Retirement Income Security Act of 1974 or, except for paragraph (d), to
33 Medicare Part D.

§33-51-10. Commissioner authorized to propose rules.

1 The Insurance Commissioner may propose rules for legislative approval in accordance
2 with §29A-3-1 et seq. of this code that are necessary to effectuate the provisions of this article.