WEST VIRGINIA LEGISLATURE

2020 REGULAR SESSION

Introduced

Senate Bill 582

BY SENATORS PREZIOSO, BALDWIN, BEACH, HARDESTY,

IHLENFELD, JEFFRIES, PALUMBO, PLYMALE, ROMANO,

STOLLINGS, WOELFEL, AND LINDSAY

[Introduced January 22, 2020; referred

to the Committee on Health and Human Resources]

1 A BILL to amend and reenact §33-51-3 and §33-51-9 of the Code of West Virginia, 1931, as
2 amended, all relating to pharmacy benefit managers; prohibiting certain conduct; requiring
3 the reporting of certain information to the Insurance Commissioner; and requiring
4 pharmacy benefit managers contracting with Medicaid managed care organizations to
5 comply with §33-51-9 of said code.

Be it enacted by the Legislature of West Virginia:

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
17 a 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 "Maximum allowable cost" means: (1) A maximum drug product reimbursement for an
33 individual drug or for a group of therapeutically and pharmaceutically equivalent multiple source
34 drugs that are listed in the United States food and drug administration's approved drug products
35 with therapeutic equivalence evaluations, commonly referred to as the orange book.

36 (2) "Maximum allowable cost" includes all of the following:

37 (A) Average acquisition cost, including national average drug acquisition cost;

38 (B) Average manufacturer price;

39 (C) Average wholesale price;

40 (D) Brand effective rate or generic effective rate;

41 (E) Discount indexing;

42 (F) Federal upper limits;

43 (G) Wholesale acquisition cost;

44 (H) Any other term that a pharmacy benefit manager or an insurer may use to establish

45 <u>reimbursement rates to a pharmacist or pharmacy for pharmacist services.</u>

46 "Network" means a pharmacy or group of pharmacies that agree to provide prescription 47 services to covered individuals on behalf of a covered entity or group of covered entities in 48 exchange for payment for its services by a pharmacy benefits manager or pharmacy services 49 administration organization. The term includes a pharmacy that generally dispenses outpatient 50 prescriptions to covered individuals or dispenses particular types of prescriptions, provides 51 pharmacy services to particular types of covered individuals or dispenses prescriptions in 52 particular health care settings, including networks of specialty, institutional or long-term care 53 facilities.

54 "Nonproprietary drug" means a drug containing any quantity of any controlled substance 55 or any drug which is required by any applicable federal or state law to be dispensed only by 56 prescription.

57 "Pharmacist" means an individual licensed by the West Virginia Board of Pharmacy to 58 engage in the practice of pharmacy.

59 "Pharmacy" means any place within this state where drugs are dispensed and pharmacist 60 care is provided.

61 "Pharmacy audit" means an audit, conducted on-site by or on behalf of an auditing entity 62 of any records of a pharmacy for prescription or nonproprietary drugs dispensed by a pharmacy 63 to a covered individual.

64 "Pharmacy benefits management" means the performance of any of the following:

65 (1) The procurement of prescription drugs at a negotiated contracted rate for dispensation 66 within the State of West Virginia to covered individuals;

67 (2) The administration or management of prescription drug benefits provided by a covered 68 entity for the benefit of covered individuals;

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

70 (A) Operating a mail-service pharmacy;

71 (B) Claims processing;

72 (C) Managing a retail pharmacy network;

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

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

77 (F) Rebate contracting administration; and

78 (G) Managing a patient compliance, therapeutic intervention, and generic substitution
79 program.

80 "Pharmacy benefits manager" means a person, business, or other entity that performs
81 pharmacy benefits management for covered entities; and includes a pharmacy benefit manager
82 under contract with a medicaid managed care organization to provide pharmacy health benefit
83 services or administration under the care management system established under §9-2-6 and §9-
84 2-9 of this code;

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

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

92 "Rebate": (1) Means a discount or other price concession or payment that meets both of
93 the following:

94 (A) It is based on utilization of a prescription drug.

95 (B) It is paid by a manufacturer or third party, directly or indirectly to a pharmacy benefit
96 manager, pharmacy services administrative organization, or a pharmacy after a claim has been

97 processed and paid at a pharmacy.

98 (2) Includes incentives, disbursements, and reasonable estimates of a volume-based
99 discount.

100 "Spread pricing" means the model of prescription drug pricing by which a pharmacy benefit
101 manager charges a plan sponsor a contracted price for a prescription drug, and that contracted
102 price differs from the amount the pharmacy benefit manager directly or indirectly pays the
103 pharmacist or pharmacy for that drug or for pharmacist services related to that drug.

104 "Third party" means any insurer, health benefit plan for employees which provides a
105 pharmacy benefits plan, a participating public agency which provides a system of health insurance
106 for public employees, their dependents and retirees, or any other insurer or organization that
107 provides health coverage, benefits, or coverage of prescription drugs as part of workers'
108 compensation insurance in accordance with state or federal law. The term does not include an
109 insurer that provides coverage under a policy of casualty or property insurance.

§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 the
3 covered individual to assist health care consumers in making informed decisions. Neither a
4 pharmacy, a pharmacist, nor a pharmacy technician may be penalized by a pharmacy benefit
5 manager for discussing information in this section or for selling a lower cost alternative to a
6 covered individual, if one is available, without using a health insurance policy.

7 (b) A pharmacy benefit manager may not collect from a pharmacy, a pharmacist, or a
8 pharmacy technician a cost share charged to a covered individual that exceeds the total submitted
9 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 may not do any of the following:
18 (1) Engage in spread pricing;
19 (2) Directly or indirectly retroactively deny a claim or aggregate of claims after the claim
20 or aggregate of claims has been adjudicated, unless any of the following apply:
21 (A) The original claim was submitted fraudulently;
22 (B) The original claim payment was incorrect because the pharmacy or pharmacist had
23 already been paid for the drug or services in question; or
24 (C) The pharmacist services were not properly rendered by the pharmacy or pharmacist.
25 (3) Reduce, directly or indirectly, payment to a pharmacy for pharmacist services to an
26 effective rate of reimbursement, including permitting an insurer or plan sponsor to make such a
27 reduction. As used in subdivision, “effective rate of reimbursement” includes generic effective
28 rates, brand effective rates, direct and indirect remuneration fees, or any other reduction or
29 aggregate reduction or payment.
30 (4) Pay or reimburse a pharmacy or pharmacist at an amount less than the national
31 average drug acquisition cost or, if the national average acquisition cost is unavailable, the
32 wholesale acquisition cost, for the ingredient drug product component of drugs provided by the
33 pharmacist or pharmacy.
34 ~~(d)~~ (e) A pharmacy benefit manager, or any other third party, that reimburses a 340B entity
35 for drugs that are subject to an agreement under 42 U.S.C. §256b shall not reimburse the 340B
36 entity for pharmacy-dispensed drugs at a rate lower than that paid for the same drug to
37 pharmacies similar in prescription volume that are not 340B entities, and shall not assess any fee,
38 charge-back, or other adjustment upon the 340B entity on the basis that the 340B entity

39 participates in the program set forth in 42 U.S.C. §256b.

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

48 (g) (1) A pharmacy benefit manager shall report to the commissioner all of the following
49 information:

50 (A) The aggregate amount of rebates received by the pharmacy benefit manager;

51 (B) The aggregate amount of rebates distributed to the related plan sponsor;

52 (C) The aggregate amount of rebates passed on to the enrollees of each plan sponsor at
53 the point of sale that reduced the enrollee's applicable cost-sharing amount;

54 (D) The individual and aggregate amount paid by the plan sponsor to the pharmacy benefit
55 manager for pharmacist services itemized by pharmacy, by product, and by goods and services;

56 (E) The individual and aggregate amount a pharmacy benefit manager paid for pharmacist
57 services itemized by pharmacy, by product, and by goods and services.

58 (2) The information required by this subsection shall be provided on a quarterly basis and
59 for each plan sponsor for which the pharmacy benefit manager provides services.

60 (3) The information required by this subsection shall be considered confidential
61 information, may not be released, and may not be considered a public record under §29B-1-1 *et*
62 *seq.* of this code.

63 ~~(f)~~ (h) This section does not apply with respect to claims under an employee benefit plan
64 under the Employee Retirement Income Security Act of 1974 or, except for paragraph (d), to

65 Medicare Part D.

NOTE: The purpose of this bill is to impose certain requirements on pharmacy benefit managers contracting with Medicaid managed care organizations.

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