

WEST VIRGINIA LEGISLATURE

2021 REGULAR SESSION

Introduced

Senate Bill 83

BY SENATORS TAKUBO, STOLLINGS, MARONEY, AND

LINDSAY

[Introduced February 10, 2021; referred
to the Committee on Health and Human Resources]

1 A BILL to amend and reenact §33-51-3 of the Code of West Virginia, 1931, as amended; and to
 2 amend said code by adding thereto a new article, designated §33-51A-1, §33-51A-2, §33-
 3 51A-3, §33-51A-4, and §33-51A-5, all relating to the regulation of pharmacy services
 4 administrative organizations.

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 “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~~ administrative organization. The term includes a pharmacy that generally
36 dispenses outpatient prescriptions to covered individuals or dispenses particular types of
37 prescriptions, provides pharmacy services to particular types of covered individuals or dispenses
38 prescriptions in particular health care settings, including networks of specialty, institutional or long-
39 term care 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 onsite 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~~ administrative organization” ~~means any entity that~~

72 ~~contracts with a pharmacy to assist with third-party payer interactions and that may provide a~~
 73 ~~variety of other administrative services, including contracting with pharmacy benefits managers~~
 74 ~~on behalf of pharmacies and managing pharmacies' claims payments from third-party payers has~~
 75 ~~the same meaning as defined in §33-51A-1 of this code.~~

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

ARTICLE 51A. PHARMACY SERVICES ADMINISTRATIVE ORGANIZATION
TRANSPARENCY ACT.

§33-51A-1. Definitions.

- 1 For purposes of this article:
- 2 "Independent pharmacy" means a pharmacy operating within the state that is under
 3 common ownership with not more than two other pharmacies;
- 4 "Pharmacy benefits manager" has the same meaning as defined in §33-51-3 of this code;
- 5 "Pharmacy services administrative organization" means an entity operating within the
 6 state that does all of the following:
- 7 (1) Contracts with independent pharmacies to conduct business on their behalf with third-
 8 party payers;
- 9 (2) Provides administrative services to pharmacies and negotiates and enters into
 10 contracts with third-party payers or pharmacy benefits managers on behalf of pharmacies; and
- 11 (3) Performs one or more of the following administrative services to pharmacies:
- 12 (A) Assistance with claims;

- 13 (B) Assistance with audits;
 14 (C) Centralized payment;
 15 (D) Certification in specialized care programs;
 16 (E) Compliance support;
 17 (F) Setting flat fees for generic drugs;
 18 (G) Assistance with store layout;
 19 (H) Inventory management;
 20 (I) Marketing support;
 21 (J) Management and analysis of payment and drug dispensing data; and
 22 (K) Provision of resources for retail cash cards;

23 “Pharmacy services administrative organization - pharmacy contract” means a contractual
 24 agreement between a pharmacy services administrative organization and an independent
 25 pharmacy by which a pharmacy services administrative organization agrees to negotiate with
 26 third-party payers on behalf of an independent pharmacy; and

27 “Third-party payer” means any organization operating within the state that pays or insures
 28 health, medical, or prescription drug expenses on behalf of beneficiaries. The term includes, but
 29 is not limited to, plan sponsors, healthcare service plans, health maintenance organizations, or
 30 insurers. The term does not include a self-funded ERISA plan as described in 29 U.S.C.
 31 §1144(b)(2)(B).

§33-51A-2. Licensure of pharmacy services administrative organization.

1 (a) A person or entity shall not establish or operate as a pharmacy services administrative
 2 organization within the state without first obtaining a license from the Insurance Commissioner:
 3 Provided, That a pharmacy services administrative organization in operation within the state at
 4 the time this section takes effect may continue to do business in the state until the legislative rule
 5 of the Insurance Commissioner authorized by this section is completed: Provided, however, That
 6 the pharmacy services administrative organization shall submit an application for licensure within

7 six months of completion of the rule. The Insurance Commissioner shall make an application form
8 available on its publicly-accessible internet website that includes a request for the following
9 information:

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

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

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

14 (4) Any other information the Insurance Commissioner considers necessary and
15 appropriate to establish the qualifications to receive a license as a pharmacy services
16 administrative organization as set forth under this article.

17 (b)(1) The term of a license shall be two years from the date of issuance.

18 (2) The Insurance Commissioner shall determine the amount of the initial application fee
19 and the renewal application fee for the registration. The fee shall be submitted by the applicant
20 with an application for registration. An initial application fee is nonrefundable. A renewal
21 application fee shall be returned if the renewal of the registration is not granted.

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

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

27 (c) The Insurance Commissioner shall propose rules for legislative approval pursuant to
28 §29A-3-1 et seq. of this code, regarding the licensing, fee, and application requirements of
29 pharmacy services administrative organizations.

30 (d) No provision of this article shall be construed to require a third-party payer to enter into
31 a contract with a pharmacy services administrative organization.

§33-51A-3. Notice and disclosure requirements.

1 (a) A pharmacy services administrative organization - pharmacy contract shall include a
2 provision that requires the pharmacy services administrative organization to provide to the
3 independent pharmacy a copy of any contract, amendments, payment schedules, or
4 reimbursement rates within three calendar days after the execution of a contract, or an
5 amendment to a contract, signed on behalf of the independent pharmacy.

6 (b) Each pharmacy services administrative organization shall disclose to the Insurance
7 Commissioner the extent of any ownership or control of the pharmacy services administrative
8 organization by any parent company, subsidiary, or other organization that does any of the
9 following:

10 (1) Provides pharmacy services.

11 (2) Provides prescription drug or device services.

12 (3) Manufactures, sells, or distributes prescription drugs, biologicals, or medical devices.

13 (c) Each pharmacy services administrative organization shall notify the commissioner in
14 writing within five calendar days of any material change in its ownership or control relating to any
15 company, subsidiary, or other organization.

16 (d) Prior to entering into a pharmacy services administrative organization - pharmacy
17 contract, a pharmacy services administrative organization shall furnish to an independent
18 pharmacy a written disclosure of ownership or control in order to assist the independent pharmacy
19 in making an informed decision regarding its relationship with the pharmacy services
20 administrative organization. Such disclosure shall include the extent of any ownership or control
21 by any parent company, subsidiary, or other organization that does any of the following:

22 (1) Provides pharmacy services;

23 (2) Provides prescription drug or device services; or

24 (3) Manufactures, sells, or distributes prescription drugs, biologicals, or medical devices.

25 (e) Any pharmacy services administrative organization - pharmacy contract shall provide
26 that the pharmacy services administrative organization shall notify the independent pharmacy in

27 writing within five calendar days of any material change in its ownership or control related to any
28 company, subsidiary, or other organization as provided for in subsection (d) of this section.

29 (f) Prior to entering into a contract with a third-party payer, a pharmacy services
30 administrative organization shall furnish to a pharmacy benefits manager or third-party payer a
31 written disclosure of ownership or control in order to assist the pharmacy benefits manager or
32 third-party payer in making an informed decision regarding its relationship with the pharmacy
33 services administrative organization and the independent pharmacy or pharmacies for which the
34 pharmacy services administrative organization is negotiating. This disclosure required by this
35 subsection shall include the extent of any ownership or control by any parent company,
36 subsidiary, or other organization that:

37 (1) Provides pharmacy services;

38 (2) Provides prescription drug or device services; or

39 (3) Manufactures, sells, or distributes prescription drugs, biologicals, or medical devices.

40 (g) Any pharmacy services administrative organization contract with a third-party payer
41 shall provide that the pharmacy services administrative organization shall notify the third-party
42 payer in writing within five calendar days of any material change in its ownership or control related
43 to any company, subsidiary, or other organization as provided for in subsection (f) of this section.

§33-51A-4. Accounting; audits; remittance.

1 (a) Notwithstanding any provision of this code to the contrary, any contract between a
2 pharmacy benefit manager and a pharmacy services administrative organization, pursuant to
3 which the pharmacy benefit manager has the right or obligation to conduct audits of independent
4 pharmacies, shall contain specific language that permits the pharmacy benefit manager to obtain
5 information from the pharmacy services administrative organization in connection with the
6 pharmacy benefit's manager's audit of an independent pharmacy.

7 (b) Notwithstanding any provision of this code to the contrary, any contract between a
8 pharmacy services administrative organization and pharmacy shall provide that all remittances

9 for claims submitted by a pharmacy benefit manager or third-party payer on behalf of a pharmacy
10 to the pharmacy services administrative organization shall be passed through by the pharmacy
11 services administrative organization to the independent pharmacy within a reasonable amount of
12 time, to be established in the contract, after receipt of the remittance by the pharmacy services
13 administrative organization from a pharmacy benefit manager or third-party payer.

14 (c) Notwithstanding any provision of this code to the contrary, a pharmacy services
15 administrative organization that provides, accepts, or processes a discount, concession, or
16 product voucher, to reduce, directly or indirectly, a covered person's out-of-pocket expense for
17 the order, dispensing, substitution, sale, or purchase of a prescription drug shall provide to the
18 Insurance Commissioner an annual report, available for public audit, that includes:

19 (1) An aggregated total of all such transactions, by independent pharmacy; and

20 (2) An aggregated total of any payments received by the pharmacy services administrative
21 organization itself for providing, processing, or accepting any discount, concession, or product
22 voucher on behalf of an independent pharmacy.

§33-51A-5. Wholesale and pharmacy services administrative services in single contract.

1 (a) A pharmacy services administrative organization that owns or is owned by, in whole or
2 in part, any entity that manufactures, sells, or distributes prescription drugs, biologicals, and/or
3 medical devices shall not, as a condition of entering into contract with a pharmacy, require that
4 the independent pharmacy purchase any drugs and/or medical devices from the entity with which
5 the pharmacy services administrative organization has an ownership interest, or an entity with an
6 ownership interest in the pharmacy services administrative organization.

7 (b) A pharmacy services administrative organization that owns or is owned by, in whole or
8 in part, any entity that manufactures, sells, or distributes prescription drugs, biologicals, and/or
9 medical devices shall disclose to the Insurance Commissioner any agreement with an
10 independent pharmacy in which the independent pharmacy purchases prescription drugs,

- 11 biologicals, and/or medical devices from a pharmacy services administrative organization or any
12 entity that owns or is owned by, in whole or in part, the pharmacy services administrative
13 organization.

NOTE: The purpose of this bill is to promote transparency in the operation of pharmacy services administrative organizations by establishing a licensure requirement and providing for the regulation of the same by the Insurance Commissioner.

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