WEST VIRGINIA LEGISLATURE

2022 REGULAR SESSION

ENROLLED

Committee Substitute

for

House Bill 4112

BY DELEGATES ROHRBACH, D. JEFFRIES, TULLY, PACK,

G. WARD, BATES, WORRELL, ROWAN, FORSHT, MALLOW,

AND JENNINGS

[Passed March 12, 2022; in effect ninety days from passage.]

AN ACT to amend and reenact §33-51-3, §33-51-8, §33-51-9, and §33-51-11 of the Code of West Virginia, 1931, as amended; and to amend said code by adding thereto a new section, designated §33-51-13, all relating to the regulation of pharmacy benefit managers; defining terms; updating terminology; prohibiting a pharmacy benefit manager from limiting a consumer's access to prescription drugs through the designation of specialty drugs; prohibiting a pharmacy benefit manager from placing certain requirements or restrictions on a pharmacist or pharmacy; updating requirements placed upon 340B entities; clarifying how drug acquisition cost is to be calculated; requiring pharmacy benefit managers to disclose any sub-networks for specialty drugs to the Insurance Commissioner; prohibiting a pharmacy benefit manager from limiting network access; providing clarification regarding assessment of fees related to adjudication of claims; providing clarification regarding criteria for requirements of methodologies; requiring notice of contract changes; and providing an effective date.

Be it enacted by the Legislature of West Virginia:

ARTICLE 51. PHARMACY AUDIT INTEGRITY ACT.

§33-51-3. Definitions.

For purposes of this article:

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

"Affiliate" means a pharmacy, pharmacist, or pharmacy technician which, either directly or indirectly through one or more intermediaries: (A) Has an investment or ownership interest in a pharmacy benefits manager licensed under this chapter; (B) shares common ownership with a pharmacy benefits manager licensed under this chapter; or (C) has an investor or ownership interest holder which is a pharmacy benefits manager licensed under this article.

"Auditing entity" means a person or company that performs a pharmacy audit, including a pharmacy benefits manager, managed care organization, or third-party administrator.

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

"Claim level information" means data submitted by a pharmacy, required by a payor, or claims processor to adjudicate a claim.

"Covered individual" means a member, participant, enrollee, or beneficiary of a health benefit plan who is provided health care service coverage by a health benefit plan, including a dependent or other person provided health coverage through the policy or contract of a covered individual.

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

"Defined cost sharing" means a deductible payment or coinsurance amount imposed on an enrollee for a covered prescription drug under the enrollee's health plan.

"Health benefit plan" or "health plan" means a policy, contract, certificate, or agreement entered into, offered, or issued by a health care payor to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services.

"Health care payor" or "payor" means a health insurance company, a health maintenance organization, a hospital, medical, or dental corporation, a health care corporation, an entity that provides, administers, or manages a self-funded health benefit plan, including a governmental plan, or any other payor that provides prescription drug coverages, including a workers' compensation insurer. Health care payor does not include an insurer that provides coverage under a policy of casualty or property insurance.

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

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

"Insurance commissioner" or "commissioner" has the same meaning as defined in §33-1-5 of this code.

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

"Maximum allowable cost" means the per unit amount that a pharmacy benefits manager reimburses a pharmacist for a prescription drug, excluding dispensing fees and copayments, coinsurance, or other cost-sharing charges, if any.

"National average drug acquisition cost" means the monthly survey of retail pharmacies conducted by the federal Centers for Medicare and Medicaid Services to determine average acquisition cost for Medicaid covered outpatient drugs.

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

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

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

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

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

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

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

(3) The administration of pharmacy benefits, including:

(A) Operating a mail-service pharmacy;

(B) Claims processing;

(C) Managing a retail pharmacy network;

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

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

(F) Rebate contracting administration; and

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

"Pharmacy benefits manager" means a person, business, or other entity that performs pharmacy benefits management for health benefit plans;

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

"Pharmacy services administration organization" means any entity that contracts with a pharmacy to assist with payor interactions and that may provide a variety of other administrative

services, including contracting with pharmacy benefits managers on behalf of pharmacies and managing pharmacies' claims payments from payors.

"Point-of-sale fee" means all or a portion of a drug reimbursement to a pharmacy or other dispenser withheld at the time of adjudication of a claim for any reason.

"Rebate" means any and all payments that accrue to a pharmacy benefits manager or its health plan client, directly or indirectly, from a pharmaceutical manufacturer, including, but not limited to, discounts, administration fees, credits, incentives, or penalties associated directly or indirectly in any way with claims administered on behalf of a health plan client. The term "rebate" does not include any discount or payment that may be provided to or made to any 340B entity through such program.

"Retroactive fee" means all or a portion of a drug reimbursement to a pharmacy or other dispenser recouped or reduced following adjudication of a claim for any reason, except as otherwise permissible as described in this article.

"Specialty drug" means a drug used to treat chronic and complex, or rare medical conditions and requiring special handling or administration, provider care coordination, or patient education that cannot be provided by a non-specialty pharmacy or pharmacist.

§33-51-8. Licensure of pharmacy benefit managers.

(a) A person or organization may not establish or operate as a pharmacy benefits manager in the state of West Virginia without first obtaining a license from the Insurance Commissioner pursuant to this section: *Provided*, That a pharmacy benefit manager registered pursuant to §33-51-7 of this code may continue to do business in the state until the Insurance Commissioner has completed the legislative rule as set forth in § §33-51-10 of this code: *Provided, however*, That additionally the pharmacy benefit manager shall submit an application within six months of completion of the final rule. The Insurance Commissioner shall make an application form available on its publicly accessible internet website that includes a request for the following information:

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

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

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

(4) Any other information the Insurance Commissioner considers necessary and appropriate to establish the qualifications to receive a license as a pharmacy benefit manager to complete the licensure process, as set forth by legislative rule promulgated by the Insurance Commissioner pursuant to §33-51-10 of this code.

(b) *Term and fee*. —

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

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

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

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

(c) *Licensure*. —

(1) The Insurance Commissioner shall propose legislative rules, in accordance with §33-51-10 of this code, establishing the licensing, fees, application, financial standards, and reporting requirements of pharmacy benefit managers.

(2) Upon receipt of a completed application, evidence of financial responsibility, and fee, the Insurance Commissioner shall make a review of each applicant and shall issue a license if the applicant is qualified in accordance with the provisions of this section and the rules promulgated by the Insurance Commissioner pursuant to this section. The commissioner may

require additional information or submissions from an applicant and may obtain any documents or information reasonably necessary to verify the information contained in the application.

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

(d) *Network adequacy*. —

(1) A pharmacy benefit manager's network shall be reasonably adequate, shall provide for convenient patient access to pharmacies within a reasonable distance from a patient's residence and shall not be comprised only of mail-order benefits but must have a mix of mail-order benefits and physical stores in this state.

(2) A pharmacy benefit manager shall provide a pharmacy benefit manager's network report describing the pharmacy benefit manager's network and the mix of mail-order to physical stores in this state in a time and manner required by rule issued by the Insurance Commissioner pursuant to this section. A pharmacy benefit manager's network report shall include a detailed description of any separate, sub-networks for specialty drugs.

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

(4) A pharmacy benefit manager may not require a pharmacy or pharmacist, as a condition for participating in the pharmacy benefit manager's network, to obtain or maintain accreditation, certification, or credentialing that is inconsistent with, more stringent than, or in addition to state requirements for licensure or other relevant federal or state standards.

(e) *Enforcement*. —

(1) The Insurance Commissioner shall enforce this section and may examine or audit the books and records of a pharmacy benefit manager providing pharmacy benefits management to determine if the pharmacy benefit manager is in compliance with this section: *Provided*, That any information or data acquired during the examination or audit is considered proprietary and

confidential and exempt from disclosure under the West Virginia Freedom of Information Act pursuant to §29B-1-4(a)(1) of this code.

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

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

(a) A pharmacy, a pharmacist, and a pharmacy technician shall have the right to provide a covered individual with information related to lower cost alternatives and cost share for the covered individual to assist health care consumers in making informed decisions. Neither a pharmacy, a pharmacist, nor a pharmacy technician may be penalized by a pharmacy benefit manager for discussing information in this section or for selling a lower cost alternative to a covered individual, if one is available, without using a health insurance policy.

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

(c) A pharmacy benefit manager that reimburses a 340B entity for drugs that are subject to an agreement under 42 U.S.C. § 256b shall not reimburse the 340B entity for pharmacy-dispensed drugs at a rate lower than that paid for the same drug to pharmacies similar in prescription volume that are not 340B entities, and shall not assess any fee, charge-back, or other adjustment upon the 340B entity on the basis that the 340B entity participates in the program set forth in 42 U.S.C. §256b. For purposes of this subsection, the term “other adjustment” includes placing any additional requirements, restrictions, or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other pharmacies that do not participate in the 340B program, including affiliate pharmacies of the

pharmacy benefit manager, and further includes but is not limited to requiring a claim for a drug to include a modifier or be processed or resubmitted to indicate that the drug is a 340B drug: *Provided*, That nothing in this subsection shall be construed to prohibit the Medicaid program or a Medicaid managed care organization as described in 42 U.S.C. § 1396b(m) from preventing duplicate discounts as described in 42 U.S.C. 256b(a)(5)(A)(i). The provisions of this subsection are applicable to the West Virginia Public Employees Insurance Agency.

(d) With respect to a patient eligible to receive drugs subject to an agreement under 42 U.S.C. § 256b, a pharmacy benefit manager shall not discriminate against a 340B entity in a manner that prevents or interferes with the patient's choice to receive such drugs from the 340B entity: *Provided*, That this section, does not apply to the state Medicaid program when Medicaid is providing reimbursement for covered outpatient drugs, as that term is defined in 42 U.S.C. §1396r-8(k), on a fee-for-service basis: *Provided, however*, That this subsection does apply to a Medicaid-managed care organization as described in 42 U.S.C. § 1396b(m). For purposes of this subsection, it shall be considered a discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if a pharmacy benefit manager places additional requirements, restrictions or unnecessary burdens upon a 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other pharmacies that do not participate in the 340B program, including affiliate pharmacies of the pharmacy benefit manager or any other third-party, and further includes but is not limited to requiring a claim for a drug to include a modifier or be processed or resubmitted to indicate that the drug is a 340B drug: *Provided* further, That nothing in this subsection shall be construed to prohibit the Medicaid program or a Medicaid managed care organization as described in 42 U.S.C. § 1396b(m) from preventing duplicate discounts as described in 42 U.S.C. 256b(a)(5)(A)(i). The provisions of this subsection are applicable to the West Virginia Public Employees Insurance Agency.

(e) A pharmacy benefit manager may not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the national average drug

acquisition cost for the prescription drug or pharmacy service at the time the drug is administered or dispensed, plus a professional dispensing fee of $10.49: *Provided*, That if the national average drug acquisition cost is not available at the time a drug is administered or dispensed, a pharmacy benefit manager may not reimburse in an amount that is less than the wholesale acquisition cost of the drug, as defined in 42 U.S.C. § 1395w-3a(c)(6)(B), plus a professional dispensing fee of $10.49.

(f) A pharmacy benefit manager may not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the amount the pharmacy benefit manager reimburses itself or an affiliate for the same prescription drug or pharmacy service.

(g)The commissioner may order reimbursement to an insured, pharmacy, or dispenser who has incurred a monetary loss as a result of a violation of this article or legislative rules implemented pursuant to this article.

(h) (1) Any methodologies utilized by a pharmacy benefits manager in connection with reimbursement shall be filed with the commissioner at the time of initial licensure and at any time thereafter that the methodology is changed by the pharmacy benefit manager for use in determining maximum allowable cost appeals. The methodologies are not subject to disclosure and shall be treated as confidential and exempt from disclosure under the West Virginia Freedom of Information Act §29B-1-4(a)(1) of this code. The filed methodologies shall comply with the provisions of §33-51-9(e) of this code, and a pharmacy benefits manager shall not enter into a contract with a pharmacy that provides for reimbursement methodology not permissible under the provisions of §33-51-9(e) of this code.

(2) For purposes of complying with the provisions of §33-51-9(e) of this code, a pharmacy benefits manager shall utilize the most recently published monthly national average drug acquisition cost as a point of reference for the ingredient drug product component of a pharmacy's reimbursement for drugs appearing on the national average drug acquisition cost list; and,

(i) A pharmacy benefits manager may not:

(1) Discriminate in reimbursement, assess any fees or adjustments, or exclude a pharmacy from the pharmacy benefit manager's network on the basis that the pharmacy dispenses drugs subject to an agreement under 42 U.S.C. § 256b; or

(2) Engage in any practice that:

(A) In any way bases pharmacy reimbursement for a drug on patient outcomes, scores, or metrics. This does not prohibit pharmacy reimbursement for pharmacy care, including dispensing fees from being based on patient outcomes, scores, or metrics so long as the patient outcomes, scores, or metrics are disclosed to and agreed to by the pharmacy in advance;

(B) Includes imposing a point-of-sale fee or retroactive fee; or

(C) Derives any revenue from a pharmacy or insured in connection with performing pharmacy benefits management services: *Provided*, That this may not be construed to prohibit pharmacy benefits managers from processing deductibles or copayments as have been approved by a covered individual's health benefit plan.

(j) A pharmacy benefits manager shall offer a health plan the option of charging such health plan the same price for a prescription drug as it pays a pharmacy for the prescription drug: *Provided*, That a pharmacy benefits manager shall charge a health benefit plan administered by or on behalf of the state or a political subdivision of the state, the same price for a prescription drug as it pays a pharmacy for the prescription drug.

(k) A covered individual's defined cost sharing for each prescription drug shall be calculated at the point of sale based on a price that is reduced by an amount equal to at least 100 percent of all rebates received, or to be received, in connection with the dispensing or administration of the prescription drug. Any rebate over and above the defined cost sharing would then be passed on to the health plan to reduce premiums. Nothing precludes an insurer from decreasing a covered individual's defined cost sharing by an amount greater than what is previously stated. The commissioner may propose a legislative rule or by policy effectuate the provisions of this subsection.

§33-51-11. Freedom of consumer choice for pharmacy.

(a) A pharmacy benefits manager, may not:

(1) Prohibit or limit any covered individual from selecting a pharmacy or pharmacist of his or her choice who has agreed to participate in the health benefit plan according to the terms offered by the health benefit plan;

(2) Deny a pharmacy or pharmacist the right to participate as a contract provider under the policy or plan if the pharmacy or pharmacist agrees to provide pharmacy services, including, but not limited to, prescription drugs, that meet the terms and requirements set forth by the health benefit plan and agrees to the terms of reimbursement set forth by the insurer;

(3) Impose upon a pharmacy or pharmacist, as a condition of participation in a health benefit plan network, any course of study, accreditation, certification, or credentialing that is inconsistent with, more stringent than, or in addition to state requirements for licensure or certification as provided for in the §30-5-1 *et seq.* and legislative rules of the Board of Pharmacy.

(4) Impose upon a beneficiary of pharmacy services under a health benefit plan any copayment, fee, or condition that is not equally imposed upon all beneficiaries in the same benefit category, class, or copayment level under the health benefit plan when receiving services from a contract provider;

(5) Impose a monetary advantage or penalty under a health benefit plan that would affect a beneficiary's choice among those pharmacies or pharmacists who have agreed to participate in the plan according to the terms offered by the insurer. Monetary advantage or penalty includes higher copayment, a reduction in reimbursement for services, or promotion of one participating pharmacy over another by these methods;

(6) Reduce allowable reimbursement for pharmacy services to a beneficiary under a health benefit plan because the beneficiary selects a pharmacy of his or her choice, so long as that pharmacy has enrolled with the health benefit plan under the terms offered to all pharmacies in the plan coverage area;

(7) Prohibit or otherwise limit a beneficiary's access to prescription drugs from a pharmacy or pharmacist enrolled with the health benefit plan under the terms offered to all pharmacies in the plan coverage area by unreasonably designating the covered prescription drug as a specialty drug. Any beneficiary or pharmacy impacted by an alleged violation of this subsection may file a complaint with the Insurance Commissioner, who shall, in consultation with the West Virginia Board of Pharmacy, make a determination as to whether the covered prescription drug meets the definition of a specialty drug;

(8) Limit a beneficiary's access to specialty drugs;

(9) Require a beneficiary, as a condition of payment or reimbursement, to purchase pharmacy services, including prescription drugs, exclusively through a mail-order pharmacy; or

(10) Impose upon a beneficiary any copayment, amount of reimbursement, number of days of a drug supply for which reimbursement will be allowed, or any other payment or condition relating to purchasing pharmacy services from any pharmacy, including prescription drugs, that are more costly or more restrictive than that which would be imposed upon the beneficiary if such services were purchased from a mail-order pharmacy or any other pharmacy that is willing to provide the same services or products for the same cost and copayment as any mail order service.

(b) If a health benefit plan providing reimbursement to West Virginia residents for prescription drugs restricts pharmacy participation, the health benefit plan shall notify, in writing, all pharmacies within the geographical coverage area of the health benefit plan, and offer to the pharmacies the opportunity to participate in the health benefit plan at least 60 days prior to the effective date of the plan. All pharmacies in the geographical coverage area of the plan shall be eligible to participate under identical reimbursement terms for providing pharmacy services, including prescription drugs. Participating pharmacies shall be entitled to 30 business days effective date notice for any subsequent contract amendment or provider manual change by a health benefit plan or a pharmacy benefit manager. The health benefit plan shall, through reasonable means, on a timely basis and on regular intervals, inform the beneficiaries of the plan

of the names and locations of pharmacies that are participating in the plan as providers of pharmacy services and prescription drugs. Additionally, participating pharmacies shall be entitled to announce their participation to their customers through a means acceptable to the pharmacy and the health benefit plan. The pharmacy notification provisions of this section shall not apply when an individual or group is enrolled, but when the plan enters a particular county of the state.

(c) The Insurance Commissioner shall not approve any pharmacy benefits manager or health benefit plan providing pharmaceutical services which do not conform to this section.

(d) Any covered individual or pharmacy injured by a violation of this section may maintain a cause of action to enjoin the continuance of any such violation.

(e) This section shall apply to all pharmacy benefits managers and health benefit plans providing pharmaceutical services benefits, including prescription drugs, to any resident of West Virginia. This section shall not apply to any entity that has its own facility, employs or contracts with physicians, pharmacists, nurses, and other health care personnel, and that dispenses prescription drugs from its own pharmacy to its employees and dependents enrolled in its health benefit plan; but this section shall apply to an entity otherwise excluded that contracts with an outside pharmacy or group of pharmacies to provide prescription drugs and services.

§33-51-13. Effective date.

Notwithstanding any other effective date to the contrary, the amendments to this article enacted during the 2022 regular legislative session shall apply to all policies, contracts, plans, or agreements subject to this section that are delivered, executed, amended, adjusted, or renewed on or after January 1, 2023.

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

.....
Chairman, House Committee

.....
Chairman, Senate Committee

Originating in the House.

In effect ninety days from passage.

.....
Clerk of the House of Delegates

.....
Clerk of the Senate

.....
Speaker of the House of Delegates

.....
President of the Senate

_____

The within ..... this the.....

day of ....., 2022.

.....
Governor