WEST VIRGINIA LEGISLATURE

2019 REGULAR SESSION

Introduced

Senate Bill 489

BY SENATORS MARONEY, TAKUBO, AND TARR

[Introduced January 31, 2019; Referred

to the Committee on Health and Human Resources; and

then to the Committee on the Judiciary]

A BILL to amend and reenact §33-51-3, §33-51-4, §33-51-7, §33-51-8, and §33-51-9 of the Code of West Virginia, 1931, as amended; and to amend said code by adding thereto two new sections, designated §33-51-10 and §33-51-11, all relating generally to the Pharmacy Audit Integrity Act and the regulation of pharmacy benefit managers; defining terms; requiring pharmacy benefit managers to obtain a license from the Insurance Commissioner before doing business in the state; setting forth terms and fees for licensure of pharmacy benefit managers; authorizing the Insurance Commissioner to promulgate rules for legislative approval relating to licensing, fees, application, financial standards, and reporting requirements of pharmacy benefit managers; requiring pharmacy benefit managers provide a reasonably adequate network; providing that a pharmacy benefit manager has a fiduciary duty to certain third parties; requiring the Insurance Commissioner to enforce the licensure provisions relating to pharmacy benefit managers; providing for the applicability of provisions to pharmacy benefit managers; clarifying that requirements do not apply to certain prescription drug plans; clarifying that an auditing entity may not seek a charge-back or recoupment from a pharmacy or pharmacist except in certain circumstances; providing that pharmacy benefit managers may not reimburse a pharmacy or pharmacist for prescription drugs or pharmacy services below a certain cost plus dispensing fee; prohibiting a pharmacy benefit manager from reimbursing a pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the amount a pharmacy benefit manager reimburses its affiliates; and requiring the reporting of certain data relating to the payment of pharmacy claims.

Be it enacted by the Legislature of West Virginia:

ARTICLE 51. PHARMACY AUDIT INTEGRITY ACT.

§33-51-3. Definitions.

For purposes of this article:

<u>"Affiliate" means a pharmacy, pharmacist or pharmacy technician that directly or indirectly,</u>

through one or more intermediaries, owns or controls, is owned or controlled by, or is under common ownership or control with a pharmacy benefit manager.

"Auditing entity" means a person or company that performs a pharmacy audit, including a covered entity, 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 or required by a payer or claims processor to adjudicate a claim.

"Covered entity" means a contract holder or policy holder providing pharmacy benefits to a covered individual under a health insurance policy pursuant to a contract administered by a pharmacy benefits manager.

"Covered individual" means a member, participant, enrollee or beneficiary of a covered entity who is provided health coverage by a covered entity, 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.

"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 covered entity or group of covered entities 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.

"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 on-site 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 covered entity 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 covered entities;

"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 third-party payer 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 third-party payers.

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

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

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

(1) Except as otherwise provided by federal or state law, an auditing entity conducting a

pharmacy audit may have access to a pharmacy's previous audit report only if the report was prepared by that auditing entity.

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

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

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

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

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

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

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

(9) A pharmacy audit may not cover:

(A) A period of more than 24 months after the date a claim was submitted by the pharmacy

to the pharmacy benefits manager or covered entity unless a longer period is required by law; or

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

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

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

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

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

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

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

(D) Actual overpayment to the pharmacy.

Any charge-back or recoupment is limited to the actual financial harm associated with the dispensed product, or portion of the dispensed product, or the actual underpayment or overpayment.

~~(12)~~ (13) A pharmacy may do any of the following when a pharmacy audit is performed:

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

(B) A pharmacy may use any valid prescription, including, but not limited to, medication administration records, facsimiles, electronic prescriptions, electronically stored images of

prescriptions, electronically created annotations or documented telephone calls from the prescribing health care provider or practitioner's agent, to validate claims in connection with prescriptions or changes in prescriptions or refills of prescription or nonproprietary drugs. Documentation of an oral prescription order that has been verified by the prescribing health care provider shall meet the provisions of this subparagraph for the initial audit review.

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

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

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

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

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

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

(6) An auditing entity conducting a pharmacy audit or person acting on behalf of the entity

may not charge-back, recoup or collect penalties from a pharmacy until the time to file an appeal of a final pharmacy audit report has passed or the appeals process has been exhausted, whichever is later.

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

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

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

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

(a) Prior to conducting business in the State of West Virginia, except as provided in subsection (d) of this section, a pharmacy benefits manager or auditing entity shall register with the Insurance Commissioner. The 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; and

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

(b) *Term and fee*. —

(1) The term of registration 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. Such fee shall be submitted by the applicant with an application for registration. An initial application fee ~~shall be~~ 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 ~~shall~~ must be

sufficient to fund the Insurance Commissioner's duties in relation to its responsibilities under this article, but a single fee may not exceed $1,000.

(c) *Registration. —*

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

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

(d) *Duplicate registration*. —

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

(2) A pharmacy benefits manager that is registered as a third-party administrator pursuant to §33-46-1 *et seq.* of this code shall comply with the standards and procedures of this article but ~~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.

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

(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. 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 §33-51-9(f) 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 its 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 for legislative approval rules, in accordance with §33-51-9(f) of this code, establishing the licensing, fees, application, financial standards, and reporting requirements of pharmacy benefit managers in accordance with this article.

(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 shall provide a reasonably adequate and accessible pharmacy benefit manager network, as determined by the Insurance Commissioner, for the provision of prescription drugs that shall provide for convenient patient access to pharmacies within a reasonable distance from a patient's residence.

(2) A mail-order pharmacy may not be included in the calculations determining pharmacy benefit manager network adequacy.

(3) A pharmacy benefit manager shall provide a pharmacy benefit manager network adequacy report describing the pharmacy benefit manager network and the pharmacy benefit manager network's accessibility in this state in a time and manner required by rule issued by the Insurance Commissioner pursuant to this section.

(4) Failure to provide a reasonably adequate and accessible pharmacy benefit manager network shall result in the suspension or revocation of a pharmacy benefit manager license by the Insurance Commissioner.

(e) *Fiduciary duty. —* A pharmacy benefit manager licensed to do business in the State of West Virginia has a fiduciary duty to a third party with which the pharmacy benefit manager has entered into a contract to manage the pharmacy benefits plan of the third party and shall notify the third party in writing of any activity, policy or practice of the pharmacy benefit manager that presents a conflict of interest that interferes with the ability of the pharmacy benefit manager to discharge that fiduciary duty.

(f) *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 benefit 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.

(g) *Applicability. —*

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

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

(h) *Severability. —* If any provision of this section or the application of this section to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this section which can be given effect without the invalid provision or application, and to this end, the provisions of this act are declared severable.

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

(a) A pharmacy, a pharmacist, and a pharmacy technician ~~shall have the right to~~ may provide a covered individual with information related to lower cost alternatives and cost share for ~~such~~ the covered individual to assist health care consumers in making informed decisions. Neither a pharmacy, a pharmacist, nor a pharmacy technician ~~shall~~ 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 ~~shall~~ 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 may only directly or indirectly charge or hold a pharmacy, a pharmacist, or a pharmacy technician responsible for a fee related to the adjudication of a claim if:

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

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

(d) A pharmacy benefit manager may not reimburse a pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the lowest of either:

(1) The National Average Drug Acquisition Cost (NADAC) for the prescription drug or pharmacy service, plus a professional dispensing fee of $10.49;

(2) The pharmacy or pharmacist's acquisition cost for the prescription drug or pharmacy service, plus a dispensing fee of $10.49; or

(3) The pharmacy or pharmacist's usual and customary charge to the general public.

(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 amount the pharmacy benefit manager reimburses itself or an affiliate for the same prescription drug or pharmacy service.

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

§33-51-10. Reporting of data relating to payment of pharmacy claims.

(a) The Public Employees Insurance Agency shall include language in all contracts for

pharmacy benefits management requiring the pharmacy benefit manager to report quarterly, for all quarters through the one ending June 30, 2022, to the agency for all pharmacy claims:

(1) The amount paid to the pharmacy provider per claim, including, but not limited to, cost of drug reimbursement;

(2) Dispensing fees;

(3) Copayments; and

(4) The amount charged to the plan sponsor for each claim by the pharmacy benefit manager.

(b) If there is a difference between these amounts, the plan sponsor shall report an itemization of all administrative fees, rebates, or processing charges associated with the claim.

(c) All data and information provided by the plan sponsor shall be kept secure, and notwithstanding any other provision of law, the agency shall maintain the confidentiality of the proprietary information and not share or disclose the proprietary information contained in the report or data collected with persons outside the agency. Only those agency employees involved in collecting, securing and analyzing the data for the purpose of preparing the report provided for in this section may have access to the proprietary data.

(d) The agency shall provide a report using aggregated data to the Governor's Office and the Joint Committee on Government and Finance on the implementation of this initiative and its impact on program expenditures by December 1, 2019.

(e) The report to the Governor or the Joint Committee on Government and Finance may not contain confidential or proprietary information.

(f) If the information required by this section is not provided, the agency shall terminate the contract with the pharmacy benefit manager.

§33-51-11. Commissioner authorized to propose rules.

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

NOTE: The purpose of this bill is to require the licensure of pharmacy benefit managers with the Insurance Commissioner in order to do business in the State of West Virginia, and to set forth the minimum reimbursement rate for prescription drug or pharmacy service claims. The bill also requires reporting of data relating to the payment of pharmacy claims by the Public Employees Insurance Agency.

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