WEST VIRGINIA LEGISLATURE

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Committee Substitute

for

Senate Bill 522

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[Originating in the Committee on Banking and

Insurance; reported on March 14, 2017]

A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new article, designated §33-51-1, §33-51-2, §33-51-3, §33-51-4, §33-51-5, §33-51-6, §33-51-7 and §33-51-8, all relating to pharmacy audits; defining terms; setting forth procedures and requirements for pharmacy audits; stating applicable review process for final audit report; setting forth limitations concerning applicability of provisions of the article; requiring registration for certain pharmacy benefits managers and auditing entities; imposing registration fee; imposing application requirements; and providing rule-making authority to the Insurance Commissioner.

Be it enacted by the Legislature of West Virginia:

That the Code of West Virginia, 1931, as amended, be amended by adding thereto a new article, designated §33-51-1, §33-51-2, §33-51-3, §33-51-4, §33-51-5, §33-51-6, §33-51-7 and §33-51-8, all to read as follows:

ARTICLE 51. PHARMACY AUDIT INTEGRITY ACT.

§33-51-1. Short title.

This article may be cited and known as the Pharmacy Audit Integrity Act.

§33-51-2. Scope.

This article covers any audit of the records of a pharmacy conducted by a managed care company, third-party payer, pharmacy benefits manager or an entity that represents a covered entity.

§33-51-3. Definitions.

For purposes of this article:

"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 section one, article two, chapter two 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 section two, article forty-one of this chapter.

"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 section five, article one of this chapter.

"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.

§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 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 fourteen 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 seventy-two 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 six hundred 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 twenty-four 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 two hundred fifty 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) 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 be delivered to the pharmacy or its corporate parent within sixty 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 allowed at least thirty 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 ninety 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 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 not be reversed unless the pharmacy or pharmacist obtained adjudication by fraud or misrepresentation of claims elements.

§33-51-5. Appeals process.

A pharmacy may appeal a final audit report in accordance with the procedures established by the entity conducting the pharmacy audit.

§33-51-6. Limitations.

(a) The provisions of this article do not apply to an investigative audit of pharmacy records when:

(1) Fraud, waste, abuse or other intentional misconduct is indicated by physical review or review of claims data or statements; or

(2) Other investigative methods indicate a pharmacy is or has been engaged in criminal wrongdoing, fraud or other intentional or willful misrepresentation.

(b) This article does not supersede any audit requirements established by federal law.

§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 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 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 nontransferable and shall prominently list the expiration date of the registration.

(d) *Duplicate registration*. —

(1) A licensed insurer or a managed care plan with a certificate of authority shall comply with the standards and procedures of this article but shall not be required to separately register as either a pharmacy benefits manager or auditing entity.

(2) A pharmacy benefits manager that is registered as a third-party administrator pursuant to article forty-six of this chapter shall comply with the standards and procedures of this article but shall not be required to register separately as an auditing entity.

§33-51-8. Commissioner authorized to propose rules.

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.

NOTE: The purpose of this bill is to define audit procedures between pharmacy benefits managers and pharmacies. The bill defines terms and provides the procedures for audits by pharmacy benefits managers. The bill provides for limitations and an appeals process for pharmacy audits. The bill requires pharmacy benefits managers to register with the Insurance Commissioner and pay a registration fee. The Insurance Commissioner is authorized to propose legislative rules relating to pharmacy benefits managers.

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