WEST VIRGINIA LEGISLATURE

2016 REGULAR SESSION

Introduced

Senate Bill 322

BY SENATORS FERNS, STOLLINGS, TRUMP AND GAUNCH

[Introduced January 19, 2016;

Referred to the Committee on Health and Human

Resources; and then to the Committee on Finance.]

A BILL to amend and reenact §33-46-2, §33-46-18 and §33-46-20 of the Code of West Virginia, 1931, as amended; and to amend said code by adding thereto four new sections, designated §33-46-21, §33-46-22, §33-46-23 and §33-46-24, all relating to regulation of pharmacy benefits managers; defining terms; providing that pharmacy benefits managers conducting audits for public health programs are not exempt from pharmacy audit restrictions; setting forth duties of pharmacy benefit managers; requiring audits by pharmacy benefits managers; setting forth requirements for audits conducted by pharmacy benefits managers; providing internal review process applicable to disputed findings of pharmacy benefits manager upon audit; requiring pharmacy benefits managers to provide notice to purchasers, pharmacists and pharmacies of information relating to maximum allowable costs; requiring pharmacy benefits managers to establish a process relating to the appropriate use of maximum allowable cost pricing; and reorganizing sections providing rule-making authority to the Insurance Commissioner.

Be it enacted by the Legislature of West Virginia:

That §33-46-2, §33-46-18 and §33-46-20 of the Code of West Virginia, 1931, as amended, be amended and reenacted; and that said code be amended by adding thereto four new sections, designated §33-46-21, §33-46-22, §33-46-23 and §33-46-24, all to read as follows:

ARTICLE 46. THIRD-PARTY ADMINISTRATOR ACT.

§33-46-2. Definitions.

(a) “Administrator” or “third-party administrator” means a person who directly or indirectly underwrites or collects charges or premiums from, or adjusts or settles claims on residents of this state, in connection with life, annuity or accident and sickness coverage offered or provided by an insurer, except any of the following:

(1) An employer, or a wholly owned direct or indirect subsidiary of an employer, on behalf of its employees or the employees of one or more subsidiaries or affiliated corporations of the employer;

(2) A union on behalf of its members;

(3) An insurer that is licensed to transact insurance in this state with respect to a policy lawfully issued and delivered in and pursuant to the laws of this state or another state including:

(A) A health service corporation licensed under article twenty-four of this chapter;

(B) A health care corporation licensed under article twenty-five of this chapter;

(C) A health maintenance organization licensed under article twenty-five-a of this chapter; and

(D) A prepaid limited health service organization licensed under article twenty-five-d of this chapter.

(4) An insurance producer licensed to sell life, annuities or health coverage in this state whose activities are limited exclusively to the sale of insurance;

(5) A creditor on behalf of its debtors with respect to insurance covering a debt between the creditor and its debtors;

(6) A trust and its trustees, agents and employees acting pursuant to the trust established in conformity with 29 U.S.C. Section 186;

(7) A trust exempt from taxation under Section 501(a) of the Internal Revenue Code, its trustees and employees acting pursuant to the trust, or a custodian and the custodian's agents or employees acting pursuant to a custodian account which meets the requirements of Section 401(f) of the Internal Revenue Code;

(8) A credit union or a financial institution that is subject to supervision or examination by federal or state banking authorities, or a mortgage lender, to the extent they collect and remit premiums to licensed insurance producers or to limited lines producers or authorized insurers in connection with loan payments;

(9) A credit card issuing company that advances for and collects insurance premiums or charges from its credit card holders who have authorized collection;

(10) A person who adjusts or settles claims in the normal course of that person's practice

or employment as an attorney at law and who does not collect charges or premiums in connection with life, annuity or accident and sickness coverage;

(11) An adjuster licensed by this state whose activities are limited to adjustment of claims;

(12) A person licensed as a managing general agent in this state whose activities are limited exclusively to the scope of activities conveyed under that license; or

(13) An administrator who is affiliated with an insurer and who only performs the contractual duties, between the administrator and the insurer, of an administrator for the direct and assumed business of the affiliated insurer. The insurer is responsible for the acts of the administrator and is responsible for providing all of the administrator's books and records to the Insurance Commissioner, upon a request from the Insurance Commissioner. For purposes of this subdivision, "insurer" means a licensed insurance company, prepaid hospital or medical care plan, health maintenance organization or a health care corporation.

(b) "Affiliate or affiliated" means an entity or person who directly or indirectly through one or more intermediaries, controls or is controlled by, or is under common control with, a specified entity or person.

(c) "Commissioner" means the Insurance Commissioner of this state.

(d) "Control", "controlling", "controlled by" and "under common control with" mean the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract other than a commercial contract for goods or nonmanagement services, or otherwise, unless the power is the result of an official position with or corporate office held by the person. Control shall be presumed to exist if any person, directly or indirectly, owns, controls, holds with the power to vote or holds proxies representing ten percent or more of the voting securities of any other person. This presumption may be rebutted by a showing made in the manner provided by the West Virginia insurance holding company systems act that control does not exist in fact. The commissioner may determine, after furnishing all persons in interest notice and opportunity to be

heard and making specific findings of fact to support the determination that control exists in fact, notwithstanding the absence of a presumption to that effect.

(e) “GAAP” means United States Generally Accepted Accounting Principles consistently applied.

(f) “Home state” means the District of Columbia and any state or territory of the United States in which an administrator is incorporated or maintains its principal place of business. If neither the state in which the administrator is incorporated, nor the state in which it maintains its principal place of business has adopted the national association of Insurance Commissioners’ model third party administrator act or a substantially similar law governing administrators, the administrator may declare another state, in which it conducts business, to be its “home state”.

(g) “Insurance producer” means a person who sells, solicits or negotiates a contract of insurance as those terms are defined in this article.

(h) “Insurer” means a person undertaking to provide life, annuity or accident and sickness coverage or self-funded coverage under a governmental plan or church plan in this state. For the purposes of this article, insurer includes an employer, a licensed insurance company, a prepaid hospital or medical care plan, health maintenance organization or a health care corporation.

(i) “Negotiate” means the act of conferring directly with or offering advice directly to a purchaser or prospective purchaser of a particular contract of insurance concerning any of the substantive benefits, terms or conditions of the contract, provided that the person engaged in that act either sells insurance or obtains insurance from insurers for purchasers.

(j) “Nonresident administrator” means a person who is applying for licensure or is licensed in any state other than the administrator’s home state.

(k) “Person” means an individual or a business entity.

(l) "Pharmacy benefits manager" means an entity that performs pharmacy benefits management and includes a person or entity acting for another pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management

services, including mail order pharmacy.

(m) "Pharmacy benefits management" means the procurement of prescription drugs at a negotiated rate for dispensing in this state to covered individuals, the administration or management of prescription drug benefits provided by a covered entity for the benefit of covered individuals or, any of the following services provided with regard to the administration of pharmacy benefits:

(1) Mail service pharmacy;

(2) Claims processing retail network management and payment of claims to pharmacies or pharmacists for prescription drugs dispensed to covered individuals;

(3) Clinical formulary development and management services;

(4) Rebate contracting and administration;

(5) Patient compliance, therapeutic intervention and generic substitution programs; and

(6) Disease management programs.

~~(l)~~ (n) “Sell” means to exchange a contract of insurance by any means, for money or its equivalent, on behalf of an insurance company.

~~(m)~~ (o) “Solicit” means attempting to sell insurance or asking or urging a person to apply for a particular kind of insurance from a particular company.

~~(n)~~ (p) “Underwrites” or “underwriting” means, but is not limited to, the acceptance of employer or individual applications for coverage of individuals in accordance with the written rules of the insurer or self-funded plan; and the overall planning and coordinating of a benefits program.

~~(o)~~ (q) “Uniform application” means the current version of the national association of Insurance Commissioners uniform application for third-party administrators.

§33-46-18. Exemption for administrators of public health programs.

Programs supervised by the Department of Health and Human Resources, pursuant to chapter nine of this code; the Public Employees Insurance Agency, pursuant to articles sixteen and sixteen-c, chapter five of this code; and the Department of Administration, pursuant to article

sixteen-b, chapter five of this code, are exempted from the provisions of this article. Third-party administrators who administer the above-referenced programs are exempt from the provisions of this article with respect to these specific programs only. Pharmacy benefits managers that provide pharmacy benefits management for the above-referenced programs are not exempt from the provisions of sections twenty-one, twenty-two and twenty-three of this article.

§33-46-20. ~~Commissioner authorized to propose rules~~ Duties of pharmacy benefit managers.

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

A pharmacy benefits manager operating in this state shall:

(1) Specify the following in its contract with a purchaser:

(A) The maximum allowable cost prices for the prescription drugs that are covered under the contract and reimbursed on the basis of the maximum allowable cost price; and

(B) The methodology used to establish the maximum allowable cost prices.

(2) Disclose to purchasers:

(A) Any change to a maximum allowable cost price;

(B) Whether the pharmacy benefits manager is using the same maximum allowable cost price for a prescription drug in its charge to the purchaser and its reimbursement of all pharmacies and pharmacists in the pharmacy benefits manager's network;

(C) The difference in the amount charged to the purchaser and reimbursed to all pharmacies and pharmacists in the pharmacy benefits manager's network if the pharmacy benefits manager uses a different maximum allowable cost price; and

(D) Whether the pharmacy benefits manager uses a maximum allowable cost price for prescription drugs dispensed at retail but not for prescription drugs dispensed by mail.

(3) Specify the following in its contract with a pharmacy or pharmacist:

(A) The maximum allowable cost prices for the prescription drugs that are covered under the contract and reimbursed on the basis of the maximum allowable cost price and,

(B) The methodology used to establish the maximum allowable cost prices.

(4) Update the maximum allowable cost prices at least every seven days; and

(5) Establish a process for:

(A) Promptly notifying the pharmacies and pharmacists in its network of the maximum allowable cost prices and any updates;

(B) Eliminating prescription drugs from the maximum allowable cost price list;

(C) Establish a process for disclosing to pharmacies a current list of sources used to determine prices paid to pharmacies; and

(D) Modifying maximum allowable cost prices in a timely way to remain consistent with pricing changes in the market.

(6) Establish a procedure that allows a pharmacy or pharmacist to appeal a maximum allowable cost price for a prescription drug dispensed by the pharmacy or pharmacist;

(7) Respond to an appeal regarding a maximum allowable cost price within fifteen days after receiving the appeal; and

(8) If the pharmacy benefits manager agrees with the pharmacy or pharmacist:

(A) Alter the maximum allowable cost price retroactive to the dispensing date; and

(B) Make the altered maximum allowable cost price effective for all pharmacies and pharmacists in the pharmacy benefits manger's network.

(9) Conduct an audit of a pharmacy or pharmacist under contract with the pharmacy benefit manager in accordance with section twenty-one of this article.

§33-46-21. Audits by pharmacy benefit managers.

(a) A pharmacy benefits manager shall conduct an audit of a pharmacy or pharmacist

under contract with the pharmacy benefits manager using the same standard and parameters as other pharmacies or pharmacists audited by the pharmacy benefits manager and in accordance with this section.

(b) In conducting the audit, a pharmacy benefits manager shall:

(1) Only audit claims submitted or adjudicated within the two-year period immediately preceding the audit, unless a longer period is permitted under state or federal law;

(2) Provide notice to the pharmacy or pharmacists at least two weeks prior to conducing an onsite audit for each audit cycle. An onsite audit may not be scheduled or conducted during the first five days of a month unless requested by the pharmacist;

(3) Employ the services of a pharmacist if the audit requires the clinical or professional judgment of a pharmacist; and

(4) Allow the pharmacy or pharmacist to use hospital or physician records that are either written or transmitted electronically for purposes of validating the pharmacy record with respect to orders or refills of a drug that is a controlled substance.

(c) Following the audit a pharmacy benefit manager shall deliver a preliminary audit report to the pharmacy or pharmacists. This shall be done within one hundred twenty days following completion of the audit. The pharmacy benefit manager and the pharmacy or pharmacist may agree to a reasonable extension of this time period. The preliminary audit report shall include an explanation of the internal appeal process, instructions on how to file an internal appeal and contact information on where to file an internal appeal.

(d) As part of every contract, pharmacy benefit managers shall establish an internal review process where a pharmacy or pharmacists may file an internal appeal of any disputed claim in a preliminary audit report. The request for an internal appeal shall be made within thirty days from receipt of the preliminary audit report. The pharmacy benefit manager and the pharmacy or

pharmacist may agree to a reasonable extension of this time period. The pharmacy or pharmacists is permitted to produce documentation or address any discrepancies they find in the preliminary audit report.

(e) Thirty days following the conclusion of an internal appeal, the pharmacy benefit manager shall forward a final audit report to a pharmacist or pharmacy. The decision of the pharmacy benefit manager on any discrepancies addressed in the internal appeal shall be reflected in the final audit report. If no request was made for an internal appeal, the final audit report shall be filed within six months from the date of the delivery of the preliminary audit report.

§33-46-22. Audit practices by pharmacy benefit manager.

(a) In conducting an audit as set forth in section twenty-one of this article, a pharmacy benefit manager may not use the accounting practice of extrapolation to calculate overpayments or underpayments;.

(b) If the audit results in the need for recoupment of a claim payment from a pharmacy or pharmacist by a pharmacy benefit manager, the recoupment shall be based upon an actual overpayment or denial of an audited claim unless the projected overpayment or denial is part of a settlement agreed to by the pharmacy or pharmacist.

(c) A pharmacy benefit manager may not recoup by setoff any money for an overpayment or denial of a claim discovered in an audit until thirty days following the delivery of the final audit report to the pharmacy or pharmacist.

(d) A pharmacy benefit manager shall remit any money due to a pharmacy or pharmacists as a result of an underpayment of a claim discovered in an audit within thirty days following delivery of the final audit report to the pharmacy or pharmacist.

(e) A pharmacy benefits manager may withhold future payments before the final audit report has been delivered to the pharmacy or pharmacist if the identified discrepancy for all

disputed claims in a preliminary audit report for an individual audit exceeds $25,000.

§33-46-23. Internal review process.

(a) A pharmacy benefits manager shall establish a reasonable internal review process for a pharmacy or pharmacist to request the review of a failure to pay the contractual reimbursement amount of a submitted claim.

(b) A pharmacy or pharmacist may request a pharmacy benefits manager to review a failure to pay the contractual reimbursement amount of a claim within one hundred-eighty days after the date the submitted claim was paid by the pharmacy benefits manager.

(c) The pharmacy benefits manager shall give written notice to the pharmacy or pharmacist of the review of its decision not to pay the contractual reimbursement amount of a claim within ninety days after receipt of a request for review from a pharmacy or pharmacist pursuant to this section.

(d) If the pharmacy benefits manager determines through the internal review process established pursuant to this section that the pharmacy benefits manager underpaid a pharmacy or pharmacist, the pharmacy benefits manager shall pay any money due to the pharmacy or pharmacist within thirty days after completion of the internal review process.

(e) This section does not limit the ability of a pharmacy, pharmacist and a pharmacy benefits manager to contractually agree that a pharmacy or pharmacist may have more than one hundred-eighty days to request an internal review of a failure of the pharmacy benefits manager to pay the contractual amount of a submitted claim.

§33-46-24. 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 this article relating to pharmacy benefits managers.

NOTE: The purpose of this bill is to regulate pharmacy benefits managers. The bill defines terms and provides that pharmacy benefits managers conducting audits for public health programs are not exempt from pharmacy audit restrictions. The bill sets out the duties of pharmacy benefit managers and requires audits by pharmacy benefits managers. The bill provides an internal review process applicable to disputed findings of pharmacy benefits manager upon audit. It requires pharmacy benefits managers to provide notice to purchasers, pharmacists and pharmacies of information relating to maximum allowable costs and the establishment of a process relating to the appropriate use of maximum allowable cost pricing. The Insurance Commissioner is authorized 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.