WEST VIRGINIA LEGISLATURE

2016 REGULAR SESSION

Introduced

Senate Bill 694

BY SENATOR GAUNCH

[Introduced February 22, 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 and §33-46-18 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; imposing restrictions upon 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; and requiring pharmacy benefits managers to provide a process relating to the appropriate use of maximum allowable cost pricing.

Be it enacted by the Legislature of West Virginia:

That §33-46-2 and §33-46-18 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, <u>including a pharmacy benefits manager,</u> 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 dispensation within 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 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: *Provided,* That pharmacy benefits managers that provide pharmacy benefits management for the above-

referenced programs are not exempt from the provisions of sections twenty-one and twenty-two 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.

§33-46-21. Audits by pharmacy benefits manager.

(a) Scope of section. - This section does not apply to an audit that involves probable or potential fraud or willful misrepresentation by a pharmacy or pharmacist.

(b) In general. - A pharmacy benefits manager shall conduct an audit of a pharmacy or pharmacist under contract with the pharmacy benefits manager in accordance with this section.

(c) Audit during first five days of month.- A pharmacy benefits manager may not schedule or conduct an onsite audit to begin during the first five calendar days of a month, unless requested by the pharmacy or pharmacist.

(d) Conduct of audit. - When conducting an audit, a pharmacy benefits manager shall:

(1) If the audit is onsite, provide written notice to the pharmacy or pharmacist at least two weeks before conducting the initial onsite audit for each audit cycle;

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

(3) For purposes of validating the pharmacy record with respect to orders or refills of a drug that is a controlled substance, allow the pharmacy or pharmacist to use hospital or physician records that are:

(A) Written; or

(B) Transmitted electronically;

(4) Audit each pharmacy and pharmacist under the same standards and parameters as other similarly situated pharmacies or pharmacists audited by the pharmacy benefits manager;

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

(6) Deliver the preliminary audit report to the pharmacy or pharmacist within one hundred

twenty calendar days after the completion of the audit, with reasonable extensions allowed;

(7) In accordance with subsection (g) of this section, allow a pharmacy or pharmacist to produce documentation to address any discrepancy found during the audit; and

(8) Deliver the final audit report to the pharmacy or pharmacist:

(A) Within six months after delivery of the preliminary audit report if the pharmacy or pharmacist does not request an internal appeal under subsection (g) of this section; or

(B) Within thirty days after the conclusion of the internal appeal process under subsection (g) of this section if the pharmacy or pharmacist requests an internal appeal.

(e) Use of extrapolation prohibited.- A pharmacy benefits manager may not use the accounting practice of extrapolation to calculate overpayments or underpayments.

(f) Basis for recoupment.- The recoupment of a claim payment from a pharmacy or pharmacist by a pharmacy benefits manager shall be based on 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.

(g) Internal appeal process.-

(1) A pharmacy benefits manager shall establish an internal appeal process under which a pharmacy or pharmacist may appeal any disputed claim in a preliminary audit report.

(2) Under the internal appeal process, a pharmacy benefits manager shall allow a pharmacy or pharmacist to request an internal appeal within thirty working days after receipt of the preliminary audit report, with reasonable extensions allowed.

(3) The pharmacy benefits manager shall include in its preliminary audit report a written explanation of the internal appeal process, including the name, address, and telephone number of the person to whom an internal appeal should be addressed.

(4) The decision of the pharmacy benefits manager on an appeal of a disputed claim in a preliminary audit report by a pharmacy or pharmacist shall be reflected in the final audit report.

(5) The pharmacy benefits manager shall deliver the final audit report to the pharmacy or

pharmacist within thirty calendar days after conclusion of the internal appeal process.

(h) Timing for setoff for overpayment or remittance of underpayment.-

(1) A pharmacy benefits manager may not recoup by setoff any money for an overpayment or denial of a claim until thirty working days after the date the final audit report has been delivered to the pharmacy or pharmacist.

(2) A pharmacy benefits manager shall remit any money due to a pharmacy or pharmacist as a result of an underpayment of a claim within thirty working days after the final audit report has been delivered to the pharmacy or pharmacist.

(3) Notwithstanding the provisions of subdivision (1) of this subsection, a pharmacy benefits manager may withhold future payments before the date 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.

(i) Copy of audit procedures or internal appeal process to commissioner.- On request of the commissioner or the commissioner's designee, a pharmacy benefits manager shall provide a copy of its audit procedures or internal appeal process.

§33-46-22. Internal review process.

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

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

(c) Notice of review decision.- The pharmacy benefits manager shall give written notice of its review decision within ninety calendar days after receipt of a request for review from a pharmacy under this section.

(d) Underpayment.- If the pharmacy benefits manager determines through the internal

review process established under subsection (a) of this section that the pharmacy benefits manager underpaid a pharmacy, the pharmacy benefits manager shall pay any money due to the pharmacy within thirty working days after completion of the internal review process.

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

§33-46-23. Duty of pharmacy benefits managers to purchasers.

(a) A pharmacy benefits manager shall specify the following in its contract with a purchaser:

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

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

(b) A pharmacy benefits manager shall disclose to purchasers: (1) Any change to a maximum allowable cost price; (2) whether or not the pharmacy benefits manager is using the same maximum allowable cost price for a prescription drug in (A) Its charge to the purchaser and (B) its reimbursement of all pharmacies and pharmacists in the pharmacy benefits manager's network; (3) if the pharmacy benefits manager uses a different maximum allowable cost price, the difference in the amount (A) Charged to the purchaser and (B) reimbursed to all pharmacies and pharmacists in the pharmacy benefits manager's network; and (4) 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.

§33-46-24. Duty of pharmacy benefits managers to pharmacists and pharmacies.

(a) A pharmacy benefits manager shall:

(1) Specify in its contract with a pharmacy or pharmacist:

(A) The maximum allowable cost prices for the prescription drugs that are:

(i) Covered under the contract; and

(ii) Reimbursed on the basis of the maximum allowable cost price; and

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

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

(3) 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; and

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

(b) A pharmacy benefits manager shall:

(1) 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;

(2) Respond to an appeal within fifteen calendar days after receiving the appeal; and

(3) 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.

(C) To include a maximum allowable cost price for a prescription drug in a contract with a pharmacy or pharmacist, a pharmacy benefits manager shall ensure that the prescription drug:

(i) Has at least three nationally available and therapeutically equivalent multiple sources with a significant cost difference;

(ii) Is listed as therapeutically and pharmaceutically equivalent ("A" Rated) in the most recent version of the U.S. Food and Drug Administration Publication "Approved Drug Products with Therapeutic Equivalence Evaluations;"

(iii) Is available for purchase without limitation, from national or regional wholesale

distributors, by all pharmacies and pharmacists in the state; and

(iv) Is not obsolete or temporarily unavailable.

NOTE: The purpose of this bill is to include pharmacy benefits manager within the definition of third-party administrator; to impose reasonable restrictions on audits conducted by pharmacy benefits managers, including an internal appeal process; and to require pharmacy benefits managers to provide notice to purchasers, pharmacies, and pharmacists information relating to maximum allowable costs. .

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