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H.B. 370
2nd Sub. (Gray)

Senator Evan J. Vickers proposes the following substitute bill:

PHARMACY BENEFIT MANAGER AMENDMENTS

2019 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Paul Ray

Senate Sponsor: Evan J. Vickers

Cosponsors:
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LONG TITLE

General Description:

This bill amends and creates requirements for pharmacy benefit managers.

Highlighted Provisions:

This bill:

- creates a pharmacy benefit manager license;

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- requires a person who acts as a pharmacy benefit manager in the state to be licensed by the Insurance Department; and
- creates certain operating and reporting requirements for pharmacy benefit managers.

Money Appropriated in this Bill:

None

Other Special Clauses:

This bill provides a special effective date.

Utah Code Sections Affected:

AMENDS:

31A-2-201.2, as last amended by Laws of Utah 2018, Chapter 319

ENACTS:

31A-46-101, Utah Code Annotated 1953

31A-46-102, Utah Code Annotated 1953

31A-46-103, Utah Code Annotated 1953

31A-46-201, Utah Code Annotated 1953

31A-46-202, Utah Code Annotated 1953

31A-46-301, Utah Code Annotated 1953

31A-46-304, Utah Code Annotated 1953

31A-46-401, Utah Code Annotated 1953

31A-46-402, Utah Code Annotated 1953

RENUMBERS AND AMENDS:

31A-46-302, (Renumbered from 58-17b-626, as enacted by Laws of Utah 2018, Chapter 305)

31A-46-303, (Renumbered from 31A-22-640, as last amended by Laws of Utah 2015, Chapter 258)

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **31A-2-201.2** is amended to read:

31A-2-201.2. Evaluation of health insurance market.

(1) Each year the commissioner shall:

(a) conduct an evaluation of the state's health insurance market;

(b) report the findings of the evaluation to the Health and Human Services Interim Committee before December 1 of each year; and

(c) publish the findings of the evaluation on the department website.

(2) The evaluation required by this section shall:

(a) analyze the effectiveness of the insurance regulations and statutes in promoting a healthy, competitive health insurance market that meets the needs of the state, and includes an analysis of:

(i) the availability and marketing of individual and group products;

(ii) rate changes;

(iii) coverage and demographic changes;

(iv) benefit trends;

(v) market share changes; and

(vi) accessibility;

(b) assess complaint ratios and trends within the health insurance market, which assessment shall include complaint data from the Office of Consumer Health Assistance within the department;

(c) contain recommendations for action to improve the overall effectiveness of the health insurance market, administrative rules, and statutes; [~~and~~]

(d) include claims loss ratio data for each health insurance company doing business in the state[~~.~~]; and

(e) include information about pharmacy benefit managers collected under Section 31A-46-301.

(3) When preparing the evaluation and report required by this section, the commissioner may seek the input of insurers, employers, insured persons, providers, and others with an interest in the health insurance market.

(4) The commissioner may adopt administrative rules for the purpose of collecting the data required by this section, taking into account the business confidentiality of the insurers.

(5) Records submitted to the commissioner under this section shall be maintained by the commissioner as protected records under Title 63G, Chapter 2, Government Records Access and Management Act.

Section 2. Section **31A-46-101** is enacted to read:

CHAPTER 46. PHARMACY BENEFIT MANAGER LICENSING ACT

Part 1. General Provisions

31A-46-101. Title.

This chapter is known as the "Pharmacy Benefit Manager Licensing Act."

Section 3. Section **31A-46-102** is enacted to read:

31A-46-102. Definitions.

As used in this chapter:

(1) "Administrative fee" means any payment, other than a rebate, that a pharmaceutical manufacturer makes directly or indirectly to a pharmacy benefit manager.

(2) "Contracting insurer" means an insurer as defined in Section 31A-22-636 with whom a pharmacy benefit manager contracts to provide a pharmacy benefit management service.

(3) "Pharmacist" means the same as that term is defined in Section 58-17b-102.

(4) "Pharmacy" means the same as that term is defined in Section 58-17b-102.

(5) "Pharmacy benefits management service" means any of the following services provided to a health benefit plan, or to a participant of a health benefit plan:

(a) negotiating the amount to be paid by a health benefit plan for a prescription drug; or

(b) administering or managing a prescription drug benefit provided by the health benefit plan for the benefit of a participant of the health benefit plan, including administering or managing:

(i) a mail service pharmacy;

(ii) a specialty pharmacy;

(iii) claims processing;

(iv) payment of a claim;

(v) retail network management;

(vi) clinical formulary development;

(vii) clinical formulary management services;

(viii) rebate contracting;

(ix) rebate administration;

(x) a participant compliance program;

(xi) a therapeutic intervention program;

(xii) a disease management program; or

(xiii) a service that is similar to, or related to, a service described in Subsection (5)(a) or (5)(b)(i) through (xii).

(6) "Pharmacy benefit manager" means a person licensed under this chapter to provide a pharmacy benefit management service.

(7) "Pharmacy service" means a product, good, or service provided to an individual by a pharmacy or pharmacist.

(8) (a) "Rebate" means a refund, discount, or other price concession that is paid by a pharmaceutical manufacturer to a pharmacy benefit manager based on a prescription drug's utilization or effectiveness.

(b) "Rebate" does not include an administrative fee.

Section 4. Section **31A-46-103** is enacted to read:

31A-46-103. Applicability.

This chapter does not apply to an employee welfare benefit plan under the Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829.

Section 5. Section **31A-46-201** is enacted to read:

Part 2. Licensure

31A-46-201. License required.

(1) A person may not perform, offer to perform, or advertise any pharmacy benefits management service in the state unless the person is licensed as a pharmacy benefit manager under this chapter.

(2) A person may not utilize the services of another person as a pharmacy benefit manager if the person knows or has reason to know that the other person does not have a license under this chapter.

Section 6. Section **31A-46-202** is enacted to read:

31A-46-202. Application for licensure.

(1) To obtain or renew a license as a pharmacy benefit manager, a person shall:

(a) submit an application to the commissioner on forms and in a manner established by the commissioner by rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act; and

(b) pay a licensure fee established by the department in accordance with Section

31A-3-103.

(2) (a) The commissioner may require an applicant to submit information or documentation regarding the management and ownership of the pharmacy benefit manager in the application described in Subsection (1)(a).

(b) Any material change in the information submitted in an application described in Subsection (1)(a) shall be reported to the department within 30 days after the day on which the information changes.

(3) The term of a license issued under this section is one year.

Section 7. Section **31A-46-301** is enacted to read:

Part 3. Operating Requirements

31A-46-301. Reporting requirements.

(1) Before April 1 of each year, a pharmacy benefit manager operating in the state shall report to the department, for the previous calendar year:

(a) any insurer, pharmacy, or pharmacist in the state with which the pharmacy benefit manager had a contract;

(b) the total value, in the aggregate, of all rebates and administrative fees that are attributable to enrollees of a contracting insurer; and

(c) the percentage of aggregate rebates that the pharmacy benefit manager retained under the pharmacy benefit manager's agreement to provide pharmacy benefits management services to a contracting insurer.

(2) Records submitted to the commissioner under Subsections (1)(b) and (c) are a protected record under Title 63G, Chapter 2, Government Records Access and Management Act.

(3) (a) The department shall publish the information provided by a pharmacy benefit manager under Subsection (1)(b) in the annual report described in Section 31A-2-201.2.

(b) The department may not publish information submitted under Subsection (1)(b) or (c) in a manner that:

(i) makes a specific submission from a contracting insurer or pharmacy benefit manager identifiable; or

(ii) is likely to disclose information that is a trade secret as defined in Section 13-24-2.

(c) At least 30 days before the day on which the department publishes the data, the

department shall provide a pharmacy benefit manager that submitted data under Subsection (1)(b) or (c) with:

(i) a general description of the data that will be published by the department;

(ii) an opportunity to submit to the department, within a reasonable period of time and in a manner established by the department by rule made in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act:

(A) any correction of errors, with supporting evidence and comments; and

(B) information that demonstrates that the publication of the data will violate Subsection (3)(b), with supporting evidence and comments.

Section 8. Section **31A-46-302**, which is renumbered from Section 58-17b-626 is renumbered and amended to read:

[~~58-17b-626~~]. 31A-46-302. Direct or indirect remuneration by pharmacy benefit managers -- Disclosure of customer costs -- Limit on customer payment for prescription drugs.

(1) As used in this section:

(a) "Allowable claim amount" means the amount paid by an insurer under the customer's health benefit plan.

[~~(a)~~] (b) "Cost share" means the amount paid by an insured customer under the customer's health benefit plan.

[~~(b)~~] (c) "Direct or indirect remuneration" means any adjustment in the total compensation:

(i) received by a pharmacy from a pharmacy [~~benefits manager or coordinator~~] benefit manager for the sale of a drug, device, or other product or service; and

(ii) that is determined after the sale of the product or service.

[~~(c)~~] (d) "Health benefit plan" means the same as that term is defined in Section 31A-1-301.

(e) "Pharmacy reimbursement" means the amount paid to a pharmacy by a pharmacy benefit manager for a dispensed prescription drug.

[~~(d)~~] (f) "Pharmacy services administration organization" means an entity that contracts with a pharmacy to assist with third-party payer interactions and administrative services related to third-party payer interactions, including:

(i) contracting with a pharmacy [~~benefits manager or coordinator~~] benefit manager on behalf of the pharmacy; and

(ii) managing a pharmacy's claims payments from third-party payers.

[~~(e)~~] (g) "Pharmacy service entity" means:

(i) a pharmacy services administration organization; or

(ii) a pharmacy [~~benefits manager or coordinator~~] benefit manager.

[~~(f)~~] (h) (i) "Reimbursement report" means a report on the adjustment in total compensation for a claim.

(ii) "Reimbursement report" does not include a report on adjustments made pursuant to a pharmacy audit or reprocessing.

[~~(g)~~] (i) "Sale" means a prescription drug claim covered by a health benefit plan.

(2) If a pharmacy service entity engages in direct or indirect remuneration with a pharmacy, the pharmacy service entity shall make a reimbursement report available to the pharmacy upon the pharmacy's request.

(3) For the reimbursement report described in Subsection (2), the pharmacy service entity shall:

(a) include the adjusted compensation amount related to a claim and the reason for the adjusted compensation; and

(b) provide the reimbursement report:

(i) in accordance with the contract between the pharmacy and the pharmacy service entity;

(ii) in an electronic format that is easily accessible; and

(iii) within 120 days after the day on which the pharmacy [~~benefits manager or coordinator~~] benefit manager receives a report of a sale of a product or service by the pharmacy.

(4) A pharmacy service entity shall, upon a pharmacy's request, provide the pharmacy with:

(a) the reasons for any adjustments contained in a reimbursement report; and

(b) an explanation of the reasons provided in Subsection (4)(a).

(5) (a) A pharmacy [~~benefits manager or coordinator~~] benefit manager may not prohibit or penalize the disclosure by a pharmacist of:

(i) an insured customer's cost share for a covered prescription drug;

(ii) the availability of any therapeutically equivalent alternative medications; or

(iii) alternative methods of paying for the prescription medication, including paying the cash price, that are less expensive than the cost share of the prescription drug.

(b) Penalties that are prohibited under Subsection (5)(a) include increased utilization review, reduced payments, and other financial disincentives.

(6) A pharmacy [~~benefits manager or coordinator~~] benefit manager may not require an insured customer to pay, for a covered prescription drug, more than the lesser of:

(a) the applicable cost share of the prescription drug being dispensed; [~~or~~]

(b) the applicable allowable claim amount of the prescription drug being dispensed;

(c) the applicable pharmacy reimbursement of the prescription drug being dispensed; or

[~~(b)~~] (d) the retail price of the drug without prescription drug coverage.

Section 9. Section **31A-46-303**, which is renumbered from Section 31A-22-640 is renumbered and amended to read:

[~~31A-22-640~~]. 31A-46-303. Insurer and pharmacy benefit management services -- Registration -- Maximum allowable cost -- Audit restrictions.

(1) [~~For purposes of~~] As used in this section:

(a) "Maximum allowable cost" means:

(i) a maximum reimbursement amount for a group of pharmaceutically and therapeutically equivalent drugs; or

(ii) any similar reimbursement amount that is used by a pharmacy benefit manager to reimburse pharmacies for multiple source drugs.

(b) "Obsolete" means a product that may be listed in national drug pricing compendia but is no longer available to be dispensed based on the expiration date of the last lot manufactured.

(c) " Pharmacy benefit manager" means a person or entity that provides pharmacy benefit management services as defined in Section 49-20-502 on behalf of an insurer as defined in Subsection 31A-22-636(1).

(2) An insurer and an insurer's pharmacy benefit manager is subject to the pharmacy audit provisions of Section 58-17b-622.

(3) A pharmacy benefit manager shall not use maximum allowable cost as a basis for

reimbursement to a pharmacy unless:

(a) the drug is listed as "A" or "B" rated in the most recent version of the United States Food and Drug Administration's approved drug products with therapeutic equivalent evaluations, also known as the "Orange Book," or has an "NR" or "NA" rating or similar rating by a nationally recognized reference; and

(b) the drug is:

(i) generally available for purchase in this state from a national or regional wholesaler; and

(ii) not obsolete.

(4) The maximum allowable cost may be determined using comparable and current data on drug prices obtained from multiple nationally recognized, comprehensive data sources, including wholesalers, drug file vendors, and pharmaceutical manufacturers for drugs that are available for purchase by pharmacies in the state.

(5) For every drug for which the pharmacy benefit manager uses maximum allowable cost to reimburse a contracted pharmacy, the pharmacy benefit manager shall:

(a) include in the contract with the pharmacy information identifying the national drug pricing compendia and other data sources used to obtain the drug price data;

(b) review and make necessary adjustments to the maximum allowable cost, using the most recent data sources identified in Subsection (5)(a), at least once per week;

(c) provide a process for the contracted pharmacy to appeal the maximum allowable cost in accordance with Subsection (6); and

(d) include in each contract with a contracted pharmacy a process to obtain an update to the pharmacy product pricing files used to reimburse the pharmacy in a format that is readily available and accessible.

(6) (a) The right to appeal in Subsection (5)(c) shall be:

(i) limited to 21 days following the initial claim adjudication; and

(ii) investigated and resolved by the pharmacy benefit manager within 14 business days.

(b) If an appeal is denied, the pharmacy benefit manager shall provide the contracted pharmacy with the reason for the denial and the identification of the national drug code of the drug that may be purchased by the pharmacy at a price at or below the price determined by the

pharmacy benefit manager.

(7) The contract with each pharmacy shall contain a dispute resolution mechanism in the event either party breaches the terms or conditions of the contract.

[~~(8) (a) To conduct business in the state, a pharmacy benefit manager shall register with the Division of Corporations and Commercial Code within the Department of Commerce and annually renew the registration. To register under this section, the pharmacy benefit manager shall submit an application which shall contain only the following information:~~]

[~~(i) the name of the pharmacy benefit manager;~~]

[~~(ii) the name and contact information for the registered agent for the pharmacy benefit manager; and~~]

[~~(iii) if applicable, the federal employer identification number for the pharmacy benefit manager.~~]

[~~(b) The Department of Commerce may establish a fee in accordance with Title 63J, Chapter 1, Budgetary Procedures Act, for the initial registration and the annual renewal of the registration, which may not exceed $100 per year.~~]

[~~(c) The following entities do not have to register as a pharmacy benefit manager under Subsection (8)(a) when the entity is providing formulary services to its own patients, employees, members, or beneficiaries:~~]

[~~(i) a health care facility licensed under Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act;~~]

[~~(ii) a pharmacy licensed under Title 58, Chapter 17b, Pharmacy Practice Act;~~]

[~~(iii) a health care professional licensed under Title 58, Occupations and Professions;~~]

[~~(iv) a health insurer; and~~]

[~~(v) a labor union.~~]

[~~(9)~~] (8) This section does not apply to a pharmacy benefit manager when the pharmacy benefit manager is providing pharmacy benefit management services on behalf of the state Medicaid program.

Section 10. Section **31A-46-304** is enacted to read:

31A-46-304. Claims practices.

(1) A pharmacy benefit manager shall permit a pharmacy to collect the amount of a customer's cost share from any source.

(2) A pharmacy benefit manager may not deny or reduce a reimbursement to a pharmacy or a pharmacist after the adjudication of the claim, unless:

(a) the pharmacy or pharmacist submitted the original claim fraudulently;

(b) the original reimbursement was incorrect because:

(i) the pharmacy or pharmacist had already been paid for the pharmacy service; or

(ii) an unintentional error resulted in an incorrect reimbursement; or

(c) the pharmacy service was not rendered by the pharmacy or pharmacist.

(3) Subsection (2) does not apply if an investigative audit of pharmacy records for fraud, waste, abuse, or other intentional misrepresentation indicates that the pharmacy or pharmacist engaged in criminal wrongdoing, fraud, or other intentional misrepresentation.

Section 11. Section **31A-46-401** is enacted to read:

Part 4. Miscellaneous

31A-46-401. Penalties.

A person that violates a provision of this chapter is subject to the penalties described in Section 31A-2-308.

Section 12. Section **31A-46-402** is enacted to read:

31A-46-402. Severability.

If any provision of this chapter or the application of any provision of this chapter is found invalid, the remainder of this chapter shall be given effect without the invalid provision or application.

Section 13. **Effective date.**

This bill takes effect on July 1, 2019.