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S.B. 230

PHARMACEUTICAL SUPPLY CHAIN

2020 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Todd Weiler

House Sponsor: _____

LONG TITLE

General Description:

This bill creates the Prescription Drug Price Transparency Act and the Pharmaceutical Development and Marketing Act and amends the Insurance Code.

Highlighted Provisions:

This bill:

- addresses the information a health insurer must provide to a potential enrollee with respect to the insurer's medical exceptions process and the potential enrollee's cost sharing for certain drugs and devices;
- requires a health insurer to annually report to the Insurance Department certain information related to prior authorization requests;
- creates definitions;
- amends provisions related to pharmacy benefit manager information reported to and published by the Insurance Department;
- requires insurers, pharmacy benefit managers, pharmacy services administration organizations, pharmaceutical wholesalers or distributors, and pharmacies to annually report information about certain drugs to the Insurance Department;
- requires the Insurance Department to annually publish information reported to the department about certain drugs;
- requires rulemaking;
- requires a pharmacy benefit manager or pharmacy services administration

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organization to report to a health insurer, upon request, the amount of rebates received by the pharmacy benefit manager or pharmacy services administration organization and the amount of rebates passed on to the insurer;

- requires a patient assistance program to publish contributions the program receives from health insurers, drug manufacturers, pharmacy benefit managers, and related trade or advocacy organizations;
- prohibits a health care provider or pharmaceutical manufacturer from waiving or taking other actions to reduce an enrollee's deductible, copayment, or coinsurance;
- requires the Insurance Department to report to the Legislature on the effectiveness of the Prescription Drug Price Transparency Act;
- requires substitution of a drug with a drug product equivalent under certain circumstances;
- requires substitution of a biological product with an interchangeable biological product under certain circumstances;
- requires a drug manufacturer to make a drug available to a developer seeking to submit an application for approval or licensing of a drug;
- limits the price that may be charged by the manufacturer for the supplied drug;
- limits the price that may be charged by the developer for the approved drug;
- provides an exemption from liability;
- provides for injunctive relief;
- requires periodic reporting and publication of the names of a pharmaceutical manufacturer's sales representatives;
- requires periodic reporting and analysis of the activities of a pharmaceutical manufacturer's sales representatives;
- requires a person that engages in prescription drug marketing to provide a health care provider with certain written materials; and
- makes technical amendments.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

31A-22-613.5, as last amended by Laws of Utah 2019, Chapter 439

31A-22-650, as enacted by Laws of Utah 2019, Chapter 439

31A-46-102, as enacted by Laws of Utah 2019, Chapter 241

31A-46-301, as enacted by Laws of Utah 2019, Chapter 241

31A-46-302, as renumbered and amended by Laws of Utah 2019, Chapter 241

58-17b-605, as last amended by Laws of Utah 2013, Chapter 423

58-17b-605.5, as last amended by Laws of Utah 2015, Chapter 266

ENACTS:

31A-46-305, Utah Code Annotated 1953

31A-46-306, Utah Code Annotated 1953

31A-47-101, Utah Code Annotated 1953

31A-47-102, Utah Code Annotated 1953

31A-47-103, Utah Code Annotated 1953

31A-47-104, Utah Code Annotated 1953

31A-47-105, Utah Code Annotated 1953

31A-47-106, Utah Code Annotated 1953

31A-47-107, Utah Code Annotated 1953

31A-47-108, Utah Code Annotated 1953

58-17c-101, Utah Code Annotated 1953

58-17c-102, Utah Code Annotated 1953

58-17c-103, Utah Code Annotated 1953

58-17c-104, Utah Code Annotated 1953

58-17c-105, Utah Code Annotated 1953

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

Section 1. Section **31A-22-613.5** is amended to read:

31A-22-613.5. Price and value comparisons of health insurance.

(1) (a) This section applies to all health benefit plans.

(b) Subsection (2) applies to:

(i) all health benefit plans; and

(ii) coverage offered to state employees under Subsection 49-20-202(1)(a).

(2) The commissioner shall promote informed consumer behavior and responsible health benefit plans by requiring an insurer issuing a health benefit plan to provide to all enrollees, before enrollment in the health benefit plan, written disclosure of:

(a) restrictions or limitations on prescription drugs and biologics, including:

(i) the use of a formulary;

(ii) [~~co-payments and~~] copayments, deductibles, and coinsurance for prescription drugs; [~~and~~]

(iii) requirements for generic substitution; and

(iv) information regarding the health benefit plan's medical exceptions process, including information on the procedure though which an enrollee may submit an exceptions request;

(b) coverage limits under the plan;

(c) any limitation or exclusion of coverage, including:

(i) a limitation or exclusion for a secondary medical condition related to a limitation or exclusion from coverage; and

(ii) easily understood examples of a limitation or exclusion of coverage for a secondary medical condition;

(d) (i) (A) each drug, device, and covered service that is subject to a preauthorization requirement as defined in Section 31A-22-650; or

(B) if listing each device or covered service in accordance with Subsection (2)(d)(i)(A) is too numerous to list separately, all devices or covered services in a particular category where all devices or covered services have the same preauthorization requirement;

(ii) each requirement for authorization as defined in Section 31A-22-650 for:

(A) each drug, device, or covered service described in Subsection (2)(d)(i)(A); and

(B) each category of devices or covered services described in Subsection (2)(d)(i)(B); and

(iii) sufficient information to allow a network provider or enrollee to submit all of the information to the insurer necessary to meet each requirement for authorization described in Subsection (2)(d)(ii);

(e) whether the insurer permits an exchange of the adoption indemnity benefit in Section 31A-22-610.1 for infertility treatments, in accordance with Subsection 31A-22-610.1(1)(c)(ii) and the terms associated with the exchange of benefits; and

(f) whether the insurer provides coverage for telehealth services in accordance with Section 26-18-13.5 and terms associated with that coverage.

(3) An insurer shall provide the disclosure required by Subsection (2) in writing to the commissioner:

(a) upon commencement of operations in the state; and

(b) anytime the insurer amends any of the following described in Subsection (2):

(i) treatment policies;

(ii) practice standards;

(iii) restrictions;

(iv) coverage limits of the insurer's health benefit plan or health insurance policy; or

(v) limitations or exclusions of coverage including a limitation or exclusion for a secondary medical condition related to a limitation or exclusion of the insurer's health insurance plan.

(4) (a) An insurer shall provide the enrollee with notice of an increase in costs for prescription drug coverage due to a change in benefit design under Subsection (2)(a):

(i) either:

(A) in writing; or

(B) on the insurer's website; and

(ii) at least 30 days prior to the date of the implementation of the increase in cost, or as soon as reasonably possible.

(b) If under Subsection (2)(a) a formulary is used, the insurer shall make available to prospective enrollees and maintain evidence of the fact of the disclosure of:

(i) the drugs included;

(ii) the patented drugs not included;

(iii) any cost sharing for a drug or device that varies according to the quantity of the drug or device dispensed, including a drug or device that is not subject to a preauthorization requirement, as defined in Section 31A-22-650;

[~~(iii)~~] (iv) any conditions that exist as a precedent to coverage; and

[~~(iv)~~] (v) any exclusion from coverage for secondary medical conditions that may result from the use of an excluded drug.

(c) The commissioner shall develop examples of limitations or exclusions of a secondary medical condition that an insurer may use under Subsection (2)(c).

(5) Examples of a limitation or exclusion of coverage provided under this section or otherwise are for illustrative purposes only, and the failure of a particular fact situation to fall within the description of an example does not, by itself, support a finding of coverage.

(6) An insurer shall:

(a) post the information described in Subsection (2)(d) on the insurer's website and provider portal;

(b) if requested by an enrollee, provide the enrollee with the information required by this section by mail or email; and

(c) if requested by a network provider for a specific drug, device, or covered service, provide the network provider with the information described in Subsection (2)(d) for the drug, device, or covered service by mail or email.

Section 2. Section **31A-22-650** is amended to read:

31A-22-650. Health care preauthorization requirements.

(1) As used in this section:

(a) "Adverse preauthorization determination" means a determination by an insurer that health care does not meet the preauthorization requirement for the health care.

(b) "Authorization" means a determination by an insurer that for health care with a preauthorization requirement:

(i) the proposed drug, device, or covered service meets all requirements, restrictions, limitations, and clinical criteria for authorization established by the insurer;

(ii) the drug, device, or covered service is covered by the enrollee's insurance policy; and

(iii) the insurer will provide coverage for the drug, device, or covered service subject to the provisions of the insurance policy, including any cost sharing responsibilities of the enrollee.

(c) "Device" means a prescription device as defined in Section 58-17b-102.

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

(e) "Insurer" means the same as that term is defined in Section 31A-22-634.

(f) "Preauthorization requirement" means a requirement by an insurer that an enrollee obtain authorization for a drug, device, or service covered by the insurance policy, before receiving the drug, device, or service.

(2) (a) An insurer may not modify an existing requirement for authorization unless, at least 30 days before the day on which the modification takes effect, the insurer:

(i) posts a notice of the modification on the website described in Subsection 31A-22-613.5(6)(a); and

(ii) if requested by a network provider or the network provider's representative, provides to the network provider by mail or email a written notice of modification to a particular requirement for authorization described in the request from the network provider.

(b) Subsection (2)(a) does not apply if:

(i) complying with Subsection (2)(a) would create a danger to the enrollee's health or safety; or

(ii) the modification is for a newly covered drug or device.

(c) An insurer may not revoke an authorization for a drug, device, or covered service if:

(i) the network provider submits a request for authorization for the drug, device, or covered service to the insurer;

(ii) the insurer grants the authorization requested under Subsection (2)(c)(i);

(iii) the network provider renders the drug, device, or covered service to the enrollee in accordance with the authorization and any terms and conditions of the network provider's contract with the insurer;

(iv) on the day on which the network provider renders the drug, device, or covered service to the enrollee:

(A) the enrollee is eligible for coverage under the enrollee's insurance policy; and

(B) the enrollee's condition or circumstances related to the enrollee's care have not changed;

(v) the network provider submits an accurate claim that matches the information in the request for authorization under Subsection (2)(c)(i); and

(vi) the authorization was not based on fraudulent or materially incorrect information from the network provider.

(3) (a) An insurer that receives a request for authorization shall treat the request as a pre-service claim as defined in 29 C.F.R. Sec. 2560.503-1 and process the request in accordance with:

(i) 29 C.F.R. Sec. 2560.503-1, regardless of whether the coverage is offered through an individual or group health insurance policy;

(ii) Subsection 31A-4-116(2); and

(iii) Section 31A-22-629.

(b) If a network provider submits a claim to an insurer that includes an unintentional error that results in a denial of the claim, the insurer shall permit the network provider with an opportunity to resubmit the claim with corrected information within a reasonable amount of time.

(c) Except as provided in Subsection (3)(d), the appeal of an adverse preauthorization determination regarding clinical or medical necessity as requested by a physician may only be reviewed by a physician who is currently licensed as a physician and surgeon in a state, district, or territory of the United States.

(d) The appeal of an adverse determination requested by a physician regarding clinical or medical necessity of a drug, may only be reviewed by an individual who is currently licensed in a state, district, or territory of the United States as:

(i) a physician and surgeon; or

(ii) a pharmacist.

(e) An insurer shall ensure that an adverse preauthorization determination regarding clinical or medical necessity is made by an individual who:

(i) has knowledge of the medical condition or disease of the enrollee for whom the authorization is requested; or

(ii) consults with a specialist who has knowledge of the medical condition or disease of the enrollee for whom the authorization is requested regarding the request before making the determination.

(f) An insurer shall specify how long an authorization is valid.

(4) (a) An insurer that removes a drug from the insurer's formulary shall:

(i) permit an enrollee, an enrollee's designee, or an enrollee's network provider to request an exemption from the change to the formulary for the purpose of providing the patient

with continuity of care; and

(ii) have a process to review and make a decision regarding an exemption requested under Subsection (4)(a)(i).

(b) If an insurer makes a change to the formulary for a drug in the middle of a plan year, the insurer may not implement the changes for an enrollee that is on an active course of treatment for the drug unless the insurer provides the enrollee with notice at least 30 days before the day on which the change is implemented.

(5) Before April 1, 2021, and before April 1 of each year thereafter, an insurer with a preauthorization requirement shall report to the department, for the previous calendar year, the percentage of authorizations, not including a claim involving urgent care as defined in 29 C.F.R. Sec. 2560.503-1, for which the insurer notified a provider regarding an authorization or adverse preauthorization determination more than one week after the day on which the insurer received the request for authorization.

(6) An insurer may not have a preauthorization requirement for emergency health care as described in Section 31A-22-627.

(7) For each of an insurer's health benefit plans offered in the state, an insurer shall annually report to the department the following information for the plan year:

(a) the percentage of prescription drug prior authorization requests denied;

(b) the percentage of total adjudicated prior authorization appeals denied at each level of internal or external appeal; and

(c) except for prior authorization requests that resulted in an appeal, the minimum, maximum, and average number of hours between the time an enrollee submitted a request for prior authorization and the time the health benefit plan provided the enrollee with notice of a final decision.

Section 3. Section **31A-46-102** is amended 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 benefits management service.

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

(8) "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:

(a) contracting with a pharmacy benefit manager on behalf of the pharmacy; and

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

[~~(8)~~] (9) (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-46-301** is amended to read:

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.~~]

(b) for each insurer with which the pharmacy benefit manager had a contract:

(i) the total value of all rebates attributable to the insurer's enrollees;

(ii) the total value of administrative fees attributable to the insurer's enrollees; and

(iii) the percentage of rebates retained by the pharmacy benefit manager.

(2) Records submitted to the commissioner under [~~Subsections~~] Subsection (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)[~~(c)~~](b) in the annual report described in Section 31A-2-201.2.

(b) The department may not publish information:

(i) submitted under Subsection (1)(b) [~~or (c)~~] in a manner that:

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

[~~(ii)~~] (B) is likely to disclose information that is a trade secret as defined in Section 13-24-2[-]; or

(ii) submitted under Subsection (1)(a).

(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 5. Section **31A-46-302** is amended to read:

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.

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

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

(i) received by a pharmacy from a pharmacy 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.

(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.

[~~(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 benefit manager on behalf of the pharmacy; and~~]

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

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

(i) a pharmacy services administration organization; or

(ii) a pharmacy benefit manager.

[~~(h)~~] (g) (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.

[~~(i)~~] (h) "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 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 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 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;

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

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

(d) the retail price of the drug without prescription drug coverage.

Section 6. Section **31A-46-305** is enacted to read:

31A-46-305. Reporting of rebates.

(1) Upon the request of a health insurer, a pharmacy benefit manager shall annually report to the health insurer:

(a) the amount of rebates received by the pharmacy benefit manager that are attributable to enrollees of the health insurer's health benefit plans; and

(b) the amount of rebates described in Subsection (1)(a) that the pharmacy benefit manager passes on to the health insurer.

(2) Upon the request of a health insurer, a pharmacy services administration organization shall annually report to the health insurer:

(a) the amount of rebates received by the pharmacy services administration organization that are attributable to enrollees of the health insurer's health benefit plans during the previous plan year; and

(b) the amount of rebates described in Subsection (2)(a) that the pharmacy services administration organization passes on to the health insurer.

Section 7. Section **31A-46-306** is enacted to read:

31A-46-306. Enrollee cost sharing -- Safe harbor -- Rulemaking.

(1) As used in this section, "health care provider" means a person that:

(a) meets the definition of a health care provider as defined in Section 78B-3-403; and

(b) is licensed under this title.

(2) Except as provided in Subsection (3), a health care provider or a pharmaceutical manufacturer may not waive or offer to waive, provide a rebate for, or pay all or a portion of an enrollee's deductible, copayment, or coinsurance owed under the enrollee's health benefit plan.

(3) Subsection (2) does not apply to a waiver or offer to waive, a rebate, a gift, a payment for, or other offer that falls within a safe harbor:

(a) under federal laws related to fraud and abuse regarding patient cost sharing, including federal laws related to anti-kickback, self-referral, false claims, or civil monetary penalties; or

(b) described in an advisory opinion issued by the Centers for Medicare and Medicaid Services or the United States Department of Health and Human Services Office of Inspector General related to a federal law described in Subsection (3)(a).

(4) The department shall makes rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to implement this section.

Section 8. Section **31A-47-101** is enacted to read:

CHAPTER 47. PRESCRIPTION DRUG PRICE TRANSPARENCY ACT

31A-47-101. Title.

This chapter is known as "Prescription Drug Price Transparency Act."

Section 9. Section **31A-47-102** is enacted to read:

31A-47-102. Definitions.

As used in this chapter:

(1) "Drug" means a prescription drug, as defined in Section 58-17b-102.

(2) "Health insurer" means:

(a) an insurer that offers health care insurance;

(b) the Public Employees' Benefit and Insurance Program created in Section 49-20-103; or

(c) a workers' compensation insurer that is:

(i) authorized to provide workers' compensation insurance in the state; or

(ii) a self-insured employer as defined in Section 34A-2-201.5.

(3) "Manufacturer" means a person that is engaged in the manufacturing of a drug that is available for purchase by residents of the state.

(4) "Pharmacy benefit manager" means the same as that term is defined in Section 31A-46-102.

(5) "Purchaser" means a:

(a) health insurer;

(b) pharmacy service entity as defined in Section 31A-46-302; or

(c) department, division, or other agency or instrumentality of the state, including an independent state agency as defined in Section 63E-1-102.

(6) "Wholesale acquisition cost" means the same as that term is defined in 42 U.S.C. Sec. 1395w-3a.

Section 10. Section **31A-47-103** is enacted to read:

31A-47-103. Prescription drug spending reports to department -- Department report.

(1) As used in this section:

(a) "Pharmacy services administration organization" means the same as that term is defined in Section 31A-46-102.

(b) "Post-rebate spending" means the net amount spent by an insurer for coverage of a drug, after deduction of associated rebates paid to the insurer by a pharmacy benefit manager.

(c) "Total post-rebate spending" means the sum of post-rebate spending for a specific drug across all health benefit plans offered by an insurer.

(2) (a) Subject to Subsection (2)(b), an insurer shall report to the department no later than May 1 each year the following information for each drug covered by one or more health benefit plans offered by the insurer on or after January 1, 2020:

(i) the name of the drug;

(ii) the dosage form of the drug;

(iii) the strength of the drug;

(iv) total post-rebate spending; and

(v) the percentage calculated by dividing the amount in Subsection (2)(a)(iv) by total premiums received by the insurer for health benefit plans that:

(A) are offered by the insurer; and

(B) cover the drug.

(b) The report under Subsection (2)(a) is limited to the following drugs covered by the insurer during the preceding health benefit plan year:

(i) the 25 drugs for which total post-rebate spending is the greatest; and

(ii) the 25 drugs for which total post-rebate spending increased the most since the previous health benefit plan year.

(3) (a) Subject to Subsection (3)(b), if a pharmacy benefit manager purchases drugs, the pharmacy benefit manager shall report to the department no later than May 1 each year the following information for each drug purchased by the pharmacy benefit manager during the preceding calendar year:

(i) the name of the drug;

(ii) the dosage form of the drug;

(iii) the strength of the drug; and

(iv) the total amount spent by the pharmacy benefit manager for purchases of the drug:

(A) prior to the deduction of rebates applicable to the drug; and

(B) after the deduction of rebates that are applicable to the drug and retained by the pharmacy benefit manager.

(b) The report under Subsection (3)(a) is limited to:

(i) the 25 drugs for which spending by the pharmacy benefit manager is the greatest, after the deduction of rebates that are applicable to the drug and retained by the pharmacy benefit manager; and

(ii) the 25 drugs for which spending by the pharmacy benefit manager increased the most since the previous year, after the deduction of rebates that are applicable to the drug and retained by the pharmacy benefit manager.

(4) (a) Subject to Subsection (4)(b), if a pharmacy services administration organization purchases drugs, the pharmacy services administration organization shall report to the department no later than May 1 each year the following information for each drug purchased by the pharmacy services administration organization during the preceding calendar year:

(i) the name of the drug;

(ii) the dosage form of the drug;

(iii) the strength of the drug; and

(iv) the total amount spent by the pharmacy services administration organization for purchases of the drug:

(A) prior to the deduction of any applicable refunds, discounts, or other price concessions received by the pharmacy services administration organization; and

(B) after the deduction of any applicable refunds, discounts, or other price concessions received and retained by the pharmacy services administration organization.

(b) The report under Subsection (4)(a) is limited to:

(i) the 25 drugs for which spending by the pharmacy services administration organization is the greatest, after the deduction of any applicable refunds, discounts, or other price concessions received and retained by the pharmacy services administration organization; and

(ii) the 25 drugs for which spending by the pharmacy services administration organization increased the most since the previous year, after the deduction of any applicable refunds, discounts, or other price concessions received and retained by the pharmacy services administration organization.

(5) (a) Subject to Subsection (5)(b), a wholesaler or distributor shall report to the department no later than May 1 each year the following information for each drug purchased by the wholesaler or distributor during the preceding calendar year for distribution or delivery in the state:

(i) the name of the drug;

(ii) the dosage form of the drug;

(iii) the strength of the drug; and

(iv) the total amount spent by the wholesaler or distributor for purchases of the drug:

(A) prior to the deduction of any applicable refunds, discounts, or other price concessions received by the wholesaler or distributor; and

(B) after the deduction of any applicable refunds, discounts, or other price concessions received by the wholesaler or distributor.

(b) The report under Subsection (5)(a) is limited to:

(i) the 25 drugs for which spending by the wholesaler or distributor is the greatest, after the deduction of any applicable refunds, discounts, or other price concessions received by the wholesaler or distributor; and

(ii) the 25 drugs for which spending by the wholesaler or distributor increased the most since the previous year, after the deduction of any applicable refunds, discounts, or other price concessions received by the wholesaler or distributor.

(6) (a) Subject to Subsection (6)(b), a retail pharmacy shall report to the department no later than May 1 each year the following information for each drug purchased by the retail pharmacy during the preceding calendar year:

(i) the name of the drug;

(ii) the dosage form of the drug;

(iii) the strength of the drug; and

(iv) the total amount spent by the retail pharmacy for purchases of the drug:

(A) prior to the deduction of any applicable refunds, discounts, or other price concessions received by the retail pharmacy; and

(B) after the deduction of any applicable refunds, discounts, or other price concessions received by the retail pharmacy.

(b) The report under Subsection (6)(a) is limited to:

(i) the 25 drugs for which spending by the retail pharmacy is the greatest, after the deduction of any applicable refunds, discounts, or other price concessions received by the retail pharmacy; and

(ii) the 25 drugs for which spending by the retail pharmacy increased the most since the previous year, after the deduction of any applicable refunds, discounts, or other price concessions received by the retail pharmacy.

(7) (a) Before July 1 each year, the department shall prepare and publish on the department's website a report based on the information received under Subsections (2) through (6).

(b) The report shall be published in a manner that does not permit the identification of one or more:

(i) insurers;

(ii) pharmacy benefit managers;

(iii) pharmacy services administration organizations;

(iv) pharmaceutical wholesalers or distributors; or

(v) pharmacies.

(c) The report shall include current-year data and identify multi-year trends regarding:

(i) insurer post-rebate spending on individual drugs;

(ii) insurer post-rebate spending on individual drugs as a percentage of premiums;

(iii) pharmacy benefit manager spending on individual drugs and the retention of rebates;

(iv) pharmacy services administration organization spending on individual drugs and

the retention of applicable refunds, discounts, or other price concessions;

(v) wholesaler or distributor spending on individual drugs; and

(vi) pharmacy spending on individual drugs.

(8) Except for information published by the department under Subsection (7), information reported to the department under Subsections (2) through (6) is a protected record under Title 63G, Chapter 2, Government Records Access and Management Act.

Section 11. Section **31A-47-104** is enacted to read:

31A-47-104. Manufacturer notice of drug cost increase.

(1) As used in this section:

(a) (i) "Qualified drug" means a drug whose wholesale acquisition cost increases 10% or more over a 12-month period.

(ii) "Qualified drug" does not include a new drug introduced into the market by a manufacturer.

(b) "Registered purchaser" means a purchaser that submits a request for notice to the department under Subsection 31A-47-106(2)(b).

(c) "Research and development costs" means all expenses and expenditures by a manufacturer that are:

(i) incurred during a calendar year; and

(ii) related to the research and development of a new product, process, or service, including the acquisition of a license.

(2) A manufacturer shall send a notice in accordance with this section for each qualified drug no later than 60 days before the day on which the increase to the wholesale acquisition cost of the qualified drug results in a one-year percentage increase greater than or equal to 10%.

(3) A manufacturer shall send a notice to each registered purchaser that includes:

(a) the date on which the wholesale acquisition cost of the qualified drug will increase;

(b) a description of any improvements or other changes to the qualified drug that makes the increase in the wholesale acquisition cost of the qualified drug necessary;

(c) the wholesale acquisition cost of the qualified drug after the increase to the wholesale acquisition cost;

(d) the amount of the increase to the wholesale acquisition cost of the qualified drug;

(e) the percentage increase to the wholesale acquisition cost of the qualified drug;

(f) the wholesale acquisition cost of the qualified drug 12 months before the date of the increase to the wholesale acquisition cost of the qualified drug;

(g) the amount of the increase in the wholesale acquisition cost over the 12-month period immediately before the increase in the wholesale acquisition cost of the qualified drug; and

(h) the percentage increase in the wholesale acquisition cost of the qualified drug over the 12-month period immediately before the increase in the wholesale acquisition cost of the qualified drug.

(4) Except as provided in Subsection (5), a manufacturer shall send a notice to the department that includes:

(a) the information described in Subsection (3);

(b) an explanation of how financial and nonfinancial factors justify the increase in the wholesale acquisition cost of the qualified drug, including any improvement or other modification of the qualified drug;

(c) (i) for a qualified drug that has been manufactured by the manufacturer for longer than the previous five years:

(A) the wholesale acquisition cost of the qualified drug over the previous five-year period;

(B) for each of the previous five years, the research and development costs of the drug; and

(C) for each of the previous five years, all other costs incurred by the manufacturer for the manufacturing and marketing of the drug; or

(ii) for a qualified drug that has been manufactured by the manufacturer for less than five years:

(A) the date on which the manufacturer began manufacturing the qualified drug;

(B) the date on which the manufacturer began selling the qualified drug;

(C) the wholesale acquisition cost of the qualified drug over the period beginning on the day on which the manufacturer began selling the qualified drug;

(D) for each of the previous five years, the research and development costs of the drug; and

(E) for each of the previous five years, all other costs incurred by the manufacturer for the manufacturing and marketing of the drug; and

(d) for a qualified drug that the manufacturer acquired the right to manufacture within the previous five years, to the extent the information is publicly available:

(i) the name of the person from which the manufacturer acquired the right to manufacture the qualified drug;

(ii) the wholesale acquisition cost of the qualified drug immediately before the manufacturer acquired the right to manufacture the qualified drug; and

(iii) the wholesale acquisition cost of the qualified drug one year before the day on which the manufacturer acquired the right to manufacture the qualified drug.

(5) A manufacturer is not required to report a trade secret as defined in Section 13-24-2, in the notice to the department under Subsection (4).

Section 12. Section **31A-47-105** is enacted to read:

31A-47-105. Manufacturer submission of new drug information to the department -- Report of new drug.

If a new drug available for purchase by residents of the state has a wholesale acquisition cost that exceeds the upper limit of payment for the new drug under 42 C.F.R. Sec. 447.512, the manufacturer of the new drug shall submit to the department:

(1) no later than three days after the day on which the new drug is sold in the state, a written notice of the introduction of the new drug; and

(2) no later than 30 days after the day on which the new drug is sold in the state, a report that includes publicly available information regarding:

(a) the wholesale acquisition cost of the new drug;

(b) a description of the marketing and pricing plans used in the launch of the new drug:

(i) in the United States; and

(ii) outside of the United States;

(c) the estimated number of patients that are expected to be prescribed the new drug;

(d) whether the new drug was granted breakthrough therapy designation or priority review by the United States Food and Drug Administration; and

(e) if the manufacturer did not develop the drug, the acquisition date and price for the new drug.

Section 13. Section **31A-47-106** is enacted to read:

31A-47-106. Publication of information submitted to the department -- Rulemaking -- Penalties.

(1) The department shall publish on the department's website the information submitted by a manufacturer under Sections 31A-47-104 and 31A-47-105 no later than 60 days after the day on which the department receives the information from the manufacturer.

(2) The department shall make rules in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, regarding:

(a) the format for a manufacturer to submit a notice under Sections 31A-47-104 and 31A-47-105;

(b) procedures for a purchaser to register to receive notice of a drug price increase as a registered purchaser under Section 31A-47-104; and

(c) procedures for a manufacturer to obtain the contact information for each registered purchaser.

(3) The department may impose a penalty of up to $1,000 per day for each day a manufacturer is in violation of this chapter.

Section 14. Section **31A-47-107** is enacted to read:

31A-47-107. Patient assistance program -- Report of contributions.

(1) As used in this section:

(a) "Applicable entity" means:

(i) a health insurer;

(ii) a manufacturer;

(iii) a pharmacy benefit manager; or

(iv) a trade or advocacy organization for an entity described in Subsections (1)(a)(i) through (iii).

(b) "Contribution" means money, donations, loans, subsidies, or any other consideration of value.

(c) "Gross income" means the sum of income and the fair value of any other contributions received by a patient assistance program from an applicable entity.

(d) "Patient assistance program" means a program that is offered by an independent nonprofit organization that:

(i) advocates on behalf of patients in the state;

(ii) funds medical research in the state;

(iii) reduces consumer out-of-pocket costs of a drug; or

(iv) provides grants to defray medical expenses.

(2) On or before February 1 each year, a patient assistance program shall prepare a report for the preceding calendar year that lists:

(a) for each contribution received by the patient assistance program from an applicable entity:

(i) the amount of the contribution; and

(ii) the applicable entity from which the patient assistance program received the contribution; and

(b) for each applicable entity from which the patient assistance program received a contribution, the percentage of the patient assistant program's gross income attributable to contributions from the applicable entity.

(3) (a) Except as provided in Subsection (3)(b), a patient assistance program shall post the report described in Subsection (2) to a publicly accessible website maintained by the patient assistance program.

(b) If the patient assistance program does not maintain a publicly accessible website:

(i) the patient assistance program shall submit the report to the department; and

(ii) the department shall post the report to the department's website.

Section 15. Section **31A-47-108** is enacted to read:

31A-47-108. Report to Legislature.

The department shall report to the Business and Labor Interim Committee and the Health and Human Services Interim Committee before October 1, 2022, on the implementation of this chapter, including the effectiveness of the provisions of this chapter in:

(1) promoting pharmaceutical pricing transparency;

(2) enhancing understanding of pharmaceutical spending trends; and

(3) assisting the state and other payers of health care services in the management of pharmaceutical spending.

Section 16. Section **58-17b-605** is amended to read:

58-17b-605. Drug product equivalents.

(1) For the purposes of this section:

(a) (i) "Drug" [~~is as~~] means the same as that term is defined in Section 58-17b-102.

(ii) "Drug" does not [~~mean~~] include a "biological product" as defined in Section 58-17b-605.5.

(b) "Drug product equivalent" means a drug product that is designated as the therapeutic equivalent of another drug product in the Approved Drug Products with Therapeutic Equivalence Evaluations prepared by the Center for Drug Evaluation and Research of the United States Food and Drug Administration.

(2) A pharmacist or pharmacy intern dispensing a prescription order for a specific drug by brand or proprietary name [~~may~~] shall substitute a drug product equivalent for the prescribed drug [~~only~~] if:

[~~(a) the purchaser specifically requests or consents to the substitution of a drug product equivalent;~~]

[~~(b)~~] (a) the drug product equivalent is of the same generic type and is designated the therapeutic equivalent in the approved drug products with therapeutic equivalence evaluations prepared by the Center for Drug Evaluation and Research of the Federal Food and Drug Administration;

[~~(c)~~] (b) the drug product equivalent is permitted to move in interstate commerce;

[~~(d)~~] (c) the pharmacist or pharmacy intern counsels the patient on the use and the expected response to the prescribed drug, whether a substitute or not, and the substitution is not otherwise prohibited by this chapter;

[~~(e)~~] (d) the prescribing practitioner has not indicated that a drug product equivalent may not be substituted for the drug, as provided in Subsection [~~(6)~~] (5); and

[~~(f)~~] (e) the substitution is not otherwise prohibited by law.

(3) (a) Each out-of-state mail service pharmacy dispensing a drug product equivalent as a substitute for another drug into this state shall notify the patient of the substitution either by telephone or in writing.

(b) Each out-of-state mail service pharmacy shall comply with the requirements of this chapter with respect to a drug product equivalent substituted for another drug, including labeling and record keeping.

[~~(4) Pharmacists or pharmacy interns may not substitute without the prescriber's~~

~~authorization on trade name drug product prescriptions unless the product is currently categorized in the approved drug products with therapeutic equivalence evaluations prepared by the Center for Drug Evaluation and Research of the Federal Food and Drug Administration as a drug product considered to be therapeutically equivalent to another drug product.~~]

[~~(5)~~] (4) A pharmacist or pharmacy intern who dispenses a prescription with a drug product equivalent under this section assumes no greater liability than would be incurred had the pharmacist or pharmacy intern dispensed the prescription with the drug product prescribed.

[~~(6)~~] (5) (a) If, in the opinion of the prescribing practitioner, it is in the best interest of the patient that a drug product equivalent not be substituted for a prescribed drug, the practitioner may indicate a prohibition on substitution either by writing "dispense as written" or signing in the appropriate space where two lines have been preprinted on a prescription order and captioned "dispense as written" or "substitution permitted".

(b) If the prescription is communicated orally by the prescribing practitioner to the pharmacist or pharmacy intern, the practitioner shall indicate the prohibition on substitution and that indication shall be noted in writing by the pharmacist or pharmacy intern with the name of the practitioner and the words "orally by" and the initials of the pharmacist or pharmacy intern written after it.

[~~(7)~~] (6) A pharmacist or pharmacy intern who substitutes a drug product equivalent for a prescribed drug shall communicate the substitution to the purchaser. The drug product equivalent container shall be labeled with the name of the drug dispensed, and the pharmacist, pharmacy intern, or pharmacy technician shall indicate on the file copy of the prescription both the name of the prescribed drug and the name of the drug product equivalent dispensed in its place.

[~~(8)~~] (7) (a) For purposes of this Subsection [~~(8)~~] (7), "substitutes" means to substitute:

(i) a generic drug for another generic drug;

(ii) a generic drug for a nongeneric drug;

(iii) a nongeneric drug for another nongeneric drug; or

(iv) a nongeneric drug for a generic drug.

(b) A prescribing practitioner who makes a finding under Subsection [~~(6)~~] (5)(a) for a patient with a seizure disorder shall indicate a prohibition on substitution of a drug product equivalent in the manner provided in Subsection [~~(6)~~] (5)(a) or (b).

(c) Except as provided in Subsection [~~(8)~~] (7)(d), a pharmacist or pharmacy intern who cannot dispense the prescribed drug as written, and who needs to substitute a drug product equivalent for the drug prescribed to the patient to treat or prevent seizures shall notify the prescribing practitioner prior to the substitution.

(d) Notification under Subsection [~~(8)~~] (7)(c) is not required if the drug product equivalent is paid for in whole or in part by Medicaid.

[~~(9)~~] (8) Failure of a licensed medical practitioner to specify that no substitution is authorized does not constitute evidence of negligence.

Section 17. Section **58-17b-605.5** is amended to read:

58-17b-605.5. Interchangeable biological products.

(1) For the purposes of this section:

(a) "Biological product" means the same as that term is defined in 42 U.S.C. Sec. 262.

(b) "Interchangeable biological product" means a biological product that the federal Food and Drug Administration:

(i) has:

(A) licensed; and

(B) determined meets the standards for interchangeability pursuant to 42 U.S.C. Sec. 262(k)(4); or

(ii) has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations.

(2) A pharmacist or pharmacy intern dispensing a prescription order for a specific biological product by brand or proprietary name [~~may~~] shall substitute an interchangeable biological product for the prescribed biological product [~~only~~] if:

[~~(a) the purchaser specifically requests or consents to the substitute of an interchangeable biological product;~~]

[~~(b)~~] (a) the interchangeable biological product is permitted to move in interstate commerce;

[~~(c)~~] (b) the pharmacist or pharmacy intern counsels the patient on the use and the expected response to the prescribed biological product, whether a substitute or not, and the substitution is not otherwise prohibited by this chapter;

[~~(d)~~] (c) the prescribing practitioner has not prohibited the substitution of an interchangeable biological product for the prescribed biological product, as provided in Subsection (6); and

[~~(c)~~] (d) the substitution is not otherwise prohibited by law.

(3) Each out-of-state mail service pharmacy dispensing an interchangeable biological product as a substitute for another biological product into this state shall:

(a) notify the patient of the substitution either by telephone or in writing; and

(b) comply with the requirements of this chapter with respect to an interchangeable biological product substituted for another biological product, including labeling and record keeping.

(4) Pharmacists or pharmacy interns may not substitute without the prescriber's authorization biological product prescriptions unless the product has been determined by the United States Food and Drug Administration to be interchangeable with the prescribed biological product.

(5) A pharmacist or pharmacy intern who dispenses a prescription with an interchangeable biological product under this section assumes no greater liability than would be incurred had the pharmacist or pharmacy intern dispensed the prescription with the biological product prescribed.

(6) (a) If, in the opinion of the prescribing practitioner, it is in the best interest of the patient that an interchangeable biological product not be substituted for a prescribed biological product, the practitioner may prohibit a substitution either by writing "dispense as written" or by signing in the appropriate space where two lines have been preprinted on a prescription order and captioned "dispense as written" or "substitution permitted."

(b) (i) If the prescription is communicated orally by the prescribing practitioner to the pharmacist or pharmacy intern, the practitioner shall direct the prohibition or substitution.

(ii) The pharmacist or pharmacy intern shall make a written note of the practioner's direction by writing the name of the practitioner and the words "orally by" and the initials of the pharmacist or pharmacy intern written after it.

(7) A pharmacist or pharmacy intern who substitutes an interchangeable biological product for a prescribed biological product shall communicate the substitution to the purchaser. The interchangeable biological product container shall be labeled with the name of the

interchangeable biological product dispensed, and the pharmacist, pharmacy intern, or pharmacy technician shall indicate on the file copy of the prescription both the name of the prescribed biological product and the name of the interchangeable biological product dispensed in its place.

[~~(8) Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry into an interoperable electronic medical records system, through an electronic prescribing technology, a pharmacy benefit management system, or a pharmacy record that is electronically accessible by the prescriber. Entry into an electronic records system as described in this Subsection (8) is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:~~]

[~~(a) there is no FDA-approved interchangeable biological product for the product prescribed;~~]

[~~(b) a refill prescription is not changed from the product dispensed on the prior filling of the prescription; or~~]

[~~(c) the product is paid for using cash or cash equivalent.~~]

Section 18. Section **58-17c-101** is enacted to read:

CHAPTER 17c. PHARMACEUTICAL DEVELOPMENT AND MARKETING ACT

58-17c-101. Title.

This chapter is known as "Pharmaceutical Development and Marketing Act."

Section 19. Section **58-17c-102** is enacted to read:

58-17c-102. Definitions.

As used in this chapter:

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

(2) "Health care entity" means:

(a) a health care provider;

(b) a health care facility as that term is defined in Section 26-21-2; or

(c) a pharmacy.

(3) "Health care provider" means a person that:

(a) meets the definition of a health care provider as defined in Section 78B-3-403; and

(b) is licensed under this title.

(4) "Pharmaceutical manufacturer" means a person that is engaged in the manufacturing of a drug or pharmaceutical device that is available for purchase by residents of the state.

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

(6) "Prescription drug marketing" means providing to a health care entity, on behalf of a pharmaceutical manufacturer, educational or marketing information or materials regarding a drug that is available to a resident of the state, including through:

(a) a face-to-face meeting;

(b) a physical mailing;

(c) a telephone conversation;

(d) electronic mail or facsimile; or

(e) an event.

Section 20. Section **58-17c-103** is enacted to read:

58-17c-103. Availability of drug for testing -- Limits on prices -- Liability exemption -- Enforcement -- Rulemaking.

(1) As used in this section:

(a) "Application" means an application for:

(i) the approval of a drug under 21 U.S.C. Sec. 355(a); or

(ii) the licensing of a biological product under 42 U.S.C. Sec. 262(a)(1).

(b) "Developer" means a person seeking to submit an application.

(c) "Pharmaceutical wholesaler or distributor" means the same as that term is defined in Section 58-17b-102.

(d) "Wholesale acquisition cost" means the same as that term is defined in 42 U.S.C. Sec. 1395w-3a.

(2) (a) In accordance with Subsection (2)(b), a pharmaceutical manufacturer or a pharmaceutical wholesaler or distributor shall, for a developer, make available for sale a drug distributed in the state for the purpose of conducting testing required to support the application.

(b) A pharmaceutical manufacturer or a pharmaceutical wholesaler or distributor shall

make the drug available for sale under Subsection (2)(a):

(i) at a price no higher than the drug's wholesale acquisition cost; and

(ii) without any restriction that would block or delay the application.

(3) A developer that buys a drug made available for sale in accordance with Subsection (2) may not charge a consumer a price for the drug higher than the price for which the developer bought the drug.

(4) A pharmaceutical manufacturer or a pharmaceutical wholesaler or distributor that makes available a drug for sale under Subsection (2)(a) is not liable for a claim arising out of the failure of a developer that buys the drug to follow adequate safeguards to ensure safe use of the drug during the testing described in Subsection (2)(a), including:

(a) transportation;

(b) handling;

(c) use; or

(d) disposal of the drug.

(5) (a) Notwithstanding any other provision of law, the attorney general may seek injunctive relief against a pharmaceutical manufacturer or a pharmaceutical wholesaler or distributor that violates the provisions of this section.

(b) If the attorney general prevails in an action described in Subsection (5)(a), the court shall order the pharmaceutical manufacturer or the pharmaceutical wholesaler or distributor to pay the attorney general's investigative costs, court costs, and attorney fees.

(6) The division shall make rules as necessary, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to implement this section.

Section 21. Section **58-17c-104** is enacted to read:

58-17c-104. Manufacturer reporting of sales representatives -- Sales representative reporting -- Division report -- Rulemaking.

(1) As used in this section:

(a) "Compensation" means the total payment or transfer of value provided by a pharmaceutical sales representative to a health care entity.

(b) "Pharmaceutical sales representative" means an individual who engages in prescription drug marketing to a health care entity.

(2) A pharmaceutical manufacturer shall provide to the division each month a list of all

pharmaceutical sales representatives that the pharmaceutical manufacturer employs or has a contract with to engage in prescription drug marketing.

(3) The division shall provide to a health care entity electronic access to the lists described in Subsection (2).

(4) A pharmaceutical sales representative on a list described in Subsection (2):

(a) may engage, on behalf of any pharmaceutical manufacturer, in prescription drug marketing to any health care entity; and

(b) shall, on or before March 1 each year, submit to the division a report for the immediately preceding calendar year that includes:

(i) a list of all health care entities to which the pharmaceutical sales representative provided:

(A) compensation by an individual transaction of $10 or more; or

(B) compensation for the year totaling a fair market value of $100 or more;

(ii) the name and pharmaceutical manufacturer of each drug of which the pharmaceutical sales representative provided a free sample to a health care entity; and

(iii) the name of each health care entity to which the pharmaceutical manufacturer provided a free sample of a drug.

(5) (a) The division shall develop an annual report, based on the reports to the division described in this section, that includes an analysis of the activities of pharmaceutical sales representatives in the state.

(b) The annual report shall include:

(i) the names of all pharmaceutical sales representatives included on any list described in Subsection (2);

(ii) the names of all pharmaceutical manufacturers that provide to the division a list described in Subsection (2);

(iii) the names of all drugs described in Subsection (4)(b)(ii); and

(iv) the number of health care entities described in Subsection (4)(b)(i).

(c) On or before June 1 of each year, the division shall:

(i) post the annual report on the division's website; and

(ii) submit the annual report to the governor and the Business and Labor Interim Committee.

(6) The division shall make rules as necessary, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to implement this section.

(7) The division may assess a pharmaceutical manufacturer or a pharmaceutical sales representative a fine of up to $10,000 for each violation of this section.

Section 22. Section **58-17c-105** is enacted to read:

58-17c-105. Written materials for prescription drug marketing -- Rulemaking.

(1) A person that engages in prescription drug marketing to a health care provider with the intent that the health care provider prescribe the drug for use by the health care provider's patients shall provide to the health care provider written materials that include:

(a) the date the written materials were prepared;

(b) the name of the drug;

(c) the name of the pharmaceutical manufacturer that manufactures the drug;

(d) the average wholesale price of the drug for each labeled indication, including any differences in the average wholesale price as a result of different strengths or dosage forms approved for sale; and

(e) (i) if the drug is designed to be administered for 30 days or more, the average wholesale price of a 30-day supply of the drug; or

(ii) if the drug is designed to be administered for less than 30 days, the average wholesale price of a supply for the period of time for which the drug is designed to be administered.

(2) A person shall provide to a health care provider all of the written materials required by Subsection (1) no later than the earlier of:

(a) the time the person provides any written materials to the health care provider while engaging in prescription drug marketing regarding the drug; or

(b) one business day after engaging in prescription drug marketing regarding the drug.

(3) The division shall make rules as necessary, in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, to implement this section.