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S.B. 223

PHARMACEUTICAL ENTITY TRANSPARENCY ACT

2019 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Kirk A. Cullimore

House Sponsor: Norman K. Thurston

LONG TITLE

General Description:

This bill enacts and amends provisions related to prescription drugs.

Highlighted Provisions:

This bill:

- defines terms;
- amends provisions related to the information an insurer and health benefit plan must provide to an enrollee or prospective enrollee, including information regarding formulary changes;
- removes provisions related to a pharmacy benefit manager's registration with the Department of Commerce;
- requires a pharmacy benefit manager to be licensed by the Insurance Department to conduct business in the state;
- requires reports by certain entities to the Insurance Department regarding the impact of costs of prescription drugs, including information on the costliest drugs and drugs with high increases in spending;
- requires a pharmacy benefit manager to report certain information to a health insurer or plan sponsor regarding drug utilization payments;
- requires pharmaceutical manufacturers to report certain information related to prescription drug price increases and introduction;
- requires a patient assistance program to report certain information related to

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contributions from certain entities;

- requires other reports related to prescription drugs;
- enacts provisions regarding inducement related to health care services;
- amends provisions related to a pharmacist substituting a prescription drug;
- enacts provisions related to prescription drug marketing;
- enacts provisions related to testing a prescription drug for federal approval;
- provides rulemaking authority; and
- makes technical and conforming changes.

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 2017, Chapters 241 and 292

31A-22-640, as last amended by Laws of Utah 2015, Chapter 258

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-46-101, Utah Code Annotated 1953

31A-46-102, Utah Code Annotated 1953

31A-46-103, Utah Code Annotated 1953

31A-46-104, Utah Code Annotated 1953

31A-46-105, Utah Code Annotated 1953

31A-46-106, Utah Code Annotated 1953

31A-46-107, Utah Code Annotated 1953

31A-46-108, Utah Code Annotated 1953

31A-46-109, Utah Code Annotated 1953

31A-46-110, Utah Code Annotated 1953

31A-46-111, Utah Code Annotated 1953

31A-46-112, Utah Code Annotated 1953

31A-46-113, 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~~], coinsurance, deductibles, and cost-sharing information for prescription drugs; and

(iii) requirements for generic substitution;

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

(c) a description of how an enrollee or prospective enrollee can access information regarding, if applicable:

(i) whether a prescription drug is preferred under the health benefit plan;

(ii) a prescription drug's formulary tier;

(iii) any prior authorization, step therapy, quantity limit, pharmacy restriction, or other pharmaceutical benefit management program limitation on access to a prescription drug under

the health plan;

[~~(b)~~] (d) coverage limits under the plan;

[~~(c)~~] (e) 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)~~] (f) 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

[~~(e)~~] (g) 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)(a)(i) 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;~~]

(i) a copy of the formulary;

(ii) the prescription drugs included on the formularly, including information on each prescription drug covered under the health benefit plan's prescription drug benefit or outpatient medical benefit that is administered in an outpatient setting:

(A) by a health professional; or

(B) under a health professional's direct supervision;

[~~(ii)~~] (iii) the patented drugs not included;

(iv) information regarding the extent to which cost-sharing varies depending on the supply of a drug on the formulary;

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

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

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

(ii) Examples of a limitation or exclusion of coverage provided under Subsection (2)[~~(c)~~](e) 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.

(5) (a) An insurer that offers a health benefit plan in the state shall make the health benefit plan's formulary and other prescription drug benefit information, as determined by the department:

(i) easily accessible to an enrollee or a prospective enrollee; and

(ii) searchable by health benefit plan type and name.

(b) An insurer may not require an enrollee or a prospective enrollee to provide an account, a plan, or a policy number to access the information described in Subsection (5)(a).

(6) An insurer that offers a health benefit plan in the state shall annually report to the department for each of the insurer's health benefit plans:

(a) the percentage of prescription drug prior authorization requests that the health benefit plan denied out of the total requests the health benefit plan received over the prior

calendar year;

(b) the percentage of prior authorization appeals that the health benefit plan denied at each level of internal or external appeal out of the total appeals the health benefit plan adjudicated over the prior calendar year; and

(c) the maximum, minimum, and average number of hours that passed between an enrollee submitting a prior authorization request to the health benefit plan and the health benefit plan providing the enrollee with notice of a final decision, after accounting for any internal or external appeals.

(7) (a) An insurer or a health benefit plan shall provide notice as described in Subsection (7)(b) when it makes or approves a change in a formulary that:

(i) causes a prescription drug to no longer be covered on formulary;

(ii) applies a new or revised dose restriction that limits the doses of a prescription drug that are covered; or

(iii) applies a new or revised prior authorization, step therapy, quantity limit, or other pharmaceutical benefit management procedure or restriction on access to a prescription drug under the health benefit plan.

(b) An insurer or a health benefit plan shall ensure that a notice described in Subsection (7)(a) is provided to the following no later than 60 days before the insurer or health benefit plan approves the change described in Subsection (7)(a):

(i) all health benefit plan enrollees with a prescription for the prescription drug;

(ii) all in-network prescribers; and

(iii) all in-network pharmacies.

(8) When an insurer or health benefit plan makes or approves a change described in Subsection (7)(a), the insurer or health benefit plan shall provide an enrollee with a prescription drug affected by the change:

(a) for at least 60 days after providing the notice described in Subsection (7); or

(b) (i) for as long as the prescription drug is prescribed to the enrollee; and

(ii) under the same terms that applied before the change.

Section 2. Section **31A-22-640** is amended to read:

31A-22-640. 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 3. Section **31A-46-101** is enacted to read:

CHAPTER 46. PHARMACEUTICAL SUPPLY CHAIN

Part 1. Pharmaceutical Supply Chain Transparency

31A-46-101. Title.

This chapter is known as "Pharmaceutical Supply Chain."

Section 4. Section **31A-46-102** is enacted to read:

31A-46-102. Definitions.

As used in this part:

(1) "Course of therapy" means the recommended daily dosage units of a drug pursuant to the drug's prescribing label as approved by the United States Food and Drug Administration for:

(a) 30 days; or

(b) a normal course of treatment that is less than 30 days.

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

(3) "Drug utilization payment" means any direct or indirect financial payment by a pharmaceutical manufacturer to a person that results from the purchase or anticipated purchase of a drug, including:

(a) a rebate;

(b) a credit;

(c) a fee;

(d) a chargeback;

(e) a grant; or

(f) another item of value.

(4) "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 Title 58, Occupations and Professions.

(5) "Health insurer" means:

(a) an insurer that offers health care insurance as defined in Section 31A-1-301;

(b) for health benefits offered to state employees under Section 49-20-202, 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.

(6) "Large purchaser" means a purchaser that provides coverage to more than 500 lives.

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

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

(b) funds medical research in the state;

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

(d) provides grants to defray medical expenses.

(8) "Pharmaceutical manufacturer" means:

(a) a person that is engaged in the manufacturing of a drug or pharmaceutical device that is available for purchase by residents of the state; or

(b) a person that is responsible for setting the price of a drug that is available for purchase by residents of the state on behalf of a person described in Subsection (8)(a).

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

(10) "Pharmacy benefit manager" means the same as that term is defined in Section 31A-22-640.

(11) "Pharmacy services administrative organization" means a person that provides contracting and other administrative services to a pharmacy to assist the pharmacy in the

pharmacy's interaction, including reimbursement rate negotiations, with third-party payers, pharmacy benefit managers, drug wholesalers, and other entities.

(12) "Purchaser" means an insurance puchaser that is:

(a) (i) a state purchaser, including:

(A) the department;

(B) the Public Employees' Health Plan;

(C) the Department of Administrative Services;

(D) the State Board of Regents;

(E) the State Board of Education; and

(F) the Department of Corrections; or

(ii) an entity acting on behalf of a state purchaser;

(b) a health insurer; or

(c) a pharmacy benefit manager as defined in Section 58-17b-102.

(13) "Third party" means:

(a) a health insurer;

(b) a public agency or local governmental agency of the state that provides a system of health insurance for the agency's officers, the agency's employees, and dependents of the agency's officers and employees; or

(c) any other insurer or organization that provides health coverage or benefits in accordance with state or federal law.

(14) "Wholesale acquisition cost" means a pharmaceutical manufacturer's list price:

(a) for selling a brand-name or generic drug to a wholesaler or a direct purchaser in the United States;

(b) that is the list price:

(i) per person, either per year or per course of therapy; and

(ii) for the most recent month for which information is available; and

(c) that does not include any discounts or rebates.

Section 5. Section **31A-46-103** is enacted to read:

31A-46-103. Department licensure of pharmacy benefit manager.

(1) A pharmacy benefit manager may not conduct business in the state without a license issued by the department.

(2) In accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, the department shall establish licensure requirements for a pharmacy benefit manager to conduct business in the state.

Section 6. Section **31A-46-104** is enacted to read:

31A-46-104. Prescription drug reports to department -- Costliest drugs, drugs with high year-over-year increase in spending, impact of costs on premium rates -- Annual report -- Protected records.

(1) As used in this section, "drug cost information" means:

(a) the 25 costliest drugs by total net annual plan spending;

(b) the 25 drugs with the highest year-over-year increase in total annual plan spending; and

(c) the impact of the costs of drugs on premium rates.

(2) The following entities shall annually report drug cost information to the department:

(a) a health insurer regarding drugs reimbursed by the health insurer under policies issued in the state;

(b) a pharmacy benefit manager for all of the pharmacy benefit manager's contracted clients in aggregate;

(c) pharmaceutical wholesaler or distributor for all of the pharmaceutical wholesaler or distributor's contracted pharmacies in aggregate;

(d) a pharmacy services administrative organization regarding drugs at all pharmacies for which the pharmacy services administrative organization provides services; and

(e) a pharmacy regarding drugs the pharmacy dispenses.

(3) A pharmacy benefit manager shall annually report to the department for all of the pharmacy benefit manager's contracted clients in aggregate:

(a) the combined amount of rebates, discounts, and price concessions that the pharmacy benefit manager negotiates that are attributable to patient utilization under a plan; and

(b) the combined amount of the rebates, discounts, and price concessions described in Subsection (3)(a) that are passed through to the plan sponsor.

(4) (a) The department shall create an annual report using the reports described in this

section that demonstrates the overall impact of drug costs on health care premiums.

(b) The report described in Subsection (4)(a) shall include, using the data from the reports described in this section, an analysis that identifies:

(i) trends in drug pricing; and

(ii) the impact of pharmacy costs on premiums.

(c) The report:

(i) shall include aggregate data from the reports described in this section; and

(ii) may not include information that can be reasonably identified in relation to a specific:

(A) health insurer;

(B) pharmacy benefit manager;

(C) pharmaceutical wholesaler or distributor;

(D) pharmacy services administrative organization; or

(E) pharmacy.

(5) Except for the information in the annual report described in Subsection (4)(a), information submitted in a report to the department in accordance with this section is a protected record under Title 63G, Chapter 2, Government Records Access and Management Act.

Section 7. Section **31A-46-105** is enacted to read:

31A-46-105. Pharmaceutical manufacturer reports to department -- Annual report -- Protected records.

(1) As used in this section:

(a) "Rebate" means any rebate, discount, or other price concession that:

(i) a purchaser receives or expects to receive, directly or indirectly, from a pharmaceutical manufacturer; and

(ii) is related to utilization of a drug produced by the pharmaceutical manufacturer.

(b) "Research and development expenditures" means all costs that a pharmaceutical manufacturer incurs during a calendar year that relate to the research and development of a new product, process, or service, including a cost from obtaining a license.

(2) The department shall annually identify up to 25 drugs:

(a) (i) on which the state spends significant health care dollars, after accounting for

rebates; or

(ii) for which the wholesale acquisition cost has increased by 10% or more over the prior calendar year;

(b) that represent different drug classes; and

(c) that include generic drugs.

(3) For each drug identified under Subsection (2), the department shall require the pharmaceutical manufacturer of the drug to report to the department:

(a) the drug's wholesale acquisition cost increases over the previous five calendar years;

(b) a written description, for public release, of factors that contributed to the increases described in Subsection (3)(a); and

(c) for the most recent year for which final audited data are available, the pharmaceutical manufacturer's:

(i) aggregate research and development expenditures; and

(ii) other relevant expenditures in aggregate.

(4) The department shall establish:

(a) after consultation with pharmaceutical manufacturers, a format for reporting information described in this section;

(b) requirements related to the level and type of data for a report to the department described in this section; and

(c) annually publish on the department's website a report based on the information in the reports to the department described in this section.

(5) Except for the description described in Subsection (3)(b), information submitted in a report to the department in accordance with this section is a protected record under Title 63G, Chapter 2, Government Records Access and Management Act.

(6) Information in a report to the department described in this section is not subject to further regulation by a political subdivision of the state.

Section 8. Section **31A-46-106** is enacted to read:

31A-46-106. Reports to a health insurer or plan sponsor.

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

(a) the aggregate of all drug utilization payments received by the pharmacy benefit manager due to the health insurer's or plan sponsor's utilization; and

(b) the aggregate of all drug utilization payments described in Subsection (1)(a) that the pharmacy benefit manager passes on to the health insurer or the plan sponsor.

(2) Upon the request of a health insurer or a plan sponsor, a pharmacy services administrative organization shall annually report to the health insurer or plan sponsor:

(a) the aggregate of all drug utilization payments received by the pharmacy services administrative organization due to the health insurer's or plan sponsor's utilization; and

(b) the aggregate of all drug utilization payments described in Subsection (1)(a) that the pharmacy services administrative organization passes on to the health insurer or the plan sponsor.

Section 9. Section **31A-46-107** is enacted to read:

31A-46-107. Pharmaceutical manufacturer -- Advance notice of price increase to purchasers.

(1) A pharmaceutical manufacturer shall submit a notice to purchasers in accordance with Subsection (2) for a price increase of a drug that will result in an increase in the wholesale acquisition cost of the drug that is equal to:

(a) 10% or more in a year for a drug that has a wholesale acquisition cost of $150 to $1,000 for a course of therapy; or

(b) 5% or more in a year for a drug that has a wholesale acquisition cost of more than $1,000 for a course of therapy.

(2) A pharmaceutical manufacturer required to submit a notice under Subsection (1) shall:

(a) submit the notice in writing to each purchaser on the list described in Subsection (3) no later than 60 days before the day on which the price increase takes effect; and

(b) include in the notice, for each drug for which notice is required under Subsection (1):

(i) the increase in the price of the drug, expressed as:

(A) a percentage increase based on the price of the drug before the price increase; and

(B) the dollar amount of the increase;

(ii) the date on which the price increase takes effect;

(iii) the current wholesale acquisition cost of the drug; and

(iv) a description of the change or improvement in the drug, if any, that necessitates the price increase.

(3) The department shall:

(a) maintain a list of purchasers that register to receive a notice described in Subsection (1);

(b) determine how a purchaser may register to be placed on the list described in Subsection (3)(a); and

(c) make the list described in Subsection (3)(a) available to pharmaceutical manufacturers to provide the notice described in Subsection (1).

Section 10. Section **31A-46-108** is enacted to read:

31A-46-108. Pharmaceutical manufacturer -- Report of price increase to the department.

(1) A pharmaceutical manufacturer shall submit a report to the department in accordance with Subsection (2) for each price increase of a drug that is subject to the notice requirement described in Section 31A-46-107.

(2) Subject to Subsection (3), a pharmaceutical manufacturer required to submit a report under Subsection (1) shall:

(a) submit the report in writing to the department no later than 60 days before the day on which the price increase takes effect; and

(b) include in the report, for each drug for which a report is required under Subsection (1):

(i) the information about the increase in price described in Subsection 31A-46-107(2)(b)(i);

(ii) a description of the specific financial and nonfinancial factors used to make the decision to increase the wholesale acquisition cost of the drug, including:

(A) an explanation of how the factors explain the increase; and

(B) a description of the change or improvement in the drug, if any, that necessitates the price increase;

(iii) for a pharmaceutical manufacturer that has manufactured the drug for the previous five years, a schedule of wholesale acquisition cost increases for the drug for the previous five

years; and

(iv) for a pharmaceutical manufacturer that acquired the drug within the previous five years:

(A) the wholesale acquisition cost at the time of acquisition;

(B) the wholesale acquisition cost of the drug in the calendar year prior to acquisition;

(C) the name of the company from which the pharmaceutical manufacturer acquired the drug;

(D) the date on which the pharmaceutical manufacturer acquired the drug;

(E) the purchase price of the drug;

(F) the year in which the drug was introduced into the market; and

(G) the wholesale acquisition cost of the drug at the time the drug was introduced into the market.

(3) A pharmaceutical manufacturer is not required to report information described in Subsection (2) that is not publicly available.

(4) The department shall publish on the department's website a report the department receives under Subsection (1) no later than 60 days after the day on which the department receives the report.

(5) (a) The department may bring a civil action against a pharmaceutical manufacturer that violates this section.

(b) A pharmaceutical manufacturer that violates this section is liable for a penalty of $1,000 per day that the pharmaceutical manufacturer is in violation.

(c) A court may reduce or waive a penalty described in Subsection (5)(b) for good cause.

Section 11. Section **31A-46-109** is enacted to read:

31A-46-109. Pharmaceutical manufacturer -- Report of new prescription drug.

(1) A pharmaceutical manufacturer that introduces a new drug to market at a wholesale acquisition cost that exceeds the payment threshold for the drug as determined by the United States Food and Drug Administration under 42 C.F.R. Sec. 447.512 shall submit a written notice of the introduction to the department no later than three days after the day on which the pharmaceutical manufacturer introduces the new drug.

(2) Subject to Subsection (3), a pharmaceutical manufacturer that submits a

notification as described in Subsection (1) shall, no later than 30 days after the day on which the pharmaceutical manufacturer submits the notification, report to the department:

(a) the price of the drug;

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

(i) the launch of the drug in the United States; and

(ii) the launch of the drug internationally;

(c) the estimated number of patients that may be prescribed the drug;

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

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

(3) A pharmaceutical manufacturer is not required to report information described in Subsection (2) that is not publicly available.

(4) (a) The department shall publish on the department's website a report the department receives under Subsection (2) no later than 60 days after the day on which the department receives the report.

(b) The department shall ensure that the publication described in Subsection (4)(a) allows information to be separately identified for each drug for which a report is submitted.

(5) (a) The department may bring a civil action against a pharmaceutical manufacturer that violates this section.

(b) A pharmaceutical manufacturer that violates this section is liable for a penalty of $1,000 per day that the pharmaceutical manufacturer is in violation.

(c) A court may reduce or waive a penalty described in Subsection (5)(b) for good cause.

Section 12. Section **31A-46-110** is enacted to read:

31A-46-110. Patient assistance program -- Report of contributions.

(1) As used in this section:

(a) "Applicable entity" means:

(i) a pharmaceutical manufacturer;

(ii) a pharmacy benefit manager;

(iii) a third party; or

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

(b) "Contribution" means a payment, donation, subsidy, or any other contribution of value.

(2) (a) On or before February 1 each year, a patient assistance program that received a contribution from an applicable entity during the immediately preceding calendar year shall create a report that includes a list of all the contributions.

(b) The report shall include:

(i) for each contribution from an applicable entity:

(A) the amount of the contribution; and

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

(ii) for each applicable entity, the percentage of the patient assistant program's total gross income that is attributable to the total contributions from the applicable entity.

(3) (a) Except as provided in Subsection (3)(b), a patient assistance program described in Subsection (2) 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 described in Subsection (2) to the department; and

(ii) after receiving a report described in Subsection (3)(b)(i), the department shall post the report to the department's website.

Section 13. Section **31A-46-111** is enacted to read:

31A-46-111. Rulemaking -- Report to Legislature.

(1) Beginning on July 1, 2020, the department shall enforce the provisions of this part.

(2) In accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, the department may make rules to implement the provisions of this part, including rules that:

(a) provide requirements related to a report to the department described in this section; or

(b) provide for administrative penalties against a patient assistance program that violates the provisions of Section 31A-46-110.

(3) On or before January 1, 2022, the department shall report to the Business and Labor Interim Committee on the implementation of this part, including the effectiveness of the provisions of this part at addressing:

(a) the promotion of transparency in pharmaceutical pricing for the state and other payers;

(b) the enhancement of understanding about pharmaceutical spending trends; and

(c) assisting the state and other payers in management of pharmaceutical drug costs.

(4) The department shall pay to the Medicaid Restricted Account created in Section 26-18-402 any money the department receives under this part or in accordance with the rules described in Subsection (2).

Section 14. Section **31A-46-112** is enacted to read:

31A-46-112. Pharmacy benefit manager reports and duties -- Aggregate retained rebate percentage.

(1) As used in this section:

(a) "Aggregate rebates received" means aggregate rebates that the pharmacy benefit manager received during the prior calendar year from a pharmaceutical manufacturer related to utilization of the manufacturer's prescription drug by health plan enrollees.

(b) "Aggregate retained rebate percentage" means a percentage:

(i) that is the percentage, out of the aggregate rebates received, of the aggregate rebates that a pharmacy benefit manager received during the prior calendar year from a pharmaceutical manufacturer related to utilization of the manufacturer's prescription drug by health plan enrollees and did not pass through to the health plan or health insurer;

(ii) calculated for each prescription drug for which a pharmacy benefit manager receives rebates under a particular health plan; and

(iii) expressed without disclosing identifying information regarding a health plan, prescription drug, or therapeutic class.

(c) (i) "Rebates" means all rebates, discounts, or other price concessions:

(A) based on utilization of a prescription drug;

(B) paid by the manufacturer or other party that is not an enrollee; and

(C) paid directly or indirectly to a pharmacy benefit manager after a claim has been adjudicated at the pharmacy.

(ii) "Rebates" includes a reasonable estimate of any volume-based or other discounts.

(2) A pharmacy benefit manager shall annually report to the department the following information from the prior calendar year:

(a) for each of the pharmacy benefit manager's contractual or other relationships with a health plan or health insurer, the aggregate amount of all rebates that pharmacy benefit manager received from all pharmaceutical manufacturers;

(b) for each of the pharmacy benefit manager's contractual or other relationships with a health plan or health insurer, the aggregate administrative fees that the pharmacy benefit manager received;

(c) for each of the pharmacy benefit manager's contractual or other relationships with a health plan or health insurer, the aggregate rebates that the pharmacy benefit manager received from all pharmaceutical manufacturers and did not pass through to the health plan or health insurer; and

(d) for each of the pharmacy benefit manager's contractual or other relationships with a health plan or health insurer:

(i) the highest aggregate retained rebate percentage;

(ii) the lowest aggregate retained rebate percentage; and

(iii) the mean aggregate retained rebate percentage.

(3) The department shall publish on the department's website a report that includes the information the department receives under Subsection (2):

(a) in a timely manner; and

(b) in a form that does not disclose:

(i) the identity of a specific health plan or health insurer;

(ii) the prices charged for specific drugs or classes of drugs; or

(iii) the amount of any rebates provided for specific drugs or classes of drugs.

(4) Except for the report described in Subsection (3), the information submitted in a report to the department under Subsection (2) is a protected record under Title 63G, Chapter 2, Government Records Access and Management Act.

(5) A pharmacy benefit manager shall, for each of the pharmacy benefit manager's contracts with a health plan, publish on a publicly accessible website:

(a) the health plan formulary; and

(b) timely notification of formulary changes or product exclusions.

(6) A pharmacy benefit manager may not contractually prohibit a pharmacy or pharmacist from, or penalize a pharmacy or pharmacist for:

(a) disclosing to a health plan enrollee information regarding:

(i) the cost-sharing amounts that the enrollee, without requesting any health plan reimbursement, is required to pay for a particular prescription drug:

(A) under the enrollee's health plan prescription drug benefit; or

(B) outside the enrollee's health plan prescription drug benefit; or

(ii) the existence and clinical efficacy of a therapeutically equivalent drug that would, without requesting any health plan reimbursement, and as compared to the drug that was originally prescribed, be less expensive to the enrollee:

(A) under the enrollee's health plan prescription drug benefit; or

(B) outside the enrollee's health plan prescription drug benefit; or

(b) selling to a health plan enrollee, instead of a particular prescribed drug, a therapeutically equivalent drug that would, without requesting any health plan reimbursement, and as compared to the drug that was originally prescribed, be less expensive to the enrollee:

(i) under the enrollee's health plan prescription drug benefit; or

(ii) outside the enrollee's health plan prescription drug benefit.

Section 15. Section **31A-46-113** is enacted to read:

31A-46-113. Inducement for health care services -- Safe harbor -- Rulemaking.

(1) Except as provided in Subsection (3), a health care provider or a pharmaceutical manufacturer violates this section if the health care provider or pharmaceutical manufacturer:

(a) waives or offers to waive, provides a rebate for, or pays all or a portion of one of the following owed by a covered individual under the covered individual's health benefits plan:

(i) a deductible;

(ii) a copayment; or

(iii) coinsurance; and

(b) engages in the conduct described in Subsection (1)(a) with the intent to induce the covered individual to seek health care services from the health care provider or pharmaceutical manufacturer.

(2) A health care provider or a pharmaceutical manufacturer that engages in a pattern

of the conduct described in Subsection (1)(a) is presumed to be engaging with the intent described in Subsection (1)(b) for purposes of this section.

(3) The provisions of this section do not apply to a waiver or offer to waive, rebate, gift, payment, 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) In accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, the department shall makes rules to implement this section.

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 SUPPLY ENTITIES

Part 1. Pharmaceutical Supply Chain

58-17c-101. Title.

This chapter is known as "Pharmaceutical Supply Entities."

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

58-17c-102. Definitions.

As used in this part:

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

(2) "Course of therapy" means the recommended daily dosage units of a drug pursuant to the drug's prescribing label as approved by the United States Food and Drug Administration for:

(a) 30 days; or

(b) a normal course of treatment that is less than 30 days.

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

(4) "Health care entity" means:

(a) a health care provider;

(b) a pharmacy or pharmacy employee; or

(c) an operator or employee of a health care facility.

(5) "Health care facility" means the same as that term is defined in Section 26-21-2.

(6) "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.

(7) "Pharmaceutical manufacturer" means:

(a) a person that is engaged in the manufacturing of a drug or pharmaceutical device that is available for purchase by residents of the state; or

(b) a person that is responsible for setting the price of a drug that is available for purchase by residents of the state on behalf of a person described in Subsection (4)(a).

(8) "Pharmaceutical sales representative" means a person who engages in prescription drug marketing to a health care entity.

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

(10) "Prescription drug marketing" means to provide 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.

(11) "Wholesale acquisition cost" means a pharmaceutical manufacturer's list price:

(a) for selling a brand-name or generic drug to a wholesaler or a direct purchaser in the United States;

(b) that is the list price:

(i) per person, either per year or per course of therapy; and

(ii) for the most recent month for which information is available; and

(c) that does not include any discounts or rebates.

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

58-17c-103. Prescription drug marketing -- Reports -- Rulemaking.

(1) 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.

(2) The division shall provide to a health care entity electronic access to a list described in Subsection (1).

(3) A pharmaceutical sales representative on a list described in Subsection (1):

(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 for 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.

(4) (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 (1);

(ii) the names of all pharmaceutical manufacturers that provide to the division a list described in Subsection (1);

(iii) the names of all drugs described in Subsection (3)(b)(ii); and

(iv) the aggregate number of health care entities described in Subsection (3)(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.

(5) In accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, the division may establish rules that:

(a) provide requirements related to a report to the division described in this section; or

(b) provide for administrative penalties against a pharmaceutical manufacturer or a pharmaceutical sales representative that violates the provisions of this section.

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

58-17c-104. Prescription drug marketing and price information -- 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:

(A) the period of time for which the drug is designed to be administered; and

(B) the average wholesale price for the period of time described in Subsection (1)(e)(ii)(A).

(2) A person shall provide the written materials described in Subsection (1) to the health care provider at the earlier of the following:

(a) the time the person provides any written materials as part of the prescription drug marketing to the health care provider; or

(b) within one business day of the person engaging in the prescription drug marketing to the health care provider.

(3) In accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, the division shall make rules to implement and enforce the provisions of this section.

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

58-17c-105. Availability of drug for testing -- Liability for injury -- Enforcement.

(1) As used in this section:

(a) "Application" means an application for:

(i) the approval of a drug under the Food, Drug, and Cosmetic Act, Sec. 505(b) or (j), 21 U.S.C. Sec. 355c(1)(A); or

(ii) the licensing of a biological product under the Public Health Service Act, Sec. 351, 42 U.S.C. Sec. 262(a)(1).

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

(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 higher price for the drug than the price for which the person 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 assure 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 distributer 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 a pharmaceutical wholesaler or distributer costs and attorney fees.

(6) In accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act, the division may make rules regarding the implementation and enforcement of the provisions of this section.