S.92

An act relating to interchangeable biological products.

The House proposes to the Senate to amend the bill by striking all after the enacting clause and inserting in lieu thereof the following:

* * * Interchangeable Biological Products * * *

Sec. 1. 18 V.S.A. § 4601 is amended to read:

§ 4601. DEFINITIONS

~~For the purposes of this chapter, unless the context otherwise clearly requires~~ As used in this chapter:

(1) ~~"Brand name" means the registered trademark name given to a drug product by its manufacturer or distributor;~~ "Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition in human beings.

(2) ~~"Generic name" means the official name of a drug product as established by the United States Adopted Names Council (USAN) or its successor, if applicable;~~ "Brand name" means the registered trademark name given to a drug product by its manufacturer or distributor.

(3) ~~"Pharmacist" means a natural person licensed by the state board of pharmacy to prepare, compound, dispense, and sell drugs, medicines, chemicals, and poisons;~~

~~(4)~~ "Generic drug" means a drug listed by generic name and considered to be chemically and therapeutically equivalent to a drug listed by brand name, as both names are identified in the most recent edition of or supplement to the ~~federal~~ U.S. Food and Drug Administration's ~~"Orange Book" of approved drug products;~~ Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book).

(4) "Generic name" means the official name of a drug product as established by the U.S. Adopted Names Council (USAN) or its successor, if applicable.

(5) "Interchangeable biological product" means a biological product that the U.S. Food and Drug Administration has:

(A) licensed and determined, pursuant to 42 U.S.C. § 262(k)(4), to be interchangeable with the reference product against which it was evaluated; or

(B) determined to be therapeutically equivalent as set forth in the latest edition of or supplement to the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book).

(6) "Pharmacist" means a natural person licensed by the State Board of Pharmacy to prepare, compound, dispense, and sell drugs, medicines, chemicals, and poisons.

~~(5)~~(7) "Prescriber" means any duly licensed physician, dentist, veterinarian, or other practitioner licensed to write prescriptions for the treatment or prevention of disease in man or animal.

(8) "Proper name" means the non-proprietary name of a biological product.

(9) "Reference product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which the interchangeable biological product was evaluated by the U.S. Food and Drug Administration pursuant to 42 U.S.C. § 262(k).

Sec. 2. 18 V.S.A. § 4605 is amended to read:

§ 4605. ALTERNATIVE DRUG OR BIOLOGICAL PRODUCT SELECTION

(a)(1) When a pharmacist receives a prescription for a drug ~~which~~ that is listed either by generic name or brand name in the most recent edition of or supplement to the U.S. Department of Health and Human Services' publication Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book") of approved drug products, the pharmacist shall select the lowest priced drug from the list which is equivalent as defined by the "Orange

Book," unless otherwise instructed by the prescriber, or by the purchaser if the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost for the higher priced drug.

(2) When a pharmacist receives a prescription for a biological product, the pharmacist shall select the lowest priced interchangeable biological product unless otherwise instructed by the prescriber, or by the purchaser if the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost for the higher priced biological product.

(3) Notwithstanding subdivisions (1) and (2) of this subsection, when a pharmacist receives a prescription from a Medicaid beneficiary, the pharmacist shall select the preferred brand-name or generic drug or biological product from the Department of Vermont Health Access's preferred drug list.

(b) The purchaser shall be informed by the pharmacist or his or her representative that an alternative selection as provided under subsection (a) of this section will be made unless the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if

allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost for the higher priced drug or biological product.

(c) When refilling a prescription, pharmacists shall receive the consent of the prescriber to dispense a drug or biological product different from that originally dispensed, and shall inform the purchaser that a ~~generic~~ substitution shall be made pursuant to this section unless the purchaser agrees to pay any additional cost in excess of the benefits provided by the purchaser's health benefit plan if allowed under the legal requirements applicable to the plan, or otherwise to pay the full cost for the higher priced drug or biological product.

(d) Any pharmacist substituting a generically equivalent drug or interchangeable biological product shall charge no more than the usual and customary retail price for that selected drug or biological product. This charge shall not exceed the usual and customary retail price for the prescribed brand.

(e)(1) Except as described in subdivision (4) of this subsection, within five business days following the dispensing of a biological product, the dispensing pharmacist or designee shall communicate the specific biological product provided to the patient, including the biological product's name and manufacturer, by submitting the information in a format that is accessible to the prescriber electronically through one of the following:

(A) an interoperable electronic medical records system;

(B) an electronic prescribing technology;

(C) a pharmacy benefit management system; or

(D) a pharmacy record.

(2) Entry into an electronic records system as described in subdivision (1) of this subsection shall be presumed to provide notice to the prescriber.

(3)(A) If a pharmacy does not have access to one or more of the electronic systems described in subdivision (1) of this subsection (e), the pharmacist or designee shall communicate to the prescriber the information regarding the biological product dispensed using telephone, facsimile, electronic transmission, or other prevailing means.

(B) If a prescription is communicated to the pharmacy by means other than electronic prescribing technology, the pharmacist or designee shall communicate to the prescriber the information regarding the biological product dispensed using the electronic process described in subdivision (1) of this subsection (e) unless the prescriber requests a different means of communication on the prescription.

(4) Notwithstanding any provision of this subsection to the contrary, a pharmacist shall not be required to communicate information regarding the biological product dispensed in the following circumstances:

(A) the U.S. Food and Drug Administration has not approved any interchangeable biological products for the product prescribed; or

(B) the pharmacist dispensed a refill prescription in which the product dispensed was unchanged from the product dispensed at the prior filling of the prescription.

(f) The Board of Pharmacy shall maintain a link on its website to the current lists of all biological products that the U.S. Food and Drug Administration has determined to be interchangeable biological products.

Sec. 3. 18 V.S.A. § 4606 is amended to read:

§ 4606. BRAND CERTIFICATION

If the prescriber has determined that the generic equivalent of a drug or the interchangeable biological product for the biological product being prescribed has not been effective or with reasonable certainty is not expected to be effective in treating the patient's medical condition or causes or is reasonably expected to cause adverse or harmful reactions in the patient, the prescriber shall indicate "brand necessary," "no substitution," "dispense as written," or "DAW" in the prescriber's own handwriting on the prescription blank or shall indicate the same using electronic prescribing technology and the pharmacist shall not substitute the generic equivalent or interchangeable biological product. If a prescription is unwritten and the prescriber has determined that the generic equivalent of the drug or the interchangeable biological product for the biological product being prescribed has not been effective or with reasonable certainty is not expected to be effective in treating the patient's

medical condition or causes or is reasonably expected to cause adverse or harmful reactions in the patient, the prescriber shall expressly indicate to the pharmacist that the brand-name drug or biological product is necessary and substitution is not allowed and the pharmacist shall not substitute the generic equivalent drug or interchangeable biological product.

Sec. 4. 18 V.S.A. § 4607 is amended to read:

§ 4607. INFORMATION; LABELING

(a) Every pharmacy in the ~~state~~ State shall have posted a sign in a prominent place that is in clear unobstructed view which shall read: "Vermont law requires pharmacists in some cases to select a less expensive generic equivalent drug or interchangeable biological product for the drug or biological product prescribed unless you or your physician direct otherwise. Ask your pharmacist."

(b) The label of the container of all drugs and biological products dispensed by a pharmacist under this chapter shall indicate the generic or proper name using an abbreviation if necessary, the strength of the drug or biological product, if applicable, and the name or number of the manufacturer or distributor.

Sec. 5. 18 V.S.A. § 4608 is amended to read:

§ 4608. LIABILITY

(a) Nothing in this chapter shall affect a licensed hospital with the development and maintenance of a hospital formulary system in accordance with that institution's policies and procedures that pertain to its drug distribution system developed by the medical staff in cooperation with the hospital's pharmacist and administration.

(b) The substitution of a generic drug or interchangeable biological product by a pharmacist under the provisions of this chapter does not constitute the practice of medicine.

Sec. 6. 8 V.S.A. § 4089i is amended to read:

§ 4089i. PRESCRIPTION DRUG COVERAGE

* * *

(g) A health insurance or other health benefit plan offered by a health insurer or by a pharmacy benefit manager on behalf of a health insurer that provides coverage for prescription drugs shall apply the same cost-sharing requirements to interchangeable biological products as apply to generic drugs under the plan.

(h) As used in this section:

* * *

(6) "Interchangeable biological products" shall have the same meaning as in 18 V.S.A. § 4601.

~~(h)~~(i) The Department of Financial Regulation shall enforce this section and may adopt rules as necessary to carry out the purposes of this section.

* * * Health Insurance Plan Reporting * * *

Sec. 7. 8 V.S.A. § 4062 is amended to read:

§ 4062. FILING AND APPROVAL OF POLICY FORMS AND PREMIUMS

* * *

(b)(1) In conjunction with a rate filing required by subsection (a) of this section, an insurer shall file a plain language summary of the proposed rate. All summaries shall include a brief justification of any rate increase requested, the information that the Secretary of the U.S. Department of Health and Human Services (HHS) requires for rate increases over 10 percent, and any other information required by the Board. The plain language summary shall be in the format required by the Secretary of HHS pursuant to the Patient Protection and Affordable Care Act of 2010, Public Law 111-148, as amended by the Health Care and Education Reconciliation Act of 2010, Public Law 111-152, and shall include notification of the public comment period established in subsection (c) of this section. In addition, the insurer shall post the summaries on its website.

(2)(A) In conjunction with a rate filing required by subsection (a) of this section, an insurer shall disclose to the Board:

(i) for all covered prescription drugs, including generic drugs, brand-name drugs excluding specialty drugs, and specialty drugs dispensed at a pharmacy, network pharmacy, or mail-order pharmacy for outpatient use:

(I) the percentage of the premium rate attributable to prescription drug costs for the prior year for each category of prescription drugs;

(II) the year-over-year increase or decrease, expressed as a percentage, in per-member, per-month total health plan spending on each category of prescription drugs; and

(III) the year-over-year increase or decrease in per-member, per-month costs for prescription drugs compared to other components of the premium rate; and

(ii) the specialty tier formulary list.

(B) The insurer shall provide, if available, the percentage of the premium rate attributable to prescription drugs administered by a health care provider in an outpatient setting that are part of the medical benefit as separate from the pharmacy benefit.

(C) The insurer shall include information on its use of a pharmacy benefit manager, if any, including which components of the prescription drug

coverage described in subdivisions (A) and (B) of this subdivision (2) are managed by the pharmacy benefit manager, as well as the name of the pharmacy benefit manager or managers used.

(c)(1) The Board shall provide information to the public on the Board's website about the public availability of the filings and summaries required under this section.

(2)(A) ~~Beginning no later than January 1, 2014, the~~ The Board shall post the rate filings pursuant to subsection (a) of this section and summaries pursuant to subsection (b) of this section on the Board's website within five calendar days ~~of~~ following filing. The Board shall also establish a mechanism by which members of the public may request to be notified automatically each time a proposed rate is filed with the Board.

* * *

Sec. 8. 18 V.S.A. § 4636 is added to read:

§ 4636. IMPACT OF PRESCRIPTION DRUG COSTS ON HEALTH INSURANCE PREMIUMS; REPORT

(a)(1) Each health insurer with more than 1,000 covered lives in this State shall report to the Green Mountain Care Board, for all covered prescription drugs, including generic drugs, brand-name drugs, and specialty drugs provided in an outpatient setting or sold in a retail setting:

(A) the 25 most frequently prescribed drugs and the average wholesale price for each drug;

(B) the 25 most costly drugs by total plan spending and the average wholesale price for each drug; and

(C) the 25 drugs with the highest year-over-year price increases and the average wholesale price for each drug.

(2) A health insurer shall not be required to provide to the Green Mountain Care Board the actual price paid, net of rebates, for any prescription drug.

(b) The Green Mountain Care Board shall compile the information reported pursuant to subsection (a) of this section into a consumer-friendly report that demonstrates the overall impact of drug costs on health insurance premiums. The data in the report shall be aggregated and shall not reveal information as specific to a particular health benefit plan.

(c) The Board shall publish the report required pursuant to subsection (b) of this section on its website on or before January 1 of each year.

* * * Prescription Drug Price Transparency and Notice of New High-Cost Drugs * * *

Sec. 9. 18 V.S.A. § 4635 is amended to read:

§ 4635. ~~PHARMACEUTICAL~~ PRESCRIPTION DRUG COST TRANSPARENCY

(a) As used in this section:

(1) "Manufacturer" shall have the same meaning as "pharmaceutical manufacturer" in section 4631a of this title.

(2) "Prescription drug" means a drug as defined in 21 U.S.C. § 321.

(b)(1)(A) The ~~Green Mountain Care Board, in collaboration with the~~ Department of Vermont Health Access~~,~~ shall ~~identify~~ create annually ~~up to 15~~ a list of 10 prescription drugs on which the State spends significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or by 15 percent or more ~~over the past 12 months~~ during the previous calendar year, creating a substantial public interest in understanding the development of the drugs' pricing. ~~The drugs identified shall represent different drug classes.~~ The list shall include at least one generic and one brand-name drug and shall indicate each of the drugs on the list that the Department considers to be specialty drugs. The Department shall include the percentage of the wholesale acquisition cost increase for each drug on the list; rank the drugs on the list from those with the largest increase in wholesale acquisition cost to those with the smallest increase; indicate whether each drug was included on the list based on its cost increase over the past five years or during the previous calendar year, or both; and provide the Department's total expenditure for each drug on the list during the most recent calendar year.

(B) The Department of Vermont Health Access shall create annually a list of 10 prescription drugs on which the State spends significant health care dollars and for which the cost to the Department of Vermont Health Access, net of rebates and other price concessions, has increased by 50 percent or more over the past five years or by 15 percent or more during the previous calendar year, creating a substantial public interest in understanding the development of the drugs' pricing. The list shall include at least one generic and one brand-name drug and shall indicate each of the drugs on the list that the Department considers to be specialty drugs. The Department shall rank the drugs on the list from those with the greatest increase in net cost to those with the smallest increase and indicate whether each drug was included on the list based on its cost increase over the past five years or during the previous calendar year, or both.

(C)(i) Each health insurer with more than 5,000 covered lives in this State for major medical health insurance shall create annually a list of 10 prescription drugs on which its health insurance plans spend significant amounts of their premium dollars and for which the cost to the plans, net of rebates and other price concessions, has increased by 50 percent or more over the past five years or by 15 percent or more during the previous calendar year, or both, creating a substantial public interest in understanding the development of the drugs' pricing. The list shall include at least one generic and one brand-

name drug and shall indicate each of the drugs on the list that the health insurer considers to be specialty drugs.

(ii) A health insurer shall not be required to identify the exact percentage by which the net cost to its plans for any prescription drug increased over any specific period of time, but shall rank the drugs on its list in order from the largest to the smallest cost increase and shall provide the insurer's total expenditure, net of rebates and other price concessions, for each drug on the list during the most recent calendar year.

(2) The ~~Board~~ Department of Vermont Health Access and the health insurers shall provide to the Office of the Attorney General and the Green Mountain Care Board the ~~list~~ lists of prescription drugs developed pursuant to this subsection ~~and the percentage of the wholesale acquisition cost increase for each drug and~~ annually on or before June 1. The Office of the Attorney General and the Green Mountain Care Board shall make all of the information available to the public on ~~the Board's website~~ their respective websites.

(c)(1)(A) ~~For each prescription drug identified~~ Of the prescription drugs listed by the Department of Vermont Health Access and the health insurers pursuant to ~~subsection (b)~~ subdivisions (b)(1)(B) and (C) of this section, the Office of the Attorney General shall identify 15 drugs as follows:

(i) of the drugs appearing on more than one payer's list, the Office of the Attorney General shall identify the top 15 drugs on which the greatest

amount of money was spent across all payers during the previous calendar year, to the extent information is available; and

(ii) if fewer than 15 drugs appear on more than one payer's list, the Office of the Attorney General shall rank the remaining drugs based on the amount of money spent by any one payer during the previous calendar year, in descending order, and select as many of the drugs at the top of the list as necessary to reach a total of 15 drugs.

(B) For the 15 drugs identified by the Office of the Attorney General pursuant to subdivision (A) of this subdivision (1), the Office of the Attorney General shall require the ~~drug's~~ manufacturer of each such drug to provide ~~a~~ ~~justification~~ all of the following:

(i) Justification for the increase in the ~~wholesale acquisition~~ net cost of the drug to the Department of Vermont Health Access, to one or more health insurers, or both, which shall be provided to the Office of the Attorney General in a format that the Office of the Attorney General determines to be understandable and appropriate and shall be provided in accordance with a timeline specified by the Office of the Attorney General. The manufacturer shall submit to the Office of the Attorney General all relevant information and supporting documentation necessary to justify the manufacturer's ~~wholesale acquisition~~ net cost increase ~~over~~ to the Department of Vermont Health

Access, to one or more more health insurers, or both during the identified period of time, ~~which may include~~ including:

~~(A)~~(I) ~~all factors that have contributed to the wholesale acquisition~~ each factor that specifically caused the net cost increase ~~over~~ to the Department of Vermont Health Access, to one or more health insurers, or both during the specified period of time;

~~(B)~~(II) the percentage of the total ~~wholesale acquisition~~ cost increase attributable to each factor; and

~~(C)~~(III) an explanation of the role of each factor in contributing to the ~~wholesale acquisition~~ cost increase.

(ii) A separate version of the information submitted pursuant to subdivision (i) of this subdivision (1)(B), which shall be made available to the public by the Office of the Attorney General and the Green Mountain Care Board pursuant to subsection (d) of this section. In the event that the manufacturer believes it necessary to redact certain information in the public version as proprietary or confidential, the manufacturer shall provide an explanation for each such redaction to the Office of the Attorney General. The information, format, and any redactions shall be subject to approval by the Office of the Attorney General.

(iii) Additional information in response to all requests for such information by the Office of the Attorney General.

(2) Nothing in this section shall be construed to restrict the legal ability of a prescription drug manufacturer to change prices to the extent permitted under federal law.

(d)(1) The Attorney General~~, in consultation with the Department of Vermont Health Access,~~ shall provide a report to the General Assembly on or before December 1 of each year based on the information received from manufacturers pursuant to this section. The Attorney General shall ~~also~~ post the report and the public version of each manufacturer's information submitted pursuant to subdivision (c)(1)(B)(ii) of this section on the Office of the Attorney General's website.

(2) The Green Mountain Care Board shall post on its website the report prepared by the Attorney General pursuant to subdivision (1) of this subsection and the public version of each manufacturer's information submitted pursuant to subdivision (c)(1)(B)(ii) of this section, and may inform the public of the availability of the report and the manufacturers' justification information.

(e) Information provided to the Office of the Attorney General pursuant to this section is exempt from public inspection and copying under the Public Records Act and shall not be released in a manner that allows for the identification of an individual drug or manufacturer or that is likely to compromise the financial, competitive, or proprietary nature of the

information, except for the information prepared for release to the public pursuant to subdivision (c)(1)(B)(ii) of this section.

(f) The Attorney General may bring an action in the Civil Division of the Superior Court, Washington County for injunctive relief, costs, and attorney's fees, and to impose on a manufacturer that fails to provide any of the information required by subsection (c) of this section, in the format requested by the Office of the Attorney General and in accordance with the timeline specified by the Office of the Attorney General, a civil penalty of ~~no~~ not more than $10,000.00 per violation. Each unlawful failure to provide information shall constitute a separate violation. In any action brought pursuant to this section, the Attorney General shall have the same authority to investigate and to obtain remedies as if the action were brought under the Consumer Protection Act, 9 V.S.A. chapter 63.

Sec. 10. 18 V.S.A. § 4637 is added to read:

§ 4637. NOTICE OF INTRODUCTION OF NEW HIGH-COST PRESCRIPTION DRUGS

(a) As used in this section:

(1) "Manufacturer" shall have the same meaning as "pharmaceutical manufacturer" in section 4631a of this title.

(2) "Prescription drug" means a drug as defined in 21 U.S.C. § 321.

(b) A prescription drug manufacturer shall notify the Office of the Attorney General in writing if it is introducing a new prescription drug to market at a wholesale acquisition cost that exceeds the threshold set for a specialty drug under the Medicare Part D program. The manufacturer shall provide the written notice within three calendar days following the release of the drug in the commercial market. A manufacturer may make the notification pending approval by the U.S. Food and Drug Administration (FDA) if commercial availability is expected within three calendar days following the approval.

(c) Not later than 30 calendar days following notification pursuant to subsection (b) of this section, the manufacturer shall provide all of the following information to the Office of the Attorney General in a format that the Office prescribes:

(1) a description of the marketing and pricing plans used in the launch of the new drug in the United States and internationally;

(2) the estimated volume of patients who may be prescribed the drug;

(3) whether the drug was granted breakthrough therapy designation or priority review by the FDA prior to final approval; and

(4) the date and price of acquisition if the drug was not developed by the manufacturer.

(d) The manufacturer may limit the information reported pursuant to subsection (c) of this section to that which is otherwise in the public domain or publicly available.

(e) The Office of the Attorney General shall publish on its website at least quarterly the information reported to it pursuant to this section. The information shall be published in a manner that identifies the information that is disclosed on a per-drug basis and shall not be aggregated in a manner that would not allow identification of the drug.

(f) The Attorney General may bring an action in the Civil Division of the Superior Court, Washington County for injunctive relief, costs, and attorney's fees and to impose on a manufacturer that fails to provide the information required by subsection (c) of this section a civil penalty of not more than $1,000.00 per day for every day after the notification period described in subsection (b) of this section that the required information is not reported. In any action brought pursuant to this section, the Attorney General shall have the same authority to investigate and to obtain remedies as if the action were brought under the Consumer Protection Act, 9 V.S.A. chapter 63.

* * * Disclosures by Pharmacists * * *

Sec. 11. 18 V.S.A. § 9473(b) is amended to read:

(b) A pharmacy benefit manager or other entity paying pharmacy claims shall not:

(1) impose a higher co-payment for a prescription drug than the co-payment applicable to the type of drug purchased under the insured's health plan;

(2) impose a higher co-payment for a prescription drug than the maximum allowable cost for the drug; ~~or~~

(3) require a pharmacy to pass through any portion of the insured's co-payment to the pharmacy benefit manager or other payer;

(4) prohibit or penalize a pharmacy or pharmacist for providing information to an insured regarding the insured's cost-sharing amount for a prescription drug; or

(5) prohibit or penalize a pharmacy or pharmacist for the pharmacist or other pharmacy employee disclosing to an insured the cash price for a prescription drug or selling a lower cost drug to the insured if one is available.

* * * Effective Dates * * *

Sec. 12. EFFECTIVE DATES

(a) Secs. 1–6 (interchangeable biological products) shall take effect on July 1, 2018.

(b) Sec. 11 (18 V.S.A. § 9473; disclosures by pharmacists) shall take effect on July 1, 2018 and shall apply to all contracts taking effect on or after that date.

(c) The remaining sections shall take effect on passage.

and that after passage the title of the bill be amended to read: "An act relating to prescription drug price transparency and cost containment"