

1 TO THE HOUSE OF REPRESENTATIVES:

2 The Committee on Health Care to which was referred Senate Bill No. 92
3 entitled “An act relating to interchangeable biological products” respectfully
4 reports that it has considered the same and recommends that the House propose
5 to the Senate that the bill be amended by striking out all after the enacting
6 clause and inserting in lieu thereof the following:

7 * * * Interchangeable Biological Products * * *

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

9 § 4601. DEFINITIONS

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

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

19 (2) ~~“Generic name” means the official name of a drug product as~~
20 ~~established by the United States Adopted Names Council (USAN) or its~~

1 ~~successor, if applicable;~~ “Brand name” means the registered trademark name
2 given to a drug product by its manufacturer or distributor.

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

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

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

15 (5) “Interchangeable biological product” means a biological product that
16 the U.S. Food and Drug Administration has:

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

19 (B) determined to be therapeutically equivalent as set forth in the
20 latest edition of or supplement to the U.S. Food and Drug Administration’s

1 Approved Drug Products with Therapeutic Equivalence Evaluations (the
2 Orange Book).

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

6 ~~(5)~~(7) “Prescriber” means any duly licensed physician, dentist,
7 veterinarian, or other practitioner licensed to write prescriptions for the
8 treatment or prevention of disease in man or animal.

9 (8) “Proper name” means the non-proprietary name of a biological
10 product.

11 (9) “Reference product” means the single biological product licensed
12 pursuant to 42 U.S.C. § 262(a) against which the interchangeable biological
13 product was evaluated by the U.S. Food and Drug Administration pursuant to
14 42 U.S.C. § 262(k).

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

16 § 4605. ALTERNATIVE DRUG OR BIOLOGICAL PRODUCT

17 SELECTION

18 (a)(1) When a pharmacist receives a prescription for a drug which is listed
19 either by generic name or brand name in the most recent edition of or
20 supplement to the U.S. Department of Health and Human Services’ publication
21 Approved Drug Products With Therapeutic Equivalence Evaluations (the

1 “Orange Book”) of approved drug products, the pharmacist shall select the
2 lowest priced drug from the list which is equivalent as defined by the “Orange
3 Book,” unless otherwise instructed by the prescriber, or by the purchaser if the
4 purchaser agrees to pay any additional cost in excess of the benefits provided
5 by the purchaser’s health benefit plan if allowed under the legal requirements
6 applicable to the plan, or otherwise to pay the full cost for the higher priced
7 drug.

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

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

19 (b) The purchaser shall be informed by the pharmacist or his or her
20 representative that an alternative selection as provided under subsection (a) of
21 this section will be made unless the purchaser agrees to pay any additional cost

1 in excess of the benefits provided by the purchaser's health benefit plan if
2 allowed under the legal requirements applicable to the plan, or otherwise to
3 pay the full cost for the higher priced drug or biological product.

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

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

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

21 (A) an interoperable electronic medical records system;

1 (B) an electronic prescribing technology;

2 (C) a pharmacy benefit management system; or

3 (D) a pharmacy record.

4 (2) Entry into an electronic records system as described in subdivision

5 (1) of this subsection shall be presumed to provide notice to the prescriber.

6 (3)(A) If a pharmacy does not have access to one or more of the

7 electronic systems described in subdivision (1) of this subsection, the

8 pharmacist or designee shall communicate to the prescriber the information

9 regarding the biological product dispensed using telephone, facsimile,

10 electronic transmission, or other prevailing means.

11 (B) If a prescription is communicated to the pharmacy by means

12 other than electronic prescribing technology, the pharmacist or designee shall

13 communicate to the prescriber the information regarding the biological product

14 dispensed using the electronic process described in subdivision (1) of this

15 subsection unless the prescriber requests a different means of communication

16 on the prescription.

17 (4) Notwithstanding any provision of this subsection to the contrary, a

18 pharmacist shall not be required to communicate information regarding the

19 biological product dispensed in the following circumstances:

20 (A) the U.S. Food and Drug Administration has not approved any

21 interchangeable biological products for the product prescribed; or

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

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

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

8 § 4606. BRAND CERTIFICATION

9 If the prescriber has determined that the generic equivalent of a drug or the
10 interchangeable biological product for the biological product being prescribed
11 has not been effective or with reasonable certainty is not expected to be
12 effective in treating the patient’s medical condition or causes or is reasonably
13 expected to cause adverse or harmful reactions in the patient, the prescriber
14 shall indicate “brand necessary,” “no substitution,” “dispense as written,” or
15 “DAW” in the prescriber’s own handwriting on the prescription blank or shall
16 indicate the same using electronic prescribing technology and the pharmacist
17 shall not substitute the generic equivalent or interchangeable biological
18 product. If a prescription is unwritten and the prescriber has determined that
19 the generic equivalent of the drug or the interchangeable biological product for
20 the biological product being prescribed has not been effective or with
21 reasonable certainty is not expected to be effective in treating the patient’s

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

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

7 § 4607. INFORMATION; LABELING

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

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

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

2 § 4608. LIABILITY

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

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

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

12 § 4089i. PRESCRIPTION DRUG COVERAGE

13 * * *

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

19 (h) As used in this section:

20 * * *

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

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

5 * * * Health Insurance Plan Reporting * * *

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

7 § 4062. FILING AND APPROVAL OF POLICY FORMS AND PREMIUMS

8 * * *

9 (b)(1) In conjunction with a rate filing required by subsection (a) of this
10 section, an insurer shall file a plain language summary of the proposed rate.
11 All summaries shall include a brief justification of any rate increase requested,
12 the information that the Secretary of the U.S. Department of Health and
13 Human Services (HHS) requires for rate increases over 10 percent, and any
14 other information required by the Board. The plain language summary shall be
15 in the format required by the Secretary of HHS pursuant to the Patient
16 Protection and Affordable Care Act of 2010, Public Law 111-148, as amended
17 by the Health Care and Education Reconciliation Act of 2010, Public Law 111-
18 152, and shall include notification of the public comment period established in
19 subsection (c) of this section. In addition, the insurer shall post the summaries
20 on its website.

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

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

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

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

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

15 (ii) the specialty tier formulary list.

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

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

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

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

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

13 * * *

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

15 § 4636. IMPACT OF PRESCRIPTION DRUG COSTS ON HEALTH

16 INSURANCE PREMIUMS; REPORT

17 (a)(1) Each health insurer with more than 200 1,000 covered lives in this
18 State shall report to the Green Mountain Care Board, for all covered
19 prescription drugs, including generic drugs, brand-name drugs, and specialty
20 drugs provided in an outpatient setting or sold in a retail setting:

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

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

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

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

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

15 (c) The Board shall publish the report required pursuant to subsection (b) of
16 this section on its website on or before January 1 of each year. **Information**
17 **provided to the Board pursuant to this section is exempt from inspection**
18 **and copying under the Public Records Act and shall be kept confidential**
19 **except to the extent it is aggregated and included in the report described**
20 **in subsection (b) of this section.**

1 * * * Prescription Drug Price Transparency and Notice of

2 New High-Cost Drugs * * *

3 Sec. 9. 18 V.S.A. § 4635 is amended to read: **(revised for 4/13/18)**

4 § 4635. ~~PHARMACEUTICAL~~ PRESCRIPTION DRUG COST

5 TRANSPARENCY

6 (a) As used in this section:

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

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

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

1 in wholesale acquisition cost to those with the smallest increase; indicate
2 whether each drug was included on the list based on its cost increase over the
3 past five years or during the previous calendar year, or both; and provide the
4 Department's total expenditure for each drug on the list during the most recent
5 calendar year.

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

19 (C)(i) Each health insurer with more than 5,000 covered lives in this
20 State for major medical health insurance shall create annually a list of 10
21 prescription drugs on which its health insurance plans spend significant

1 amounts of their premium dollars and for which the cost to the plans, net of
2 rebates and other price concessions, has increased by 50 percent or more over
3 the past five years or by 15 percent or more during the previous calendar year,
4 or both, creating a substantial public interest in understanding the development
5 of the drugs' pricing. The list shall include at least one generic and one brand-
6 name drug and shall indicate each of the drugs on the list that the health insurer
7 considers to be specialty drugs.

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

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

1 (c)(1)(A) ~~For each prescription drug identified~~ Of the prescription drugs
2 listed by the Department of Vermont Health Access and the health insurers
3 pursuant to ~~subsection (b)~~ subdivisions (b)(1)(B) and (C) of this section, the
4 Office of the Attorney General shall identify 15 drugs ~~that either appeared~~
5 ~~on more than one payer's list or on which the most money was spent~~
6 ~~during the previous calendar year across all payers, to the extent~~
7 ~~information is available, or both, and as follows:~~
8 (i) of the drugs appearing on more than one payer's list, the
9 Office of the Attorney General shall identify the top 15 drugs on which the
10 greatest amount of money was spent across all payers during the previous
11 calendar year, to the extent information is available; and
12 (ii) if fewer than 15 drugs appear on more than one payer's
13 list, the Office of the Attorney General shall rank the remaining drugs
14 based on the amount of money spent by any one payer during the previous
15 calendar year, in descending order, and select as many of the drugs at the
16 top of the list as necessary to reach a total of 15 drugs.
17 (B) For the 15 drugs identified by the Office of the Attorney
18 General pursuant to subdivision (A) of this subdivision (1), the Office of
19 the Attorney General shall require the ~~drug's~~ manufacturer of each such drug
20 to provide a ~~justification~~ all of the following:

1 **(i)** Justification for the increase in the ~~wholesale acquisition~~ **net**
2 cost of the drug **to the Department of Vermont Health Access, to one more**
3 **health insurers, or both**, which shall be provided to the Office of the Attorney
4 General in a format that the Office of the Attorney General determines to be
5 understandable and appropriate and shall be provided in accordance with a
6 timeline specified by the Office of the Attorney General. The manufacturer
7 shall submit to the Office of the Attorney General all relevant information and
8 supporting documentation necessary to justify the manufacturer's ~~wholesale~~
9 ~~acquisition~~ **net** cost increase over **to the Department of Vermont Health**
10 **Access, to one more health insurers, or both during** the identified period of
11 time, which may include including:

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

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

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

20 **(ii)** A separate version of the information submitted pursuant to
21 subdivision (i) of this subdivision (1)(B), which shall be made available to the

1 public **by the Office of the Attorney General and the Green Mountain**
2 **Care Board pursuant to subsection (d) of this section. **If In the event that****
3 the manufacturer believes it necessary to redact certain information in the
4 public version as proprietary or confidential, the manufacturer shall provide an
5 explanation for each such redaction to the Office of the Attorney General. The
6 information, format, and any redactions shall be subject to approval by the
7 Office of the Attorney General.

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

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

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

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

6 (e) **Information** ~~Except for the version of the information prepared for~~
7 ~~release to the public pursuant to subdivision (c)(1)(B) of this section, all~~
8 ~~information~~ provided to the Office of the Attorney General pursuant to this
9 section is exempt from public inspection and copying under the Public Records
10 Act and shall not be released in a manner that **allows for the identification of**
11 **an individual drug or manufacturer or that** is likely to compromise the
12 financial, competitive, or proprietary nature of the information, **except for the**
13 **information prepared for release to the public pursuant to subdivision**
14 **(c)(1)(B)(ii) of this section.**

15 (f) The Attorney General may bring an action in the Civil Division of the
16 Superior Court, Washington County for injunctive relief, costs, and attorney’s
17 fees, and to impose on a manufacturer that fails to provide any of the
18 information required by subsection (c) of this section, in the format requested
19 by the Office of the Attorney General and in accordance with the timeline
20 specified by the Office of the Attorney General, a civil penalty of ~~no~~ not more
21 than \$10,000.00 per violation. Each unlawful failure to provide information

1 shall constitute a separate violation. In any action brought pursuant to this
2 section, the Attorney General shall have the same authority to investigate and
3 to obtain remedies as if the action were brought under the Consumer Protection
4 Act, 9 V.S.A. chapter 63.

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

6 § 4637. NOTICE OF INTRODUCTION OF NEW HIGH-COST

7 PRESCRIPTION DRUGS

8 (a) As used in this section:

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

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

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

20 (c) Not later than 30 calendar days following notification pursuant to
21 subsection (b) of this section, the manufacturer shall provide all of the

1 following information to the Office of the Attorney General in a format that the
2 Office prescribes:

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

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

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

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

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

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

18 (f) The Attorney General may bring an action in the Civil Division of the
19 Superior Court, Washington County for injunctive relief, costs, and attorney's
20 fees and to impose on a manufacturer that fails to provide the information
21 required by subsection (c) of this section a civil penalty of not more than

1 \$1,000.00 per day for every day after the notification period described in
2 subsection (b) of this section that the required information is not reported. In
3 any action brought pursuant to this section, the Attorney General shall have the
4 same authority to investigate and to obtain remedies as if the action were
5 brought under the Consumer Protection Act, 9 V.S.A. chapter 63.

6 * * * Disclosures by Pharmacists * * *

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

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

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

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

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

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

