

PX 12

**Summary of Bills Leading
to Enactment of Vermont Act 80 §§ 17(2007)**

The following is a summary created by Hunton & Williams LLP of the bills contained in the legislative record of Vermont Acts 80, section 17 (2007).

TAB

Date: 2/13/07

PX 89 LR 1426-1463

As originally introduced, including a New Hampshire-style ban on prescriber-identifiable data.

A

Date: 3/13/07 (1:57)

PX 81 LC 338-359

Contains the Senate Health and Welfare version of the bill, which removes the prescription drug confidentiality and inserts a legislative counsel report on the result of the NH lawsuit.

(Version LC 000381 contains handwritten notes noting testimony prior to the amendment.)

B

Date: 4/10/07 (handwritten)

PX 89 LR 182-226

Version as passed by the Senate, which includes a New Hampshire-style ban on prescriber-identifiable information.

C

Date: 4/24/07 (5:40)

PX 81 LC 002769-002804]

Contains the House Health Care Committee version of the bill, which includes a New Hampshire-style ban.

D

Date: 5/1/07 (11:26 a.m.)

PX 81 LC 002652-002657

Contains 7 findings regarding Vermont spending on prescription drugs; spending by manufacturers on marketing in Vermont; therapeutic choices have impacts on third-party payers; and marketing impacts on prescriber providing patterns.

E

Date: 5/2/07 (10:14 a.m.)

PX 81 LC 002631-002644

Amendment prepared regarding House Health Care Committee Changes. Contains 24 findings and the prescriber opt-in language.

F

A-1484

Date: 5/2/07 (2:33 p.m.) G
PX 81 LC 002616-2630
Contains 27 findings and mandatory disclosure provision.
(Version LC 2601 contains subsequent handwritten notes “reordering” and “add sources”
penned next to the findings.)

Date: 5/3/07 (9:40 a.m.) H
PX 81 LC 002550-002559
Contains all 31 findings.

Date: 5/3/07 (1:20) I
PX 81 LC 002533-002549
Contains all 31 findings. Finding 20 (regarding prescribers and sales representatives)
now contains language used in final form).

Date: 5/3/07 (3:00) J
PX 81 LC 002516-002532
Contains all 31 findings with handwritten proofreading marks.

Date: 5/4/07 K
PX 81 LC 002514
Amendment proposed by Rep. Sunderland requiring an annual report regarding a detailed
account of all amounts paid by the state with state or federal funds in connection with any
litigation regarding S. 115.

Date: 5/10/07 L
PX 81 LC 002219-002249
As passed by the House and Senate.

Date: 6/09/07 M
PX 81 LC 000001-78
Appears to be final, enrolled version of the bill with governor’s signature.

TAB A

(dr req 07-1148 – draft 1)
2/13/2007 - RJL

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(1.2)

1 Introduced by Committee on Finance

2 Date:

3 Subject: Health; prescription drugs; pharmaceuticals; pharmacy benefit

4 managers; drug education; preferred drug list; pricing; confidentiality

5 Statement of purpose: This bill proposes to increase transparency in

6 prescription drug information and pricing by limiting fraudulent advertising of

7 prescription drugs to consumers and health care professionals, requiring

8 increased disclosure to clients by pharmacy benefit managers, strengthening

9 the Medicaid preferred drug list, establishing an evidence-based education

10 program, providing additional pricing information to the Medicaid program

11 from drug manufacturers, and requiring disclosure of education programs

12 funded by drug manufacturers.

13 AN ACT RELATING TO INCREASING TRANSPARENCY OF
14 PRESCRIPTION DRUG PRICING AND INFORMATION

15 It is hereby enacted by the General Assembly of the State of Vermont:

16 Sec. 1. 33 V.S.A. § 1998 is amended to read:

17 § 1998. PHARMACY BEST PRACTICES AND COST CONTROL

18 PROGRAM ESTABLISHED

19 (a) The director of the office of Vermont health access shall establish and

20 maintain a pharmacy best practices and cost control program designed to

1 reduce the cost of providing prescription drugs, while maintaining high quality
2 in prescription drug therapies. The program shall include:

3 (1) A Use of an evidence-based preferred list of covered prescription
4 drugs that identifies preferred choices within therapeutic classes for particular
5 diseases and conditions, including generic alternatives and over-the-counter
6 drugs.

7 ~~(A) The director and the commissioner of banking, insurance,~~
8 ~~securities, and health care administration shall implement the preferred drug~~
9 ~~list as a uniform, statewide preferred drug list by encouraging all health benefit~~
10 ~~plans in this state to participate in the program.~~

11 ~~(B) The commissioner of human resources shall use the preferred~~
12 ~~drug list in the state employees health benefit plan only if participation in the~~
13 ~~program will provide economic and health benefits to the state employees~~
14 ~~health benefit plan and to beneficiaries of the plan, and only if agreed to~~
15 ~~through the bargaining process between the state of Vermont and the~~
16 ~~authorized representatives of the employees of the state of Vermont. The~~
17 ~~provisions of this subdivision do not authorize the actuarial pooling of the state~~
18 ~~employees health benefit plan with any other health benefit plan, unless~~
19 ~~otherwise agreed to through the bargaining process between the state of~~
20 ~~Vermont and the authorized representatives of the employees of the state of~~
21 ~~Vermont. No later than November 1, 2004, the commissioner of human~~

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(1.2)

1 ~~resources shall report to the health access oversight committee and the senate~~
2 ~~and house committees on health and welfare on whether use of the preferred~~
3 ~~drug list in the state employees health benefit plan would, in his or her opinion,~~
4 ~~provide economic and health benefits to the state employees health benefit plan~~
5 ~~and to beneficiaries of the plan.~~

6 ~~(C) The director shall encourage all health benefit plans to implement~~
7 ~~the preferred drug list as a uniform, statewide preferred drug list by inviting the~~
8 ~~representatives of each health benefit plan providing prescription drug~~
9 ~~coverage to residents of this state to participate as observers or nonvoting~~
10 ~~members in the director's drug utilization review board, and by inviting such~~
11 ~~plans to use the preferred drug list in connection with the plans' prescription~~
12 ~~drug coverage.~~

13 (2) Utilization review procedures, including a prior authorization review
14 process.

15 (3) Any strategy designed to negotiate with pharmaceutical
16 manufacturers to lower the cost of prescription drugs for program participants,
17 including a supplemental rebate program.

18 (4) ~~With input from physicians, pharmacists, private insurers, hospitals,~~
19 ~~pharmacy benefit managers, and the drug utilization review board, an~~
20 ~~evidence based research education program designed to provide information~~
21 ~~and education on the therapeutic and cost effective utilization of prescription~~

1 ~~drugs to physicians, pharmacists, and other health care professionals~~
2 ~~authorized to prescribe and dispense prescription drugs. To the extent~~
3 ~~possible, the program shall inform prescribers about drug marketing that is~~
4 ~~intended to circumvent competition from generic alternatives. Details of the~~
5 ~~program, including the scope of the program and funding recommendations,~~
6 ~~shall be contained in a report submitted to the health access oversight~~
7 ~~committee and the senate and house committees on health and welfare no later~~
8 ~~than January 1, 2005.~~

9 ~~(5)~~(4) Alternative pricing mechanisms, including consideration of using
10 maximum allowable cost pricing for generic and other prescription drugs.

11 ~~(6)~~(5) Alternative coverage terms, including consideration of providing
12 coverage of over-the-counter drugs where cost-effective in comparison to
13 prescription drugs, and authorizing coverage of dosages capable of permitting
14 the consumer to split each pill if cost-effective and medically appropriate for
15 the consumer.

16 ~~(7)~~(6) A simple, uniform prescription form, designed to implement the
17 preferred drug list, and to enable prescribers and consumers to request an
18 exception to the preferred drug list choice with a minimum of cost and time to
19 prescribers, pharmacists and consumers.

20 (7) A plan to encourage Vermonters to use federally qualified health
21 centers (FOHC) and FOHC look-alikes, focusing on participants in the

1 Medicaid and Medicaid waiver programs, state employees, individuals under
2 the supervision of corrections, individuals receiving workers' compensation
3 benefits if applicable, and any other state or publicly funded purchaser of
4 prescription drugs, including contracting with one or more FOHCs or FOHC
5 look-alikes to provide case management or record management services.

6 (8) A joint pharmaceuticals purchasing consortium as provided for in
7 subdivision (c)(1) of this section.

8 (8)(9) Any other cost containment activity adopted, by rule, by the
9 director that is designed to reduce the cost of providing prescription drugs
10 while maintaining high quality in prescription drug therapies.

11 * * *

12 (c)(1) The director may implement the pharmacy best practices and cost
13 control program for any other health benefit plan within or outside this state
14 that agrees to participate in the program. For entities in Vermont, the director
15 shall directly or by contract implement the program through a joint
16 pharmaceuticals purchasing consortium. The joint pharmaceuticals purchasing
17 consortium shall be offered on a voluntary basis no later than January 1, 2008,
18 with mandatory participation by state or publicly funded, administered, or
19 subsidized purchasers to the extent practicable and consistent with the
20 purposes of this chapter, by January 1, 2010. "State or publicly funded
21 purchasers" shall include the department of corrections, the division of mental

1 health, Medicaid, the Vermont Health Access Program (VHAP), Dr. Dynasaur,
2 Vermont Rx, Healthy Vermonters, Healthy Vermonters Plus, workers'
3 compensation, and any other state or publicly funded purchaser of prescription
4 drugs.

5 * * *

6 (f)(1) The drug utilization review board shall make recommendations to the
7 director for the adoption of the preferred drug list. The board's
8 recommendations shall be based upon evidence-based considerations of
9 clinical efficacy, adverse side effects, safety, appropriate clinical trials, and
10 cost-effectiveness. "Evidence-based" shall have the same meaning as in
11 section 4261 of Title 18.

12 * * *

13 (6) The director shall encourage participation in the joint purchasing
14 consortium by inviting representatives of the programs and entities specified in
15 (a)(8) of this section to participate as observers or nonvoting members in the
16 drug utilization review board, and by inviting the representatives to use the
17 preferred drug list in connection with the plans' prescription drug coverage.

18 Sec. 2. 33 V.S.A. § 1998(g) is added to read:

19 (g) The office, in collaboration with the department of health, shall enter
20 into a contract with the Oregon Health and Science University Drug
21 Effectiveness Review Project (DERP) to provide technical and clinical support

1 in the development and the administration of the preferred drug list and the
2 evidence-based education program established in subchapter 2 of Title 18.

3 * * * Pharmaceutical Marketer Disclosures * * *

4 Sec. 3. 33 V.S.A. § 2005(a)(4) is amended and (d) is added to read:

5 (4) The following shall be exempt from disclosure:

6 * * *

7 (D) scholarship or other support for medical students, residents, and
8 fellows to attend a significant educational, scientific, or policy-making
9 conference of a national, regional, or specialty medical or other professional
10 association if the recipient of the scholarship or other support is selected by the
11 association; and

12 (E) ~~unrestricted grants for continuing medical education programs;~~

13 ~~and~~

14 ~~(F) prescription drug rebates and discounts.~~

15 * * *

16 (d) Disclosures of unrestricted grants for continuing medical education
17 programs shall be limited to the value, nature, and purpose of the grant and the
18 name of the grantee. It shall not include disclosure of the individual
19 participants in such a program.

1 * * * Price Disclosure and Certification * * *

2 Sec. 4. 33 V.S.A. § 2010 is added to read:

3 § 2010. ACTUAL PRICE DISCLOSURE AND CERTIFICATION .

4 (a) A manufacturer of prescription drugs dispensed in this state under a
5 health program directed or administered by the state shall, on a quarterly basis,
6 report by National Drug Code the following pharmaceutical pricing criteria to
7 the director of the office of Vermont health access for each of its drugs:

8 (1) the average manufacturer price as defined in 42 U.S.C.

9 § 1396r-8(k); and

10 (2) the best price as defined in 42 U.S.C. § 1396r-8(c)(1)(C).

11 (b) The pricing information required under this section is for drugs defined
12 under the Medicaid drug rebate program and must be submitted to the director
13 following its submission to the federal government in accordance with
14 42 U.S.C. § 1396r-8(b)(3).

15 (c) When a manufacturer of prescription drugs dispensed in this state
16 reports the average manufacturer price or best price, the president or chief
17 executive officer of the manufacturer shall certify to the office, on a form
18 provided by the director of the office of Vermont health access, that the
19 reported prices are the same as those reported to the federal government as
20 required by 42 U.S.C. § 1396r-8(b)(3) for the applicable rebate period.

1 and the “Healthy Vermonters Plus” program, for Vermonters without adequate
2 coverage for prescription drugs. The provisions of ~~section 1992 of this title~~
3 subchapter 8 of this chapter shall apply to the director’s authority to administer
4 the pharmacy discount plans established by this section.

5 (b) The Healthy Vermonters program shall offer beneficiaries an initial
6 discounted cost for covered drugs. ~~Upon approval by the Centers for Medicare~~
7 ~~and Medicaid Services of a Section 1115 Medicaid waiver program, and upon~~
8 ~~subsequent legislative approval, the~~ The Healthy Vermonters program and the
9 Healthy Vermonters Plus program shall offer beneficiaries a secondary
10 discounted cost, which shall reflect a state payment toward the cost of each
11 dispensed drug as well as any rebate amount negotiated by the commissioner.

12 * * *

13 (n) ~~The department shall seek a waiver from the Centers for Medicare and~~
14 ~~Medicaid Services (CMS) requesting authorization necessary to implement the~~
15 ~~provisions of this section, including application of manufacturer and labeler~~
16 ~~rebates to the pharmacy discount plans. The secondary discounted cost shall~~
17 ~~not be available to beneficiaries of the pharmacy discount plans until the~~
18 ~~department receives written notification from CMS that the waiver requested~~
19 ~~under this section has been approved and until the general assembly~~
20 ~~subsequently approves all aspects of the pharmacy discount plans, including~~

1 ~~funding for positions and related operating costs associated with eligibility~~
2 ~~determinations.~~

3 * * * PBM Regulation * * *

4 Sec. 6. 18 V.S.A. chapter 221, subchapter 9 is added to read:

5 Subchapter 9. Pharmacy Benefit Managers

6 § 9471. DEFINITIONS

7 As used in this subchapter:

8 (1) “Beneficiary” means an individual enrolled in a health plan in which
9 coverage of prescription drugs is administered by a pharmacy benefit manager
10 and includes his or her dependent or other person provided health coverage
11 through that health plan.

12 (2) “Health insurer” is defined by subdivision 9402(9) of this title. As
13 used in this subchapter, the term includes the state of Vermont and any agent
14 or instrumentality of the state that offers, administers, or provides financial
15 support to state government. It also includes Medicaid, the Vermont health
16 access plan, Vermont Rx, and any other public health care assistance program.

17 (3) “Health plan” means a health benefit plan offered, administered, or
18 issued by a health insurer doing business in Vermont.

19 (4) “Pharmacy benefit management” means an arrangement for the
20 procurement of prescription drugs at a negotiated rate for dispensation within
21 this state to beneficiaries, the administration or management of prescription

1 drug benefits provided by a health plan for the benefit of beneficiaries, or any
2 of the following services provided with regard to the administration of
3 pharmacy benefits:

4 (A) mail service pharmacy;

5 (B) claims processing, retail network management, and payment of
6 claims to pharmacies for prescription drugs dispensed to beneficiaries;

7 (C) clinical formulary development and management services;

8 (D) rebate contracting and administration;

9 (E) certain patient compliance, therapeutic intervention, and generic
10 substitution programs; and

11 (F) disease management programs.

12 (5) “Pharmacy benefit manager” means an entity that performs
13 pharmacy benefit management. The term includes a person or entity acting for
14 a pharmacy benefit manager in a contractual or employment relationship in the
15 performance of pharmacy benefit management for a health plan.

16 § 9472. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES

17 (a) A pharmacy benefit manager that provides pharmacy benefit
18 management for a health plan shall:

19 (1) Discharge its duties with the care, skill, prudence, and diligence
20 under the circumstances then prevailing that a prudent pharmacy benefit

1 manager acting in like capacity and familiar with such matters would use in the
2 conduct of an enterprise of a like character and with like aims.

3 (2) Provide all financial and utilization information requested by a
4 health plan relating to the provision of benefits to beneficiaries through that
5 health plan and all financial and utilization information relating to services to
6 that health plan. A pharmacy benefit manager providing information under
7 this subsection may designate that material as confidential. Information
8 designated as confidential by a pharmacy benefit manager and provided to a
9 health plan under this subsection may not be disclosed by the health plan to
10 any person without the consent of the pharmacy benefit manager, except that
11 disclosure may be made in a court filing under the consumer fraud provisions
12 of chapter 63 of Title 9 or when authorized by that chapter or ordered by a
13 court for good cause shown.

14 (3) Notify a health plan in writing of any proposed or ongoing activity,
15 policy, or practice of the pharmacy benefit manager that presents, directly or
16 indirectly, any conflict of interest with the requirements of this section.

17 (4) Adhere to the following provisions with regard to the dispensation of
18 a substitute prescription drug for a prescribed drug to a beneficiary:

19 (A) With regard to substitutions in which the substitute drug costs
20 more than the prescribed drug, disclose to the health plan the cost of both drugs

1 and any benefit or payment directly or indirectly accruing to the pharmacy
2 benefit manager as a result of the substitution.

3 (B) Transfer in full to the health plan any benefit or payment received
4 in any form by the pharmacy benefit manager either as a result of a
5 prescription drug substitution under subdivision (A) of this subdivision (4) or
6 as a result of the pharmacy benefit manager's substituting a lower-priced
7 generic and therapeutically equivalent drug for a higher-priced prescribed
8 drug.

9 (5) If the pharmacy benefit manager derives any payment or benefit for
10 the dispensation of prescription drugs within the state based on volume of sales
11 for certain prescription drugs or classes or brands of drugs within the state,
12 pass that payment or benefit on in full to the health plan, unless the contract
13 between the pharmacy benefit manager and the health plan provides otherwise.

14 (6) Disclose to the health plan all financial terms and arrangements for
15 remuneration of any kind that apply between the pharmacy benefit manager
16 and any prescription drug manufacturer, including formulary management and
17 drug-switch programs, educational support, claims processing, pharmacy
18 network fees charged from retail pharmacies and data sales fees. A pharmacy
19 benefit manager providing information under this subsection may designate
20 that material as confidential. Information designated as confidential by a
21 pharmacy benefit manager and provided to a health plan under this subsection

1 may not be disclosed by the health plan to any person without the consent of
2 the pharmacy benefit manager, except that disclosure may be made in a court
3 filing under the consumer fraud provisions of chapter 63 of Title 9 or when
4 authorized by that chapter or ordered by a court for good cause shown.

5 (b) Compliance with the requirements of this section is required in all
6 contracts for pharmacy benefit management entered into in this state by a
7 health plan in this state.

8 § 9473. ENFORCEMENT

9 (a) In addition to any remedy available to the commissioner under this title
10 and any other remedy provided by law, a violation of this subchapter shall be
11 considered a violation of the Vermont Consumer Fraud Act in subchapter 1 of
12 chapter 63 of Title 1. All rights, authority, and remedies available to the
13 attorney general and private parties to enforce the Vermont Consumer Fraud
14 Act shall be available to enforce the provisions of this subchapter.

15 (b) In connection with any action for violation of the Vermont Consumer
16 Fraud Act, the commissioner's determinations concerning the interpretation
17 and administration of the provisions of this subchapter and any rules adopted
18 hereunder shall carry a presumption of validity. The attorney general and the
19 commissioner shall consult with each other prior to the commencement of any
20 investigation or enforcement action with respect to any pharmacy benefit
21 manager. The commissioner may enforce a violation of this subchapter by a

1 pharmacy benefit manager under section 9412 of this title. Notwithstanding
2 the foregoing, the commissioner and the attorney general may bring a joint
3 enforcement action against any person or entity for a violation of this
4 subchapter.

5 Sec. 7. 18 V.S.A. § 9421 is added to read:

6 § 9421. PHARMACY BENEFIT MANAGEMENT; REGISTRATION;

7 AUDIT

8 (a) A pharmacy benefit manager shall not do business in this state without
9 first registering with the commissioner on a form and in a manner prescribed
10 by the commissioner.

11 (b) In accordance with rules adopted by the commissioner, pharmacy
12 benefit managers operating in the state of Vermont and proposing to contract
13 for the provision of pharmacy benefit management services shall offer health
14 insurance plans a quotation for an administrative-services-only contract with
15 full pass through of negotiated prices, rebates, and other such financial benefits
16 which would identify to the health insurance plan external sources of revenue
17 and profit, in addition to quotations for any other alternative pricing
18 arrangement. Quotations for an administrative-services-only contract shall
19 include a reasonable fee payable by the health insurance plan which represents
20 a competitive pharmacy benefit profit.

1 (c) In order to enable periodic verification of pricing arrangements,
2 pharmacy benefit managers shall allow access, in accordance with rules
3 adopted by the commissioner, by the health insurance plan to financial and
4 contractual information necessary to conduct a complete and independent audit
5 designed to verify the following:

6 (1) if applicable under an administrative-services-only contract under
7 subsection (a) of this section, full pass through of negotiated drug prices and
8 fees associated with all drugs dispensed to beneficiaries of the health insurance
9 plan in both retail and mail order settings or resulting from any of the
10 pharmacy benefit management functions defined in this section;

11 (2) if applicable under an administrative-services-only contract under
12 subsection (a) of this section, full pass through of all financial remuneration
13 associated with all drugs dispensed to beneficiaries of the health insurance plan
14 in both retail and mail order settings or resulting from any of the pharmacy
15 benefit management functions defined in this section; and

16 (3) any other verifications relating to the pricing arrangements and
17 activities of the pharmacy benefit manager required by the commissioner.

18 (d) The department's reasonable expenses in administering the provisions
19 of this section may be charged to pharmacy benefit managers in the manner
20 provided for in section 18 of Title 8. Such expenses shall be allocated in
21 proportion to the lives of Vermonters covered by each pharmacy benefit

1 manager as reported annually to the commissioner in a manner and form
2 prescribed by the commissioner.

3 (e) The commissioner may adopt such rules as are necessary or desirable in
4 carrying out the purposes of this section. The rules also shall ensure that
5 proprietary information is kept confidential and not disclosed by health
6 insurance plans.

7 (f) As used in this section:

8 (1) “Health insurance plan” is defined in subdivision 9471(2) of this
9 title.

10 (2) “Health insurer” is defined in subdivision 9402(9) of this title. As
11 used in this section, the term includes the state of Vermont and any agent or
12 instrumentality of the state that offers, administers, or provides financial
13 support to state government. The term also includes Medicaid, the Vermont
14 health access plan, Vermont Rx, and any other public health care assistance
15 program, unless the state has an administrative-services-only contract.

16 (3) “Pharmacy benefit management” is defined in subdivision 9471(4)
17 of this title.

18 (4) “Pharmacy benefit manager” is defined in subdivision 9471(5) of this
19 title.

1 Sec. 8. APPLICATION

2 Sec. 6 and 7 of this act applies to contracts executed or renewed on or after
3 September 1, 2007. For purposes of this section, a contract executed pursuant
4 to a memorandum of agreement executed prior to September 1, 2007 is
5 deemed to have been executed prior to September 1, 2007 even if the contract
6 was executed after that date.

7 Sec. 9. 18 V.S.A. chapter 91 is amended to read:

8 CHAPTER 91. GENERIC DRUGS PRESCRIPTION DRUG
9 COST CONTAINMENT

10 Sec. 10. 18 V.S.A. chapter 91, sections 4601–4608 are designated as
11 subchapter 1 which is added to read:

12 Subchapter 1. Generic Drugs

13 Sec. 11. 18 V.S.A. chapter 91, subchapter 2 is added to read:

14 Subchapter 2. Evidence-Based Education Program

15 § 4621. DEFINITIONS

16 For the purposes of this subchapter,

17 (1) “Department” means the department of health.

18 (2) “Evidence-based” means based on criteria and guidelines that reflect
19 high-quality, cost-effective care. The methodology used to determine such
20 guidelines shall meet recognized standards for systematic evaluation of all
21 available research and shall be free from conflicts of interest. Consideration of

1 the best available scientific evidence does not preclude consideration of
2 experimental or investigational treatment or services under a clinical
3 investigation approved by an institutional review board.

4 § 4622. EVIDENCE-BASED EDUCATION PROGRAM

5 (a) The department, in collaboration with the attorney general, shall
6 establish an evidence-based prescription drug education program for health
7 care professionals designed to provide information and education on the
8 therapeutic and cost-effective utilization of prescription drugs to physicians,
9 pharmacists, and other health care professionals authorized to prescribe and
10 dispense prescription drugs. The department may collaborate with other states
11 in establishing this program.

12 (b) The department shall request information and collaboration from
13 physicians, pharmacists, private insurers, hospitals, pharmacy benefit
14 managers, the drug utilization review board, medical schools, the attorney
15 general, and any other programs providing an evidence-based education to
16 prescribers on prescription drugs in developing and maintaining the program.

17 (c) As provided for under subsection 1998(g) of this title, the department
18 shall have technical and clinical support in the development and the
19 administration of the program from the Oregon Health and Science University
20 Drug Effectiveness Review Project (DERP).

1 (d) The department and the attorney general shall collaborate in reviewing
2 the marketing activities of pharmaceutical manufacturing companies in
3 Vermont and determining appropriate funding sources for the program,
4 including awards from suits brought by the attorney general against
5 pharmaceutical manufacturers.

6 * * * Prescription Drug Data Confidentiality * * *

7 Sec. 12. 18 V.S.A. chapter 91, subchapter 3 is added to read:

8 Subchapter 3. Information Requirements

9 § 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

10 (a) The general assembly finds that it has become an increasingly common
11 practice for information identifying physicians and other prescribers in
12 prescription records to be used to target pharmaceutical marketing and gifts
13 toward physicians who prescribe the most expensive drugs for their patients.
14 This practice raises drug costs for all Vermont residents and compromises the
15 professional autonomy of physicians. It is the intent of the general assembly to
16 ensure the privacy of Vermonters and health care professionals by prohibiting
17 the commercial use of prescription information.

18 (b) As used in this section:

19 (1) “Commercial purpose” shall include advertising, marketing,
20 promotion, or any activity that is intended to be used or is used to influence
21 sales or the market share of a pharmaceutical product, influence or evaluate the

1 prescribing behavior of an individual health care professional, market
2 prescription drugs to patients, or evaluate the effectiveness of a professional
3 pharmaceutical detailing sales force.

4 (2) “Electronic transmission intermediary” means an entity that provides
5 the infrastructure that connects the computer systems or other electronic
6 devices used by health care professionals, prescribers, pharmacies, health care
7 facilities and pharmacy benefit managers, health insurers, third-party
8 administrators, and agents and contractors of those persons in order to facilitate
9 the secure transmission of an individual’s prescription drug order, refill,
10 authorization request, claim, payment, or other prescription drug information.

11 (3) “Health care facility” shall have the same meaning as in section
12 9402 of this title.

13 (4) “Health care professional” shall have the same meaning as in section
14 9402 of this title.

15 (5) “Health insurer” shall have the same meaning as in section 9410 of
16 this title.

17 (6) “Pharmacy” means any individual or entity licensed or registered
18 under chapter 36 of Title 26.

19 (7) “Prescriber” means an individual allowed by law to prescribe and
20 administer prescription drugs in the course of professional practice.

1 (8) “Regulated records” means information or documentation from a
2 prescription written by a prescriber doing business in Vermont or a
3 prescription dispensed in Vermont.

4 (c) A health insurer, a self-insured employer, an electronic transmission
5 intermediary, a pharmacy, or other similar entity shall not license, transfer, use,
6 or sell regulated records which include prescription information containing
7 patient-identifiable or prescriber-identifiable data for any commercial purpose.

8 (d) This section shall not apply to:

9 (1) the license, transfer, use, or sale of regulated records for the limited
10 purposes of pharmacy reimbursement; prescription drug formulary
11 compliance; patient care management; utilization review by a health care
12 professional, the patient’s health insurer, or the agent of either; health care
13 research; or as otherwise provided by law;

14 (2) the dispensing of prescription medications to a patient or to the
15 patient’s authorized representative;

16 (3) the transmission of prescription information between an authorized
17 prescriber and a licensed pharmacy, between licensed pharmacies, or that may
18 occur in the event a pharmacy’s ownership is changed or transferred;

19 (4) care management educational communications provided to a patient
20 about the patient’s health condition, adherence to a prescribed course of

1 therapy and other information relating to the drug being dispensed, treatment
2 options, or clinical trials;

3 (5) the use or disclosure of prescription information as authorized by
4 chapter 84 or 84A, or both, of this title; and

5 (6) the collection, use, transfer, or sale of patient and prescriber
6 data for commercial purposes if the data do not identify a person, and there is
7 no reasonable basis to believe that the data provided could be used to identify a
8 person.

9 (e) In addition to any other remedy provided by law, the attorney general
10 may file an action in superior court for a violation of this section or of rules
11 adopted under this section. The attorney general shall have the same authority
12 to investigate and to obtain remedies as if the action were brought under the
13 consumer fraud act, chapter 63 of Title 9. Each violation of this section or of
14 rules adopted under this section constitutes a separate civil violation for which
15 the attorney general may obtain relief.

16 Sec. 13. 18 V.S.A. § 9410(e) is amended to read:

17 (e)(1) Records or information protected by the provisions of the
18 physician-patient privilege under subsection 1612(a) of Title 12, or otherwise
19 required by law to be held confidential, shall be filed in a manner that does not
20 disclose the identity of the protected person.

1 (2) Records or information protected by section 4621 of this title shall
2 be filed in a manner that does not disclose the identity of the patient or the
3 prescriber.

4 Sec. 14. 18 V.S.A. chapter 91, subchapter 4 is added to read:

5 Subchapter 4. Consumer Provisions

6 § 4641. CO-PAYMENT PRICING

7 A person licensed or registered under chapter 36 of Title 26 shall charge a
8 consumer the lesser of the co-payment required by the insurer or the usual
9 retail cost of the prescription drug.

10 Sec. 15. 8 V.S.A. § 4100f is added to read:

11 § 4100f. PRESCRIPTION DRUG CO-PAYMENTS

12 A health insurance or other health benefit plan offered by a health insurer
13 licensed under this chapter or a prescription drug plan offering coverage under
14 Medicare Part C or D shall require the insured to pay only the lesser of the
15 co-payment required by the insurer or the usual retail cost of the prescription
16 drug.

17 * * * Unconscionable Pricing * * *

18 Sec. 16. 18 V.S.A. chapter 91, subchapter 5 is added to read:

19 Subchapter 5. Unconscionable Pricing

1 § 4651. PURPOSE

2 The purpose of this subchapter is to ensure Vermonters affordable access to
3 prescription drugs necessary for the treatment of certain health conditions
4 determined to be a serious public health problem in the state.

5 § 4652. DEFINITIONS

6 For purposes of this subchapter:

7 (1) “Affected party” means any person directly or indirectly affected by
8 unconscionable prices of prescription drugs, including any organization
9 representing such persons or any person or organization representing the public
10 interest.

11 (2) “Most favored purchase price” means the price offered with all
12 rights and privileges accorded by the seller to the most favored purchaser in
13 Vermont.

14 (3) “Purchaser” means any person who engages primarily in selling
15 drugs directly to consumers.

16 (4) “Seller” means any person who trades in drugs for resale to
17 purchasers in this state.

18 § 4653. UNCONSCIONABLE PRICING OF PRESCRIPTION DRUGS

19 A manufacturer of prescription drugs or its licensee shall not sell, supply for
20 sale, or impose minimum resale requirements for a prescription drug necessary

1 to treat a specified health condition that results in that prescription drug being
2 sold in Vermont for an unconscionable price.

3 § 4653. SPECIFIED HEALTH CONDITION

4 (a)(1) The commissioner of health may issue a declaration that a health
5 condition is prevalent in Vermont to such an extent as to constitute a serious
6 public health problem.

7 (2) The attorney general may request a determination by the
8 commissioner of health on whether a health condition meets the criteria in this
9 section. If the attorney general makes a request under this subdivision, the
10 commissioner of health shall consider the request.

11 (b) At minimum, the commissioner shall consider the following factors
12 when declaring that a health condition is a serious public health problem:

13 (1) how many Vermonters suffer from the health condition;

14 (2) the costs to the state, employer-sponsored insurance, and private
15 insurers of treating the health condition with prescription drugs;

16 (3) the cost of a prescription drug or a class of prescription drugs used to
17 treat the health condition to the extent that information is available;

18 (4) whether a prescription drug or class of prescription drugs is essential
19 for maintaining health or life; and

20 (5) other relevant factors as determined by the commissioner.

1 § 4654. UNCONSCIONABLE PRICING

2 A prima facie case of unconscionable pricing shall be established where the
3 wholesale price of a prescription drug in Vermont is over 30 percent higher
4 than the prices available to federal agencies under the federal supply schedule,
5 the prices available through the Healthy Vermonters program, or the most
6 favored purchase price.

7 § 4655. CIVIL INVESTIGATION

8 (a) The attorney general or a state’s attorney whenever he or she has reason
9 to believe any person to be or to have been in violation of this chapter may
10 examine or cause to be examined by any agent or representative designated by
11 him or her for that purpose, any books, records, papers, memoranda, and
12 physical objects of any nature bearing upon each alleged violation, and may
13 demand written responses under oath to questions bearing upon each alleged
14 violation. The attorney general or state’s attorney may require the attendance
15 of such person or of any other person having knowledge in the premises in the
16 county where such person resides or has a place of business or in Washington
17 County if such person is a nonresident or has no place of business within the
18 state, and may take testimony and require proof material for his or her
19 information, and may administer oaths or take acknowledgment in respect of
20 any book, record, paper, or memorandum. The attorney general or a state’s
21 attorney shall serve notice of the time, place, and cause of such examination or

1 attendance, or notice of the cause of the demand for written responses, at least
2 ten days prior to the date of such examination, personally or by certified mail,
3 upon such person at his or her principal place of business, or, if such place is
4 not known, to his or her last known address. Any book, record, paper,
5 memorandum, or other information produced by any person pursuant to this
6 section shall not, unless otherwise ordered by a court of this state for good
7 cause shown, be disclosed to any person other than the authorized agent or
8 representative of the attorney general or a state's attorney or another law
9 enforcement officer engaged in legitimate law enforcement activities, unless
10 with the consent of the person producing the same. This subsection shall not
11 be applicable to any criminal investigation or prosecution brought under the
12 laws of this or any state.

13 (b) A person upon whom a notice is served pursuant to the provisions of
14 this section shall comply with the terms thereof unless otherwise provided by
15 the order of a court of this state. Any person who, with intent to avoid, evade,
16 or prevent compliance, in whole or in part, with any civil investigation under
17 this section, removes from any place, conceals, withholds, or destroys,
18 mutilates, alters, or by any other means falsifies any documentary material in
19 the possession, custody, or control of any person subject of any such notice, or
20 mistakes or conceals any information, shall be fined not more than \$5,000.00.

1 (c) Whenever any person fails to comply with any notice served upon him
2 or her under this section or whenever satisfactory copying or reproduction of
3 any such material cannot be done and such person refuses to surrender such
4 material, the attorney general or a state's attorney may file, in the superior
5 court in which such person resides or has his or her principal place of business
6 or in Washington County if such person is a nonresident or has no principal
7 place of business in this state, and serve upon such person a petition for an
8 order of such court for the enforcement of this section. Whenever any petition
9 is filed under this section, such court shall have jurisdiction to hear and
10 determine the matter so presented, and to enter such order or orders as may be
11 required to carry into effect the provisions of this section. Any disobedience of
12 any order entered under this section by any court shall be punished as
13 contempt.

14 § 4656. CIVIL ACTION

15 (a) Any affected party, including the attorney general on behalf of the state,
16 shall have standing to file a civil suit in a court of competent jurisdiction for a
17 violation of this chapter and to seek a remedy, including declaratory and
18 injunctive relief. If the state is the plaintiff, it may seek remedies on its own
19 behalf or on behalf of all residents, or both.

20 (b) If a prima facie case of unconscionable pricing is shown, the burdens of
21 providing evidence and of proving by a preponderance of the evidence shall

1 shift to the defendant to show that a prescription drug is not unconscionably
2 priced by showing the demonstrated costs of invention, development, and
3 production of the prescription drug, global sales and profits to date,
4 consideration of any government-funded research that supported the
5 development of the drug, and the impact of price on access to a prescription
6 drug by residents and the government of Vermont.

7 (c) Whenever an affected party, other than the attorney general, brings an
8 action pursuant to this chapter, a copy of any pleadings shall be served on the
9 attorney general pursuant to Rule 5 of the Vermont Rules of Civil Procedure.
10 Failure to comply with this provision shall not affect the validity of the
11 proceedings commenced under this section.

12 § 4657. REMEDIES

13 (a) If a court determines that any person has violated this chapter, the court
14 is authorized to render:

15 (1) the imposition of a civil penalty of not more than \$10,000.00 for
16 each violation;

17 (2) temporary, preliminary, or permanent injunctions to enjoin the sales
18 of prescription drugs in Vermont at unconscionable prices;

19 (3) an order of damages, including treble damages;

1 from a manufacturer or wholesaler and repackages them for later retail sale and
2 has a labeler code from the federal Food and Drug Administration under 21
3 Code of Federal Regulations, 2027.20 (1999).

4 (26) “Regulated advertisement” means the presentation to the general
5 public of a commercial message regarding a prescription drug or biological
6 product by a manufacturer of prescription drugs that is broadcast on television
7 or radio from a station that is physically located in the state, broadcast over the
8 internet from a location in the state, or printed in magazines or newspapers that
9 are printed, distributed, or sold in the state.

10 § 4052. MANUFACTURE, SALE, DELIVERY; PROHIBITIONS

11 The following acts and the causing thereof within the state of Vermont are
12 hereby prohibited:

13 * * *

14 (12) A manufacturer of prescription drugs may not present or cause to
15 be presented in the state a regulated advertisement, unless that advertisement
16 meets the requirements concerning misbranded drugs and devices and
17 prescription drug advertising of federal law and regulations under 21 United
18 States Code, Sections 331 and 352(n) and 21 Code of Federal Regulations, Part
19 202 and state rules.

20 (13) No person shall sell, offer for sale, or distribute electronic
21 prescribing software that advertises, uses instant messaging and pop-up

1 advertisements, or uses other means to influence or attempt to influence the
2 prescribing decision of a health care professional through economic incentives
3 or otherwise and which is triggered or in specific response to the input,
4 selection, or act of a health care professional or agent in prescribing a specific
5 prescription drug or directing a patient to a certain pharmacy.

6 (14) No person shall sell, offer for sale, distribute, or transport for sale
7 within this state in a package or container intended for general home and
8 household use any misbranded package of a hazardous substance.

9 * * *

10 § 4054. PENALTIES

11 (a) A person who violates any of the provisions of section 4052 of this title
12 shall be imprisoned for not more than one year or fined not more than
13 \$1,000.00 or both; but if the violation is committed after a conviction of the
14 person under this section has become final, the person shall be imprisoned for
15 not more than one year, or fined not more than \$2,500.00, or both.

16 (b) A person shall not be subject to the penalties of subsection (a) of this
17 section for having violated ~~section~~ subsection 4052(a) or (c) of this title if ~~he~~
18 the person establishes a guaranty or undertaking signed by, and containing the
19 name and address of the person residing in the state of Vermont from whom ~~he~~
20 the person received in good faith the article, to the effect that the article is not

1 adulterated or misbranded within the meaning of this chapter, designating this
2 chapter.

3 (c) No publisher, radio broadcast licensee, or agency or medium for the
4 dissemination of an advertisement, except the manufacturer or pharmaceutical
5 manufacturer, packer, distributor or seller of the article to which a false
6 advertisement relates, shall be liable under this section by reason of the
7 dissemination by him or her of such false advertisement, unless he or she has
8 refused, on the request of the board to furnish the board the name and post
9 office address of the manufacturer or pharmaceutical manufacturer, packer,
10 distributor, seller, or advertising agency, residing in the state of Vermont, who
11 causes him or her to disseminate such advertisement.

12 * * *

13 § 4068. ADVERTISING REGULATIONS

14 (a) An advertisement of a food, drug, device, or cosmetic shall be deemed
15 to be false if it is false or misleading in any particular;

16 (b) For the purpose of this chapter, the advertisement of a drug or device
17 representing it to have any effect in albuminuria, appendicitis, arterio-sclerosis,
18 blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis,
19 diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases,
20 high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis
21 media, paralysis, pneumonia, poliomyelitis (infantile paralysis), prostate gland

1 disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, smallpox,
2 tuberculosis, tumors, typhoid, uremia, venereal disease, shall also be deemed to
3 be false, except that no advertisement, not in violation of subsection (a) of this
4 section, shall be deemed to be false under this subsection if it is disseminated
5 only to members of the medical, dental, or veterinary professions, or appears
6 only in the scientific periodicals of these professions, or is disseminated only
7 for the purpose of public health education by persons not commercially
8 interested, directly or indirectly, in the sale of the drugs or devices; ~~provided,~~
9 ~~that whenever the board determines that an advance in medical science has~~
10 ~~made any type of self-medication safe as to any of the diseases named above,~~
11 ~~the board shall by regulation authorize the advertisement of drugs having~~
12 ~~curative or therapeutic effect for the disease, subject to such conditions and~~
13 ~~restrictions as the board may deem necessary in the interests of public health;~~
14 ~~provided, that this subsection shall not be construed as indicating that self-~~
15 ~~medication for diseases other than those named herein is safe or efficacious.~~

16 * * *

17 Sec. 18. 33 V.S.A. § 1998a is added to read:

18 § 1998a. MANUFACTURER FEE

19 (a) For purposes of this section, “pharmaceutical manufacturer” shall have
20 the same meaning as in section 4051 of Title 18.

1 (b) Annually, each pharmaceutical manufacturer of prescription drugs that
2 are paid for by Medicaid, the Vermont Health Access Program, Dr. Dynasaur,
3 VPharm or Vermont Rx shall pay a fee of \$1,000.00 per calendar year to the
4 agency of human services.

5 (c) Fees collected under this section shall fund the implementation and
6 operation of subdivision 4052(a)(12) of Title 18 and the evidence-based
7 education program established in subchapter 2 of Title 18.

8 (d) The secretary of human services or designee shall make rules for the
9 implementation of this section.

10 Sec. 19. 9 V.S.A. § 2466a is added to read:

11 § 2466a. CONSUMER PROTECTIONS: PRESCRIPTION DRUGS

12 (a) A violation of subdivisions 4052(a)(12) and (13) and sections 4631, and
13 9472 of Title 18 shall be considered a violation under this section.

14 (b) It shall be an unfair practice under this section for a health insurance or
15 other health benefit plan offered by a health insurer to sell, solicit, or negotiate
16 the purchase of health insurance in this state by:

17 (1) Advertising by making use directly or indirectly of any method of
18 marketing which fails to disclose in a conspicuous manner that a purpose of the
19 method of marketing is solicitation of insurance and that contact will be made
20 by an insurance agent or insurance company.

1 (2) Using an appointment that was made to discuss Medicare products
2 or to solicit the sale of Medicare products to solicit sales of any other insurance
3 products unless the consumer specifically agreed in advance of the
4 appointment to discuss other types of insurance products during the same
5 appointment. As used in this subdivision, the term “Medicare products”
6 includes Medicare Part A, Medicare Part B, Medicare Part C, Medicare Part D,
7 and Medicare supplement plans.

8 Sec. 20. RECODIFICATION

9 The following sections of Title 33 as amended by this act are recodified as
10 follows:

11 (1) Section 2005 shall be section 4632 of Title 18.

12 (2) Section 2005a shall be section 4633 of Title 18.

13 (3) Section 2008 shall be section 4634 of Title 18.

14 (4) Section 2006 shall be section 852 of Title 2.

15 Sec. 21. REPEAL

16 Section 2009 of Title 33 is repealed.

TAB B

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TO THE HONORABLE SENATE

The Committee on Health and Welfare, to which was referred Senate Bill S.115, entitled "AN ACT RELATING TO INCREASING TRANSPARENCY OF PRESCRIPTION DRUG PRICING AND INFORMATION"

respectfully report that they have met and considered the same and recommend that the bill be amended as follows:

First: In Sec. 1, by striking 33 V.S.A. § 1998(a)(7) and inserting a new subdivision (7) to read:

(7) A plan to encourage inform Vermonters to use of the availability of health services provided by federally qualified health centers (FOHC) and FOHC look-alikes, when the when including that prescription drug pricing is more affordable, focusing on participants in the Medicaid and Medicaid waiver programs, state employees, individuals under the supervision of corrections, individuals receiving workers' compensation benefits if applicable, and any other state or publicly funded purchaser of prescription drugs, including contracting with one or more FOHCs or FOHC look-alikes to provide case management or record management services.

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Second: In Sec. 1, by striking 33 V.S.A. § 1998(c)(1) and inserting in lieu thereof a new subdivision (1) to read:

(c)(1) The director may implement the pharmacy best practices and cost control program for any other health benefit plan within or outside this state that agrees to participate in the program. For entities in Vermont, the director shall directly or by contract implement the program through a joint pharmaceuticals purchasing consortium. The joint pharmaceuticals purchasing consortium shall be offered on a voluntary basis no later than January 1, 2008, with mandatory participation by state or publicly funded, administered, or subsidized purchasers to the extent practicable and consistent with the purposes of this chapter, by January 1, 2010. If necessary, the office of Vermont health access shall seek authorization from the Centers for Medicare and Medicaid to include purchases funded by Medicaid. “State or publicly funded purchasers” shall include the department of corrections, the division of mental health, Medicaid, the Vermont Health Access Program (VHAP), Dr. Dynasaur, Vermont Rx, VPharm, Healthy Vermonters, Healthy Vermonters Plus, workers’ compensation, and any other state or publicly funded purchaser of prescription drugs.

Third: In Sec. 1, 33 V.S.A. § 1998(f)(6), by striking the reference to subdivision (a)(8) on page 7, line 4 and inserting in lieu thereof “(c)(1)”

Fourth: In Sec. 2, 33 V.S.A. § 1998(g), on page 7, lines 9 to 10, by striking the words “, such as the Oregon Health and Science University Drug Effectiveness Review Project (DERP),”

Fifth: In Sec. 3, 33 V.S.A. § 2005(a)(3), on page 7, line 18, by inserting the words “and the office of Vermont health access” after the words “department of health”

Sixth: In Sec. 5, 33 V.S.A. § 2010(b), on page 10, line 8, by striking the words “or may adopt its own standards by rule”

Seventh: In Sec. 5, by striking subsection 33 V.S.A. § 2010(d) and inserting a new subsection (d) to read:

(d) When a manufacturer of prescription drugs dispensed in this state reports the ~~average manufacturer price or best price information required under subsection (a) of this section~~, the president, chief executive officer, or a designated employee of the manufacturer shall certify to the office, on a form provided by the director of the office of Vermont health access, that the reported prices are the same as those reported to the federal government as required by 42 U.S.C. § 1396r-8(b)(3) for the applicable rebate period. A designated employee shall be an employee who reports directly to the chief executive officer or president and who has been delegated to make the certification under this section.

Eighth: In Sec. 6, 33 V.S.A. § 2003, on page 12, line 11, inserting before the

symbol “* * *” the following:

(c) As used in this section:

(1) "Beneficiary" means any individual enrolled in either the Healthy Vermonters program or the Healthy Vermonters Plus program.

(2) "Healthy Vermonters beneficiary" means any individual Vermont resident without adequate coverage:

(A) who is at least 65 years of age, or is disabled and is eligible for Medicare or Social Security disability benefits, with household income equal to or less than 400 percent of the federal poverty level, as calculated under the rules of the Vermont health access plan, as amended; or

(B) whose household income is equal to or less than 300 percent of the federal poverty level, as calculated under the rules of the Vermont Health access plan, as amended.

(3) "Healthy Vermonters Plus beneficiary" means any individual Vermont resident without adequate coverage:

(A) whose household income is greater than 300 percent and equal to or less than 350 percent of the federal poverty level, as calculated under the rules of the Vermont health access plan, as amended; or

~~(B) whose family incurs unreimbursed expenses for prescription drugs, including insurance premiums, that equal five percent or more of~~

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~~household income or whose total unreimbursed medical expenses, including insurance premiums, equal 15 percent or more of household income.~~

Ninth: In Sec. 7, by striking subdivision 18 V.S.A. § 9472(a)(1) and inserting a new subdivision (a)(1) to read:

(a) Unless the contract provides otherwise, a pharmacy benefit manager that provides pharmacy benefit management for a health plan shall:

(1) Discharge its duties ~~with the care, skill, prudence, and diligence~~ reasonable care and diligence and be generally fair and truthful under the circumstances then prevailing that a ~~prudent~~ pharmacy benefit manager acting in like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims. In the case of a health benefit plan offered by a health insurer as defined by subdivision 9471(2)(A) of this title, the health insurer shall remain responsible for administering the health benefit plan in accordance with the health insurance policy or subscriber contract or plan and in compliance with all applicable provisions of Title 8 and this title.

Tenth: In Sec. 7, by striking subsection 18 V.S.A. § 9472(c) and inserting a new subsection (c) to read:

(c) Compliance with the requirements of this section is required for pharmacy benefit managers entering into contracts with a health insurer in this state for pharmacy benefit management in this state.

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Eleventh: In Sec. 8, by striking subsections 18 V.S.A. § 9421(b) and subdivision (c)(1) and inserting a new (b) and (c)(1) to read:

(b) In accordance with rules adopted by the commissioner, pharmacy benefit managers operating in the state of Vermont and proposing to contract for the provision of pharmacy benefit management shall notify health insurers when the pharmacy benefit manager provides a quotation that a quotation for an administrative-services-only contract with full pass through of negotiated prices, rebates, and other such financial benefits which would identify to the health insurer external sources of revenue and profit is generally available and whether the pharmacy benefits manager offers that type of arrangement. Quotations for an administrative-services-only contract shall include a reasonable fee payable by the health insurer which represents a competitive pharmacy benefit profit. **This subsection shall not be interpreted to require a pharmacy benefits manager to offer an administrative-services-only contract.**

(c)(1) In order to enable periodic verification of pricing arrangements in administrative-services-only contracts, pharmacy benefit managers shall allow access, in accordance with rules adopted by the commissioner, by the health insurer who is a party to the administrative-services-only contract to financial and contractual information necessary to conduct a complete and independent audit designed to verify the following:

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(A) ~~if applicable under an administrative services only contract~~
under subsection (b) of this section, full pass through of negotiated drug
prices and fees associated with all drugs dispensed to beneficiaries of the
health plan in both retail and mail order settings or resulting from any of the
pharmacy benefit management functions defined ~~in this section in the~~
contract;

(B) ~~if applicable under an administrative services only contract~~
under subsection (b) of this section, full pass through of all financial
remuneration associated with all drugs dispensed to beneficiaries of the health
plan in both retail and mail order settings or resulting from any of the
pharmacy benefit management functions defined in ~~this section~~ the contract;
and

(C) any other verifications relating to the pricing arrangements and
activities of the pharmacy benefit manager required by ~~the contract~~ if required
by commissioner.

Twelfth: In Sec. 12, 18 V.S.A. § 4622(a), on page 23, line 7, by adding the words “and the office of Vermont health access” after the words “attorney general”

Thirteenth: In Sec. 12, 18 V.S.A. § 4622(c), on page 23, line 21 and page 24, lines 1 and 2, by striking the words “, such as the Oregon Health and Science University Drug Effectiveness Review Project (DERP)”

Fourteenth: By inserting a Sec. 13a to read:

Sec. 13a. 1 V.S.A. § 316(c)(38) is added to read:

(38) records held by the agency of human services, which include prescription information containing patient-identifiable or prescriber-identifiable data or data that could be used to identify a patient or prescriber, except that these records shall be made available upon request to state or federal entities for purposes consistent with those contained in subchapter 3 of chapter 91 of Title 18 or chapter 19 of Title 33 or for law enforcement activities.

JESSICA – IGNORE THE REST OF THIS – IT IS NOT AMENDED YET.

Sec. 13. 18 V.S.A. chapter 91, subchapter 3 is added to read:

Subchapter 3. Information Requirements

§ 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

(a) The general assembly finds that it has become an increasingly common practice for information identifying physicians and other prescribers in prescription records to be used to target pharmaceutical marketing and gifts toward physicians who prescribe the most expensive drugs for their patients. This practice raises drug costs for all Vermont residents and compromises the professional autonomy of physicians. It is the intent of the general assembly to

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ensure the privacy of Vermonters and health care professionals by prohibiting the commercial use of prescription information.

(b) As used in this section:

(1) “Commercial purpose” shall include advertising, marketing, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a pharmaceutical product, influence or evaluate the prescribing behavior of an individual health care professional, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

(2) “Electronic transmission intermediary” means an entity that provides the infrastructure that connects the computer systems or other electronic devices used by health care professionals, prescribers, pharmacies, health care facilities and pharmacy benefit managers, health insurers, third-party administrators, and agents and contractors of those persons in order to facilitate the secure transmission of an individual’s prescription drug order, refill, authorization request, claim, payment, or other prescription drug information.

(3) “Health care facility” shall have the same meaning as in section 9402 of this title.

(4) “Health care professional” shall have the same meaning as in section 9402 of this title.

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(5) "Health insurer" shall have the same meaning as in section 9410 of this title.

(6) "Pharmacy" means any individual or entity licensed or registered under chapter 36 of Title 26.

(7) "Prescriber" means an individual allowed by law to prescribe and administer prescription drugs in the course of professional practice.

(8) "Regulated records" means information or documentation from a prescription written by a prescriber doing business in Vermont or a prescription dispensed in Vermont.

(c) A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity shall not license, transfer, use, or sell regulated records which include prescription information containing patient-identifiable or prescriber-identifiable data for any commercial purpose.

(d) This section shall not apply to:

(1) the license, transfer, use, or sale of regulated records for the limited purposes of pharmacy reimbursement; prescription drug formulary compliance; patient care management; utilization review by a health care professional, the patient's health insurer, or the agent of either; or health care research;

(2) the dispensing of prescription medications to a patient or to the patient's authorized representative;

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(3) the transmission of prescription information between an authorized prescriber and a licensed pharmacy, between licensed pharmacies, or that may occur in the event a pharmacy's ownership is changed or transferred;

(4) care management educational communications provided to a patient about the patient's health condition, adherence to a prescribed course of therapy and other information relating to the drug being dispensed, treatment options, recall or patient safety notices, or clinical trials;

(5) the collection, use, or disclosure of prescription information or other regulatory activity as authorized by chapter 84, chapter 84A, or section 9410 of this title, or as otherwise provided by law;

(6) the collection and transmission of prescription information to a Vermont or federal law enforcement officer engaged in his or her official duties as otherwise provided by law;

(7) the collection, use, transfer, or sale of patient and prescriber data for commercial purposes if the data do not identify a person, and there is no reasonable basis to believe that the data provided could be used to identify a person.

(e) In addition to any other remedy provided by law, the attorney general may file an action in superior court for a violation of this section or of any rules adopted under this section by the attorney general. The attorney general shall have the same authority to investigate and to obtain remedies as if the

action were brought under the Vermont consumer fraud act, chapter 63 of Title 9. Each violation of this section or of any rules adopted under this section by the attorney general constitutes a separate civil violation for which the attorney general may obtain relief.

Sec. 14. 18 V.S.A. § 9410(e) is amended to read:

(e) Records or information protected by the provisions of the physician-patient privilege under subsection 1612(a) of Title 12, protected by section 4631 of this title, or otherwise required by law to be held confidential, shall be filed in a manner that does not disclose the identity of the protected person.

Sec. 15. 18 V.S.A. chapter 91, subchapter 4 is added to read:

Subchapter 4. Consumer Provisions

§ 4641. CO-PAYMENT PRICING

A person licensed or registered under chapter 36 of Title 26 shall charge a consumer the lesser of the co-payment required by the insurer or the usual retail cost of the prescription drug.

Sec. 16. 8 V.S.A. § 4100f is added to read:

§ 4100f. PRESCRIPTION DRUG CO-PAYMENTS

A health insurance or other health benefit plan offered by a health insurer licensed under this chapter shall require the insured to pay only the lesser of

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the co-payment required by the insurer or the usual retail cost of the
prescription drug.

* * * Unconscionable Pricing * * *

Sec. 17. 18 V.S.A. chapter 91, subchapter 5 is added to read:

Subchapter 5. Unconscionable Pricing

§ 4651. PURPOSE

The purpose of this subchapter is to ensure Vermonters affordable access to prescription drugs necessary for the treatment of certain health conditions determined to be a serious public health problem in the state.

§ 4652. DEFINITIONS

For purposes of this subchapter:

(1) “Affected party” means any person directly or indirectly affected by unconscionable prices of prescription drugs, including any organization representing such persons or any person or organization representing the public interest.

(2) “Most favored purchase price” means the price offered with all rights and privileges accorded by the seller to the most favored purchaser in Vermont.

(3) “Purchaser” means any person who engages primarily in selling drugs directly to consumers.

(4) “Seller” means any person who trades in drugs for resale to purchasers in this state.

§ 4653. UNCONSCIONABLE PRICING PROHIBITED

A manufacturer of prescription drugs or its licensee shall not sell, supply for sale, or impose minimum resale requirements for a prescription drug necessary to treat a serious public health problem that results in that prescription drug being sold in Vermont for an unconscionable price.

§ 4654. SERIOUS PUBLIC HEALTH PROBLEM

(a)(1) The commissioner of health may issue a declaration that a health condition is prevalent in Vermont to such an extent as to constitute a serious public health problem.

(2) The attorney general may request a determination by the commissioner of health on whether a health condition meets the criteria in this section. If the attorney general makes a request under this subdivision, the commissioner of health shall consider the request.

(b) At minimum, the commissioner shall consider the following factors when declaring that a health condition is a serious public health problem:

(1) how many Vermonters suffer from the health condition;

(2) the costs to the state, employer-sponsored insurance, and private insurers of treating the health condition with prescription drugs;

(3) the cost of a prescription drug or a class of prescription drugs used to treat the health condition to the extent that information is available;

(4) whether a prescription drug or class of prescription drugs is essential for maintaining health or life;

(5) whether consumers affected with the health condition are unable to afford the prescription drug at the current price; and

(6) other relevant factors as determined by the commissioner.

§ 4655. UNCONSCIONABLE PRICING; PRIMA FACIE CASE

(a) A prima facie case of unconscionable pricing shall be established where the wholesale price of a prescription drug in Vermont is over 30 percent higher than the prices available to federal agencies under the federal supply schedule, the prices available through the Healthy Vermonters program, or the most favored purchase price.

(b) If a prima facie case of unconscionable pricing is shown, the burdens of providing evidence and of proving by a preponderance of the evidence shall shift to the defendant to show that a prescription drug is not unconscionably priced by showing the demonstrated costs of invention, development, and production of the prescription drug, global sales and profits to date, consideration of any government-funded research that supported the development of the drug, and the impact of price on access to a prescription drug by residents and the government of Vermont.

§ 4656. CONSUMER FRAUD ACTION

The attorney general or state's attorney shall enforce the provisions of this section under the Vermont consumer fraud act in chapter 63 of Title 9. All rights, authority, and remedies available to enforce the consumer fraud act shall be available to enforce the provisions of this subchapter.

§ 4657. CIVIL ACTION

(a) Any affected party shall have standing to file a civil suit in a court of competent jurisdiction for a violation of this chapter and to seek a remedy, including declaratory and injunctive relief.

(b) Whenever an affected party, other than the attorney general, brings an action pursuant to this chapter, a copy of any pleadings shall be served on the attorney general pursuant to Rule 5 of the Vermont Rules of Civil Procedure. Failure to comply with this provision shall not affect the validity of the proceedings commenced under this section.

§ 4658. REMEDIES FOR CIVIL ACTIONS

If in an action brought by an affected party under section 4657 of this title, a court determines that any person has violated this chapter, the court is authorized to render:

- (1) temporary, preliminary, or permanent injunctions to enjoin the sales of prescription drugs in Vermont at unconscionable prices;
- (2) an order of damages, including treble damages;

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(1.1)

(3) an order requiring reimbursement to the state of Vermont for the reasonable value of its services and its expenses in investigating and prosecuting the action;

(4) costs and reasonable attorney's fees; and

(5) any other relief deemed appropriate by the court.

Sec. 18. 33 V.S.A. § 1998a is added to read:

§ 1998a. MANUFACTURER FEE

(a) For purposes of this section, "pharmaceutical manufacturer" shall have the same meaning as in section 4051 of Title 18.

(b) Annually, each pharmaceutical manufacturer of prescription drugs that are paid for by Medicaid, the Vermont Health Access Program, Dr. Dynasaur, VPharm or Vermont Rx shall pay a fee of \$1,000.00 per calendar year to the agency of human services.

(c) Fees collected under this section shall fund the implementation and operation of subdivision 2466a(c)(1) of Title 9 and the evidence-based education program established in subchapter 2 of Title 18.

(d) The secretary of human services or designee shall make rules for the implementation of this section.

* * * Consumer Protection; False Advertising * * *

Sec. 19. 9 V.S.A. § 2466a is added to read:

§ 2466a. CONSUMER PROTECTIONS; PRESCRIPTION DRUGS

(a) A violation of sections 4631 and 4655 of Title 18 shall be considered a violation under this chapter.

(b) As provided in section 9473 of Title 18, a violation of section 9472 shall be considered a violation under this chapter.

(c)(1) It shall be a violation under this chapter for a manufacturer of prescription drugs to present or cause to be presented in the state a regulated advertisement, unless that advertisement meets the requirements concerning misbranded drugs and devices and prescription drug advertising of federal law and regulations under 21 United States Code, Sections 331 and 352(n) and 21 Code of Federal Regulations, Part 202 and state rules.

(2) For purposes of this section:

(A) "Manufacturer of prescription drugs" means a person authorized by law to manufacture, bottle, or pack drugs or biological products, a licensee or affiliate of that person, or a labeler that receives drugs or biological products from a manufacturer or wholesaler and repackages them for later retail sale and has a labeler code from the federal Food and Drug Administration under 21 Code of Federal Regulations, 2027.20 (1999).

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(B) "Regulated advertisement" means the presentation to the general public of a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs that is broadcast on television, cable, or radio from a station or cable company that is physically located in the state, broadcast over the internet from a location in the state, or printed in magazines or newspapers that are printed, distributed, or sold in the state.

(d) No person shall sell, offer for sale, or distribute electronic prescribing software that advertises, uses instant messaging and pop-up advertisements, or uses other means to influence or attempt to influence the prescribing decision of a health care professional through economic incentives or otherwise and which is triggered or in specific response to the input, selection, or act of a health care professional or agent in prescribing a specific prescription drug or directing a patient to a certain pharmacy.

* * * Insurance Marketing * * *

Sec. 20. 8 V.S.A. § 4804(a) is amended to read:

(a) The commissioner may suspend, revoke, or refuse to continue or renew any license issued under this chapter if, after notice to the licensee and to the insurer represented, and opportunity for hearing, he or she finds as to the licensee any one or more of the following conditions:

* * *

(8) The licensee has committed any unfair trade practice or fraud as defined in this title. It shall be an unfair practice under this section for a licensee to sell, solicit, or negotiate the purchase of health insurance in this state by:

(A) Advertising by making use directly or indirectly of any method of marketing which fails to disclose in a conspicuous manner that a purpose of the method of marketing is solicitation of insurance, and that contact will be made by an insurance agent or insurance company.

(B) Using an appointment that was made to discuss Medicare products or to solicit the sale of Medicare products to solicit sales of any other insurance products unless the consumer specifically agreed in advance of the appointment to discuss other types of insurance products during the same appointment. As used in this subdivision, the term “Medicare products” includes Medicare Part A, Medicare Part B, Medicare Part C, Medicare Part D, and Medicare supplement plans;

* * *

Sec. 21. RECODIFICATION

The following sections of Title 33 as amended by this act are recodified as follows:

- (1) Section 2005 shall be section 4632 of Title 18.
- (2) Section 2005a shall be section 4633 of Title 18.
- (3) Section 2008 shall be section 4634 of Title 18.

1 Sec. 1. 33 V.S.A. § 1998 is amended to read:

2 § 1998. PHARMACY BEST PRACTICES AND COST CONTROL
3 PROGRAM ESTABLISHED

4 (a) The director of the office of Vermont health access shall establish and
5 maintain a pharmacy best practices and cost control program designed to
6 reduce the cost of providing prescription drugs, while maintaining high quality
7 in prescription drug therapies. The program shall include:

8 (1) ~~A~~ Use of an evidence-based preferred list of covered prescription
9 drugs that identifies preferred choices within therapeutic classes for particular
10 diseases and conditions, including generic alternatives and over-the-counter
11 drugs.

12 ~~(A) The director and the commissioner of banking, insurance,~~
13 ~~securities, and health care administration shall implement the preferred drug~~
14 ~~list as a uniform, statewide preferred drug list by encouraging all health benefit~~
15 ~~plans in this state to participate in the program.~~

16 ~~(B) The commissioner of human resources shall use the preferred~~
17 ~~drug list in the state employees health benefit plan only if participation in the~~
18 ~~program will provide economic and health benefits to the state employees~~
19 ~~health benefit plan and to beneficiaries of the plan, and only if agreed to~~
20 ~~through the bargaining process between the state of Vermont and the~~
21 ~~authorized representatives of the employees of the state of Vermont. The~~

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1 provisions of this subdivision do not authorize the actuarial pooling of the state
2 employees health benefit plan with any other health benefit plan, unless
3 otherwise agreed to through the bargaining process between the state of
4 Vermont and the authorized representatives of the employees of the state of
5 Vermont. No later than November 1, 2004, the commissioner of human
6 resources shall report to the health access oversight committee and the senate
7 and house committees on health and welfare on whether use of the preferred
8 drug list in the state employees health benefit plan would, in his or her opinion,
9 provide economic and health benefits to the state employees health benefit plan
10 and to beneficiaries of the plan.

11 (C) ~~The director shall encourage all health benefit plans to implement~~
12 ~~the preferred drug list as a uniform, statewide preferred drug list by inviting the~~
13 ~~representatives of each health benefit plan providing prescription drug~~
14 ~~coverage to residents of this state to participate as observers or nonvoting~~
15 ~~members in the director's drug utilization review board, and by inviting such~~
16 ~~plans to use the preferred drug list in connection with the plans' prescription~~
17 ~~drug coverage.~~

18 (2) Utilization review procedures, including a prior authorization review
19 process.

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1 (3) Any strategy designed to negotiate with pharmaceutical
2 manufacturers to lower the cost of prescription drugs for program participants,
3 including a supplemental rebate program.

4 ~~(4) With input from physicians, pharmacists, private insurers, hospitals,~~
5 ~~pharmacy benefit managers, and the drug utilization review board, an~~
6 ~~evidence-based research education program designed to provide information~~
7 ~~and education on the therapeutic and cost-effective utilization of prescription~~
8 ~~drugs to physicians, pharmacists, and other health care professionals~~
9 ~~authorized to prescribe and dispense prescription drugs. To the extent~~
10 ~~possible, the program shall inform prescribers about drug marketing that is~~
11 ~~intended to circumvent competition from generic alternatives. Details of the~~
12 ~~program, including the scope of the program and funding recommendations,~~
13 ~~shall be contained in a report submitted to the health access oversight~~
14 ~~committee and the senate and house committees on health and welfare no later~~
15 ~~than January 1, 2005.~~

16 ~~(5)~~(4) Alternative pricing mechanisms, including consideration of using
17 maximum allowable cost pricing for generic and other prescription drugs.

18 ~~(6)~~(5) Alternative coverage terms, including consideration of providing
19 coverage of over-the-counter drugs where cost-effective in comparison to
20 prescription drugs, and authorizing coverage of dosages capable of permitting

1 the consumer to split each pill if cost-effective and medically appropriate for
2 the consumer.

3 ~~(7)~~(6) A simple, uniform prescription form, designed to implement the
4 preferred drug list, and to enable prescribers and consumers to request an
5 exception to the preferred drug list choice with a minimum of cost and time to
6 prescribers, pharmacists and consumers.

7 ~~(7)~~ A plan to ~~encourage~~ ^{inform} Vermonters to use federally qualified health
8 centers (FOHC) and FOHC look-alikes when the prescription drug pricing is
9 more affordable, focusing on participants in the Medicaid and Medicaid waiver
10 programs, state employees, individuals under the supervision of corrections,
11 individuals receiving workers' compensation benefits if applicable, and any
12 other state or publicly funded purchaser of prescription drugs ^{including}
13 ~~contracting with one or more FOHCs or FOHC look-alikes to provide case~~
14 ~~management or record management services.~~

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15 (8) A joint pharmaceuticals purchasing consortium as provided for in
16 subdivision (c)(1) of this section.

17 ~~(8)~~(9) Any other cost containment activity adopted, by rule, by the
18 director that is designed to reduce the cost of providing prescription drugs
19 while maintaining high quality in prescription drug therapies.

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1 (c)(1) The director may implement the pharmacy best practices and cost
2 control program for any other health benefit plan within or outside this state
3 that agrees to participate in the program. For entities in Vermont, the director
4 shall directly or by contract implement the program through a joint
5 pharmaceuticals purchasing consortium. The joint pharmaceuticals purchasing
6 consortium shall be offered on a voluntary basis no later than January 1, 2008,
7 with mandatory participation by state or publicly funded, administered, or
8 subsidized purchasers to the extent practicable and consistent with the
9 purposes of this chapter, by January 1, 2010. "State or publicly funded
10 purchasers" shall include the department of corrections, the division of mental
11 health, Medicaid, the Vermont Health Access Program (VHAP), Dr. Dynasaur,
12 Vermont Rx, ^{V Pharm} Healthy Vermonters, Healthy Vermonters Plus, workers'
13 compensation, and any other state or publicly funded purchaser of prescription
14 drugs.

✓

* * *

16 (f)(1) The drug utilization review board shall make recommendations to the
17 director for the adoption of the preferred drug list. The board's
18 recommendations shall be based upon evidence-based considerations of
19 clinical efficacy, adverse side effects, safety, appropriate clinical trials, and
20 cost-effectiveness. "Evidence-based" shall have the same meaning as in
21 section 4261 of Title 18.

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(6) The director shall encourage participation in the joint purchasing consortium by inviting representatives of the programs and entities specified in (c)(1) (a)(8) of this section to participate as observers or nonvoting members in the drug utilization review board, and by inviting the representatives to use the preferred drug list in connection with the plans' prescription drug coverage.

Sec. 2. 33 V.S.A. § 1998(g) is added to read:

(g) The office shall seek assistance from entities conducting independent research into the effectiveness of prescription drugs, [such as the Oregon Health and Science University Drug Effectiveness Review Project (DERP)] to provide technical and clinical support in the development and the administration of the preferred drug list and the evidence-based education program established in subchapter 2 of Title 18.

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* * * Pharmaceutical Marketer Disclosures * * *

Sec. 3. 33 V.S.A. § 2005(a)(3) is amended to read:

(3) The office of the attorney general shall keep confidential all trade secret information, as defined by subdivision 317(b)(9) of Title 1, except that the office may disclose the information to the department of health for the purpose of informing and prioritizing the activities of the evidence-based education program in subchapter 2 of chapter 91 of Title 18. The department of health shall keep the information confidential. The disclosure form shall

1 permit the company to identify any information that it claims is a trade secret
2 as defined in subdivision 317(c)(9) of Title 1. In the event that the attorney
3 general receives a request for any information designated as a trade secret, the
4 attorney general shall promptly notify the company of such request. Within 30
5 days after such notification, the company shall respond to the requester and the
6 attorney general by either consenting to the release of the requested
7 information or by certifying in writing the reasons for its claim that the
8 information is a trade secret. Any requester aggrieved by the company's
9 response may apply to the superior court of Washington County for a
10 declaration that the company's claim of trade secret is invalid. The attorney
11 general shall not be made a party to the superior court proceeding. Prior to and
12 during the pendency of the superior court proceeding, the attorney general
13 shall keep confidential the information that has been claimed as trade secret
14 information, except that the attorney general may provide the requested
15 information to the court under seal.

16 Sec. 4. 33 V.S.A. § 2005(a)(4) is amended and (d) is added to read:

17 (4) The following shall be exempt from disclosure:

18 * * *

19 (D) scholarship or other support for medical students, residents, and
20 fellows to attend a significant educational, scientific, or policy-making
21 conference of a national, regional, or specialty medical or other professional

1 association if the recipient of the scholarship or other support is selected by the
2 association; and

3 ~~(E) unrestricted grants for continuing medical education programs;~~ *jh*
4 and

5 ~~(F)~~ prescription drug rebates and discounts.

6 * * *

7 (d) Disclosures of unrestricted grants for continuing medical education
8 programs shall be limited to the value, nature, and purpose of the grant and the
9 name of the grantee. It shall not include disclosure of the individual
10 participants in such a program.

11 * * * Price Disclosure and Certification * * *

12 Sec. 5. 33 V.S.A. § 2010 is added to read:

13 § 2010. ACTUAL PRICE DISCLOSURE AND CERTIFICATION

14 (a) A manufacturer of prescription drugs dispensed in this state under a
15 health program directed or administered by the state shall, on a quarterly basis,
16 report by National Drug Code the following pharmaceutical pricing criteria to
17 the director of the office of Vermont health access for each of its drugs:

18 (1) the average manufacturer price as defined in 42 U.S.C.

19 § 1396r-8(k);

20 (2) the best price as defined in 42 U.S.C. § 1396r-8(c)(1)(C); and

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1 (3) the price that each wholesaler in this state pays the manufacturer
2 to purchase the drug.

3 (b) When reporting the prices as provided for in subsection (a) of this
4 section, the manufacturer shall include a summary of its methodology in
5 determining the price. The office may accept the standards of the National
6 Drug Rebate agreement entered into by the U.S. Department of Health and
7 Human Services and Section 1927 of the Social Security Act for reporting
8 pricing methodology or may adopt its own standards by rule.

8

9 (c) The pricing information required under this section is for drugs defined
10 under the Medicaid drug rebate program and must be submitted to the director
11 following its submission to the federal government in accordance with
12 42 U.S.C. § 1396r-8(b)(3).

3 prices

13 (d) When a manufacturer of prescription drugs dispensed in this state
14 reports the average manufacturer price or best price, the president, chief
15 executive officer, or a designated employee of the manufacturer shall certify to
16 the office, on a form provided by the director of the office of Vermont health
17 access, that the reported prices are the same as those reported to the federal
18 government as required by 42 U.S.C. § 1396r-8(b)(3) for the applicable rebate
19 period. A designated employee shall be an employee who reports directly to
20 the chief executive officer or president and who has been delegated to make
21 the certification under this section.

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1 coverage for prescription drugs. The provisions of ~~section 1992 of this title~~
2 subchapter 8 of this chapter shall apply to the director's authority to administer
3 the pharmacy discount plans established by this section.

4 (b) The Healthy Vermonters program shall offer beneficiaries an initial
5 discounted cost for covered drugs. ~~Upon approval by the Centers for Medicare~~
6 ~~and Medicaid Services of a Section 1115 Medicaid waiver program, and upon~~
7 ~~subsequent legislative approval, the~~ The Healthy Vermonters program and the
8 Healthy Vermonters Plus program shall offer beneficiaries a secondary
9 discounted cost, which shall reflect a state payment toward the cost of each
10 dispensed drug as well as any rebate amount negotiated by the commissioner.

11 * * *

12 (n) ~~The department shall seek a waiver from the Centers for Medicare and~~
13 ~~Medicaid Services (CMS) requesting authorization necessary to implement the~~
14 ~~provisions of this section, including application of manufacturer and labeler~~
15 ~~rebates to the pharmacy discount plans. The secondary discounted cost shall~~
16 ~~not be available to beneficiaries of the pharmacy discount plans until the~~
17 ~~department receives written notification from CMS that the waiver requested~~
18 ~~under this section has been approved and until the general assembly~~
19 ~~subsequently approves all aspects of the pharmacy discount plans, including~~
20 ~~funding for positions and related operating costs associated with eligibility~~
21 ~~determinations.~~

1 *** PBM Regulation ***

2 Sec. 7. 18 V.S.A. chapter 221, subchapter 9 is added to read:

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Subchapter 9. Pharmacy Benefit Managers

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John Hollar
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§ 9471. DEFINITIONS

As used in this subchapter:

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to insurer.

(1) "Beneficiary" means an individual enrolled in a health plan in which coverage of prescription drugs is administered by a pharmacy benefit manager and includes his or her dependent or other person provided health coverage through that health plan.

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(2) "Health insurer" is defined by subdivision 9402(9) of this title and shall include:

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(A) a health insurance company, a nonprofit hospital and medical service corporation, and health maintenance organizations;

(B) an employer, labor union, or other group of persons organized in Vermont that provides a health plan to beneficiaries who are employed or reside in Vermont;

(C) the state of Vermont and any agent or instrumentality of the state that offers, administers, or provides financial support to state government; and

(D) Medicaid, the Vermont health access plan, Vermont Rx, and any other public health care assistance program.

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1 (3) "Health plan" means a health benefit plan offered, administered, or
2 issued by a health insurer doing business in Vermont.

3 (4) "Pharmacy benefit management" means an arrangement for the
4 procurement of prescription drugs at a negotiated rate for dispensation within
5 this state to beneficiaries, the administration or management of prescription
6 drug benefits provided by a health plan for the benefit of beneficiaries, or any
7 of the following services provided with regard to the administration of
8 pharmacy benefits:

9 (A) mail service pharmacy;

10 (B) claims processing, retail network management, and payment of
11 claims to pharmacies for prescription drugs dispensed to beneficiaries;

12 (C) clinical formulary development and management services;

13 (D) rebate contracting and administration;

14 (E) certain patient compliance, therapeutic intervention, and generic
15 substitution programs; and

16 (F) disease or chronic care management programs.

17 (5) "Pharmacy benefit manager" means an entity that performs
18 pharmacy benefit management. The term includes a person or entity in a
19 contractual or employment relationship with an entity performing pharmacy
20 benefit management for a health plan.

1 § 9472. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES

2 (a) Unless the contract provides otherwise, a pharmacy benefit manager
3 that provides pharmacy benefit management for a health plan shall:

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4 (1) Discharge its duties with the care, skill, prudence, and diligence
5 under the circumstances then prevailing that a prudent pharmacy benefit
6 manager acting in like capacity and familiar with such matters would use in the
7 conduct of an enterprise of a like character and with like aims. In the case of a
8 health benefit plan offered by a health insurer as defined by subdivision
9 9471(2)(A) of this title, the health insurer shall remain responsible for
10 administering the health benefit plan in accordance with the health insurance
11 policy or subscriber contract or plan and in compliance with all applicable
12 provisions of Title 8 and this title.

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13 (2) Provide all financial and utilization information requested by a
14 health insurer relating to the provision of benefits to beneficiaries through that
15 health insurer's health plan and all financial and utilization information
16 relating to services to that health insurer. A pharmacy benefit manager
17 providing information under this subsection may designate that material as
18 confidential. Information designated as confidential by a pharmacy benefit
19 manager and provided to a health insurer under this subsection may not be
20 disclosed by the health insurer to any person without the consent of the

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1 pharmacy benefit manager, except that disclosure may be made by the health
2 insurer:

3 (A) in a court filing under the consumer fraud provisions of chapter
4 63 of Title 9, provided that the information shall be filed under seal and that
5 prior to the information being unsealed, the court shall give notice and an
6 opportunity to be heard to the pharmacy benefit manager on why the
7 information should remain confidential;

8 (B) when authorized by chapter 63 of Title 9;

9 (C) when ordered by a court for good cause shown; or

10 (D) when ordered by the commissioner as to a health insurer as
11 defined in subdivision 9471(2)(A) of this title pursuant to the provisions of
12 Title 8 and this title.

13 (3) Notify a health insurer in writing of any proposed or ongoing
14 activity, policy, or practice of the pharmacy benefit manager that presents,
15 directly or indirectly, any conflict of interest with the requirements of this
16 section.

17 (4) With regard to the dispensation of a substitute prescription drug for a
18 prescribed drug to a beneficiary in which the substitute drug costs more than
19 the prescribed drug and the pharmacy benefit manager receives a benefit or
20 payment directly or indirectly, disclose to the health insurer the cost of both

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1 drugs and the benefit or payment directly or indirectly accruing to the
2 pharmacy benefit manager as a result of the substitution.

3 (5) If the pharmacy benefit manager derives any payment or benefit for
4 the dispensation of prescription drugs within the state based on volume of sales
5 for certain prescription drugs or classes or brands of drugs within the state,
6 pass that payment or benefit on in full to the health insurer.

7 (6) Disclose to the health insurer all financial terms and arrangements
8 for remuneration of any kind that apply between the pharmacy benefit manager
9 and any prescription drug manufacturer that relate to benefits provided to
10 beneficiaries under or services to the health insurer's health plan, including
11 formulary management and drug-switch programs, educational support, claims
12 processing, and pharmacy network fees charged from retail pharmacies and
13 data sales fees. A pharmacy benefit manager providing information under this
14 subsection may designate that material as confidential. Information designated
15 as confidential by a pharmacy benefit manager and provided to a health insurer
16 under this subsection may not be disclosed by the health insurer to any person
17 without the consent of the pharmacy benefit manager, except that disclosure
18 may be made by the health insurer:

19 (A) in a court filing under the consumer fraud provisions of chapter
20 63 of Title 9, provided that the information shall be filed under seal and that
21 prior to the information being unsealed, the court shall give notice and an

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1 opportunity to be heard to the pharmacy benefit manager on why the
2 information should remain confidential;

3 (B) when authorized by chapter 63 of Title 9;

4 (C) when ordered by a court for good cause shown; or

5 (D) when ordered by the commissioner as to a health insurer as

6 defined in subdivision 9471(2)(A) of this title pursuant to the provisions of

7 Title 8 and this title.

8 (b) A pharmacy benefit manager shall provide notice to the health insurer

9 that the terms contained in this section may be included in the contract between

10 the pharmacy benefit manager and the health insurer.

11 (c) Compliance with the requirements of this section is required for
12 pharmacy benefit managers entering into contracts^{w/} for pharmacy benefit
13 management in this state by a health insurer in this state.

14 § 9473. ENFORCEMENT

15 (a) In addition to any remedy available to the commissioner under this title

16 and any other remedy provided by law, a violation of this subchapter shall be

17 considered a violation of the Vermont consumer fraud act in subchapter 1 of

18 chapter 63 of Title 1. All rights, authority, and remedies available to the

19 attorney general and private parties to enforce the Vermont consumer fraud act

20 shall be available to enforce the provisions of this subchapter.

21 (b) In connection with any action for violation of the Vermont consumer

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1 would identify to the health insurer external sources of revenue and profit, is
2 available when the pharmacy benefit manager provides a quotation for any
3 other alternative pricing arrangement. Quotations for an administrative-
4 services-only contract shall include a reasonable fee payable by the health
5 insurer which represents a competitive pharmacy benefit profit.

6 (c)(1) In order to enable periodic verification of pricing arrangements,
7 pharmacy benefit managers shall allow access, in accordance with rules
8 adopted by the commissioner, by the health insurer to financial and contractual
9 information necessary to conduct a complete and independent audit designed
10 to verify the following:

11 (A) if applicable under an administrative-services-only contract
12 under subsection (b) of this section, full pass through of negotiated drug prices
13 and fees associated with all drugs dispensed to beneficiaries of the health plan
14 in both retail and mail order settings or resulting from any of the pharmacy
15 benefit management functions defined in this section;

16 (B) if applicable under an administrative-services-only contract under
17 subsection (b) of this section, full pass through of all financial remuneration
18 associated with all drugs dispensed to beneficiaries of the health plan in both
19 retail and mail order settings or resulting from any of the pharmacy benefit
20 management functions defined in this section; and

*add
admin
only*

*PBM
language
see email
clarify that
it's only
admin serv
K*

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1 (C) any other verifications relating to the pricing arrangements and
2 activities of the pharmacy benefit manager required by the commissioner.

3 (2) The pharmacy benefit manager and the health insurer may waive the
4 audit provided for in subdivision (1) of this subsection in a contract if the
5 health insurer has been notified prior to entering into the contract that the
6 ability to audit is available.

7 (d) The department's reasonable expenses in administering the provisions
8 of this section may be charged to pharmacy benefit managers in the manner
9 provided for in section 18 of Title 8. Such expenses shall be allocated in
10 proportion to the lives of Vermonters covered by each pharmacy benefit
11 manager as reported annually to the commissioner in a manner and form
12 prescribed by the commissioner.

13 (e) The commissioner may adopt such rules as are necessary or desirable in
14 carrying out the purposes of this section. The rules also shall ensure that
15 proprietary information is kept confidential and not disclosed by a health
16 insurer.

Medico
- What would
be regulated?
- don't see need for
to be a licensing
statute.

17 (f) As used in this section:

18 (1) "Health insurer" is defined in subdivision 9471(2) of this title.

19 (2) "Health plan" is defined in subdivision 9471(3) of this title.

20 (3) "Pharmacy benefit management" is defined in subdivision 9471(4)
21 of this title.

1 (4) "Pharmacy benefit manager" is defined in subdivision 9471(5) of this
2 title.

3 Sec. 9. APPLICATION

4 Secs. 7 and 8 of this act apply to contracts executed or renewed on or after
5 September 1, 2007. For purposes of this section, a contract executed pursuant
6 to a memorandum of agreement executed prior to September 1, 2007 is
7 deemed to have been executed prior to September 1, 2007 even if the contract
8 was executed after that date.

9 Sec. 10. 18 V.S.A. chapter 91 is amended to read:

10 CHAPTER 91. ~~GENERIC DRUGS~~ PRESCRIPTION DRUG
11 COST CONTAINMENT

12 Sec. 11. 18 V.S.A. chapter 91, sections 4601–4608 are designated as
13 subchapter 1 which is added to read:

14 Subchapter 1. Generic Drugs

15 Sec. 12. 18 V.S.A. chapter 91, subchapter 2 is added to read:

16 Subchapter 2. Evidence-Based Education Program

17 § 4621. DEFINITIONS

18 For the purposes of this subchapter:

19 (1) "Department" means the department of health.

20 (2) "Evidence-based" means based on criteria and guidelines that reflect
21 high-quality, cost-effective care. The methodology used to determine such

1 guidelines shall meet recognized standards for systematic evaluation of all
2 available research and shall be free from conflicts of interest. Consideration of
3 the best available scientific evidence does not preclude consideration of
4 experimental or investigational treatment or services under a clinical
5 investigation approved by an institutional review board.

6 § 4622. EVIDENCE-BASED EDUCATION PROGRAM

7 (a) The department, in collaboration with the attorney general, shall
8 establish an evidence-based prescription drug education program for health
9 care professionals designed to provide information and education on the
10 therapeutic and cost-effective utilization of prescription drugs to physicians,
11 pharmacists, and other health care professionals authorized to prescribe and
12 dispense prescription drugs. The department may collaborate with other states
13 in establishing this program.

14 (b) The department shall request information and collaboration from
15 physicians, pharmacists, private insurers, hospitals, pharmacy benefit
16 managers, the drug utilization review board, medical schools, the attorney
17 general, and any other programs providing an evidence-based education to
18 prescribers on prescription drugs in developing and maintaining the program.

19 (c) The department may contract for technical and clinical support in the
20 development and the administration of the program from entities conducting
21 independent research into the effectiveness of prescription drugs, such as the

1 Oregon Health and Science University Drug Effectiveness Review Project

2 (DERP)

3 (d) The department and the attorney general shall collaborate in reviewing
4 the marketing activities of pharmaceutical manufacturing companies in
5 Vermont and determining appropriate funding sources for the program,
6 including awards from suits brought by the attorney general against
7 pharmaceutical manufacturers.

8 *** Prescription Drug Data Confidentiality ***

9 Sec. 13 18 V.S.A. chapter 91, subchapter 3 is added to read:

10 Subchapter 3. Information Requirements

11 § 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

12 (a) The general assembly finds that it has become an increasingly common
13 practice for information identifying physicians and other prescribers in
14 prescription records to be used to target pharmaceutical marketing and gifts
15 toward physicians who prescribe the most expensive drugs for their patients.
16 This practice raises drug costs for all Vermont residents and compromises the
17 professional autonomy of physicians. It is the intent of the general assembly to
18 ensure the privacy of Vermonters and health care professionals by prohibiting
19 the commercial use of prescription information.

20 (b) As used in this section:

Pharma
✓ *prescriber data very imp in FDA process, thus would hinder.*
✓ *AMA opt-out*

Data miners company

↑ cost pressure
• alzheimers
e-s.

IMS

marketing is very effective
not direct

✓ *more info is better*
✓ *patient-identifier = HIPAA*
✓ *AMA has low exclusive database they use; conversion to another ID wouldn't be cost-effective.*

have IMS - counterproductive if goal is to ↓ cost of marketing but not sure there is a direct connection w/ cost of drugs

✓ *node who has to see a marketer*

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1 (1) "Commercial purpose" shall include advertising, marketing,
2 promotion, or any activity that is intended to be used or is used to influence
3 sales or the market share of a pharmaceutical product, influence or evaluate the
4 prescribing behavior of an individual health care professional, market
5 prescription drugs to patients, or evaluate the effectiveness of a professional
6 pharmaceutical detailing sales force.

7 (2) "Electronic transmission intermediary" means an entity that provides
8 the infrastructure that connects the computer systems or other electronic
9 devices used by health care professionals, prescribers, pharmacies, health care
10 facilities and pharmacy benefit managers, health insurers, third-party
11 administrators, and agents and contractors of those persons in order to facilitate
12 the secure transmission of an individual's prescription drug order, refill,
13 authorization request, claim, payment, or other prescription drug information.

14 (3) "Health care facility" shall have the same meaning as in section
15 9402 of this title.

16 (4) "Health care professional" shall have the same meaning as in section
17 9402 of this title.

18 (5) "Health insurer" shall have the same meaning as in section 9410 of
19 this title.

20 (6) "Pharmacy" means any individual or entity licensed or registered
21 under chapter 36 of Title 26.

1 (7) "Prescriber" means an individual allowed by law to prescribe and
2 administer prescription drugs in the course of professional practice.

3 (8) "Regulated records" means information or documentation from a
4 prescription written by a prescriber doing business in Vermont or a
5 prescription dispensed in Vermont.

6 (c) A health insurer, a self-insured employer, an electronic transmission
7 intermediary, a pharmacy, or other similar entity shall not license, transfer, use,
8 or sell regulated records which include prescription information containing
9 patient-identifiable or prescriber-identifiable data for any commercial purpose.

10 (d) This section shall not apply to:

11 (1) the license, transfer, use, or sale of regulated records for the limited
12 purposes of pharmacy reimbursement; prescription drug formulary
13 compliance; patient care management; utilization review by a health care
14 professional, the patient's health insurer, or the agent of either; or health care
15 research;

16 (2) the dispensing of prescription medications to a patient or to the
17 patient's authorized representative;

18 (3) the transmission of prescription information between an authorized
19 prescriber and a licensed pharmacy, between licensed pharmacies, or that may
20 occur in the event a pharmacy's ownership is changed or transferred;

Medco -
add to
marketing
pg 35

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1 (4) care management educational communications provided to a patient
2 about the patient's health condition, adherence to a prescribed course of
3 therapy and other information relating to the drug being dispensed, treatment
4 options, recall or patient safety notices, or clinical trials;

5 (5) the collection, use, or disclosure of prescription information or other
6 regulatory activity as authorized by chapter 84, chapter 84A, or section 9410 of
7 this title, or as otherwise provided by law;

8 (6) the collection and transmission of prescription information to a
9 Vermont or federal law enforcement officer engaged in his or her official
10 duties as otherwise provided by law;

11 (7) the collection, use, transfer, or sale of patient and prescriber
12 data for commercial purposes if the data do not identify a person, and there is
13 no reasonable basis to believe that the data provided could be used to identify a
14 person.

15 (e) In addition to any other remedy provided by law, the attorney general
16 may file an action in superior court for a violation of this section or of any
17 rules adopted under this section by the attorney general. The attorney general
18 shall have the same authority to investigate and to obtain remedies as if the
19 action were brought under the Vermont consumer fraud act, chapter 63 of Title
20 9. Each violation of this section or of any rules adopted under this section by

1 the attorney general constitutes a separate civil violation for which the attorney
2 general may obtain relief.

3 Sec. 14. 18 V.S.A. § 9410(e) is amended to read:

4 (e) Records or information protected by the provisions of the
5 physician-patient privilege under subsection 1612(a) of Title 12, protected by
6 section 4631 of this title, or otherwise required by law to be held confidential,
7 shall be filed in a manner that does not disclose the identity of the protected
8 person.

9 Sec. 15 18 V.S.A. chapter 91, subchapter 4 is added to read:

Subchapter 4. Consumer Provisions

§ 4641. CO-PAYMENT PRICING

A person licensed or registered under chapter 36 of Title 26 shall charge a
consumer the lesser of the co-payment required by the insurer or the usual
retail cost of the prescription drug.

10 Sec. 16. 8 V.S.A. § 4100f is added to read:

§ 4100f. PRESCRIPTION DRUG CO-PAYMENTS

11 A health insurance or other health benefit plan offered by a health insurer
12 licensed under this chapter shall require the insured to pay only the lesser of
13 the co-payment required by the insurer or the usual retail cost of the
14 prescription drug.

*Pharmacies
Walmart
necessaries
major chains
indep.
don't know if
regime provides
rate & customary
happens now
the computer.*

*BISHOP
NOT sure this
is necessary*

Susan to email it to memo.

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2007 Chapter PL-580 Maine law. - unconscionable pricing

*** Unconscionable Pricing ***

Pharma

→ DC didn't appeal commerce clause ruling. → they don't feel that it cures the commerce cl. issue

Sec. 17. 18 V.S.A. chapter 91, subchapter 5 is added to read:

Subchapter 5. Unconscionable Pricing

§ 4651. PURPOSE

The purpose of this subchapter is to ensure Vermonters affordable access to prescription drugs necessary for the treatment of certain health conditions determined to be a serious public health problem in the state.

Susan Gretowski

§ 4652. DEFINITIONS

For purposes of this subchapter:

VT - all - unc not DC - patented - unc = foreign - any drug uncon if 30% over 7 more countries

(1) "Affected party" means any person directly or indirectly affected by unconscionable prices of prescription drugs, including any organization representing such persons or any person or organization representing the public interest.

still transaction out of state → many out → wholesaler not mostly

(2) "Most favored purchase price" means the price offered with all rights and privileges accorded by the seller to the most favored purchaser in Vermont.

(3) "Purchaser" means any person who engages primarily in selling drugs directly to consumers.

specific lang DC police power

(4) "Seller" means any person who trades in drugs for resale to purchasers in this state.

D.C. Court gen. police power creating a public health exc. under quest of except.

unconscionable pricing → do we have a general provision?

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*Include all
sect 7*

1 § 4653. UNCONSCIONABLE PRICING PROHIBITED

2 A manufacturer of prescription drugs or its licensee shall not sell, supply for
3 sale, or impose minimum resale requirements for a prescription drug necessary
4 to treat a serious public health problem that results in that prescription drug
5 being sold in Vermont for an unconscionable price.

threat exists

6 § 4654. SERIOUS PUBLIC HEALTH PROBLEM

7 (a)(1) The commissioner of health may issue a declaration that a health
8 condition is prevalent in Vermont to such an extent as to constitute a serious
9 public health problem.

*Clinical
on text*
*disease, short-
duration
large # of
people*
*closer to
emergency
epidemic*

10 (2) The attorney general may request a determination by the
11 commissioner of health on whether a health condition meets the criteria in this
12 section. If the attorney general makes a request under this subdivision, the
13 commissioner of health shall consider the request.

14 (b) At minimum, the commissioner shall consider the following factors
15 when declaring that a health condition is a serious public health problem:

16 (1) how many Vermonters suffer from the health condition;
17 (2) the costs to the state, employer-sponsored insurance, and private
18 insurers of treating the health condition with prescription drugs;

19 (3) the cost of a prescription drug or a class of prescription drugs used to
20 treat the health condition to the extent that information is available;

1 (4) whether a prescription drug or class of prescription drugs is essential
2 for maintaining health or life;

3 (5) whether consumers affected with the health condition are unable to
4 afford the prescription drug at the current price; and

5 (6) other relevant factors as determined by the commissioner.

6 § 4655. UNCONSCIONABLE PRICING; PRIMA FACIE CASE

7 (a) A prima facie case of unconscionable pricing shall be established where
8 the wholesale price of a prescription drug in Vermont is over 30 percent higher
9 than the prices available to federal agencies under the federal supply schedule,
10 the prices available through the Healthy Vermonters program, or the most
11 favored purchase price.

12 (b) If a prima facie case of unconscionable pricing is shown, the burdens of
13 providing evidence and of proving by a preponderance of the evidence shall
14 shift to the defendant to show that a prescription drug is not unconscionably
15 priced by showing the demonstrated costs of invention, development, and
16 production of the prescription drug, global sales and profits to date,
17 consideration of any government-funded research that supported the
18 development of the drug, and the impact of price on access to a prescription
19 drug by residents and the government of Vermont.

*ref 4653 r
4654*

1 § 4656. CONSUMER FRAUD ACTION

2 The attorney general or state's attorney shall enforce the provisions of this
3 section under the Vermont consumer fraud act in chapter 63 of Title 9. All
4 rights, authority, and remedies available to enforce the consumer fraud act
5 shall be available to enforce the provisions of this subchapter.

6 § 4657. CIVIL ACTION

7 (a) Any affected party shall have standing to file a civil suit in a court of
8 competent jurisdiction for a violation of this chapter and to seek a remedy,
9 including declaratory and injunctive relief.

10 (b) Whenever an affected party, other than the attorney general, brings an
11 action pursuant to this chapter, a copy of any pleadings shall be served on the
12 attorney general pursuant to Rule 5 of the Vermont Rules of Civil Procedure.
13 Failure to comply with this provision shall not affect the validity of the
14 proceedings commenced under this section.

15 § 4658. REMEDIES FOR CIVIL ACTIONS

16 If in an action brought by an affected party under section 4657 of this title, a
17 court determines that any person has violated this chapter, the court is
18 authorized to render:

19 (1) temporary, preliminary, or permanent injunctions to enjoin the sales
20 of prescription drugs in Vermont at unconscionable prices;

21 (2) an order of damages, including treble damages;

1 (3) an order requiring reimbursement to the state of Vermont for the
2 reasonable value of its services and its expenses in investigating and
3 prosecuting the action;

4 (4) costs and reasonable attorney's fees; and

5 (5) any other relief deemed appropriate by the court.

6 Sec. 18. 33 V.S.A. § 1998a is added to read:

7 § 1998a. MANUFACTURER FEE

8 (a) For purposes of this section, "pharmaceutical manufacturer" shall have
9 the same meaning as in section 4051 of Title 18.

10 (b) Annually, each pharmaceutical manufacturer of prescription drugs that
11 are paid for by Medicaid, the Vermont Health Access Program, Dr. Dynasaur,
12 VPharm or Vermont Rx shall pay a fee of \$1,000.00 per calendar year to the
13 agency of human services.

14 (c) Fees collected under this section shall fund the implementation and
15 operation of subdivision 2466a(c)(1) of Title 9 and the evidence-based
16 education program established in subchapter 2 of Title 18.

17 (d) The secretary of human services or designee shall make rules for the
18 implementation of this section.

1 * * * Consumer Protection; False Advertising * * *

2 Sec. 19. 9 V.S.A. § 2466a is added to read:

3 § 2466a. CONSUMER PROTECTIONS; PRESCRIPTION DRUGS

4 (a) A violation of sections 4631 and 4655 of Title 18 shall be considered a
5 violation under this chapter.

6 (b) As provided in section 9473 of Title 18, a violation of section 9472
7 shall be considered a violation under this chapter.

8 (c)(1) It shall be a violation under this chapter for a manufacturer of
9 prescription drugs to present or cause to be presented in the state a regulated
10 advertisement, unless that advertisement meets the requirements concerning
11 misbranded drugs and devices and prescription drug advertising of federal law
12 and regulations under 21 United States Code, Sections 331 and 352(n) and 21
13 Code of Federal Regulations, Part 202 and state rules.

14 (2) For purposes of this section:

15 (A) "Manufacturer of prescription drugs" means a person authorized
16 by law to manufacture, bottle, or pack drugs or biological products, a licensee
17 or affiliate of that person, or a labeler that receives drugs or biological products
18 from a manufacturer or wholesaler and repackages them for later retail sale and
19 has a labeler code from the federal Food and Drug Administration under 21
20 Code of Federal Regulations, 2027.20 (1999).

Hook

*? ?
add segment
that feeds
have determine
false ads*

1 (B) "Regulated advertisement" means the presentation to the general
 2 public of a commercial message regarding a prescription drug or biological
 3 product by a manufacturer of prescription drugs that is broadcast on television,
 4 cable, or radio from a station or cable company that is physically located in the
 5 state, broadcast over the internet from a location in the state, or printed in
 6 magazines or newspapers that are printed, distributed, or sold in the state.

7 (d) No person shall sell, offer for sale, or distribute electronic prescribing
 8 software that advertises, uses instant messaging and pop-up advertisements, or
 9 uses other means to influence or attempt to influence the prescribing decision
 10 of a health care professional through economic incentives or otherwise and
 11 which is triggered or in specific response to the input, selection, or act of a
 12 health care professional or agent in prescribing a specific prescription drug or
 13 directing a patient to a certain pharmacy.

Medeo

- concerned that
 info re: PDC would
 be prohibited
 - input language
 from ~~the~~
 Rx confidential. E

PBM language
 re: not meant
 formulary
 any

*** Insurance Marketing ***

Sec. 20. 8 V.S.A. § 4804(a) is amended to read:

16 (a) The commissioner may suspend, revoke, or refuse to continue or renew
 17 any license issued under this chapter if, after notice to the licensee and to the
 18 insurer represented, and opportunity for hearing, he or she finds as to the
 19 licensee any one or more of the following conditions:

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1 (4) Section 2006 shall be section 852 of Title 2.

2 Sec. 22. REPEAL

3 Section 2009 of Title 33 is repealed.