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Introduced by Committee on Finance

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Date: 2/23/07

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Subject: Health; insurance; prescription drugs; pharmaceuticals; pharmacy

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benefit managers; drug education; preferred drug list; pricing;

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confidentiality; pharmacy benefits; prompt pay

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Statement of purpose: This bill proposes to increase transparency in

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prescription drug information and pricing by limiting fraudulent advertising of

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prescription drugs to consumers and health care professionals, requiring notice

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to clients by pharmacy benefit managers that certain types of contracts are

11

available, strengthening the Medicaid preferred drug list, establishing an

12

evidence-based education program, providing additional pricing information to

13

the Medicaid program from drug manufacturers, requiring disclosure of

14

education programs funded by drug manufacturers, and providing enforcement

15

for prescription drug provisions under the Consumer Fraud Act.

16

AN ACT RELATING TO INCREASING TRANSPARENCY OF

17

PRESCRIPTION DRUG PRICING AND INFORMATION

18

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

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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.

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

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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 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.~~

15 (7) A plan to inform Vermonters of the availability of health services
16 provided by federally qualified health centers (FOHC) and FOHC look-alikes,
17 including that prescription drug pricing is more affordable, focusing on
18 participants in the Medicaid and Medicaid waiver programs, state employees,
19 individuals under the supervision of corrections, individuals receiving
20 workers' compensation benefits if applicable, and any other state or publicly
21 funded purchaser of prescription drugs.

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

* * *

(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

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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.

* * *

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

* * *

(6) The director shall encourage participation in the joint purchasing consortium by inviting representatives of the programs and entities specified in ~~(a)(8)~~ (c) (1) 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

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1 ~~and Science University Drug Effectiveness Review Project (DERP)~~ to provide
2 technical and clinical support in the development and the administration of the
3 preferred drug list and the evidence-based education program established in
4 subchapter 2 of Title 18.

5 * * * Pharmaceutical Marketer Disclosures * * *

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

7 (3) The office of the attorney general shall keep confidential all trade
8 secret information, as defined by subdivision 317(b)(9) of Title 1, except that
9 the office may disclose the information to the department of health and the
10 office of Vermont health access for the purpose of informing and prioritizing
11 the activities of the evidence-based education program in subchapter 2 of
12 chapter 91 of Title 18. The department of health shall keep the information
13 confidential. The disclosure form shall permit the company to identify any
14 information that it claims is a trade secret as defined in subdivision 317(c)(9)
15 of Title 1. In the event that the attorney general receives a request for any
16 information designated as a trade secret, the attorney general shall promptly
17 notify the company of such request. Within 30 days after such notification, the
18 company shall respond to the requester and the attorney general by either
19 consenting to the release of the requested information or by certifying in
20 writing the reasons for its claim that the information is a trade secret. Any
21 requester aggrieved by the company's response may apply to the superior court

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1 of Washington County for a declaration that the company's claim of trade
2 secret is invalid. The attorney general shall not be made a party to the superior
3 court proceeding. Prior to and during the pendency of the superior court
4 proceeding, the attorney general shall keep confidential the information that
5 has been claimed as trade secret information, except that the attorney general
6 may provide the requested information to the court under seal.

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

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

9 * * *

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

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

16 ~~and~~

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

18 * * *

19 (d) Disclosures of unrestricted grants for continuing medical education
20 programs shall be limited to the value, nature, and purpose of the grant and the

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name of the grantee. It shall not include disclosure of the individual participants in such a program.

* * * Price Disclosure and Certification * * *

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

§ 2010. ACTUAL PRICE DISCLOSURE AND CERTIFICATION

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

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

§ 1396r-8(k);

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

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

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

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1 (c) The pricing information required under this section is for drugs defined
2 under the Medicaid drug rebate program and must be submitted to the director
3 following its submission to the federal government in accordance with
4 42 U.S.C. § 1396r-8(b)(3).

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

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

23 (e) Notwithstanding any provision of law to the contrary, information
24 submitted to the office under this section is confidential and is not a public
25 record as defined in subsection 317(b) of Title 1. Disclosure may be made by
26 the office to an entity providing services to the office under this section;

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1 however, that disclosure does not change the confidential status of the
2 information. The information may be used by the entity only for the purpose
3 specified by the office in its contract with the entity. Data compiled in
4 aggregate form by the office for the purposes of reporting required by this
5 section are public records as defined in subsection 317(b) of Title 1, provided
6 they do not reveal trade information protected by state or federal law.

7 (f) The attorney general shall enforce the provisions of this section under
8 the Vermont consumer fraud act in chapter 63 of Title 9. The attorney general
9 has the same authority to make rules, conduct civil investigations, and bring
10 civil actions with respect to acts and practices governed by this section as is
11 provided under the Vermont consumer fraud act.

12 * * * Healthy Vermonters Plus * * *

13 Sec. 6. 33 V.S.A. § 2003 is amended to read:

14 § 2003. PHARMACY DISCOUNT PLANS

15 (a) The director of the office of Vermont health access shall implement
16 pharmacy discount plans, to be known as the "Healthy Vermonters" program
17 and the "Healthy Vermonters Plus" program, for Vermonters without adequate
18 coverage for prescription drugs. The provisions of ~~section 1992 of this title~~
19 subchapter 8 of this chapter shall apply to the director's authority to administer
20 the pharmacy discount plans established by this section.

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

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

* * *

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1 (n) ~~The department shall seek a waiver from the Centers for Medicare and~~
2 ~~Medicaid Services (CMS) requesting authorization necessary to implement the~~
3 ~~provisions of this section, including application of manufacturer and labeler~~
4 ~~rebates to the pharmacy discount plans. The secondary discounted cost shall~~
5 ~~not be available to beneficiaries of the pharmacy discount plans until the~~
6 ~~department receives written notification from CMS that the waiver requested~~
7 ~~under this section has been approved and until the general assembly~~
8 ~~subsequently approves all aspects of the pharmacy discount plans, including~~
9 ~~funding for positions and related operating costs associated with eligibility~~
10 ~~determinations.~~

11 * * * PBM Regulation * * *

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

13 Subchapter 9. Pharmacy Benefit Managers

14 § 9471. DEFINITIONS

15 As used in this subchapter:

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

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

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

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

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

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

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

12 (4) "Pharmacy benefit management" means an arrangement for the
13 procurement of prescription drugs at a negotiated rate for dispensation within
14 this state to beneficiaries, the administration or management of prescription
15 drug benefits provided by a health plan for the benefit of beneficiaries, or any
16 of the following services provided with regard to the administration of
17 pharmacy benefits:

18 (A) mail service pharmacy;

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

21 (C) clinical formulary development and management services;

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1 (D) rebate contracting and administration;

2 (E) certain patient compliance, therapeutic intervention, and generic
3 substitution programs; and

4 (F) disease or chronic care management programs.

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

9 § 9472. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES

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

12 ~~(1) Discharge its duties with the care, skill, prudence, and diligence~~
13 ~~under the circumstances then prevailing that a prudent pharmacy benefit~~
14 ~~manager acting in like capacity and familiar with such matters would use in the~~
15 ~~conduct of an enterprise of a like character and with like aims. In the case of a~~
16 ~~health benefit plan offered by a health insurer as defined by subdivision~~
17 ~~9471(2)(A) of this title, the health insurer shall remain responsible for~~
18 ~~administering the health benefit plan in accordance with the health insurance~~
19 ~~policy or subscriber contract or plan and in compliance with all applicable~~
20 ~~provisions of Title 8 and this title.~~

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

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

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

20 (A) in a court filing under the consumer fraud provisions of chapter
 21 63 of Title 9, provided that the information shall be filed under seal and that
 22 prior to the information being unsealed, the court shall give notice and an
 23 opportunity to be heard to the pharmacy benefit manager on why the
 24 information should remain confidential;

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

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

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

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

8 (4) With regard to the dispensation of a substitute prescription drug for a
9 prescribed drug to a beneficiary in which the substitute drug costs more than
10 the prescribed drug and the pharmacy benefit manager receives a benefit or
11 payment directly or indirectly, disclose to the health insurer the cost of both
12 drugs and the benefit or payment directly or indirectly accruing to the
13 pharmacy benefit manager as a result of the substitution.

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

18 (6) Disclose to the health insurer all financial terms and arrangements
19 for remuneration of any kind that apply between the pharmacy benefit manager
20 and any prescription drug manufacturer that relate to benefits provided to
21 beneficiaries under or services to the health insurer's health plan, including

1 formulary management and drug-switch programs, educational support, claims
2 processing, and pharmacy network fees charged from retail pharmacies and
3 data sales fees. A pharmacy benefit manager providing information under this
4 subsection may designate that material as confidential. Information designated
5 as confidential by a pharmacy benefit manager and provided to a health insurer
6 under this subsection may not be disclosed by the health insurer to any person
7 without the consent of the pharmacy benefit manager, except that disclosure
8 may be made by the health insurer;

9 (A) in a court filing under the consumer fraud provisions of chapter
10 63 of Title 9, provided that the information shall be filed under seal and that
11 prior to the information being unsealed, the court shall give notice and an
12 opportunity to be heard to the pharmacy benefit manager on why the
13 information should remain confidential;

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

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

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

19 (b) A pharmacy benefit manager shall provide notice to the health insurer
20 that the terms contained in this section may be included in the contract between
21 the pharmacy benefit manager and the health insurer.

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

*(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.*

~~§ 9473. ENFORCEMENT~~

~~(a) In addition to any remedy available to the commissioner under this title
and any other remedy provided by law, a violation of this subchapter shall be
considered a violation of the Vermont consumer fraud act in subchapter 1 of
chapter 63 of Title 1. All rights, authority, and remedies available to the
attorney general and private parties to enforce the Vermont consumer fraud act
shall be available to enforce the provisions of this subchapter.~~

~~(b) In connection with any action for violation of the Vermont consumer
fraud act, the commissioner's determinations concerning the interpretation and
administration of the provisions of this subchapter and any rules adopted
hereunder shall carry a presumption of validity. The attorney general and the
commissioner shall consult with each other prior to the commencement of any
investigation or enforcement action with respect to any pharmacy benefit
manager. The commissioner may enforce a violation of this subchapter by a
pharmacy benefit manager under section 9412 of this title. Notwithstanding
the foregoing, the commissioner and the attorney general may bring a joint
enforcement action against any person or entity for a violation of this~~

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~~subchapter.~~

§ 9473. ENFORCEMENT

(a) Except as provided in subsection (d) of this section, in addition to any remedy available to the commissioner under this title and any other remedy provided by law, a violation of this subchapter shall be considered a violation of the Vermont consumer fraud act in subchapter 1 of chapter 63 of Title 1. Except as provided in subsection (d) of this section, all rights, authority, and remedies available to the attorney general and private parties to enforce the Vermont consumer fraud act shall be available to enforce the provisions of this subchapter.

(b) In connection with any action for violation of the Vermont consumer fraud act, the commissioner's determinations concerning the interpretation and administration of the provisions of this subchapter and any rules adopted hereunder shall carry a presumption of validity. The attorney general and the commissioner shall consult with each other prior to the commencement of any investigation or enforcement action with respect to any pharmacy benefit manager.

(c) The commissioner may investigate, examine, or otherwise enforce a violation of this subchapter by a pharmacy benefit manager under section 9412 of this title as if the pharmacy benefit manager were a health insurer.

(d) The commissioner shall have the exclusive authority to investigate, examine, and otherwise enforce the provisions of this subchapter relating to a pharmacy benefit manager in connection with the pharmacy benefit manager's contractual relationship with, and any other activity with respect to, a health insurer defined by subdivision 9471(2)(A) of this title.

(e) Notwithstanding the foregoing, the commissioner and the attorney general may bring a joint enforcement action against any person or entity for a violation of this subchapter.

Sec. 8. 18 V.S.A. § 9421 is added to read:

§ 9421. PHARMACY BENEFIT MANAGEMENT; REGISTRATION;

AUDIT

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

1 ~~(b) In accordance with rules adopted by the commissioner, pharmacy~~
2 ~~benefit managers operating in the state of Vermont and proposing to contract~~
3 ~~for the provision of pharmacy benefit management shall notify health insurers~~
4 ~~that a quotation for an administrative-services-only contract with full pass~~
5 ~~through of negotiated prices, rebates, and other such financial benefits which~~
6 ~~would identify to the health insurer external sources of revenue and profit, is~~
7 ~~available when the pharmacy benefit manager provides a quotation for any~~
8 ~~other alternative pricing arrangement. Quotations for an administrative-~~
9 ~~services-only contract shall include a reasonable fee payable by the health~~
10 ~~insurer which represents a competitive pharmacy benefit profit.~~

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

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

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

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

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

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

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

30 (A) full pass through of negotiated drug prices and fees associated
31 with all drugs dispensed to beneficiaries of the health plan in both retail and

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1 mail order settings or resulting from any of the pharmacy benefit management
2 functions defined in the contract;

3 (B) full pass through of all financial remuneration associated with all
4 drugs dispensed to beneficiaries of the health plan in both retail and mail
5 order settings or resulting from any of the pharmacy benefit management
6 functions defined in the contract; and

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

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

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

20 (f) As used in this section:

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

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

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

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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

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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, the
8 University of Vermont area health center program, and the office of Vermont
9 health access shall establish an evidence-based prescription drug education
10 program for health care professionals designed to provide information and
11 education on the therapeutic and cost-effective utilization of prescription drugs
12 to physicians, pharmacists, and other health care professionals authorized to
13 prescribe and dispense prescription drugs. The department may collaborate
14 with other states in establishing this program.

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

20 (c) The department may contract for technical and clinical support in the
21 development and the administration of the program from entities conducting

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1 independent research into the effectiveness of prescription drugs, such as the
2 Oregon Health and Science University Drug Effectiveness Review Project
3 (DERP).

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

9 ~~*** Prescription Drug Data Confidentiality ***~~

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

11 Subchapter 3. Information Requirements

12 § 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

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

21 ~~(b) As used in this section:~~

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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;~~

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~~

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

3 * * * Prescription Drug Data Confidentiality * * *

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

5 Subchapter 3. Information Requirements

6 § 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

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

15 (b) As used in this section:

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

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

30 (3) "Health care facility" shall have the same meaning as in section
31 9402 of this title.

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

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

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

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

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

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

13 (d) This section shall not apply to:

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

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

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

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

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

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

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

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(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. 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:~~

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~~§ 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 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.~~

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

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

5 § 4653. UNCONSCIONABLE PRICING PROHIBITED

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

10 § 4654. SERIOUS PUBLIC HEALTH PROBLEM

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

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

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

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

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~~(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
favorable 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~~

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1 ~~development of the drug, and the impact of price on access to a prescription~~
2 ~~drug by residents and the government of Vermont.~~

3 § 4656. CONSUMER FRAUD ACTION

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

8 § 4657. CIVIL ACTION

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

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

17 § 4658. REMEDIES FOR CIVIL ACTIONS

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

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~~(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;

(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.~~

¹⁵
Sec. ~~14~~ 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 in Vermont 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

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A manufacturer of prescription drugs or its licensee shall not sell in Vermont for an unconscionable price a prescription drug necessary to treat a serious public health threat provided for in section 4654 of this title.

§ 4654. SERIOUS PUBLIC HEALTH THREAT

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

(2) The attorney general may request a determination by the commissioner of health on whether a health condition or disease 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 or disease is a serious public health threat:

(1) the number of Vermonters that 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 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 as prohibited in section 4653 of this title shall be established where the manufacturer's price of a prescription drug in Vermont is over 30 percent higher than the prices available to federal agencies in Vermont under the federal supply schedule, the prices available through the Healthy Vermonters program, or the most favored purchase price available in Vermont.

(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

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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;

(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. ¹⁶18. 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.

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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 2466a(c)(1) of Title 9 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 * * * Consumer Protection; False Advertising * * *

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

12 **§ 2466a. CONSUMER PROTECTIONS; PRESCRIPTION DRUGS**

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

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

17 **(c)(1) It shall be a violation under this chapter for a manufacturer of**
18 **prescription drugs to present or cause to be presented in the state a regulated**
19 **advertisement, unless that advertisement meets the requirements concerning**
20 ~~misbranded drugs and devices and prescription drug advertising of federal law~~

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~~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).

(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~~

1 ~~health care professional or agent in prescribing a specific prescription drug or~~
 2 ~~directing a patient to a certain pharmacy.~~

17

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

4 § 2466a. CONSUMER PROTECTIONS; PRESCRIPTION DRUGS

5 (a) A violation of section 4655 of Title 18 shall be considered a violation
 6 under this chapter.

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

9 (c)(1) It shall be a violation under this chapter for a manufacturer of
 10 prescription drugs to present or cause to be presented in the state a regulated
 11 advertisement if that advertisement does not comply with the requirements
 12 concerning misbranded drugs and devices and prescription drug advertising of
 13 federal law and regulations under 21 United States Code, Sections 331 and
 14 352(n) and 21 Code of Federal Regulations, Part 202 and state rules. A
 15 warning or untitled letter issued by the U.S. Food and Drug Administration
 16 shall be prima facie evidence of a violation of federal law and regulations.

17 (2) For purposes of this section:

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

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

31 (d) No person shall sell, offer for sale, or distribute electronic prescribing
 32 software that advertises, uses instant messaging and pop-up advertisements, or
 33 uses other means to influence or attempt to influence the prescribing decision
 34 of a health care professional through economic incentives or otherwise and
 35 which is triggered or in specific response to the input, selection, or act of a
 36 health care professional or agent in prescribing a specific prescription drug or
 37 directing a patient to a certain pharmacy. This subsection shall not apply to

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information provided to the health care professional about pharmacy reimbursement, prescription drug formulary compliance, and patient care management.

* * * Insurance Marketing * * *

¹⁸
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"

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1 includes Medicare Part A, Medicare Part B, Medicare Part C, Medicare Part D,
2 and Medicare supplement plans;

3 * * *

4 ¹⁹
Sec. ~~21~~ RECODIFICATION

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

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

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

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

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

11 ²⁰
Sec. ~~22~~ REPEAL

12 Section 2009 of Title 33 is repealed.

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TO THE HOUSE OF REPRESENTATIVES

The Committee on Health Care, 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 House propose to the Senate that the bill be amended by striking all
after the enacting clause and inserting in lieu thereof the following:

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

§ 1998. PHARMACY BEST PRACTICES AND COST CONTROL
PROGRAM ESTABLISHED

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

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

~~(A) The director and the commissioner of banking, insurance,
securities, and health care administration shall implement the preferred drug~~

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~~list as a uniform, statewide preferred drug list by encouraging all health benefit plans in this state to participate in the program.~~

~~(B) The commissioner of human resources shall use the preferred drug list in the state employees health benefit plan only if participation in the program will provide economic and health benefits to the state employees health benefit plan and to beneficiaries of the plan, and only if agreed to through the bargaining process between the state of Vermont and the authorized representatives of the employees of the state of Vermont. The provisions of this subdivision do not authorize the actuarial pooling of the state employees health benefit plan with any other health benefit plan, unless otherwise agreed to through the bargaining process between the state of Vermont and the authorized representatives of the employees of the state of Vermont. No later than November 1, 2004, the commissioner of human resources shall report to the health access oversight committee and the senate and house committees on health and welfare on whether use of the preferred drug list in the state employees health benefit plan would, in his or her opinion, provide economic and health benefits to the state employees health benefit plan and to beneficiaries of the plan.~~

~~(C) The director shall encourage all health benefit plans to implement the preferred drug list as a uniform, statewide preferred drug list by inviting the representatives of each health benefit plan providing prescription drug~~

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~~coverage to residents of this state to participate as observers or nonvoting members in the director's drug utilization review board, and by inviting such plans to use the preferred drug list in connection with the plans' prescription drug coverage.~~

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

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

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

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

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

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

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

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

* * *

(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

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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, workers' compensation, and any other state or publicly funded purchaser of prescription drugs.

* * *

(f)(1) The drug utilization review board shall make recommendations to the director for the adoption of the preferred drug list. The board's recommendations shall be based upon evidence-based considerations of clinical efficacy, adverse side effects, safety, appropriate clinical trials, and cost-effectiveness. "Evidence-based" shall have the same meaning as in section 4622 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 subdivision (c)(1) 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 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.

* * * 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 and the office of Vermont health access 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 and the office of Vermont health access shall keep the information confidential. The disclosure form

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

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

(4) The following shall be exempt from disclosure:

* * *

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

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

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

and

(F) prescription drug rebates and discounts.

* * *

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

Sec. 5. 33 V.S.A. § 2005a(d) is amended to read:

(d) As used in this section:

* * *

(2) "Pharmaceutical manufacturing company" is defined by subdivision 2005(e)(5) 4632(c)(5) of this title.

(3) "Pharmaceutical marketer" is defined by subdivision 2005(e)(4) 4632(c)(4) of this title.

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* * * Price Disclosure and Certification * * *

Sec. 6. 33 V.S.A. § 2010 is added to read:

§ 2010. ACTUAL PRICE DISCLOSURE AND CERTIFICATION

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

(1) the prices required to be provided to the Medicaid program under federal law, including prices defined in 42 U.S.C. § 1396r-8; and

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

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

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

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(d) When a manufacturer of prescription drugs dispensed in this state reports the 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.

(e) Notwithstanding any provision of law to the contrary, information submitted to the office under this section is confidential and is not a public record as defined in subsection 317(b) of Title 1. Disclosure may be made by the office to an entity providing services to the office under this section; however, that disclosure does not change the confidential status of the information. The information may be used by the entity only for the purpose specified by the office in its contract with the entity. Data compiled in aggregate form by the office for the purposes of reporting required by this section are public records as defined in subsection 317(b) of Title 1, provided they do not reveal trade information protected by state or federal law.

(f) The attorney general shall enforce the provisions of this section under the Vermont consumer fraud act in chapter 63 of Title 9. The attorney general

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has the same authority to make rules, conduct civil investigations, and bring civil actions with respect to acts and practices governed by this section as is provided under the Vermont consumer fraud act.

* * * Healthy Vermonters * * *

Sec. 7. 33 V.S.A. § 2003 is amended to read:

§ 2003. PHARMACY DISCOUNT PLANS

(a) The director of the office of Vermont health access shall implement pharmacy discount plans, to be known as the “Healthy Vermonters” program ~~and the “Healthy Vermonters Plus” program~~, for Vermonters without adequate coverage for prescription drugs. The provisions of ~~section 1992 of this title~~ subchapter 8 of this chapter shall apply to the director’s authority to administer the pharmacy discount plans established by this section.

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

* * *

(c) As used in this section:

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(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~~ 350 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 household income or whose total unreimbursed medical expenses, including insurance premiums, equal 15 percent or more of household income.~~

* * *

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* * * PBM Regulation * * *

Sec. 8. 18 V.S.A. chapter 221, subchapter 9 is added to read:

Subchapter 9. Pharmacy Benefit Managers

§ 9471. DEFINITIONS

As used in this subchapter:

(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.

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

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

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

(A) mail service pharmacy;

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

(C) clinical formulary development and management services;

(D) rebate contracting and administration;

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

(F) disease or chronic care management programs.

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

§ 9472. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES

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(a) A pharmacy benefit manager that provides pharmacy benefit management for a health plan shall discharge its duties with reasonable care and diligence and be fair and truthful under the circumstances then prevailing that a 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.

(b) A pharmacy benefit manager shall provide notice to the health insurer that the terms contained in subsection (c) of this section may be included in the contract between the pharmacy benefit manager and the health insurer.

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

(1) Provide all financial and utilization information requested by a health insurer relating to the provision of benefits to beneficiaries through that health insurer's health plan and all financial and utilization information relating to services to that health insurer. A pharmacy benefit manager providing information under this subsection may designate that material as confidential. Information designated as confidential by a pharmacy benefit

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manager and provided to a health insurer under this subsection may not be disclosed by the health insurer to any person without the consent of the pharmacy benefit manager, except that disclosure may be made by the health insurer:

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

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

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

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

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

(3) With regard to the dispensation of a substitute prescription drug for a prescribed drug to a beneficiary in which the substitute drug costs more than the prescribed drug and the pharmacy benefit manager receives a benefit or

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payment directly or indirectly, disclose to the health insurer the cost of both drugs and the benefit or payment directly or indirectly accruing to the pharmacy benefit manager as a result of the substitution.

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

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

(A) in a court filing under the consumer fraud provisions of chapter 63 of Title 9, provided that the information shall be filed under seal and that

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prior to the information being unsealed, the court shall give notice and an opportunity to be heard to the pharmacy benefit manager on why the information should remain confidential;

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

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

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

(d) 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.

§ 9473. ENFORCEMENT

(a) Except as provided in subsection (d) of this section, in addition to any remedy available to the commissioner under this title and any other remedy provided by law, a violation of this subchapter shall be considered a violation of the Vermont consumer fraud act in subchapter 1 of chapter 63 of Title 1. Except as provided in subsection (d) of this section, all rights, authority, and remedies available to the attorney general and private parties to enforce the Vermont consumer fraud act shall be available to enforce the provisions of this subchapter.

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

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fraud act, the commissioner's determinations concerning the interpretation and administration of the provisions of this subchapter and any rules adopted hereunder shall carry a presumption of validity. The attorney general and the commissioner shall consult with each other prior to the commencement of any investigation or enforcement action with respect to any pharmacy benefit manager.

(c) The commissioner may investigate, examine, or otherwise enforce a violation of this subchapter by a pharmacy benefit manager under section 9412 of this title as if the pharmacy benefit manager were a health insurer.

(d) The commissioner shall have the exclusive authority to investigate, examine, and otherwise enforce the provisions of this subchapter relating to a pharmacy benefit manager in connection with the pharmacy benefit manager's contractual relationship with, and any other activity with respect to, a health insurer defined by subdivision 9471(2)(A) of this title.

(e) Notwithstanding the foregoing, the commissioner and the attorney general may bring a joint enforcement action against any person or entity for a violation of this subchapter.

Sec. 9. 18 V.S.A. § 9421 is added to read:

§ 9421. PHARMACY BENEFIT MANAGEMENT; REGISTRATION;

AUDIT

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

(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) 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 the contract;

(B) 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 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 the commissioner.

(d) The department's reasonable expenses in administering the provisions of this section may be charged to pharmacy benefit managers in the manner provided for in section 18 of Title 8. These expenses shall be allocated in proportion to the lives of Vermonters covered by each pharmacy benefit manager as reported annually to the commissioner in a manner and form prescribed by the commissioner. The department shall not charge its expenses to the pharmacy benefit manager contracting with the office of Vermont health access if the office notifies the department of the conditions contained in its contract with a pharmacy benefit manager.

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

(f) As used in this section:

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

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

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

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

Sec. 10. APPLICATION

Secs. 8 and 9 of this act apply to contracts executed or renewed on or after September 1, 2007. For purposes of this section, a contract executed pursuant to a memorandum of agreement executed prior to September 1, 2007 is deemed to have been executed prior to September 1, 2007 even if the contract was executed after that date.

Sec. 11. 8 V.S.A. § 4088d is added to read:

§ 4088d. NOTICE OF PREFERRED DRUG LIST CHANGES

A health insurer, as defined in subdivisions 9471(2)(A), (C), and (D) of Title 18, shall provide beneficiaries sufficient notice of any changes to the

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prescription drugs covered on its preferred drug list. For purposes of this section, “sufficient notice” means:

(1) written notice to affected beneficiaries specifying the drugs that have been added or removed from the preferred drug list, which shall be provided to beneficiaries at least 30 days prior to the effective date of such changes; or

(2) written notice to a beneficiary that a specific drug is no longer covered on the preferred drug list at the time the beneficiary seeks a refill of that drug. In such circumstances, the beneficiary shall not be denied coverage for the first requested refill after the change to the preferred drug list has taken place. Subsequent refills, however, shall be subject to the requirements of the revised preferred drug list.

Sec. 12. 18 V.S.A. chapter 91 is amended to read:

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

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

Subchapter 1. Generic Drugs

Sec. 14. 18 V.S.A. chapter 91, subchapter 2 is added to read:

Subchapter 2. Evidence-Based Education Program

§ 4621. DEFINITIONS

For the purposes of this subchapter:

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

(2) "Evidence-based" means based on criteria and guidelines that reflect high-quality, cost-effective care. The methodology used to determine such guidelines shall meet recognized standards for systematic evaluation of all available research and shall be free from conflicts of interest. Consideration of the best available scientific evidence does not preclude consideration of experimental or investigational treatment or services under a clinical investigation approved by an institutional review board.

§ 4622. EVIDENCE-BASED EDUCATION PROGRAM

(a)(1) The department, in collaboration with the attorney general, the University of Vermont area health education centers program, and the office of Vermont health access, shall establish an evidence-based prescription drug education program for health care professionals designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists, and other health care professionals authorized to prescribe and dispense prescription drugs. The department may collaborate with other states in establishing this program.

(2) The program shall notify prescribers about commonly used brand-name drugs for which the patent has expired within the last 12 months or will expire within the next 12 months. The department and the office of Vermont health access shall collaborate in issuing the notices.

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(3) To the extent permitted by funding, the program may include the distribution to prescribers of samples of generic medicines used to treat chronic conditions common in Vermont.

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

(c) The department may contract for technical and clinical support in the development and the administration of the program from entities conducting independent research into the effectiveness of prescription drugs.

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

Sec. 15. GENERIC DRUG SAMPLE PILOT PROJECT

(a) As part of the evidence-based education program established in subchapter 2 of chapter 91 of Title 18, the department of health, in collaboration with the office of Vermont health access and the University of Vermont area health education centers program, shall establish a pilot project

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to distribute vouchers for a sample of generic drugs used to treat high cholesterol, including statins, and informational and educational materials to prescribers. The department and office may expand the pilot program to include other classes of prescription drugs used to treat common chronic conditions for which there is a generic medicine available.

(b) The office of Vermont health access shall fund the vouchers from the fee established in section 1998b of Title 33 and shall provide payment to the pharmacy dispensing the prescription drugs in exchange for the voucher. The office shall establish a payment rate, including a dispensing fee, using the rules and procedures for the Medicaid program.

Sec. 16. PRESCRIPTION DRUG PRICING; FEDERALLY QUALIFIED
HEALTH CENTERS

No later than January 1, 2008, the department of health shall create a plan to inform Vermonters of the availability of health services provided by federally qualified health centers (FQHC) and FQHC look-alikes, including information about prescription drug pricing, focusing on 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 for whom the cost of prescription drugs is likely to be higher than prices under Section 340B of the Public Health Service Act.

* * * Prescription Drug Data Confidentiality * * *

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Sec. 17. 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 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

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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.

(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.

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(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;

(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;

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(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. 18. 1 V.S.A. § 317(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, that could be used to identify a patient or prescriber, except that the records shall be made available upon request for medical research purposes consistent with those expressed in sections 4621, 4631, 4632, 4633, and 9410 of Title 18 and chapters 84 and 84A of Title 18, or law enforcement activities.

Sec. 19. 18 V.S.A. § 9410(g) is amended to read:

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(g) Any person who knowingly fails to comply with the requirements of this section or rules adopted pursuant to this section shall be fined subject to an administrative penalty of not more than \$1,000.00 per violation. The commissioner may impose an administrative penalty of not more than \$10,000.00 each for those violations the commissioner finds were willful. In addition, any person who knowingly fails to comply with the confidentiality requirements of this section or rules adopted pursuant to this section and uses, sells or transfers the data or information for commercial advantage, pecuniary gain, personal gain or malicious harm shall be subject to an administrative penalty of not more than \$50,000.00 per violation. The powers vested in the commissioner by this subsection shall be in addition to any other powers to enforce any penalties, fines or forfeitures authorized by law.

Sec. 20. 33 V.S.A. § 1998b is added to read:

§ 1998b. MANUFACTURER FEE

(a) 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 to the agency of human services. The fee shall be 0.5 percent of the previous calendar year's drug spending and shall be assessed based on manufacturer labeler codes as used in the Medicaid rebate program.

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(b) 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.

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

* * * Consumer Protection; False Advertising * * *

Sec. 21. 9 V.S.A. § 2466a is added to read:

§ 2466a. CONSUMER PROTECTIONS; PRESCRIPTION DRUGS

(a) A violation of section 4631 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 if that advertisement does not comply with the requirements concerning drugs and devices and prescription drug advertising in 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. A warning or untitled letter issued by the U.S. Food and Drug Administration shall be prima facie evidence of a violation of federal law and regulations.

(2) For purposes of this section:

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(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, 207.20 (1999).

(B) “Regulated advertisement” means:

(i) 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; or

(ii) a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs or its representative that is conveyed:

(I) to the office of a health care professional doing business in Vermont, including statements by representatives or employees of the manufacturer and materials mailed or delivered to the office; or

(II) at a conference or other professional meeting occurring in Vermont.

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(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. This subsection shall not apply to information provided to the health care professional about pharmacy reimbursement, prescription drug formulary compliance, and patient care management.

* * * Insurance Marketing * * *

Sec. 22. 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:

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(A)(i) sell, solicit, or negotiate the purchase of health insurance in this state through an advertisement which makes 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.

(ii) Use 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 requests the solicitation, and the products to be discussed are clearly identified to the consumer in writing at least 48 hours in advance of the appointment.

(iii) Solicit the sale of Medicare products door-to-door prior to receiving an invitation from a consumer.

(B) 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. 23. 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.

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

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

Sec. 24. REPEAL

Section 2009 of Title 33 is repealed.

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S.115 - Prescription Drug Data Confidentiality

First, by inserting ~~the~~ Sec. 16a to read:

Sec. 16a. LEGISLATIVE FINDINGS

The general assembly makes the following findings:

(1) In 2005, Vermonters spent an estimated \$524 million on prescription and over the counter drugs and medical supplies. In 2000, spending was about \$280 million. The annual increase in spending during this period was 13.3 percent.

(2) According to the June 15, 2006 Marketing Disclosures: Report of Vermont Attorney General William H. Sorrell, as part of their marketing efforts, pharmaceutical companies made direct payments of almost \$2.2 million to prescribers, including fees and travel expenses in 2005. Estimates of total costs of marketing to prescribers in Vermont are \$10 million or more, excluding free samples and direct-to-consumer advertising.

(3) Choices among therapeutic options can have significant health and economic consequences to patients. Choices also have major financial effects on third-party payers, including the state of Vermont.

(4) Marketing efforts have been shown to have a significant effect on provider prescribing patterns. One of the most effective components of pharmaceutical marketing is "detailing" – direct one-on-one presentations to prescribers.

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(5) Studies have shown that information presented is not always accurate, or may be biased.

(6) Analysis of individual prescriptions, called "data mining," can increase the effectiveness of detailing by identifying individual prescribers who could be most receptive to marketing messages and by tailoring messages to specific prescribers.

(7) To the extent that marketing efforts either increase pharmaceutical spending without an equivalent increase in patient health status or directly endanger patient health, such marketing efforts are contrary to the best interests of the state.

Second: by striking Sec. 17 and inserting a new Sec. 17 to read:

Sec. 17. 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.~~

~~(a) It is the intent of the general assembly to advance the state's interest in protecting~~ ^{the} ~~public health of Vermonters and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of generic drugs as an alternative to more costly drugs and ensuring prescribers receive unbiased 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)(1) "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.~~

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refill, authorization request, claim, payment, or other prescription drug information.

~~(3)~~(2) "Health care facility" shall have the same meaning as in section 9402 of this title.

~~(4)~~(3) "Health care professional" shall have the same meaning as in section 9402 of this title.

~~(5)~~(4) "Health insurer" shall have the same meaning as in section 9410 of this title.

(5) "Marketing" shall include advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior of an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

(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) "Promotion" or "promote" means any activity or product the intention of which is to advertise or publicize a prescription drug,

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including a brochure, media advertisement or announcement, poster,
brochure, free sample, detailing visit or personal appearance.

(8)(9) "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
if that data is used or intended to be used to market or promote a brand-
name drug for which there is a lower-cost generic drug in the same class
or when there is another therapeutic treatment recommended by
evidence-based treatment protocols prior to the use of the brand-name
drug.

(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;

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that the brand name has a specific health benefit or risk not available from the generic drug available in the same class or other therapeutic treatment and the marketing information includes evidence-based materials as defined in section 4622 of this title describing the specific health benefits or risks, and which patients would gain from the health benefits or be susceptible to the risks described.

(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.

TAB F

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S.115 - Prescription Drug Data Confidentiality

Representative Chen of Mendon, on behalf of the committee on health care,
moves to amend S.115 as follows:

First: In Sec. 14, 18 V.S.A. § 4622(a)(1) by striking subdivision (1) and inserting a new subdivision (1) to read:

(a)(1) The department, in collaboration with the attorney general, the University of Vermont area health education centers program, and the office of Vermont health access, shall establish an evidence-based prescription drug education program for health care professionals designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists, and other health care professionals authorized to prescribe and dispense prescription drugs. To the extent practicable, the program shall use the evidence-based standards developed by the blueprint for health. The department may collaborate with other states in establishing this program.

Second: In Sec. 14, 18 V.S.A. § 4622(a)(3) by striking subdivision (3) and inserting a new subdivision (3) to read:

(3) To the extent permitted by funding, the program may include the distribution to prescribers of samples of generic medicines used for health conditions common in Vermont.

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Third: By striking Sec. 15(a) and inserting a new subsection (a) to read:

(a) As part of the evidence-based education program established in subchapter 2 of chapter 91 of Title 18, the department of health, in collaboration with the office of Vermont health access and the University of Vermont area health education centers program, shall establish a pilot project to distribute vouchers for a sample of ⁵generic drug equivalent to frequently prescribed prescription drugs that are used to treat common health conditions.

Fourth: By inserting a new Sec. 15a^g to read:

Sec. 15a. GENERIC DRUG SAMPLE PILOT; REPORT


By January 15, 2009, the office of Vermont health access, the department of banking, insurance, securities, and health care administration, and the joint fiscal office shall provide a report to the house committee on health care and the senate committee on health and welfare comparing the distribution of prescribing among generic drugs and brand name drugs before and after the first year of the generic drug sample pilot project. The comparison will review a year of prescribing data prior to the implementation of the pilot project to a year of prescribing data during the first year of the pilot project's implementation.

Fifth: By inserting a new Sec. 16a^g to read:

Sec. 16a. LEGISLATIVE FINDINGS


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The general assembly makes the following findings:

(1) Vermont has been a leader in prescription drug cost-containment and in providing transparency, to the extent allowable, in drug prices. The state has enacted the pharmacy best practices and cost control program, mandatory generic substitution, and mail order purchasing in Medicaid, VPharm and Vermont Rx and encouraged the department of human resources to have a preferred drug list in the state employees health benefit plans in efforts to control costs, while maintaining best practices in drug prescribing, in our publicly-financed prescription drug programs. The Vermont Medicaid program has been a member of multi-state purchasing pools for several years and aggressively seeks supplemental rebates to lower drug costs in the Medicaid program.



(2) In addition, Vermont has sought to control drug prices in private and employer-sponsored insurance by encouraging voluntary participation in the Medicaid's preferred drug list, requiring mandatory generic substitution for all prescriptions in Vermont, providing consumers with pricing information about the drugs they are prescribed, and assisting consumers by providing information about purchasing drugs internationally through a safe, regulated program run through the state of Illinois.

(3) Vermont has also sought transparency by requiring marketers of prescription drugs to disclose information about the amount of money spent on

marketing activities in Vermont and also to require the disclosure of pricing information to doctors during marketing visits.

(4) This act is necessary to protect prescriber privacy, to save money for the State, consumers, and businesses, and to protect public health.

(5) Most doctors in Vermont that write prescriptions for their patients have a reasonable expectation that the information in that prescription, including their own identity and that of the patient, will not be used for purposes other than the filling and processing the payment for that prescription. Doctors and patients do not consent to the trade of that information to third parties, and no such trade should take place without their consent.

(6) According to the June 15, 2006 Marketing Disclosures: Report of Vermont Attorney General William H. Sorrell, as part of their marketing efforts, pharmaceutical companies made direct payments of almost \$2.2 million to prescribers in Vermont, including fees and travel expenses in 2005. Estimates of total costs of marketing to prescribers in Vermont are \$10 million or more, excluding free samples and direct-to-consumer advertising.

(7) Some doctors in Vermont are experiencing an undesired increase in the aggressiveness of pharmaceutical sales representatives and have reported this to be coercive and harassing.

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(8) Prescriber-identifiable prescription data shows details of physicians' drug use patterns, both in terms of their gross number of prescriptions and their inclinations to prescribe particular drugs.

(9) Prescriber identified databases of prescribing habits encourage pharmaceutical companies increase the *quid pro quo* nature of relations between pharmaceutical sales representatives and prescribers. Pharmaceutical companies use prescriber identity data-mining to target increased attention and harassing and coercive practices toward those doctors that it finds are most profitable, including high prescribers, brand loyal prescribers, doctors that show themselves willing to prescribe new medicines, and doctors that are proven to be especially susceptible to sales messages.

(10) Monitoring of prescribing practices also allows the sales representative to assess the impact of various gifts and messages on a particular physician to help them select the most effective set of rewards.

(11) Added coercion and harassment occurs when doctors are informed that they are being monitored – through messages of appreciation for writing prescriptions, or messages of disappointment that they are not prescribing what was implicitly promised.

(12) Like the trading of consumer phone numbers linked to spending pattern data, the trading of prescriber identities linked to prescription data

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encourages harassing and unethical sales behaviors by pharmaceutical sales representatives toward doctors.

(13) Prescriber identity data mining allows pharmaceutical companies to track to track the prescribing habits of nearly every physician in Vermont and link those habits to specific physicians and their identities.

(14) Coincident with the rise of physician identity data mining, the pharmaceutical industry increased its spending on direct marketing to doctors by over 275 percent and doubled its sales force to over 90,000 drug reps. It is estimated that there is a pharmaceutical sales representative in Vermont for every five office-based physicians in Vermont.

(15) In 2004, the pharmaceutical industry spent \$27 billion marketing pharmaceuticals in the U.S., and spent more than any other sector in the U.S. on its sales force and media advertising. Over 85 percent of these marketing expenditures are directed at the small percentage of the population that practice medicine.

(16) The physician data restriction program offered by the American medical association (AMA) is not an adequate remedy for Vermont doctors, because the program does not prohibit the sharing of data, but merely requires manufacturers to assert that they are not using the data. In addition, other health care professionals who prescribe medications are not physicians and may not avail themselves of the AMA program.

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(17) In 2005, Vermonters spent an estimated \$524 million on prescription and over the counter drugs and medical supplies. In 2000, spending was about \$280 million. The annual increase in spending during this period was 13.3 percent.

(18) Nearly a third of the five-fold increase in U.S. spending on drugs over the last decade can be attributed to marketing induced shifts in doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments, which often have little or no increased therapeutic value.

(19) Public health is ill served by the massive imbalance in information presented to doctors and other prescribers.

(20) The marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that only brand name companies invest in expensive pharmaceutical marketing campaigns to doctors. The one sided nature of the marketing leads to doctors prescribing drugs with imperfect, misleading and biased information, particularly for prescribers that lack the time or initiative to perform substantive research assessing whether the messages they are receiving from pharmaceutical representatives is full and accurate.

(21) Newer drugs on the market do not necessarily provide additional benefits over older drugs, but do add costs and as yet unknown side effects. One example of this is the drug Vioxx, which was removed from the market

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due to potentially lethal side effects that were not adequately disclosed initially.

(22) Fifty percent of all drug withdrawals from the market and “black box warnings” are within the first two years of the release of the drug.

(23) Prescriber-identified data increases the effect of detailing programs. It supports the tailoring of presentations to individual prescriber styles, preferences, and attitudes.

(24) The goals of marketing programs are in conflict with the goals of the state. Marketing programs are designed to increase sales, income, and profit. Frequently, progress toward these goals come at the expense of cost containment activities and possibly the health of individual patients.

Sixth: By striking Sec. 17 and inserting a new Sec. 17 to read:

Sec. 17. 18 V.S.A. chapter 91, subchapter 3 is added to read:

Subchapter 3. Information Requirements

§ 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

(a) It is the intent of the general assembly to advance the state’s interest in protecting the public health of Vermonters, ~~protecting~~ the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.

Vstet

Robin
please
review.
This is
confusing

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(b) As used in this section:

(1) “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.

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

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

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

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

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(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) "Promotion" or "promote" means any activity or product, the intention of which is to advertise or publicize a prescription drug, including a brochure, media advertisement or announcement, poster, brochure, free sample, detailing visit, or personal appearance.

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

(c) The department of health and the office of professional regulation, in consultation with the appropriate licensing boards, shall establish a prescriber data sharing program to allow a prescriber to give permission for his or her identifying information to be licensed, transferred, used, or sold for the purposes described under subsection (d) of this section. The department and office shall solicit the prescriber's permission on licensing applications or renewal forms and shall provide a prescriber a method for revoking his or her permission. The department and office may establish rules for this program.

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(d) A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity may use regulated records which include prescription information containing ~~patient-identifiable or~~ prescriber-identifiable data for marketing or promoting a prescription drug only if:

(1)(A) a prescriber has provided permission for the use of that data as provided ~~in~~ in subsection (c); and *of this section*

(B) the entity using the regulated records complies with the disclosure requirements in subsection (e); or *of this section*

(2) the entity meets one of the exceptions provided ~~in~~ in subsection

(e) of this section

(e) 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; and

(7) the collection, use, transfer, or sale of patient and prescriber data for marketing or promoting 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.

(f) When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs, the marketer shall disclose to the prescriber evidence-based information as provided for by rule

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describing the specific health benefits or risks of using other
pharmaceutical drugs, including drugs available over the counter, which
patients would gain from the health benefits or be susceptible to the risks
described, the range of prescription drug treatment options, and the cost
of the treatment options. ^{As necessary, the office of Vermont health}
access, in consultation with ^{the} department of health, the area centers on
health education, the office of professional regulation, and the office of the
attorney general, shall develop rules for compliance with this subsection,
including the certification of materials which are evidence-based as
defined in section 4621 of this title and which conditions have evidence-
based treatment guidelines. To the extent practicable, the rules shall use
the evidence-based standards developed by the blueprint for health.

(g) 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.

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Seventh: By inserting a new Sec. 24b⁹ to read:

Sec. 24b. EFFECTIVE DATES

Sec. 17 shall become effective no later than January 1, 2008, except that the department of health and the office of professional regulation may begin any necessary rulemaking, revision of forms, or other administrative actions necessary to implement the program, immediately upon passage. The department may implement Sec. 17 of this act for prescribers with licenses at the time of passage of this act when the prescriber next requests a renewal of the license.

TAB G

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S.115 - Prescription Drug Data Confidentiality

Representative Chen of Mendon, on behalf of the Committee on Health Care, moves to amend the bill as amended by the Committees on Health Care and on Appropriations as follows:

First: By renumbering Sec. 1 to be Sec. 1a and inserting a new Sec. 1 to read:

Sec. 1. LEGISLATIVE FINDINGS

The general assembly makes the following findings:

(1) Vermont has been a leader in prescription drug cost-containment and in providing transparency, to the extent allowable, in drug prices. The state has enacted the pharmacy best practices and cost control program, mandatory generic substitution, and mail order purchasing in Medicaid, VPharm, and Vermont Rx and encouraged the department of human resources to have a preferred drug list in the state employees health benefit plans in efforts to control costs, while maintaining best practices in drug prescribing, in our publicly-financed prescription drug programs. The Vermont Medicaid program has been a member of multi-state purchasing pools for several years and aggressively seeks supplemental rebates to lower drug costs in Medicaid program.

(2) In addition, Vermont has sought to control drug prices in private and employer-sponsored insurance by encouraging voluntary participation in

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Medicaid's preferred drug list, requiring mandatory generic substitution for all prescriptions in Vermont, providing consumers with pricing information about the drugs they are prescribed, and assisting consumers by providing information about purchasing drugs internationally through a safe, regulated program run through the state of Illinois.

(3) Vermont has also sought transparency by requiring marketers of prescription drugs to disclose information about the amount of money spent on marketing activities in Vermont and also to require the disclosure of pricing information to doctors during marketing visits.

(4) This act is necessary to protect prescriber privacy, to save money for the state, consumers, and businesses, and to protect public health.

(5) Most doctors in Vermont who write prescriptions for their patients have a reasonable expectation that the information in that prescription, including their own identity and that of the patient, will not be used for purposes other than the filling and processing of the payment for that prescription. Doctors and patients do not consent to the trade of that information to third parties, and no such trade should take place without their consent.

(6) According to the June 15, 2006 Marketing Disclosures: Report of Vermont Attorney General William H. Sorrell, as part of their marketing efforts, pharmaceutical companies made direct payments of almost \$2.2

protect
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health

limiting marketing
to those who
want it
& requiring
disclosures
ensures

FDA requirement
is fair +
balanced
info.
FDA can't
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to avoid prescriber
harassment
which
leads to
increased
costs,

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million to prescribers in Vermont, including ^{consulting} fees and travel expenses in 2005.

Estimates of total costs of marketing to prescribers in Vermont are \$10 million or more, excluding free samples and direct-to-consumer advertising.

(7) Some doctors in Vermont are experiencing an undesired increase in the aggressiveness of pharmaceutical sales representatives and have reported this to be coercive and harassing, as well as leading to increased costs.

(8) Prescriber-identifiable prescription data show details of physicians' drug use patterns, both in terms of their gross number of prescriptions and their inclinations to prescribe particular drugs.

(9) Prescriber identified databases of prescribing habits encourage pharmaceutical companies to increase the quid pro quo nature of relations between pharmaceutical sales representatives and prescribers. Pharmaceutical companies use prescriber identity data-mining to target increased attention and harassing and coercive practices toward those doctors that they find are most ^{would lead to} ~~profitable~~ ^{result} ~~profitable~~ ^{increased} ~~profitable~~ ^{prescriptions} ~~profitable~~ ^{and profitable} ~~profitable~~, including high prescribers, brand loyal prescribers, doctors that show themselves willing to prescribe new medicines, and doctors that are proven to be especially susceptible to sales messages.

(10) Monitoring of prescribing practices also allows the sales representatives to assess the impact of various gifts and messages on a particular physician to help them select the most effective set of rewards.

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(11) Added coercion and harassment occurs when doctors are informed by sales representatives that they are being monitored – through messages of appreciation for writing prescriptions, or messages of disappointment that they are not prescribing what was implicitly promised.

leads to
increased
time +
costs

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(12) As with the trading of consumer phone numbers linked to spending pattern data, the trading of prescriber identities linked to prescription data encourages harassing and unethical sales behaviors by pharmaceutical sales representatives toward doctors. that lead to lost time + increased costs.

Use of
phone number
for
marketing

(13) Prescriber identity data mining allows pharmaceutical companies to track the prescribing habits of nearly every physician in Vermont and link those habits to specific physicians and their identities.

(14) Coincident with the rise of physician identity data mining, the pharmaceutical industry increased its spending on direct marketing to doctors by over 275 percent and doubled its sales force to over 90,000 drug representatives. It is estimated that there is a pharmaceutical sales representative in Vermont for every five office-based physicians in Vermont.

(15) In 2004, the pharmaceutical industry spent \$27 billion marketing pharmaceuticals in the United States, and spent more than any other sector in the United States on its sales force and media advertising. Over 85 percent of these marketing expenditures are directed at the small percentage of the population that practice medicine.

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(16) The physician data restriction program offered by the American Medical Association (AMA) is not an adequate remedy for Vermont doctors, because the program does not prohibit the sharing of data, but merely requires manufacturers to assert assure that they are not using the data. In addition, other health care professionals who prescribe medications are not physicians and may not avail themselves of the AMA program.

(17) In 2005, Vermonters spent an estimated \$524 million on prescription and over-the-counter drugs and medical supplies. In 2000, spending was about \$280 million. The annual increase in spending during this period was 13.3 percent.

Finally, ~~the~~
data mining companies
could use other
identifiers, not
state license
numbers,
to track
prescribing
patterns of
doctors.

(18) Nearly one-third of the five-fold increase in U.S. spending on drugs over the last decade can be attributed to marketing induced shifts in doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments, which often have little or no increased therapeutic value.

(19) Public health is ill served by the massive imbalance in information presented to doctors and other prescribers.

(20) The marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors. The one-sided nature of the marketing leads to doctors prescribing drugs based on imperfect, misleading,

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and biased information, particularly for prescribers that lack the time or initiative to perform substantive research assessing whether the messages they are receiving from pharmaceutical representatives is are full and accurate.

(21) Physicians are unable to take the time to research the quickly changing pharmaceutical market and determine which drugs are the best treatments for particular conditions. Because of this, physicians frequently rely on information provided by pharmaceutical representatives.

(22) Newer drugs on the market do not necessarily provide additional benefits over older drugs, but do add costs and as yet unknown side-effects. One example of this is the drug Vioxx, which was removed from the market due to potentially lethal side-effects that were not adequately disclosed initially.

(23) Fifty percent of all drug withdrawals from the market and “black box warnings” are within the first two years of the release of the drug.

(24) Prescriber-identified data increase the effect of detailing programs. They support the tailoring of presentations to individual prescriber styles, preferences, and attitudes.

(25) The goals of marketing programs are in conflict with the goals of the state. Marketing programs are designed to increase sales, income, and profit. Frequently, progress toward these goals comes at the expense of cost-containment activities and possibly the health of individual patients.

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(26) Several studies suggest that drug samples clearly affect prescribing behavior in favor of the sample. The presence of drug samples may influence physicians to dispense or prescribe drugs that differ from their preferred drug source according to a study by Chew et al. in the Journal of General Internal Medicine in 2000.

(27) According to testimony by Dr. Avorn, M.D., at Brigham and Women's Hospital, detailing effects the cost of medications, because it is generally "confined to high-margin, high-profit drugs, for which the manufacturer has a substantial incentive to increase sales.... Thus, the work of pharmaceutical sales representatives drives drug use toward the most expensive products..., and contributes to the strain on health care budgets for individuals as well as health care programs." *Remove*

Second: In Sec. 14, 18 V.S.A. § 4622(a)(1) by striking subdivision (1) and inserting a new subdivision (1) to read:

(a)(1) The department, in collaboration with the attorney general, the University of Vermont area health education centers program, and the office of Vermont health access, shall establish an evidence-based prescription drug education program for health care professionals designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists, and other health care professionals authorized to prescribe and dispense prescription drugs. To the

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extent practicable, the program shall use the evidence-based standards developed by the blueprint for health. The department may collaborate with other states in establishing this program.

Third: In Sec. 14, 18 V.S.A. § 4622(a)(3), by striking subdivision (3) and inserting a new subdivision (3) to read:

(3) To the extent permitted by funding, the program may include the distribution to prescribers of samples of generic medicines used for health conditions common in Vermont.

Fourth: By striking Sec. 15(a) and inserting a new subsection (a) to read:

(a) As part of the evidence-based education program established in subchapter 2 of chapter 91 of Title 18, the department of health, in collaboration with the office of Vermont health access and the University of Vermont area health education centers program, shall establish a pilot project to distribute vouchers for a sample of generic drugs equivalent to frequently prescribed prescription drugs that are used to treat common health conditions.

Fifth: By inserting a Sec. 15a to read:

Sec. 15a. GENERIC DRUG SAMPLE PILOT; REPORT

By January 15, 2009, the office of Vermont health access, the department of banking, insurance, securities, and health care administration, and the joint fiscal office shall provide a report to the house committee on health care and

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the senate committee on health and welfare comparing the distribution of prescribing among generic drugs and brand name drugs before and after the first year of the generic drug sample pilot project. The comparison will review a year of prescribing data prior to the implementation of the pilot project to a year of prescribing data during the first year of the pilot project's implementation.

Sixth: By striking Sec. 17 and inserting a new Sec. 17 to read:

Sec. 17. 18 V.S.A. chapter 91, subchapter 3 is added to read:

Subchapter 3. Information Requirements

§ 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

(a) It is the intent of the general assembly to advance the state's interest in protecting the public health of Vermonters, protecting the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.

(b) As used in this section:

(1) "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

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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.

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

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

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

(5) "Marketing" shall include advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior of an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

(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) "Promotion" or "promote" means any activity or product the intention of which is to advertise or publicize a prescription drug.

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including a brochure, media advertisement or announcement, poster, brochure, free sample, detailing visit, or personal appearance.

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

(c) The department of health and the office of professional regulation, in consultation with the appropriate licensing boards, shall establish a prescriber data-sharing program to allow a prescriber to give permission for his or her identifying information to be licensed, transferred, used, or sold for the purposes described under subsection (d) of this section. The department and office shall solicit the prescriber’s permission on licensing applications or renewal forms and shall provide a prescriber a method for revoking his or her permission. The department and office may establish rules for this program.

(d) A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity may use regulated records which include prescription information containing patient-identifiable or prescriber-identifiable data for marketing or promoting a prescription drug only if:

(1)(A) a prescriber has provided permission for the use of that data as provided in subsection (c) of this section; and

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(B) the entity using the regulated records complies with the disclosure requirements in subsection (e) of this section; or

(2) the entity meets one of the exceptions provided in subsection (e) of this section.

(e) 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;

(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;

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(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; and

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

Mandatory disclosure

(f) When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs, the marketer shall disclose to the prescriber evidence-based information as provided for by rule describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter, which patients would gain from the health benefits or be susceptible to the risks described, the range of prescription drug treatment options, and the cost of the treatment options. As necessary, the office of Vermont health access, in consultation with the department of health, the area centers on health education, the office of professional regulation, and the office of the

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attorney general, shall develop rules for compliance with this subsection, including the certification of materials which are evidence-based as defined in section 4621 of this title and which conditions have evidence-based treatment guidelines. To the extent practicable, the rules shall use the evidence-based standards developed by the blueprint for health.

(g) 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.

Seventh: By inserting a Sec. 24b to read:

Sec. 24b. EFFECTIVE DATES

Sec. 17 of this act shall become effective no later than January 1, 2008, except that the department of health and the office of professional regulation may begin any necessary rulemaking, revision of forms, or other administrative actions necessary to implement the program, immediately upon passage. The department may implement Sec. 17 for prescribers with licenses

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at the time of passage of this act when the prescriber next requests a renewal of
the license.

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*Sec. 11 OMTA
SK ~~new~~ finding*

S.115 - Prescription Drug Data Confidentiality

Representative Chen of Mendon, on behalf of the Committee on Health Care,
moves to amend the bill as amended by the Committees on Health Care and on
Appropriations as follows:

First: By renumbering Sec. 1 to be Sec. 1a and inserting a new Sec. 1 to
read:

Sec. 1. LEGISLATIVE FINDINGS

The general assembly makes the following findings:

(1) Vermont has been a leader in prescription drug cost-containment and in providing transparency, to the extent allowable, in drug prices. The state has enacted the pharmacy best practices and cost control program, mandatory generic substitution, and mail order purchasing in Medicaid, VPharm, and Vermont Rx and encouraged the department of human resources to have a preferred drug list in the state employees health benefit plans in efforts to control costs, while maintaining best practices in drug prescribing, in our publicly-financed prescription drug programs. The Vermont Medicaid program has been a member of multi-state purchasing pools for several years and aggressively seeks supplemental rebates to lower drug costs in Medicaid program.

(2) In addition, Vermont has sought to control drug prices in private and employer-sponsored insurance by encouraging voluntary participation in

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Medicaid's preferred drug list, requiring mandatory generic substitution for all prescriptions in Vermont, providing consumers with pricing information about the drugs they are prescribed, and assisting consumers by providing information about purchasing drugs internationally through a safe, regulated program run through the state of Illinois.

(3) Vermont has also sought transparency by requiring marketers of prescription drugs to disclose information about the amount of money spent on marketing activities in Vermont and also to require the disclosure of pricing information to doctors during marketing visits.

US - pg 44 court -
judged not
proven. Get
strong evd. in
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(4) This act is necessary to protect prescriber privacy, to save money for the state, consumers, and businesses, and to protect public health.

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to ↑ costs

(5) Most doctors in Vermont who write prescriptions for their patients have a reasonable expectation that the information in that prescription, including their own identity and that of the patient, will not be used for purposes other than the filling and processing of the payment for that prescription. Doctors and patients do not consent to the trade of that information to third parties, and no such trade should take place without their consent.

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Estimates of total costs of marketing to prescribers in Vermont are \$10 million or more, excluding free samples and direct-to-consumer advertising.

(7) Some doctors in Vermont are experiencing an undesired increase in the aggressiveness of pharmaceutical sales representatives and have reported this to be coercive and harassing.

(8) Prescriber-identifiable prescription data show details of physicians' drug use patterns, both in terms of their gross number of prescriptions and their inclinations to prescribe particular drugs.

(9) Prescriber identified databases of prescribing habits encourage pharmaceutical companies to increase the quid pro quo nature of relations between pharmaceutical sales representatives and prescribers. Pharmaceutical companies use prescriber identity data-mining to target increased attention and harassing and coercive practices toward those doctors that they find are most profitable, including high prescribers, brand loyal prescribers, doctors that show themselves willing to prescribe new medicines, and doctors that are proven to be especially susceptible to sales messages.

(10) Monitoring of prescribing practices also allows the sales representatives to assess the impact of various gifts and messages on a particular physician to help them select the most effective set of rewards.

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(12) As with the ^{use} ~~trading~~ of consumer phone numbers ^{for marketing ... fed} ~~linked to spending~~ ^{20-not-call}
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^{pattern data} the trading of prescriber identities linked to prescription data
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^{MS data mining 10 yr - last 5 years #1 d}
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SK

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SK

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and biased information, particularly for prescribers that lack the time or initiative to perform substantive research assessing whether the messages they are receiving from pharmaceutical representatives are full and accurate.

(21) Physicians are unable to take the time to research the quickly changing pharmaceutical market and determine which drugs are the best treatments for particular conditions. Because of this, physicians frequently rely on information provided by pharmaceutical representatives.

(22) Newer drugs on the market do not necessarily provide additional benefits over older drugs, but do add costs and as yet unknown side-effects. One example of this is the drug Vioxx, which was removed from the market due to potentially lethal side-effects that were not adequately disclosed initially.

(23) Fifty percent of all drug withdrawals from the market and "black box warnings" are within the first two years of the release of the drug.

(24) Prescriber-identified data increase the effect of detailing programs.

They support the tailoring of presentations to individual prescriber styles, preferences, and attitudes.

(25) The goals of marketing programs are in conflict with the goals of the state. Marketing programs are designed to increase sales, income, and profit. Frequently, progress toward these goals comes at the expense of cost-containment activities and possibly the health of individual patients.

EM - black box patient safety =

HO. why is this important? why effects PH & costs?

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(26) Several studies suggest that drug samples clearly affect prescribing behavior in favor of the sample. The presence of drug samples may influence physicians to dispense or prescribe drugs that differ from their preferred drug source according to a study by Chew et al. in the Journal of General Internal Medicine in 2000.

(27) According to testimony by Dr. Avorn, M.D., at Brigham and Women's Hospital, detailing effects the cost of medications, because it is generally "confined to high-margin, high-profit drugs, for which the manufacturer has a substantial incentive to increase sales....Thus, the work of pharmaceutical sales representatives drives drug use toward the most expensive products.... and contributes to the strain on health care budgets for individuals as well as health care programs."

IMS
Key witness in
NH

Second: In Sec. 14, 18 V.S.A. § 4622(a)(1) by striking subdivision (1) and inserting a new subdivision (1) to read:

(a)(1) The department, in collaboration with the attorney general, the University of Vermont area health education centers program, and the office of Vermont health access, shall establish an evidence-based prescription drug education program for health care professionals designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists, and other health care professionals authorized to prescribe and dispense prescription drugs. To the

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extent practicable, the program shall use the evidence-based standards developed by the blueprint for health. The department may collaborate with other states in establishing this program.

Third: In Sec. 14, 18 V.S.A. § 4622(a)(3), by striking subdivision (3) and inserting a new subdivision (3) to read:

(3) To the extent permitted by funding, the program may include the distribution to prescribers of samples of generic medicines used for health conditions common in Vermont.

Fourth: By striking Sec. 15(a) and inserting a new subsection (a) to read:

(a) As part of the evidence-based education program established in subchapter 2 of chapter 91 of Title 18, the department of health, in collaboration with the office of Vermont health access and the University of Vermont area health education centers program, shall establish a pilot project to distribute vouchers for a sample of generic drugs equivalent to frequently prescribed prescription drugs that are used to treat common health conditions.

Fifth: By inserting a Sec. 15a to read:

Sec. 15a. GENERIC DRUG SAMPLE PILOT; REPORT

By January 15, 2009, the office of Vermont health access, the department of banking, insurance, securities, and health care administration, and the joint fiscal office shall provide a report to the house committee on health care and

** description of program (counterdet. & samples)*

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the senate committee on health and welfare comparing the distribution of
prescribing among generic drugs and brand name drugs before and after the
first year of the generic drug sample pilot project. *The report shall compare*
The comparison will review
a year of prescribing data prior to the implementation of the pilot project to a
year of prescribing data during the first year of the pilot project's
implementation. *target to reflect what pilot did*

Sixth: By striking Sec. 17 and inserting a new Sec. 17 to read:

Sec. 17. 18 V.S.A. chapter 91, subchapter 3 is added to read:

Subchapter 3. Information Requirements

§ 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

(a) It is the intent of the general assembly to advance the state's
interest in protecting the public health of Vermonters, protecting the
privacy of prescribers and prescribing information, and to ensure costs
are contained in the private health care sector, as well as for state
purchasers of prescription drugs, through the promotion of less costly
drugs and ensuring prescribers receive unbiased information.

OPR guy
- correct

(b) As used in this section:

(1) "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

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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.

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

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

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

(5) "Marketing" shall include advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior of an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

(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) "Promotion" or "promote" means any activity or product the intention of which is to advertise or publicize a prescription drug,

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email?

including a brochure, media advertisement or announcement, poster, brochure, free sample, detailing visit, or personal appearance.

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

(c) The department of health and the office of professional regulation, in consultation with the appropriate licensing boards, shall establish a prescriber data-sharing program to allow a prescriber to give permission for his or her identifying information to be licensed, transferred, used, or sold for the purposes described under subsection (d) of this section. The department and office shall solicit the prescriber's affirmative permission on licensing applications or renewal forms and shall provide a prescriber a method for revoking his or her permission. The department and office may establish rules for this program. *Add sent. re: list.*

affirmative consent - check other opt in JB.

Steve H: doc's patient → doc's envision it will be used & that the permission is for transf.

JB: Data-mining cos. pharm. cos.

(d) A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity may use regulated records which include prescription information containing patient-identifiable or prescriber-identifiable data for marketing or promoting a prescription drug only if:

(1)(A) a prescriber has provided permission for the use of that data as provided in subsection (c) of this section; and

*Chris Winters
does OPR
will list?
entities
must obtain
the list for
bds.*

*B: easy for
cc of state -
range forms;
create a list
those who
ed box...
id: data mining
must review list
periodically - used in do-not-call
registry → every 31 days (fed); Drs 1x/2 years*


[bmo?]

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 (B) the entity using the regulated records complies with the disclosure requirements in subsection ~~(e)~~^f of this section; or

(2) the entity meets one of the exceptions provided in subsection (e) of this section.

(e) 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;

(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;

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(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; and

(7) the collection, use, transfer, or sale of patient and prescriber data for marketing or promoting 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.

mandatory disclosure -

(f) When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs, the marketer shall disclose the prescriber evidence-based information as provided for by rule describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter, which patients would gain from the health benefits or be susceptible to the risks described, the range of prescription drug treatment options, and the cost of the treatment options. As necessary, the office of Vermont health access, in consultation with the department of health, the area centers on health education, the office of professional regulation, and the office of the

Pharma -
confirm w/
FDA require-
ments.
add CROSS-
ref: FDA??

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attorney general, shall develop rules for compliance with this subsection, including the certification of materials which are evidence-based as defined in section 4621 of this title and which conditions have evidence-based treatment guidelines. To the extent practicable, the rules shall use the evidence-based standards developed by the blueprint for health.

(g) 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.

Seventh: By inserting a Sec. 24b to read:

Sec. 24b. EFFECTIVE DATES

Sec. 17 of this act shall become effective no later than January 1, 2008, except that the department of health and the office of professional regulation may begin any necessary rulemaking, revision of forms, or other administrative actions necessary to implement the program, immediately upon passage. The department may implement Sec. 17 for prescribers with licenses

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at the time of passage of this act when the prescriber next requests a renewal of
the license.

TAB H

HHC

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S.115 - Prescription Drug Data Confidentiality

Representative Chen of Mendon, on behalf of the Committee on Health Care,
moves to ^{further} amend the bill as amended by the Committees on Health Care and on
Appropriations as follows:

First: By renumbering Sec. 1 to be Sec. 1a and inserting a new Sec. 1 to
read:

Sec. 1. LEGISLATIVE FINDINGS

The general assembly makes the following findings:

(1) The state of Vermont has an interest in maximizing the well-being of its residents and in containing health care costs.

(2) There is a strong link between pharmaceutical marketing activities, health care spending, and the health of Vermonters.

(3) The goals of marketing programs are often in conflict with the goals of the state. Marketing programs are designed to increase sales, income, and profit. Frequently, progress toward these goals comes at the expense of cost-containment activities and possibly the health of individual patients.

(4) The marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors. The one-sided nature of the marketing leads to doctors prescribing drugs based on ~~imperfect, misleading,~~ incomplete and biased information, particularly for prescribers that lack the time to

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perform substantive research assessing whether the messages they are receiving from pharmaceutical representatives are full and accurate.

(5) The federal Food and Drug Administration (FDA) requires marketing and advertising to be fair and balanced, however, the FDA has limited enforcement of this requirement.

(6) Public health is ill served by the massive imbalance in information presented to doctors and other prescribers.

(7) Newer drugs on the market do not necessarily provide additional benefits over older drugs, but do add costs and as yet unknown side-effects. One example of this is the drug Vioxx, which was removed from the market due to potentially lethal side-effects that were not adequately disclosed initially.

(8) Fifty percent of all drug withdrawals from the market and “black box warnings” are within the first two years of the release of the drug. One in five of all drugs are subject to “black box warnings” or withdrawal from the market for safety reasons. Marketing which results in prescribers using the newest drugs will also result prescribing drugs that are more likely to be subject to these warnings and withdrawal.

(9) In 2005, Vermonters spent an estimated \$524 million on prescription and over-the-counter drugs and medical supplies. In 2000, spending was about

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\$280 million. The annual increase in spending during this period was 13.3 percent.

(10) Vermont has been a leader in prescription drug cost-containment and in providing transparency, to the extent allowable, in drug prices. The state has enacted the pharmacy best practices and cost control program, mandatory generic substitution, and mail order purchasing in Medicaid, VPharm, and Vermont Rx and encouraged the department of human resources to have a preferred drug list in the state employees health benefit plans in efforts to control costs, while maintaining best practices in drug prescribing, in our publicly-financed prescription drug programs. The Vermont Medicaid program has been a member of multi-state purchasing pools for several years and aggressively seeks supplemental rebates to lower drug costs in Medicaid program.

(11) In addition, Vermont has sought to control drug prices in private and employer-sponsored insurance by encouraging voluntary participation in Medicaid's preferred drug list, requiring mandatory generic substitution for all prescriptions in Vermont, providing consumers with pricing information about the drugs they are prescribed, and assisting consumers by providing information about purchasing drugs internationally through a safe, regulated program run through the state of Illinois.

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(12) Vermont has also sought transparency by requiring marketers of prescription drugs to disclose information about the amount of money spent on marketing activities in Vermont and also to require the disclosure of pricing information to doctors during marketing visits.

(13) Physicians are unable to take the time to research the quickly changing pharmaceutical market and determine which drugs are the best treatments for particular conditions. Because of this, physicians frequently rely on information provided by pharmaceutical representatives.

(14) Nearly one-third of the five-fold increase in U.S. spending on drugs over the last decade can be attributed to marketing induced shifts in doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments, which often have little or no increased therapeutic value.

(15) According to testimony by Dr. Avorn, M.D., at Brigham and Women's Hospital, detailing effects the cost of medications, because it is generally "confined to high-margin, high-profit drugs, for which the manufacturer has a substantial incentive to increase sales....Thus, the work of pharmaceutical sales representatives drives drug use toward the most expensive products...., and contributes to the strain on health care budgets for individuals as well as health care programs."

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(16) According to the June 15, 2006 Marketing Disclosures: Report of Vermont Attorney General William H. Sorrell, as part of their marketing efforts, pharmaceutical companies made direct payments of almost \$2.2 million to prescribers in Vermont, including consulting fees and travel expenses in 2005. Estimates of total costs of marketing to prescribers in Vermont are \$10 million or more, excluding free samples and direct-to-consumer advertising.

(17) In 2004, the pharmaceutical industry spent \$27 billion marketing pharmaceuticals in the United States, and spent more than any other sector in the United States on its sales force and media advertising. Over 85 percent of these marketing expenditures are directed at the small percentage of the population that practice medicine. **Pharmaceutical manufacturers spend twice as much on marketing as on research and development.**

(18) Coincident with the rise of physician identity data mining, the pharmaceutical industry increased its spending on direct marketing to doctors by over 275 percent and doubled its sales force to over 90,000 drug representatives. It is estimated that there is a pharmaceutical sales representative ~~in Vermont~~ for every five office-based physicians ~~in Vermont~~.

(19) A ^{significant} substantial portion of prescriber time is spent meeting with pharmaceutical representatives. According to a survey recently published in the New England Journal of Medicine, family practitioners reported

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the highest frequency of meetings with representatives - an average of 16 times per month. To the extent that this meeting time comes at the expense of time spent with patients, quality of care will be negatively affected.

(20) Some doctors in Vermont are experiencing an undesired increase in the aggressiveness of pharmaceutical sales representatives and have reported this to be coercive and harassing and also leads to increased costs. *reworded*

(21) Several studies suggest that drug samples clearly affect prescribing behavior in favor of the sample. The presence of drug samples may influence physicians to dispense or prescribe drugs that differ from their preferred drug source according to a study by Chew et al. in the Journal of General Internal Medicine in 2000.

(22) Prescriber-identifiable prescription data show details of physicians' drug use patterns, both in terms of their gross number of prescriptions and their inclinations to prescribe particular drugs.

(23) Prescriber identity data mining allows pharmaceutical companies to track the prescribing habits of nearly every physician in Vermont and link those habits to specific physicians and their identities.

(24) Monitoring of prescribing practices also allows the sales representatives to assess the impact of various gifts and messages on a particular physician to help them select the most effective set of rewards.

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(25) Prescriber-identified data increase the effect of detailing programs.
They support the tailoring of presentations to individual prescriber styles,
preferences, and attitudes.

(26) Prescriber identified databases of prescribing habits encourage
pharmaceutical companies to increase the quid pro quo nature of relations
between pharmaceutical sales representatives and prescribers. Pharmaceutical
companies use prescriber identity data-mining to target increased attention and
harassing and coercive practices toward those doctors that they find **are most**
profitable would lead to increased prescriptions and profitability,
including high prescribers, brand loyal prescribers, doctors that show
themselves willing to prescribe new medicines, and doctors **that are proven**
who are shown to be especially susceptible to sales messages.

(27) Added coercion and harassment occurs when doctors are informed
by sales representatives that they are being monitored – through messages of
appreciation for writing prescriptions, or messages of disappointment that they
are not prescribing what was implicitly promised.

(28) As with the **trading use** of consumer phone numbers **linked to**
spending pattern data for marketing, the trading of prescriber identities
linked to prescription data **encourages results in** harassing **and unethical**
sales behaviors by pharmaceutical sales representatives toward doctors.

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(29) ~~Most doctors~~ Health care professionals in Vermont who write prescriptions for their patients have a reasonable expectation that the information in that prescription, including their own identity and that of the patient, will not be used for purposes other than the filling and processing of the payment for that prescription. Doctors and patients do not consent to the trade of that information to third parties, and no such trade should take place without their consent.

(30) The physician data restriction program offered by the American Medical Association (AMA) is not an adequate remedy for Vermont doctors, because the program does not prohibit the sharing of data, but merely requires manufacturers to assure that they are not using the data. In addition, other health care professionals who prescribe medications are not physicians and may not avail themselves of the AMA program and only 23% of Vermont physicians belong to the AMA, which is the lowest rate in the nation. Finally, data mining companies could use other identifiers, including state licensing numbers, to track prescribing patterns.

(31) This act is necessary to protect prescriber privacy by limiting marketing to doctors who would like that type of information, to avoid harassment of prescribers which leads to increase costs, to save money for the state, consumers, and businesses, and to protect public health by requiring evidence-based disclosures.

brands well known
less well known
[w/ a shorter safety record]

more exp that may have
HTS consequences

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TAB I

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S.115 - Prescription Drug Data Confidentiality

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(2.1)

2.2

substantive research assessing whether the messages they are receiving from pharmaceutical representatives are full and accurate.

proof pls [(5) The federal Food and Drug Administration (FDA) requires marketing and advertising to be fair and balanced, however, the FDA has limited legal ability to enforce of this requirement.

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(7) Newer drugs on the market do not necessarily provide additional benefits over older drugs, but do add costs and as yet unknown side-effects. One example of this is the drug Vioxx, which was removed from the market due to potentially lethal side-effects that were not adequately disclosed initially.

(8) Between 1975 and 2000, fifty percent of all drug withdrawals from the market and “black box warnings” were within the first two years of the release of the drug. One-fifth of all drugs are subject to “black box warnings” or withdrawal from the market because of the serious public health concerns. Marketing which results in prescribers using the newest drugs will also result prescribing drugs that are more likely to be subject to these warnings and withdrawal.

(9) In 2005, Vermonters spent an estimated \$524 million on prescription and over-the-counter drugs and nondurable medical supplies. In 2000,

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spending was about \$280 million. The annual increase in spending during this period was 13.3 percent, which was the highest increase in any health care category.

(10) Vermont has been a leader in prescription drug cost-containment and in providing transparency, to the extent allowable, in drug prices. The state has enacted the pharmacy best practices and cost control program, mandatory generic substitution, and mail order purchasing in Medicaid, VPharm, and Vermont Rx and encouraged the department of human resources to have a preferred drug list in the state employees health benefit plans in efforts to control costs, while maintaining best practices in drug prescribing, in our publicly-financed prescription drug programs. The Vermont Medicaid program has been a member of multi-state purchasing pools for several years and aggressively seeks supplemental rebates to lower drug costs in Medicaid program.

(11) In addition, Vermont has sought to control drug prices in private and employer-sponsored insurance by encouraging voluntary participation in Medicaid's preferred drug list, requiring mandatory generic substitution for all prescriptions in Vermont, providing consumers with pricing information about the drugs they are prescribed, and assisting consumers by providing information about purchasing drugs internationally through a safe, regulated program run through the state of Illinois.

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(12) Vermont has also sought transparency by requiring marketers of prescription drugs to disclose information about the amount of money spent on marketing activities in Vermont and also to require the disclosure of pricing information to doctors during marketing visits.

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(14) Nearly one-third of the five-fold increase in U.S. spending on drugs over the last decade can be attributed to marketing induced shifts in doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments, which often have little or no increased therapeutic value. According to the same study, the use of more expensive drugs contributed to 36 percent of the rise in retail prescription spending in 2000 and 24 percent in 2001.

(15) According to testimony by Dr. Avorn, M.D., at Brigham and Women's Hospital, detailing effects the cost of medications, because it is generally "confined to high-margin, high-profit drugs, for which the manufacturer has a substantial incentive to increase sales.... Thus, the work of pharmaceutical sales representatives drives drug use toward the most

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(18) Coincident with the rise of physician identity data mining, the pharmaceutical industry increased its spending on direct marketing to doctors by over 275 percent and doubled its sales force to over 90,000 drug representatives. It is estimated that there is a pharmaceutical sales representative for every five office-based physicians.

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(19) A significant portion of prescriber time is spent meeting with pharmaceutical representatives. According to a survey recently published in the New England Journal of Medicine, family practitioners reported the highest frequency of meetings with representatives - an average of 16 times per month. To the extent that this meeting time comes at the expense of time spent with patients, quality of care will be negatively affected.

(20) Some doctors in Vermont are experiencing an undesired increase in the aggressiveness of pharmaceutical sales representatives and a few have reported that they felt coerced and harassed. The Vermont Medical Society, an organization representing two-thirds of Vermont doctors, unanimously passed a resolution stating 'the use of physician prescription information by sales representatives is an intrusion into the way physicians practice medicine.'

(21) Several studies suggest that drug samples clearly affect prescribing behavior in favor of the sample. The presence of drug samples may influence physicians to dispense or prescribe drugs that differ from their preferred drug source according to a study by Chew et al. in the Journal of General Internal Medicine in 2000.

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(26) Prescriber identified databases of prescribing habits encourage pharmaceutical companies to increase the quid pro quo nature of relations between pharmaceutical sales representatives and prescribers. Pharmaceutical companies use prescriber identity data-mining to target increased attention and manipulative practices toward those doctors that they find **would lead to increased prescriptions and profitability**, including high prescribers, brand loyal prescribers, doctors that show themselves willing to prescribe new medicines, and doctors **who are shown** to be especially susceptible to sales messages.

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(27) Added and unwanted pressure occurs when doctors are informed by sales representatives that they are being monitored – through messages of appreciation for writing prescriptions, or messages of disappointment that they are not prescribing what was implicitly promised.

(28) As with the use of consumer phone numbers for marketing, the trading of prescriber identities linked to prescription data can result in harassing sales behaviors by pharmaceutical sales representatives toward doctors.

(29) Health care professionals in Vermont who write prescriptions for their patients have a reasonable expectation that the information in that prescription, including their own identity and that of the patient, will not be used for purposes other than the filling and processing of the payment for that prescription. Prescribers and patients do not consent to the trade of that information to third parties, and no such trade should take place without their consent.

✓
(30) The physician data restriction program offered by the American Medical Association (AMA) is not an adequate remedy for Vermont doctors, because many physicians do not know about the program and other health care professionals who prescribe medications may not avail themselves of the AMA program. In addition, approximately 23% of Vermont physicians belong to the AMA, which one of the lowest rates in the nation. Finally,

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data mining companies could use other identifiers, including state
licensing numbers, to track prescribing patterns.

(31) This act is necessary to protect prescriber privacy by limiting
marketing to prescribers who choose to receive that type of information,
to save money for the state, consumers, and businesses by promoting the use
of less expensive drugs, and to protect public health by requiring evidence-
based disclosures and promote ^{ing} older drugs with ^{records} a longer safety record.

Second: By striking Sec. 11 and inserting a new Sec. 11 to read:

Sec. 11. 8 V.S.A. § 4088d. is added to read:

§ 4088d. NOTICE OF PREFERRED DRUG LIST CHANGES

On a periodic basis, no less than once per calendar year, a health
insurer as defined in subdivisions 9471(2)(A), (C), (D) of Title 18 shall
notify beneficiaries of changes in pharmaceutical coverage and provide
access to the preferred drug list maintained by the insurer.

Third: In Sec. 14, 18 V.S.A. § 4622(a)(1) by striking subdivision (1) and
inserting a new subdivision (1) to read:

(a)(1) The department, in collaboration with the attorney general, the
University of Vermont area health education centers program, and the office of
Vermont health access, shall establish an evidence-based prescription drug
education program for health care professionals designed to provide
information and education on the therapeutic and cost-effective utilization of

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prescription drugs to physicians, pharmacists, and other health care professionals authorized to prescribe and dispense prescription drugs. To the extent practicable, the program shall use the evidence-based standards developed by the blueprint for health. The department may collaborate with other states in establishing this program.

Fourth: In Sec. 14, 18 V.S.A. § 4622(a)(3), by striking subdivision (3) and inserting a new subdivision (3) to read:

(3) To the extent permitted by funding, the program may include the distribution to prescribers of vouchers for samples of generic medicines used for health conditions common in Vermont.

Fifth: By striking Sec. 15(a) and inserting a new subsection (a) to read:

Sec. 15. GENERIC DRUG **VOUCHER** PILOT PROJECT

(a) As part of the evidence-based education program established in subchapter 2 of chapter 91 of Title 18, the department of health, in collaboration with the office of Vermont health access and the University of Vermont area health education centers program, shall establish a pilot project to distribute vouchers for a sample of generic drugs equivalent to frequently prescribed prescription drugs that are used to treat common health conditions.

Sixth: By inserting a Sec. 15a to read:

Sec. 15a. GENERIC DRUG **VOUCHER** PILOT; REPORT

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(a) By January 15, 2009, the office of Vermont health access, the department of banking, insurance, securities, and health care administration, the area health education centers, and the joint fiscal office shall provide a report to the house committee on health care and the senate committee on health and welfare describing and evaluating the effects of the generic drug voucher pilot program.

(b) The report shall describe how the pilot project is implemented, including which health conditions were targeted, the generic drugs provided with the vouchers, and the geographic regions participating. The report shall compare the distribution of prescribing among generic drugs provided through the vouchers and brand name drugs before and after the first year of the generic drug sample pilot project and will review a year of prescribing data prior to the implementation of the pilot project to a year of prescribing data during the first year of the pilot project's implementation. The data shall be adjusted to reflect ^{where} how the pilot was implemented.

Seventh: By striking Sec. 17 and inserting a new Sec. 17 to read:

Sec. 17. 18 V.S.A. chapter 91, subchapter 3 is added to read:

Subchapter 3. Information Requirements

§ 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

(a) It is the intent of the general assembly to advance the state's interest in protecting the public health of Vermonters, protecting the privacy of

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prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.

(b) As used in this section:

(1) “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.

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

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

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

(5) “Marketing” shall include advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior of an

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individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

(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) “Promotion” or “promote” means any activity or product the intention of which is to advertise or publicize a prescription drug, including a brochure, media advertisement or announcement, poster, free sample, detailing visit, or personal appearance.

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

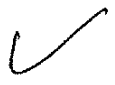
(c)(1) The department of health and the office of professional regulation, in consultation with the appropriate licensing boards, shall establish a prescriber data-sharing program to allow a prescriber to give **consent** for his or her identifying information to be **used** for the purposes described under subsection (d) of this section. The department and office shall solicit the prescriber’s **consent** on licensing applications or renewal forms and shall provide a

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prescriber a method for revoking his or her consent. The department and office may establish rules for this program.

(2) The department or office shall make available the list of prescribers who have consented to sharing ^{their} his or her information. Entities who wish to use the information as provided for in this section shall review the list at minimum every six months.



(d) A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity may use regulated records which include prescription information containing prescriber-identifiable data for marketing or promoting a prescription drug only if:

(1)(A) a prescriber has provided consent for the use of that data as provided in subsection (c) of this section; and

(B) the entity using the regulated records complies with the disclosure requirements in subsection (f) of this section; or

(2) the entity meets one of the exceptions provided in subsection (e) of this section.

(e) 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

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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;

(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; and

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

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(f) When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs as provided for under this section, the marketer shall disclose to the prescriber evidence-based information as provided for by rule describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options. As necessary, the office of Vermont health access, in consultation with the department of health, the area centers on health education, the office of professional regulation, and the office of the attorney general, shall develop rules for compliance with this subsection, including the certification of materials which are evidence-based as defined in section 4621 of this title and which conditions have evidence-based treatment guidelines. **The rules shall be consistent with the federal Food and Drug Administration's regulations regarding false and misleading advertising.** To the extent practicable, the rules shall use the evidence-based standards developed by the blueprint for health.

(g) 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

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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.

Eighth: By inserting a Sec. 24b to read:

Sec. 24b. EFFECTIVE DATES

Sec. 17 of this act shall become effective no later than January 1, 2008, except that the department of health and the office of professional regulation may begin any necessary rulemaking, revision of forms, or other administrative actions necessary to implement the program, immediately upon passage. The department and office may implement Sec. 17 for prescribers with licenses at the time of passage of this act when the prescriber next requests a renewal of the license.

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S.115 - Prescription Drug Data Confidentiality

Representative Chen of Mendon, on behalf of the Committee on Health Care,
moves to amend the bill as amended by the Committees on Health Care and on
Appropriations as follows:

First: By renumbering Sec. 1 to be Sec. 1a and inserting a new Sec. 1 to
read:

Sec. 1. LEGISLATIVE FINDINGS

The general assembly makes the following findings:

(1) The state of Vermont has an interest in maximizing the well-
being of its residents and in containing health care costs.

(2) There is a strong link between pharmaceutical marketing
activities, health care spending, and the health of Vermonters.

(3) The goals of marketing programs are often in conflict with the goals
of the state. Marketing programs are designed to increase sales, income, and
profit. Frequently, progress toward these goals comes at the expense of
cost-containment activities and possibly the health of individual patients.

(4) The marketplace for ideas on medicine safety and effectiveness is
frequently one-sided in that brand-name companies invest in expensive
pharmaceutical marketing campaigns to doctors. The one-sided nature of the
marketing leads to doctors prescribing drugs based on incomplete and biased
information, particularly for prescribers that lack the time to perform

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substantive research assessing whether the messages they are receiving from pharmaceutical representatives are full and accurate.

(5) The federal Food and Drug Administration (FDA) requires marketing and advertising to be fair and balanced, however, the FDA has limited legal ability to enforce ~~of~~ this requirement.

(6) Public health is ill served by the massive imbalance in information presented to doctors and other prescribers.

(7) Newer drugs on the market do not necessarily provide additional benefits over older drugs, but do add costs and as yet unknown side-effects. One example of this is the drug Vioxx, which was removed from the market due to potentially lethal side-effects that were not adequately disclosed initially.

(8) Between 1975 and 2000, ⁵⁰~~five~~ percent of all drug withdrawals from the market and "black box warnings" were within the first two years of the release of the drug. One-fifth of all drugs are subject to "black box warnings" or withdrawal from the market because of the serious public health concerns. Marketing which results in prescribers using the newest drugs will also result ⁱⁿ prescribing drugs that are more likely to be subject to these warnings and withdrawal.

(9) In 2005, Vermonters spent an estimated \$524 million on prescription and over-the-counter drugs and nondurable medical supplies. In 2000,

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spending was about \$280 million. The annual increase in spending during this period was 13.3 percent, which was the highest increase in any health care category.

(10) Vermont has been a leader in prescription drug cost-containment and in providing transparency, to the extent allowable, in drug prices. The state has enacted the pharmacy best practices and cost control program, mandatory generic substitution, and mail order purchasing in Medicaid, VPharm, and Vermont Rx and encouraged the department of human resources to have a preferred drug list in the state employees health benefit plans in efforts to control costs, while maintaining best practices in drug prescribing, in our publicly-financed prescription drug programs. The Vermont Medicaid program has been a member of multi-state purchasing pools for several years and aggressively seeks supplemental rebates to lower drug costs in Medicaid program.

(11) In addition, Vermont has sought to control drug prices in private and employer-sponsored insurance by encouraging voluntary participation in Medicaid's preferred drug list, requiring mandatory generic substitution for all prescriptions in Vermont, providing consumers with pricing information about the drugs they are prescribed, and assisting consumers by providing information about purchasing drugs internationally through a safe, regulated program run through the state of Illinois.

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(12) Vermont has also sought transparency by requiring marketers of prescription drugs to disclose information about the amount of money spent on marketing activities in Vermont and also to require the disclosure of pricing information to doctors during marketing visits.

(13) Physicians are unable to take the time to research the quickly changing pharmaceutical market and determine which drugs are the best treatments for particular conditions. Because of this, physicians frequently rely on information provided by pharmaceutical representatives.

(14) Nearly one-third of the five-fold increase in U.S. spending on drugs over the last decade can be attributed to marketing induced shifts in doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments, which often have little or no increased therapeutic value. According to the same study, the use of more expensive drugs contributed to 36 percent of the rise in retail prescription spending in 2000 and 24 percent in 2001.

(15) According to testimony by Dr. Avorn, M.D., at Brigham and Women's Hospital, detailing effects the cost of medications, because it is generally "confined to high-margin, high-profit drugs, for which the manufacturer has a substantial incentive to increase sales....Thus, the work of pharmaceutical sales representatives drives drug use toward the most

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expensive products..., and contributes to the strain on health care budgets for individuals as well as health care programs.”

(16) According to the June 15, 2006 Marketing Disclosures: Report of Vermont Attorney General William H. Sorrell, as part of their marketing efforts, pharmaceutical companies made direct payments of almost \$2.2 million to prescribers in Vermont, including consulting fees and travel expenses in 2005. Estimates of total costs of marketing to prescribers in Vermont are \$10 million or more, excluding free samples and direct-to-consumer advertising.

(17) In 2004, the pharmaceutical industry spent \$27 billion marketing pharmaceuticals in the United States, and spent more than any other sector in the United States on its sales force and media advertising. Over 85 percent of these marketing expenditures are directed at the small percentage of the population that practice medicine. **Pharmaceutical manufacturers spend twice as much on marketing as on research and development.**

(18) Coincident with the rise of physician identity data mining, the pharmaceutical industry increased its spending on direct marketing to doctors by over 275 percent and doubled its sales force to over 90,000 drug representatives. It is estimated that there is a pharmaceutical sales representative for every five office-based physicians.

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(19) A significant portion of prescriber time is spent meeting with pharmaceutical representatives. According to a survey recently published in the New England Journal of Medicine, family practitioners reported the highest frequency of meetings with representatives [—] an average of 16 times per month. To the extent that this meeting time comes at the expense of time spent with patients, quality of care will be negatively affected.

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(20) Some doctors in Vermont are experiencing an undesired increase in the aggressiveness of pharmaceutical sales representatives and a few have reported that they felt coerced and harassed. The Vermont Medical Society, an organization representing two-thirds of Vermont doctors, ^{<<} unanimously passed a resolution stating [^] the use of physician prescription information by sales representatives is an intrusion into the way physicians practice medicine."

(21) Several studies suggest that drug samples clearly affect prescribing behavior in favor of the sample. The presence of drug samples may influence physicians to dispense or prescribe drugs that differ from their preferred drug source according to a study by Chew et al. in the Journal of General Internal Medicine in 2000.

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(22) Prescriber-identifiable prescription data show details of physicians' drug use patterns, both in terms of their gross number of prescriptions and their inclinations to prescribe particular drugs.

(23) Prescriber identity data mining allows pharmaceutical companies to track the prescribing habits of nearly every physician in Vermont and link those habits to specific physicians and their identities.

(24) Monitoring of prescribing practices also allows the sales representatives to assess the impact of various gifts and messages on a particular physician to help them select the most effective set of rewards.

(25) Prescriber-identified data increase the effect of detailing programs. They support the tailoring of presentations to individual prescriber styles, preferences, and attitudes.

(26) Prescriber identified databases of prescribing habits encourage pharmaceutical companies to increase the quid pro quo nature of relations between pharmaceutical sales representatives and prescribers. Pharmaceutical companies use prescriber identity data-mining to target increased attention and manipulative practices toward those doctors that they find would lead to increased prescriptions and profitability, including high prescribers, brand loyal prescribers, doctors that show themselves willing to prescribe new medicines, and doctors who are shown to be especially susceptible to sales messages.

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(27) Added and unwanted pressure occurs when doctors are informed by sales representatives that they are being monitored – through messages of appreciation for writing prescriptions, or messages of disappointment that they are not prescribing what was implicitly promised.

(28) As with the use of consumer^{telen} phone numbers for marketing, the trading of prescriber identities linked to prescription data can result in harassing sales behaviors by pharmaceutical sales representatives toward doctors.

(29) Health care professionals in Vermont who write prescriptions for their patients have a reasonable expectation that the information in that prescription, including their own identity and that of the patient, will not be used for purposes other than the filling and processing of the payment for that prescription. Prescribers and patients do not consent to the trade of that information to third parties, and no such trade should take place without their consent.

(30) The physician data restriction program offered by the American Medical Association (AMA) is not an adequate remedy for Vermont doctors, because many physicians do not know about the program and other health care professionals who prescribe medications may not avail themselves of the AMA program. In addition, approximately 23^{percent}% of Vermont physicians belong to the AMA, which^{is} one of the lowest rates in the nation. Finally,

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data mining companies could use other identifiers, including state
licensing numbers, to track prescribing patterns.

(31) This act is necessary to protect prescriber privacy by limiting
marketing to prescribers who choose to receive that type of information,
to save money for the state, consumers, and businesses by promoting the use
of less expensive drugs, and to protect public health by requiring evidence-
based disclosures and promoting drugs with longer safety records.

Second: By striking Sec. 11 and inserting a new Sec. 11 to read:
Sec. 11. 8 V.S.A. § 4088d 9 is added to read:

§ 4088d. NOTICE OF PREFERRED DRUG LIST CHANGES

On a periodic basis, no less than once per calendar year, a health
insurer as defined in subdivisions 9471(2)(A), (C), ^{and} (D) of Title 18 shall
notify beneficiaries of changes in pharmaceutical coverage and provide
access to the preferred drug list maintained by the insurer.

Third: In Sec. 14, 18 V.S.A. § 4622(a)(1) by striking subdivision (1) and
inserting a new subdivision (1) to read:

(a)(1) The department, in collaboration with the attorney general, the
University of Vermont area health education centers program, and the office of
Vermont health access, shall establish an evidence-based prescription drug
education program for health care professionals designed to provide
information and education on the therapeutic and cost-effective utilization of

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prescription drugs to physicians, pharmacists, and other health care professionals authorized to prescribe and dispense prescription drugs. To the extent practicable, the program shall use the evidence-based standards developed by the blueprint for health. The department may collaborate with other states in establishing this program.

Fourth: In Sec. 14, 18 V.S.A. § 4622(a)(3), by striking subdivision (3) and inserting a new subdivision (3) to read:

(3) To the extent permitted by funding, the program may include the distribution to prescribers of **vouchers for** samples of generic medicines used for health conditions common in Vermont.

Fifth: By striking Sec. 15(a) and inserting a new subsection (a) to read:

Sec. 15. GENERIC DRUG VOUCHER PILOT PROJECT

(a) As part of the evidence-based education program established in subchapter 2 of chapter 91 of Title 18, the department of health, in collaboration with the office of Vermont health access and the University of Vermont area health education centers program, shall establish a pilot project to distribute vouchers for a sample of generic drugs equivalent to frequently prescribed prescription drugs that are used to treat common health conditions.

Sixth: By inserting a Sec. 15a to read:

Sec. 15a. GENERIC DRUG VOUCHER PILOT; REPORT

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(a) By January 15, 2009, the office of Vermont health access, the department of banking, insurance, securities, and health care administration, the area health education centers, and the joint fiscal office shall provide a report to the house committee on health care and the senate committee on health and welfare describing and evaluating the effects of the generic drug voucher pilot program.

(b) The report shall describe how the pilot project is implemented, including which health conditions were targeted, the generic drugs provided with the vouchers, and the geographic regions participating. The report shall compare the distribution of prescribing among generic drugs provided through the vouchers and brand name drugs before and after the first year of the generic drug sample pilot project and will review a year of prescribing data prior to the implementation of the pilot project to a year of prescribing data during the first year of the pilot project's implementation. The data shall be adjusted to reflect how and where the pilot was implemented.

Seventh: By striking Sec. 17 and inserting a new Sec. 17 to read:

Sec. 17. 18 V.S.A. chapter 91, subchapter 3 is added to read:

Subchapter 3. Information Requirements

§ 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

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(a) It is the intent of the general assembly to advance the state's interest in protecting the public health of Vermonters, protecting the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.

(b) As used in this section:

(1) "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.

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

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

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

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

(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) “Promotion” or “promote” means any activity or product the intention of which is to advertise or publicize a prescription drug, including a brochure, media advertisement or announcement, poster, free sample, detailing visit, or personal appearance.

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

(c)(1) The department of health and the office of professional regulation, in consultation with the appropriate licensing boards, shall establish a prescriber data-sharing program to allow a prescriber to give **consent** for his or her identifying information to be **used** for the purposes described under subsection

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(d) of this section. The department and office shall solicit the prescriber's consent on licensing applications or renewal forms and shall provide a prescriber a method for revoking his or her consent. The department and office may establish rules for this program.

(2) The department or office shall make available the list of prescribers who have consented to sharing their information. Entities who wish to use the information as provided for in this section shall review the list at minimum every six months.

(d) A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity may use regulated records which include prescription information containing prescriber-identifiable data for marketing or promoting a prescription drug only if:

(1)(A) a prescriber has provided consent for the use of that data as provided in subsection (c) of this section; and

(B) the entity using the regulated records complies with the disclosure requirements in subsection (f) of this section; or

(2) the entity meets one of the exceptions provided in subsection (e) of this section.

(e) 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;

(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; and

(7) the collection, use, transfer, or sale of patient and prescriber data for marketing or promoting if the data do not identify a **prescriber**, and there is no

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reasonable basis to believe that the data provided could be used to identify a prescriber.

(f) When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs as provided for under this section, the marketer shall disclose to the prescriber evidence-based information as provided for by rule describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options. As necessary, the office of Vermont health access, in consultation with the department of health, the area centers on health education, the office of professional regulation, and the office of the attorney general, shall develop rules for compliance with this subsection, including the certification of materials which are evidence-based as defined in section 4621 of this title and which conditions have evidence-based treatment guidelines. The rules shall be consistent with the federal Food and Drug Administration's regulations regarding false and misleading advertising. ~~To the extent practicable, the rules shall use the evidence-based standards developed by the blueprint for health.~~

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(g) 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.

Eighth: By inserting a Sec. 24b to read:

Sec. 24b. EFFECTIVE DATES

Sec. 17 of this act shall become effective no later than January 1, 2008, except that the department of health and the office of professional regulation may begin any necessary rulemaking, revision of forms, or other administrative actions necessary to implement the program, immediately upon passage. The department **and office** may implement Sec. 17 for prescribers with licenses at the time of passage of this act when the prescriber next requests a renewal of the license.

TAB K

(Draft No. 1 – S.115)
5/4/2007 - RJL - 5:11 am

Page 1
(1.1)

S.115

Representative Sunderland of Rutland Town moves to amend the bill by inserting a ~~new~~ Sec. 22a to read:

Sec. 22a. LITIGATION REPORT; AUDITOR

Beginning January 1, 2008 and annually thereafter, the state auditor shall provide a report to the general assembly with a detailed accounting of all amounts paid by the state with state or federal funds in connection with any litigation challenging the validity of this act or a section of this act. The report shall include costs, fees, damages, amounts paid to expert witnesses, salaries and benefits of state employees who work on the litigation, amounts paid to individuals under contract with the state who work on the litigation, attorney's fees awarded to the other party, any other amounts awarded by the court, and the number of hours spent by state employees involved in the litigation.

TAB L

**COPY AS PASSED BY
HOUSE AND SENATE**

BILL AS INTRODUCED
2007

S.115
Page 1

1 S.115

2 Introduced by Committee on Finance

3 Date: 2/23/07

4 Subject: Health; insurance; prescription drugs; pharmaceuticals; pharmacy

5 benefit managers; drug education; preferred drug list; pricing;

6 confidentiality; pharmacy benefits; prompt pay

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

8 prescription drug information and pricing by limiting fraudulent advertising of

9 prescription drugs to consumers and health care professionals, requiring notice

10 to clients by pharmacy benefit managers that certain types of contracts are

11 available, strengthening the Medicaid preferred drug list, establishing an

12 evidence-based education program, providing additional pricing information to

13 the Medicaid program from drug manufacturers, requiring disclosure of

14 education programs funded by drug manufacturers, and providing enforcement

15 for prescription drug provisions under the Consumer Fraud Act.

16 AN ACT RELATING TO INCREASING TRANSPARENCY OF
17 PRESCRIPTION DRUG PRICING AND INFORMATION

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

Sec. 1. *LEGISLATIVE FINDINGS*

The general assembly makes the following findings:

(1) The state of Vermont has an interest in maximizing the well-being of its residents and in containing health care costs.

(2) There is a strong link between pharmaceutical marketing activities, health care spending, and the health of Vermonters.

(3) The goals of marketing programs are often in conflict with the goals of the state. Marketing programs are designed to increase sales, income, and profit. Frequently, progress toward these goals comes at the expense of cost-containment activities and possibly the health of individual patients.

(4) The marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors. The one-sided nature of the marketing leads to doctors prescribing drugs based on incomplete and biased information, particularly for prescribers that lack the time to perform substantive research assessing whether the messages they are receiving from pharmaceutical representatives are full and accurate.

(5) The federal Food and Drug Administration (FDA) requires marketing and advertising to be fair and balanced; however, the FDA has limited legal ability to enforce this requirement.

(6) Public health is ill served by the massive imbalance in information presented to doctors and other prescribers.

(7) Newer drugs on the market do not necessarily provide additional benefits over older drugs, but do add costs and as yet unknown side-effects. One example of this is the drug Vioxx, which was removed from the market due to potentially lethal side-effects that were not adequately disclosed initially.

(8) Between 1975 and 2000, 50 percent of all drug withdrawals from the market and "black box warnings" were within the first two years of the release of the drug. One-fifth of all drugs are subject to "black box warnings" or withdrawal from the market because of the serious public health concerns. Marketing which results in prescribers using the newest drugs will also result in prescribing drugs that are more likely to be subject to these warnings and withdrawal.

(9) In 2005, Vermonters spent an estimated \$524 million on prescription and over-the-counter drugs and nondurable medical supplies. In 2000, spending was about \$280 million. The annual increase in spending during this period was 13.3 percent, which was the highest increase in any health care category.

(10) Vermont has been a leader in prescription drug cost-containment and in providing transparency, to the extent allowable, in drug prices. The state has enacted the pharmacy best practices and cost control program, mandatory generic substitution, and mail order purchasing in Medicaid, VPharm, and Vermont Rx and encouraged the department of human resources to have a preferred drug list in the state employees health benefit plans in efforts to control costs, while maintaining best practices in drug prescribing, in our publicly-financed prescription drug programs. The Vermont Medicaid program has been a member of multi-state purchasing pools for several years and aggressively seeks supplemental rebates to lower drug costs in Medicaid program.

(11) In addition, Vermont has sought to control drug prices in private and employer-sponsored insurance by encouraging voluntary participation in Medicaid's preferred drug list, requiring mandatory generic substitution for all prescriptions in Vermont, providing consumers with pricing information about the drugs they are prescribed, and assisting consumers by providing information about purchasing drugs internationally through a safe, regulated program run through the state of Illinois.

(12) Vermont has also sought transparency by requiring marketers of prescription drugs to disclose information about the amount of money spent on marketing activities in Vermont and also to require the disclosure of pricing information to doctors during marketing visits.

(13) Physicians are unable to take the time to research the quickly changing pharmaceutical market and determine which drugs are the best treatments for particular conditions. Because of this, physicians frequently rely on information provided by pharmaceutical representatives.

(14) Nearly one-third of the five-fold increase in U.S. spending on drugs over the last decade can be attributed to marketing induced shifts in doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments, which often have little or no increased

therapeutic value. According to the same study, the use of more expensive drugs contributed to 36 percent of the rise in retail prescription spending in 2000 and 24 percent in 2001.

(15) According to testimony by Dr. Avorn, M.D., at Brigham and Women's Hospital, detailing affects the cost of medications, because it is generally "confined to high-margin, high-profit drugs, for which the manufacturer has a substantial incentive to increase sales. . . . Thus, the work of pharmaceutical sales representatives drives drug use toward the most expensive products . . . , and contributes to the strain on health care budgets for individuals as well as health care programs."

(16) According to the June 15, 2006 Marketing Disclosures: Report of Vermont Attorney General William H. Sorrell, as part of their marketing efforts, pharmaceutical companies made direct payments of almost \$2.2 million to prescribers in Vermont, including consulting fees and travel expenses in 2005. Estimates of total costs of marketing to prescribers in Vermont are \$10 million or more, excluding free samples and direct-to-consumer advertising.

(17) In 2004, the pharmaceutical industry spent \$27 billion marketing pharmaceuticals in the United States, and spent more than any other sector in the United States on its sales force and media advertising. Over 85 percent of these marketing expenditures are directed at the small percentage of the population that practice medicine. Pharmaceutical manufacturers spend twice as much on marketing as on research and development.

(18) Coincident with the rise of physician identity data mining, the pharmaceutical industry increased its spending on direct marketing to doctors by over 275 percent and doubled its sales force to over 90,000 drug representatives. It is estimated that there is a pharmaceutical sales representative for every five office-based physicians.

(19) A significant portion of prescriber time is spent meeting with pharmaceutical representatives. According to a survey recently published in the New England Journal of Medicine, family practitioners reported the highest frequency of meetings with representatives – an average of 16 times per month. To the extent that this meeting time comes at the expense of time spent with patients, quality of care will be negatively affected.

(20) Some doctors in Vermont are experiencing an undesired increase in the aggressiveness of pharmaceutical sales representatives and a few have reported that they felt coerced and harassed. The Vermont Medical Society, an organization representing two-thirds of Vermont doctors, unanimously passed a resolution stating "the use of physician prescription information by sales representatives is an intrusion into the way physicians practice medicine."

(21) Several studies suggest that drug samples clearly affect prescribing behavior in favor of the sample. The presence of drug samples may influence physicians to dispense or prescribe drugs that differ from their preferred drug source according to a study by Chew et al. in the Journal of General Internal Medicine in 2000.

(22) Prescriber-identifiable prescription data show details of physicians' drug use patterns, both in terms of their gross number of prescriptions and their inclinations to prescribe particular drugs.

(23) Prescriber identity data mining allows pharmaceutical companies to track the prescribing habits of nearly every physician in Vermont and link those habits to specific physicians and their identities.

(24) Monitoring of prescribing practices also allows the sales representatives to assess the impact of various gifts and messages on a particular physician to help them select the most effective set of rewards.

(25) Prescriber-identified data increase the effect of detailing programs. They support the tailoring of presentations to individual prescriber styles, preferences, and attitudes.

(26) Prescriber identified databases of prescribing habits encourage pharmaceutical companies to increase the quid pro quo nature of relations between pharmaceutical sales representatives and prescribers. Pharmaceutical companies use prescriber identity data-mining to target increased attention and manipulative practices toward those doctors that they find would lead to increased prescriptions and profitability, including high prescribers, brand loyal prescribers, doctors that show themselves willing to prescribe new medicines, and doctors who are shown to be especially susceptible to sales messages.

(27) Added and unwanted pressure occurs when doctors are informed by sales representatives that they are being monitored – through messages of

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appreciation for writing prescriptions, or messages of disappointment that they are not prescribing what was implicitly promised.

(28) As with the use of consumer telephone numbers for marketing, the trading of prescriber identities linked to prescription data can result in harassing sales behaviors by pharmaceutical sales representatives toward doctors.

(29) Health care professionals in Vermont who write prescriptions for their patients have a reasonable expectation that the information in that prescription, including their own identity and that of the patient, will not be used for purposes other than the filling and processing of the payment for that prescription. Prescribers and patients do not consent to the trade of that information to third parties, and no such trade should take place without their consent.

(30) The physician data restriction program offered by the American Medical Association (AMA) is not an adequate remedy for Vermont doctors, because many physicians do not know about the program and other health care professionals who prescribe medications may not avail themselves of the AMA program. In addition, approximately 23 percent of Vermont physicians belong to the AMA, which is one of the lowest rates in the nation. Finally, data-mining companies could use other identifiers, including state licensing numbers, to track prescribing patterns.

(31) This act is necessary to protect prescriber privacy by limiting marketing to prescribers who choose to receive that type of information, to save money for the state, consumers, and businesses by promoting the use of less expensive drugs, and to protect public health by requiring evidence-based disclosures and promoting drugs with longer safety records.

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

§ 1998. PHARMACY BEST PRACTICES AND COST CONTROL PROGRAM ESTABLISHED

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

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

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

~~(B) The commissioner of human resources shall use the preferred drug list in the state employees health benefit plan only if participation in the program will provide economic and health benefits to the state employees health benefit plan and to beneficiaries of the plan, and only if agreed to through the bargaining process between the state of Vermont and the authorized representatives of the employees of the state of Vermont. The provisions of this subdivision do not authorize the actuarial pooling of the state employees health benefit plan with any other health benefit plan, unless otherwise agreed to through the bargaining process between the state of Vermont and the authorized representatives of the employees of the state of Vermont. No later than November 1, 2004, the commissioner of human resources shall report to the health access oversight committee and the senate and house committees on health and welfare on whether use of the preferred drug list in the state employees health benefit plan would, in his or her opinion, provide economic and health benefits to the state employees health benefit plan and to beneficiaries of the plan.~~

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

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

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

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

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

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

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

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

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

* * *

(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

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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, workers' compensation, and any other state or publicly funded purchaser of prescription drugs.

* * *

(f)(1) The drug utilization review board shall make recommendations to the director for the adoption of the preferred drug list. The board's recommendations shall be based upon evidence-based considerations of clinical efficacy, adverse side effects, safety, appropriate clinical trials, and cost-effectiveness. "Evidence-based" shall have the same meaning as in section 4622 of Title 18.

* * *

(6) The director shall encourage participation in the joint purchasing consortium by inviting representatives of the programs and entities specified in subdivision (c)(1) 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 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.

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

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

(4) The following shall be exempt from disclosure:

* * *

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

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

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

* * *

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

Sec. 5. 33 V.S.A. § 2005a(d) is amended to read:

(d) As used in this section:

* * *

(2) "Pharmaceutical manufacturing company" is defined by subdivision 2005(e)(5) 4632(c)(5) of this title.

(3) "Pharmaceutical marketer" is defined by subdivision 2005(e)(4) 4632(c)(4) of this title.

* * * Price Disclosure and Certification * * *

Sec. 6. 33 V.S.A. § 2010 is added to read:

§ 2010. ACTUAL PRICE DISCLOSURE AND CERTIFICATION

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

(1) the prices required to be provided to the Medicaid program under federal law, including prices defined in 42 U.S.C. § 1396r-8; and

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

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

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

(d) When a manufacturer of prescription drugs dispensed in this state reports the 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.

(e) Notwithstanding any provision of law to the contrary, information submitted to the office under this section is confidential and is not a public record as defined in subsection 317(b) of Title 1. Disclosure may be made by the office to an entity providing services to the office under this section; however, that disclosure does not change the confidential status of the information. The information may be used by the entity only for the purpose specified by the office in its contract with the entity. Data compiled in aggregate form by the office for the purposes of reporting required by this section are public records as defined in subsection 317(b) of Title 1, provided they do not reveal trade information protected by state or federal law.

(f) The attorney general shall enforce the provisions of this section under the Vermont consumer fraud act in chapter 63 of Title 9. The attorney general has the same authority to make rules, conduct civil investigations, and bring civil actions with respect to acts and practices governed by this section as is provided under the Vermont consumer fraud act.

*** Healthy Vermonters ***

Sec. 7. 33 V.S.A. § 2003 is amended to read:

§ 2003. PHARMACY DISCOUNT PLANS

(a) The director of the office of Vermont health access shall implement pharmacy discount plans, to be known as the "Healthy Vermonters" program and ~~the "Healthy Vermonters Plus" program~~, for Vermonters without adequate coverage for prescription drugs. The provisions of ~~section 1992 of~~

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~~this title subchapter 8 of this chapter shall apply to the director's authority to administer the pharmacy discount plans established by this section.~~

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

* * *

(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~~ 350 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 household income or whose total unreimbursed medical expenses, including insurance premiums, equal 15 percent or more of household income.~~

* * *

* * * PBM Regulation * * *

Sec. 8. 18 V.S.A. chapter 221, subchapter 9 is added to read:

Subchapter 9. Pharmacy Benefit Managers

§ 9471. DEFINITIONS

As used in this subchapter:

(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.

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

(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.

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

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

(A) mail service pharmacy;

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

(C) clinical formulary development and management services;

(D) rebate contracting and administration;

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

(F) disease or chronic care management programs.

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

§ 9472. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES

(a) A pharmacy benefit manager that provides pharmacy benefit management for a health plan shall discharge its duties with reasonable care and diligence and be fair and truthful under the circumstances then prevailing that a 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.

(b) A pharmacy benefit manager shall provide notice to the health insurer that the terms contained in subsection (c) of this section may be included in the contract between the pharmacy benefit manager and the health insurer.

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

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

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

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

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

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

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

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

(3) With regard to the dispensation of a substitute prescription drug for a prescribed drug to a beneficiary in which the substitute drug costs more than the prescribed drug and the pharmacy benefit manager receives a benefit or payment directly or indirectly, disclose to the health insurer the cost of both drugs and the benefit or payment directly or indirectly accruing to the pharmacy benefit manager as a result of the substitution.

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

(5) Disclose to the health insurer all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefit manager and any prescription drug manufacturer that relate to benefits provided to beneficiaries under or services to the health insurer's health plan, including formulary management and drug-switch programs, educational support, claims processing, and pharmacy network fees charged from retail pharmacies and data sales fees. A pharmacy benefit manager providing information under this subsection may designate that material as confidential.

Information designated as confidential by a pharmacy benefit manager and provided to a health insurer under this subsection may not be disclosed by the health insurer to any person without the consent of the pharmacy benefit manager, except that disclosure may be made by the health insurer:

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

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

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

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

(d) 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.

§ 9473. ENFORCEMENT

(a) Except as provided in subsection (d) of this section, in addition to any remedy available to the commissioner under this title and any other remedy provided by law, a violation of this subchapter shall be considered a violation of the Vermont consumer fraud act in subchapter 1 of chapter 63 of Title 1. Except as provided in subsection (d) of this section, all rights, authority, and remedies available to the attorney general and private parties to enforce the Vermont consumer fraud act shall be available to enforce the provisions of this subchapter.

(b) In connection with any action for violation of the Vermont consumer fraud act, the commissioner's determinations concerning the interpretation and administration of the provisions of this subchapter and any rules adopted hereunder shall carry a presumption of validity. The attorney general and the commissioner shall consult with each other prior to the commencement of any investigation or enforcement action with respect to any pharmacy benefit manager.

(c) The commissioner may investigate, examine, or otherwise enforce a

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violation of this subchapter by a pharmacy benefit manager under section 9412 of this title as if the pharmacy benefit manager were a health insurer.

(d) The commissioner shall have the exclusive authority to investigate, examine, and otherwise enforce the provisions of this subchapter relating to a pharmacy benefit manager in connection with the pharmacy benefit manager's contractual relationship with, and any other activity with respect to, a health insurer defined by subdivision 9471(2)(A) of this title.

(e) Notwithstanding the foregoing, the commissioner and the attorney general may bring a joint enforcement action against any person or entity for a violation of this subchapter.

Sec. 9. 18 V.S.A. § 9421 is added to read:

§ 9421. PHARMACY BENEFIT MANAGEMENT; REGISTRATION; AUDIT

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

(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) 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:

(1) 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 the contract;

(2) 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 the contract; and

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

(d) The department's reasonable expenses in administering the provisions of this section may be charged to pharmacy benefit managers in the manner provided for in section 18 of Title 8. These expenses shall be allocated in proportion to the lives of Vermonters covered by each pharmacy benefit manager as reported annually to the commissioner in a manner and form prescribed by the commissioner. The department shall not charge its expenses to the pharmacy benefit manager contracting with the office of Vermont health access if the office notifies the department of the conditions contained in its contract with a pharmacy benefit manager.

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

(f) As used in this section:

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

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

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

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

Sec. 10. APPLICATION

Secs. 8 and 9 of this act apply to contracts executed or renewed on or after September 1, 2007. For purposes of this section, a contract executed pursuant to a memorandum of agreement executed prior to September 1, 2007 is deemed to have been executed prior to September 1, 2007 even if the contract was executed after that date.

Sec. 11. 8 V.S.A. § 4088d is added to read:

§ 4088d. NOTICE OF PREFERRED DRUG LIST CHANGES

On a periodic basis, no less than once per calendar year, a health insurer as defined in subdivisions 9471(2)(A), (C), and (D) of Title 18 shall notify beneficiaries of changes in pharmaceutical coverage and provide access to the preferred drug list maintained by the insurer.

Sec. 12. 18 V.S.A. chapter 91 is amended to read:

CHAPTER 91. GENERIC DRUGS PRESCRIPTION DRUG
COST CONTAINMENT

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

Subchapter 1. Generic Drugs

Sec. 14. 18 V.S.A. chapter 91, subchapter 2 is added to read:

Subchapter 2. Evidence-Based Education Program

§ 4621. DEFINITIONS

For the purposes of this subchapter:

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

(2) "Evidence-based" means based on criteria and guidelines that reflect high-quality, cost-effective care. The methodology used to determine such guidelines shall meet recognized standards for systematic evaluation of all available research and shall be free from conflicts of interest. Consideration of the best available scientific evidence does not preclude consideration of experimental or investigational treatment or services under a clinical investigation approved by an institutional review board.

§ 4622. EVIDENCE-BASED EDUCATION PROGRAM

(a)(1) The department, in collaboration with the attorney general, the University of Vermont area health education centers program, and the office of Vermont health access, shall establish an evidence-based prescription drug education program for health care professionals designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists, and other health care professionals authorized to prescribe and dispense prescription drugs. To the extent practicable, the program shall use the evidence-based standards developed by the blueprint for health. The department may collaborate with other states in establishing this program.

(2) The program shall notify prescribers about commonly used brand-name drugs for which the patent has expired within the last 12 months or will expire within the next 12 months. The department and the office of Vermont health access shall collaborate in issuing the notices.

(3) To the extent permitted by funding, the program may include the distribution to prescribers of vouchers for samples of generic medicines used for health conditions common in Vermont.

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

(c) The department may contract for technical and clinical support in the development and the administration of the program from entities conducting independent research into the effectiveness of prescription drugs.

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

Sec. 15. GENERIC DRUG VOUCHER PILOT PROJECT

(a) As part of the evidence-based education program established in subchapter 2 of chapter 91 of Title 18, the department of health, in collaboration with the office of Vermont health access and the University of Vermont area health education centers program, shall establish a pilot project

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to distribute vouchers for a sample of generic drugs equivalent to frequently prescribed prescription drugs that are used to treat common health conditions.

(b) The office of Vermont health access shall fund the vouchers from the fee established in section 1998b of Title 33 and shall provide payment to the pharmacy dispensing the prescription drugs in exchange for the voucher. The office shall establish a payment rate, including a dispensing fee, using the rules and procedures for the Medicaid program.

Sec. 15a. GENERIC DRUG VOUCHER PILOT; REPORT

(a) By January 15, 2009, the office of Vermont health access, the department of banking, insurance, securities, and health care administration, the area health education centers, and the joint fiscal office shall provide a report to the house committee on health care and the senate committee on health and welfare describing and evaluating the effects of the generic drug voucher pilot program.

(b) The report shall describe how the pilot project is implemented, including which health conditions were targeted, the generic drugs provided with the vouchers, and the geographic regions participating. The report shall compare the distribution of prescribing among generic drugs provided through the vouchers and brand-name drugs before and after the first year of the generic drug sample pilot project and will review a year of prescribing data prior to the implementation of the pilot project to a year of prescribing data during the first year of the pilot project's implementation. The data shall be adjusted to reflect how and where the pilot was implemented.

Sec. 16. PRESCRIPTION DRUG PRICING; FEDERALLY QUALIFIED HEALTH CENTERS

No later than January 1, 2008, the department of health shall create a plan to inform Vermonters of the availability of health services provided by federally qualified health centers (FOHC) and FOHC look-alikes, including information about prescription drug pricing, focusing on 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 for whom the cost of prescription drugs is likely to be higher than prices under Section 340B of the Public Health Service Act.

* * * Prescription Drug Data Confidentiality * * *

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Sec. 17. 18 V.S.A. chapter 91, subchapter 3 is added to read:

Subchapter 3. Information Requirements

§ 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

(a) It is the intent of the general assembly to advance the state's interest in protecting the public health of Vermonters, protecting the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.

(b) As used in this section:

(1) "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.

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

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

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

(5) "Marketing" shall include advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior of an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

(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) "Promotion" or "promote" means any activity or product the intention of which is to advertise or publicize a prescription drug, including a brochure, media advertisement or announcement, poster, free sample, detailing visit, or personal appearance.

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

(c)(1) The department of health and the office of professional regulation, in consultation with the appropriate licensing boards, shall establish a prescriber data-sharing program to allow a prescriber to give consent for his or her identifying information to be used for the purposes described under subsection (d) of this section. The department and office shall solicit the prescriber's consent on licensing applications or renewal forms and shall provide a prescriber a method for revoking his or her consent. The department and office may establish rules for this program.

(2) The department or office shall make available the list of prescribers who have consented to sharing their information. Entities who wish to use the information as provided for in this section shall review the list at minimum every six months.

(d) A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity may use regulated records which include prescription information containing prescriber-identifiable data for marketing or promoting a prescription drug only if:

(1)(A) a prescriber has provided consent for the use of that data as provided in subsection (c) of this section; and

(B) the entity using the regulated records complies with the disclosure requirements in subsection (f) of this section; or

(2) the entity meets one of the exceptions provided in subsection (e) of this section.

(e) 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;

(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; and

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

(f) When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs as provided for under this section, the marketer shall disclose to the prescriber evidence-based information as provided for by rule describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options. As necessary, the office of Vermont health access, in consultation with the department of health, the area centers on health education, the office of professional regulation, and the office of the attorney general, shall develop

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rules for compliance with this subsection, including the certification of materials which are evidence-based as defined in section 4621 of this title and which conditions have evidence-based treatment guidelines. The rules shall be consistent with the federal Food and Drug Administration's regulations regarding false and misleading advertising. To the extent practicable, the rules shall use the evidence-based standards developed by the blueprint for health.

(g) 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. 18. 1 V.S.A. § 317(c)(38) and (39) are added to read:

(38) records held by the agency of human services, which include prescription information containing prescriber-identifiable data, that could be used to identify a prescriber, except that the records shall be made available upon request for medical research, consistent with and for purposes expressed in sections 4621, 4631, 4632, 4633, and 9410 of Title 18 and chapter 84 of Title 18, or as provided for in chapter 84A of Title 18 and for other law enforcement activities.

(39) records held by the agency of human services or the department of banking, insurance, securities and health care administration, which include prescription information containing patient-identifiable data, that could be used to identify a patient.

Sec. 19. 18 V.S.A. § 9410(g) is amended to read:

(g) Any person who knowingly fails to comply with the requirements of this section or rules adopted pursuant to this section shall be fined subject to an administrative penalty of not more than \$1,000.00 per violation. The commissioner may impose an administrative penalty of not more than \$10,000.00 each for those violations the commissioner finds were willful. In addition, any person who knowingly fails to comply with the confidentiality requirements of this section or confidentiality rules adopted pursuant to this

section and uses, sells, or transfers the data or information for commercial advantage, pecuniary gain, personal gain, or malicious harm shall be subject to an administrative penalty of not more than \$50,000.00 per violation. The powers vested in the commissioner by this subsection shall be in addition to any other powers to enforce any penalties, fines, or forfeitures authorized by law.

Sec. 20. 33 V.S.A. § 2004 is added to read:

§ 2004. MANUFACTURER FEE

(a) Annually, each pharmaceutical manufacturer or labeler of prescription drugs that are paid for by the office of Vermont health access for individuals participating in Medicaid, the Vermont Health Access Program, Dr. Dynasaur, VPharm, or Vermont Rx shall pay a fee to the agency of human services. The fee shall be 0.5 percent of the previous calendar year's prescription drug spending by the office and shall be assessed based on manufacturer labeler codes as used in the Medicaid rebate program.

(b) Fees collected under this section shall fund collection and analysis of information on pharmaceutical marketing activities under sections 4632 and 4633 of Title 18, analysis of prescription drug data needed by the attorney general's office for enforcement activities, and the evidence-based education program established in subchapter 2 of Title 18. The fees shall be collected in the evidence-based education and advertising fund established in section 2004a of this title.

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

Sec. 20a. 33 V.S.A. § 2004a is added to read:

§ 2004a. EVIDENCE-BASED EDUCATION AND ADVERTISING FUND

(a) The evidence-based education and advertising fund is established in the treasury as a special fund to be a source of financing for activities relating to fund collection and analysis of information on pharmaceutical marketing activities under sections 4632 and 4633 of Title 18, analysis of prescription drug data needed by the attorney general's office for enforcement activities, and for the evidence-based education program established in subchapter 2 of Title 18. Monies deposited into the fund shall be used for the purposes described in this section.

(b) Into the fund shall be deposited:

(1) revenue from the manufacturer fee established under section 2004 of this title; and

(2) the proceeds from grants, donations, contributions, taxes, and any other sources of revenue as may be provided by statute, rule, or act of the general assembly.

(c) The fund shall be administered pursuant to subchapter 5 of chapter 7 of Title 32, except that interest earned on the fund and any remaining balance shall be retained in the fund.

* * * Consumer Protection; False Advertising * * *

Sec. 21. 9 V.S.A. § 2466a is added to read:

§ 2466a. CONSUMER PROTECTIONS; PRESCRIPTION DRUGS

(a) A violation of section 4631 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 if that advertisement does not comply with the requirements concerning drugs and devices and prescription drug advertising in 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. A warning or untitled letter issued by the U.S. Food and Drug Administration shall be prima facie evidence of a violation of federal law and regulations.

(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, 202.20 (1999).

(B) "Regulated advertisement" means:

(i) 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; or

(ii) a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs or its representative that is conveyed:

(I) to the office of a health care professional doing business in Vermont, including statements by representatives or employees of the manufacturer and materials mailed or delivered to the office; or

(II) at a conference or other professional meeting occurring in Vermont.

(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. This subsection shall not apply to information provided to the health care professional about pharmacy reimbursement, prescription drug formulary compliance, and patient care management.

* * * Insurance Marketing * * *

Sec. 22. 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:

(A)(i) sell, solicit, or negotiate the purchase of health insurance in this state through an advertisement which makes 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.

(ii) Use 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 requests the solicitation, and the products to be discussed are clearly identified to the consumer in writing at least 48 hours in advance of the appointment.

(iii) Solicit the sale of Medicare products door-to-door prior to receiving an invitation from a consumer.

(B) 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. 22a. LITIGATION REPORT; AUDITOR

Beginning January 1, 2008 and annually thereafter, the state auditor shall provide a report to the general assembly with a detailed accounting of all amounts paid by the state with state or federal funds in connection with any litigation challenging the validity of this act or a section of this act. The report shall include costs, fees, damages, amounts paid to expert witnesses, salaries and benefits of state employees who work on the litigation, amounts paid to individuals under contract with the state who work on the litigation, attorney's fees awarded to the other party, any other amounts awarded by the court, and the number of hours spent by state employees involved in the litigation.

Sec. 23. 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.
- (4) Section 2006 shall be section 852 of Title 2.

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Sec. 24. REPEAL

Section 2009 of Title 33 is repealed.

Sec. 24a. APPROPRIATIONS

(a) The amount of \$200,000.00 is appropriated from the evidence-based education and advertising fund to the department of health for a grant to the area health education centers for the evidence-based education program established under subchapter 2 of Title 18.

(b) The amount of \$300,000.00 is appropriated from the evidence-based education and advertising fund to the office of Vermont health access for the evidence-based education program's generic drug sample pilot project as described in Sec. 15 of this act.

(c) The amount of \$50,000.00 is appropriated from the evidence-based education and advertising fund to the office of attorney general fund for the collection and analysis of information on pharmaceutical marketing activities under sections 4632 and 4633 of Title 18 and analysis of prescription drug data needed by the attorney general's office for enforcement activities.

Sec. 24b. EFFECTIVE DATES

Sec. 17 of this act shall become effective no later than January 1, 2008, except that the department of health and the office of professional regulation may begin any necessary rulemaking, revision of forms, or other administrative actions necessary to implement the program, immediately upon passage. The department and office may implement Sec. 17 for prescribers with licenses at the time of passage of this act when the prescriber next requests a renewal of the license.

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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~~

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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 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.~~

15 ~~(7) A plan to inform Vermonters of the availability of health services~~
16 ~~provided by federally qualified health centers (FOHC) and FOHC look-alikes,~~
17 ~~including that prescription drug pricing is more affordable, focusing on~~
18 ~~participants in the Medicaid and Medicaid waiver programs, state employees,~~
19 ~~individuals under the supervision of corrections, individuals receiving~~
20 ~~workers' compensation benefits if applicable, and any other state or publicly~~
21 ~~funded purchaser of prescription drugs.~~

22 (8) A joint pharmaceuticals purchasing consortium as provided for in
23 ~~subdivision (c)(1) of this section.~~

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1 ~~(8)(2) Any other cost containment activity adopted, by rule, by the~~
2 director that is designed to reduce the cost of providing prescription drugs
3 while maintaining high quality in prescription drug therapies.

4 * * *

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

19 (c)(1) The director may implement the pharmacy best practices and cost
20 control program for any other health benefit plan within or outside this state
21 that agrees to participate in the program. For entities in Vermont, the director
22 shall directly or by contract implement the program through a joint
23 pharmaceuticals purchasing consortium. The joint pharmaceuticals
24 purchasing consortium shall be offered on a voluntary basis no later than

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~~1 January 1, 2008, with mandatory participation by state or publicly funded
2 administered, or subsidized purchasers to the extent practicable and consistent
3 with the purposes of this chapter, by January 1, 2010. If necessary, the office
4 of Vermont health access shall seek authorization from the Centers for
5 Medicare and Medicaid to include purchases funded by Medicaid. "State or
6 publicly funded purchasers" shall include the department of corrections, the
7 division of mental health, Medicaid, the Vermont Health Access Program
8 (VHAP), Dr. Dynasaur, Vermont Rx, VPharm, Healthy Vermonters, Healthy
9 Vermonters Plus, workers' compensation, and any other state or publicly
10 funded purchaser of prescription drugs.~~

~~11 * * *~~

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

~~18 * * *~~

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

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

25 (g) The office shall seek assistance from entities conducting independent
26 ~~research into the effectiveness of prescription drugs, such as the Oregon Health~~

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1 ~~and Science University Drug Effectiveness Review Project (DERP) to provide~~
2 technical and clinical support in the development and the administration of the
3 preferred drug list and the evidence-based education program established in
4 subchapter 2 of Title 18.

5 * * * Pharmaceutical Marketer Disclosures * * *

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

7 (3) The office of the attorney general shall keep confidential all trade
8 secret information, as defined by subdivision 317(b)(9) of Title 1, except that
9 the office may disclose the information to the department of health and the
10 office of Vermont health access for the purpose of informing and prioritizing
11 the activities of the evidence-based education program in subchapter 2 of
12 chapter 91 of Title 18. The department of health shall keep the information
13 confidential. The disclosure form shall permit the company to identify any
14 information that it claims is a trade secret as defined in subdivision 317(c)(9)
15 of Title 1. In the event that the attorney general receives a request for any
16 information designated as a trade secret, the attorney general shall promptly
17 notify the company of such request. Within 30 days after such notification, the
18 company shall respond to the requester and the attorney general by either
19 consenting to the release of the requested information or by certifying in
20 writing the reasons for its claim that the information is a trade secret. Any
21 ~~requester aggrieved by the company's response may apply to the superior court~~

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1 ~~of Washington County for a declaration that the company's claim of trade~~
2 secret is invalid. The attorney general shall not be made a party to the superior
3 court proceeding. Prior to and during the pendency of the superior court
4 proceeding, the attorney general shall keep confidential the information that
5 has been claimed as trade secret information, except that the attorney general
6 may provide the requested information to the court under seal.

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

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

9 * * *

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

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

16 and

17 (F) prescription drug rebates and discounts.

18 * * *

19 (d) Disclosures of unrestricted grants for continuing medical education

20 ~~programs shall be limited to the value, nature, and purpose of the grant and the~~

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1 ~~name of the grantee. It shall not include disclosure of the individual~~

2 participants in such a program.

3 * * * Price Disclosure and Certification * * *

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

5 § 2010. ACTUAL PRICE DISCLOSURE AND CERTIFICATION

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

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

11 § 1396r-8(k);

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

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

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

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1 ~~(c) The pricing information required under this section is for drugs defined~~
2 ~~under the Medicaid drug rebate program and must be submitted to the director~~
3 ~~following its submission to the federal government in accordance with~~
4 ~~42 U.S.C. § 1396r-8(b)(3).~~

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

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

23 ~~(e) Notwithstanding any provision of law to the contrary, information~~
24 ~~submitted to the office under this section is confidential and is not a public~~
25 ~~record as defined in subsection 317(b) of Title 1. Disclosure may be made by~~
26 ~~the office to an entity providing services to the office under this section;~~

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1 ~~however, that disclosure does not change the confidential status of the~~
2 information. The information may be used by the entity only for the purpose
3 specified by the office in its contract with the entity. Data compiled in
4 aggregate form by the office for the purposes of reporting required by this
5 section are public records as defined in subsection 317(b) of Title 1, provided
6 they do not reveal trade information protected by state or federal law.

7 (f) The attorney general shall enforce the provisions of this section under
8 the Vermont consumer fraud act in chapter 63 of Title 9. The attorney general
9 has the same authority to make rules, conduct civil investigations, and bring
10 civil actions with respect to acts and practices governed by this section as is
11 provided under the Vermont consumer fraud act.

12 * * * Healthy Vermonters Plus * * *

13 Sec. 6. 33 V.S.A. § 2003 is amended to read:

14 § 2003. PHARMACY DISCOUNT PLANS

15 (a) The director of the office of Vermont health access shall implement
16 pharmacy discount plans, to be known as the "Healthy Vermonters" program
17 and the "Healthy Vermonters Plus" program, for Vermonters without adequate
18 coverage for prescription drugs. The provisions of ~~section 1992 of this title~~
19 subchapter 8 of this chapter shall apply to the director's authority to administer
20 ~~the pharmacy discount plans established by this section~~

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

8 (c) As used in this section:

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

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

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

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

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

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

25 ~~(B) whose family incurs unreimbursed expenses for prescription~~
26 ~~drugs, including insurance premiums, that equal five percent or more of~~
27 ~~household income or whose total unreimbursed medical expenses, including~~
28 ~~insurance premiums, equal 15 percent or more of household income.~~

29

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

* * * PBM Regulation * * *

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

Subchapter 9. Pharmacy Benefit Managers

§ 9471. DEFINITIONS

As used in this subchapter:

(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.

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

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

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

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

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

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

12 ~~(4) "Pharmacy benefit management" means an arrangement for the~~
13 ~~procurement of prescription drugs at a negotiated rate for dispensation within~~
14 ~~this state to beneficiaries, the administration or management of prescription~~
15 ~~drug benefits provided by a health plan for the benefit of beneficiaries, or any~~
16 ~~of the following services provided with regard to the administration of~~
17 ~~pharmacy benefits:~~

18 ~~(A) mail service pharmacy;~~

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

21 ~~(C) clinical formulary development and management services;~~

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- 1 ~~(D) rebate contracting and administration;~~
2 (E) certain patient compliance, therapeutic intervention, and generic
3 substitution programs; and
4 (F) disease or chronic care management programs.

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

9 § 9472. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES

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

12 (1) Discharge its duties with the care, skill, prudence, and diligence
13 under the circumstances then prevailing that a prudent pharmacy benefit
14 manager acting in like capacity and familiar with such matters would use in the
15 conduct of an enterprise of a like character and with like aims. In the case of a
16 health benefit plan offered by a health insurer as defined by subdivision
17 9471(2)(A) of this title, the health insurer shall remain responsible for
18 administering the health benefit plan in accordance with the health insurance
19 policy or subscriber contract or plan and in compliance with all applicable
20 provisions of Title 8 and this title.

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

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~~(1) Discharge its duties with reasonable care and diligence and be fair and truthful under the circumstances then prevailing that a 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.~~

(2) Provide all financial and utilization information requested by a health insurer relating to the provision of benefits to beneficiaries through that health insurer's health plan and all financial and utilization information relating to services to that health insurer. A pharmacy benefit manager providing information under this subsection may designate that material as confidential. Information designated as confidential by a pharmacy benefit manager and provided to a health insurer under this subsection may not be disclosed by the health insurer to any person without the consent of the pharmacy benefit manager, except that disclosure may be made by the health insurer:

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

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

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

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1 ~~(D) when ordered by the commissioner as to a health insurer as~~
2 ~~defined in subdivision 9471(2)(A) of this title pursuant to the provisions of~~
3 ~~Title 8 and this title.~~
4 ~~(3) Notify a health insurer in writing of any proposed or ongoing~~
5 ~~activity, policy, or practice of the pharmacy benefit manager that presents,~~
6 ~~directly or indirectly, any conflict of interest with the requirements of this~~
7 ~~section.~~
8 ~~(4) With regard to the dispensation of a substitute prescription drug for a~~
9 ~~prescribed drug to a beneficiary in which the substitute drug costs more than~~
10 ~~the prescribed drug and the pharmacy benefit manager receives a benefit or~~
11 ~~payment directly or indirectly, disclose to the health insurer the cost of both~~
12 ~~drugs and the benefit or payment directly or indirectly accruing to the~~
13 ~~pharmacy benefit manager as a result of the substitution.~~
14 ~~(5) If the pharmacy benefit manager derives any payment or benefit for~~
15 ~~the dispensation of prescription drugs within the state based on volume of sales~~
16 ~~for certain prescription drugs or classes or brands of drugs within the state,~~
17 ~~pass that payment or benefit on in full to the health insurer.~~
18 ~~(6) Disclose to the health insurer all financial terms and arrangements~~
19 ~~for remuneration of any kind that apply between the pharmacy benefit manager~~
20 ~~and any prescription drug manufacturer that relate to benefits provided to~~
21 ~~beneficiaries under or services to the health insurer's health plan, including~~

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1 ~~formulary management and drug switch programs, educational support, claims~~
2 ~~processing, and pharmacy network fees charged from retail pharmacies and~~
3 ~~data sales fees. A pharmacy benefit manager providing information under this~~
4 ~~subsection may designate that material as confidential. Information designated~~
5 ~~as confidential by a pharmacy benefit manager and provided to a health insurer~~
6 ~~under this subsection may not be disclosed by the health insurer to any person~~
7 ~~without the consent of the pharmacy benefit manager, except that disclosure~~
8 ~~may be made by the health insurer:~~

9 ~~(A) in a court filing under the consumer fraud provisions of chapter~~
10 ~~63 of Title 9, provided that the information shall be filed under seal and that~~
11 ~~prior to the information being unsealed, the court shall give notice and an~~
12 ~~opportunity to be heard to the pharmacy benefit manager on why the~~
13 ~~information should remain confidential;~~

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

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

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

19 ~~(b) A pharmacy benefit manager shall provide notice to the health insurer~~
20 ~~that the terms contained in this section may be included in the contract between~~
21 ~~the pharmacy benefit manager and the health insurer.~~

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1 ~~(e) Compliance with the requirements of this section is required for~~
2 ~~pharmacy benefit managers entering into contracts for pharmacy benefit~~
3 ~~management in this state by a health insurer in this state.~~

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

7 ~~§ 9473. ENFORCEMENT~~

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

14 ~~(b) In connection with any action for violation of the Vermont consumer~~
15 ~~fraud act, the commissioner's determinations concerning the interpretation and~~
16 ~~administration of the provisions of this subchapter and any rules adopted~~
17 ~~hereunder shall carry a presumption of validity. The attorney general and the~~
18 ~~commissioner shall consult with each other prior to the commencement of any~~
19 ~~investigation or enforcement action with respect to any pharmacy benefit~~
20 ~~manager. The commissioner may enforce a violation of this subchapter by a~~
21 ~~pharmacy benefit manager under section 9412 of this title. Notwithstanding~~
22 ~~the foregoing, the commissioner and the attorney general may bring a joint~~
23 ~~enforcement action against any person or entity for a violation of this~~

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1 ~~subchapter.~~

2 ~~§ 9473. ENFORCEMENT~~

3 (a) Except as provided in subsection (d) of this section, in addition to any
4 remedy available to the commissioner under this title and any other remedy
5 provided by law, a violation of this subchapter shall be considered a violation
6 of the Vermont consumer fraud act in subchapter 1 of chapter 63 of Title 1.
7 Except as provided in subsection (d) of this section, all rights, authority, and
8 remedies available to the attorney general and private parties to enforce the
9 Vermont consumer fraud act shall be available to enforce the provisions of this
10 subchapter.

11 (b) In connection with any action for violation of the Vermont consumer
12 fraud act, the commissioner's determinations concerning the interpretation
13 and administration of the provisions of this subchapter and any rules adopted
14 hereunder shall carry a presumption of validity. The attorney general and the
15 commissioner shall consult with each other prior to the commencement of any
16 investigation or enforcement action with respect to any pharmacy benefit
17 manager.

18 (c) The commissioner may investigate, examine, or otherwise enforce a
19 violation of this subchapter by a pharmacy benefit manager under section
20 9412 of this title as if the pharmacy benefit manager were a health insurer.

21 (d) The commissioner shall have the exclusive authority to investigate,
22 examine, and otherwise enforce the provisions of this subchapter relating to a
23 pharmacy benefit manager in connection with the pharmacy benefit manager's
24 contractual relationship with, and any other activity with respect to, a health
25 insurer defined by subdivision 9471(2)(A) of this title.

26 (e) Notwithstanding the foregoing, the commissioner and the attorney
27 general may bring a joint enforcement action against any person or entity for
28 a violation of this subchapter.

29 Sec. 8. 18 V.S.A. § 9421 is added to read:

30 § 9421. PHARMACY BENEFIT MANAGEMENT; REGISTRATION;

31 AUDIT

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

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1 ~~-(b) In accordance with rules adopted by the commissioner, pharmacy~~
2 benefit managers operating in the state of Vermont and proposing to contract
3 for the provision of pharmacy benefit management shall notify health insurers
4 that a quotation for an administrative-services-only contract with full pass
5 through of negotiated prices, rebates, and other such financial benefits which
6 would identify to the health insurer external sources of revenue and profit, is
7 available when the pharmacy benefit manager provides a quotation for any
8 other alternative pricing arrangement. Quotations for an administrative-
9 services-only contract shall include a reasonable fee payable by the health
10 insurer which represents a competitive pharmacy benefit profit.

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

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

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

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

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

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

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

30 (A) full pass through of negotiated drug prices and fees associated
31 ~~with all drugs dispensed to beneficiaries of the health plan in both retail and~~

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1 ~~mail order settings or resulting from any of the pharmacy benefit management~~
2 ~~functions defined in the contract;~~

3 (B) full pass through of all financial remuneration associated with all
4 drugs dispensed to beneficiaries of the health plan in both retail and mail
5 order settings or resulting from any of the pharmacy benefit management
6 functions defined in the contract; and

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

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

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

20 (f) As used in this section:

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

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

23 (3) "Pharmacy benefit management" is defined in subdivision 9471(4)

24 of this title.

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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~~

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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, the
8 University of Vermont area health center program, and the office of Vermont
9 health access shall establish an evidence-based prescription drug education
10 program for health care professionals designed to provide information and
11 education on the therapeutic and cost-effective utilization of prescription drugs
12 to physicians, pharmacists, and other health care professionals authorized to
13 prescribe and dispense prescription drugs. The department may collaborate
14 with other states in establishing this program.

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

20 (c) The department may contract for technical and clinical support in the
21 ~~development and the administration of the program from entities conducting~~

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~~independent research into the effectiveness of prescription drugs, such as the
Oregon Health and Science University Drug Effectiveness Review Project
(DERP).~~

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

~~*** Prescription Drug Data Confidentiality ***~~

~~Sec. 13. 18 V.S.A. chapter 9, 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
ensure the privacy of Vermonters and health care professionals by prohibiting
the commercial use of prescription information.

~~(b) As used in this section:~~

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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 26 of Title 26.

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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;

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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 ~~2. Each violation of this section or of any rules adopted under this section by~~

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

**** Prescription Drug Data Confidentiality ****

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 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.

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

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~~(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;~~

~~(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.~~

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~~(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. 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.~~

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1 ~~§ 4100f. PRESCRIPTION DRUG CO-PAYMENTS~~

2 ~~A health insurance or other health benefit plan offered by a health insurer~~
3 ~~licensed under this chapter shall require the insured to pay only the lesser of~~
4 ~~the co-payment required by the insurer or the usual retail cost of the~~
5 ~~prescription drug.~~

6 * * * Unconscionable Pricing * * *

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

8 Subchapter 5. Unconscionable Pricing

9 § 4651. PURPOSE

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

13 § 4652. DEFINITIONS

14 For purposes of this subchapter:

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

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

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

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

5 § 4653. UNCONSCIONABLE PRICING PROHIBITED

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

10 § 4654. SERIOUS PUBLIC HEALTH PROBLEM

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

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

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

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

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- 1 ~~(2) the costs to the state, employer sponsored insurance, and private~~
2 ~~insurers of treating the health condition with prescription drugs;~~
3 ~~(3) the cost of a prescription drug or a class of prescription drugs used to~~
4 ~~treat the health condition to the extent that information is available;~~
5 ~~(4) whether a prescription drug or class of prescription drugs is essential~~
6 ~~for maintaining health or life;~~
7 ~~(5) whether consumers affected with the health condition are unable to~~
8 ~~afford the prescription drug at the current price; and~~
9 ~~(6) other relevant factors as determined by the commissioner.~~

10 § 4655. UNCONSCIONABLE PRICING; PRIMA FACIE CASE

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

16 (b) If a prima facie case of unconscionable pricing is shown, the burdens of
17 providing evidence and of proving by a preponderance of the evidence shall
18 shift to the defendant to show that a prescription drug is not unconscionably
19 priced by showing the demonstrated costs of invention, development, and
20 production of the prescription drug, global sales and profits to date,
21 consideration of any government funded research that supported the

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1 ~~development of the drug, and the impact of price on access to a prescription~~
2 ~~drug by residents and the government of Vermont.~~

3 § 4656. CONSUMER FRAUD ACTION

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

8 § 4657. CIVIL ACTION

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

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

17 § 4658. REMEDIES FOR CIVIL ACTIONS

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

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~~(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;~~

~~(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 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 in Vermont 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~~

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~~1 A manufacturer of prescription drugs or its licensee shall not sell in~~
~~2 Vermont for an unconscionable price a prescription drug necessary to treat a~~
~~3 serious public health threat provided for in section 4654 of this title.~~

~~4 § 4654. SERIOUS PUBLIC HEALTH THREAT~~

~~5 (a)(1) The commissioner of health may issue a declaration that a health~~
~~6 condition or disease is prevalent in Vermont to such an extent as to constitute~~
~~7 a serious public health threat.~~

~~8 (2) The attorney general may request a determination by the~~
~~9 commissioner of health on whether a health condition or disease meets the~~
~~10 criteria in this section. If the attorney general makes a request under this~~
~~11 subdivision, the commissioner of health shall consider the request.~~

~~12 (b) At minimum, the commissioner shall consider the following factors~~
~~13 when declaring that a health condition or disease is a serious public health~~
~~14 threat:~~

~~15 (1) the number of Vermonters that suffer from the health condition;~~

~~16 (2) the costs to the state, employer-sponsored insurance, and private~~
~~17 insurers of treating the health condition with prescription drugs;~~

~~18 (3) the cost of a prescription drug or a class of prescription drugs used~~
~~19 to treat the health to the extent that information is available;~~

~~20 (4) whether a prescription drug or class of prescription drugs is~~
~~21 essential for maintaining health or life;~~

~~22 (5) whether consumers affected with the health condition are unable to~~
~~23 afford the prescription drug at the current price; and~~

~~24 (6) other relevant factors as determined by the commissioner.~~

~~25 § 4655. UNCONSCIONABLE PRICING; PRIMA FACIE CASE~~

~~26 (a) A prima facie case of unconscionable pricing as prohibited in section~~
~~27 4653 of this title shall be established where the manufacturer's price of a~~
~~28 prescription drug in Vermont is over 30 percent higher than the prices~~
~~29 available to federal agencies in Vermont under the federal supply schedule, the~~
~~30 prices available through the Healthy Vermonters program, or the most favored~~
~~31 purchase price available in Vermont.~~

~~32 (b) If a prima facie case of unconscionable pricing is shown, the burdens of~~
~~33 providing evidence and of proving by a preponderance of the evidence shall~~
~~34 shift to the defendant to show that a prescription drug is not unconscionably~~
~~35 priced by showing the demonstrated costs of invention, development, and~~
~~36 production of the prescription drug, global sales and profits to date,~~
~~37 consideration of any government-funded research that supported the~~

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~~1 development of the drug, and the impact of price on access to a prescription
2 drug by residents and the government of Vermont.~~

3 § 4656. CONSUMER FRAUD ACTION

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

8 § 4657. CIVIL ACTION

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

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

17 § 4658. REMEDIES FOR CIVIL ACTIONS

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

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

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

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

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

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

29 ¹⁶
Sec. 18. 33 V.S.A. § 1998a is added to read:

30 § 1998a. MANUFACTURER FEE

31 (a) For purposes of this section, "pharmaceutical manufacturer" shall have

32 ~~the same meaning as in section 4051 of Title 18.~~

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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 2466a(c)(1) of Title 9 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 ~~*** Consumer Protection, False Advertising ***~~

11 ~~Sec. 19.9 V.S.A. § 2466a is added to read:~~

12 § 2466a. CONSUMER PROTECTIONS; PRESCRIPTION DRUGS

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

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

17 (c)(1) It shall be a violation under this chapter for a manufacturer of
18 prescription drugs to present or cause to be presented in the state a regulated
19 advertisement, unless that advertisement meets the requirements concerning
20 misbranded drugs and devices and prescription drug advertising of federal law

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1 ~~and regulations under 21 United States Code, Sections 331 and 352(n) and 21~~
2 Code of Federal Regulations, Part 202 and state rules.

3 (2) For purposes of this section:

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

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

16 (d) No person shall sell, offer for sale, or distribute electronic prescribing
17 software that advertises, uses instant messaging and pop-up advertisements, or
18 uses other means to influence or attempt to influence the prescribing decision
19 of a health care professional through economic incentives or otherwise and
20 ~~which is triggered or in specific response to the input, selection, or act of a~~

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1 ~~health care professional or agent in prescribing a specific prescription drug or~~
2 ~~directing a patient to a certain pharmacy.~~

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

4 § 2466a. CONSUMER PROTECTIONS; PRESCRIPTION DRUGS

5 (a) A violation of section 4655 of Title 18 shall be considered a violation
6 under this chapter.

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

9 (c)(1) It shall be a violation under this chapter for a manufacturer of
10 prescription drugs to present or cause to be presented in the state a regulated
11 advertisement if that advertisement does not comply with the requirements
12 concerning misbranded drugs and devices and prescription drug advertising of
13 federal law and regulations under 21 United States Code, Sections 331 and
14 352(n) and 21 Code of Federal Regulations, Part 202 and state rules. A
15 warning or untitled letter issued by the U.S. Food and Drug Administration
16 shall be prima facie evidence of a violation of federal law and regulations.

17 (2) For purposes of this section:

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

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

31 (d) No person shall sell, offer for sale, or distribute electronic prescribing
32 software that advertises, uses instant messaging and pop-up advertisements, or
33 uses other means to influence or attempt to influence the prescribing decision
34 of a health care professional through economic incentives or otherwise and
35 which is triggered or in specific response to the input, selection, or act of a
36 health care professional or agent in prescribing a specific prescription drug or
37 directing a patient to a certain pharmacy. This subsection shall not apply to

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~~information provided to the health care professional about pharmacy reimbursement, prescription drug formulary compliance, and patient care management.~~

* * * Insurance Marketing * * *

¹⁸
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"

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1 ~~includes Medicare Part A, Medicare Part B, Medicare Part C, Medicare Part D,~~
2 ~~and Medicare supplement plans;~~

3 * * *

4 ¹⁹
Sec. ~~21~~ RECODIFICATION

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

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

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

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

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

11 ²⁰
Sec. ~~22~~ REPEAL

12 ~~Section 2009 of Title 33 is repealed.~~

RSL

ok to go

Please check this bill over and let us know if it is okay to send to the Governor. It is being checked by our editorial staff at this time. Does the title still reflect the bill?

Yes

TAB M

ORIGINAL

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1

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2

Introduced by Committee on Finance

3

Date: *February 23, 2007*

4

Subject: Health; insurance; prescription drugs; pharmaceuticals; pharmacy

5

benefit managers; drug education; preferred drug list; pricing;

6

confidentiality; pharmacy benefits; prompt pay

7

Statement of purpose: This bill proposes to increase transparency in

8

prescription drug information and pricing by limiting fraudulent advertising of

9

prescription drugs to consumers and health care professionals, requiring notice

10

to clients by pharmacy benefit managers that certain types of contracts are

11

available, strengthening the Medicaid preferred drug list, establishing an

12

evidence-based education program, providing additional pricing information to

13

the Medicaid program from drug manufacturers, requiring disclosure of

14

education programs funded by drug manufacturers, and providing enforcement

15

for prescription drug provisions under the Consumer Fraud Act.

16

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

18

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

Sec. 1. *LEGISLATIVE FINDINGS*

The general assembly makes the following findings:

(1) The state of Vermont has an interest in maximizing the well-being of its residents and in containing health care costs.

(2) There is a strong link between pharmaceutical marketing activities, health care spending, and the health of Vermonters.

(3) The goals of marketing programs are often in conflict with the goals of the state. Marketing programs are designed to increase sales, income, and profit. Frequently, progress toward these goals comes at the expense of cost-containment activities and possibly the health of individual patients.

(4) The marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand-name companies invest in expensive pharmaceutical marketing campaigns to doctors. The one-sided nature of the marketing leads to doctors prescribing drugs based on incomplete and biased information, particularly for prescribers that lack the time to perform substantive research assessing whether the messages they are receiving from pharmaceutical representatives are full and accurate.

(5) The federal Food and Drug Administration (FDA) requires marketing and advertising to be fair and balanced; however, the FDA has limited legal ability to enforce this requirement.

(6) Public health is ill served by the massive imbalance in information presented to doctors and other prescribers.

(7) Newer drugs on the market do not necessarily provide additional benefits over older drugs, but do add costs and as yet unknown side-effects. One example of this is the drug Vioxx, which was removed from the market due to potentially lethal side-effects that were not adequately disclosed initially.

(8) Between 1975 and 2000, 50 percent of all drug withdrawals from the market and "black box warnings" were within the first two years of the release of the drug. One-fifth of all drugs are subject to "black box warnings" or withdrawal from the market because of the serious public health concerns. Marketing which results in prescribers using the newest drugs will also result in prescribing drugs that are more likely to be subject to these warnings and withdrawal.

(9) In 2005, Vermonters spent an estimated \$524 million on prescription and over-the-counter drugs and nondurable medical supplies. In 2000, spending was about \$280 million. The annual increase in spending during this period was 13.3 percent, which was the highest increase in any health care category.

(10) Vermont has been a leader in prescription drug cost-containment and in providing transparency, to the extent allowable, in drug prices. The state has enacted the pharmacy best practices and cost control program, mandatory generic substitution, and mail order purchasing in Medicaid, VPharm, and Vermont Rx and encouraged the department of human resources to have a preferred drug list in the state employees health benefit plans in efforts to control costs, while maintaining best practices in drug prescribing, in our publicly-financed prescription drug programs. The Vermont Medicaid program has been a member of multi-state purchasing pools for several years and aggressively seeks supplemental rebates to lower drug costs in Medicaid program.

(11) In addition, Vermont has sought to control drug prices in private and employer-sponsored insurance by encouraging voluntary participation in Medicaid's preferred drug list, requiring mandatory generic substitution for all prescriptions in Vermont, providing consumers with pricing information about the drugs they are prescribed, and assisting consumers by providing information about purchasing drugs internationally through a safe, regulated program run through the state of Illinois.

(12) Vermont has also sought transparency by requiring marketers of prescription drugs to disclose information about the amount of money spent on marketing activities in Vermont and also to require the disclosure of pricing information to doctors during marketing visits.

(13) Physicians are unable to take the time to research the quickly changing pharmaceutical market and determine which drugs are the best treatments for particular conditions. Because of this, physicians frequently rely on information provided by pharmaceutical representatives.

(14) Nearly one-third of the five-fold increase in U.S. spending on drugs over the last decade can be attributed to marketing induced shifts in doctors' prescribing from existing, effective, and lower cost (often generic) therapies to new and more expensive treatments, which often have little or no increased

therapeutic value. According to the same study, the use of more expensive drugs contributed to 36 percent of the rise in retail prescription spending in 2000 and 24 percent in 2001.

(15) According to testimony by Dr. Avorn, M.D., at Brigham and Women's Hospital, detailing affects the cost of medications, because it is generally "confined to high-margin, high-profit drugs, for which the manufacturer has a substantial incentive to increase sales. . . . Thus, the work of pharmaceutical sales representatives drives drug use toward the most expensive products . . . , and contributes to the strain on health care budgets for individuals as well as health care programs."

(16) According to the June 15, 2006 Marketing Disclosures: Report of Vermont Attorney General William H. Sorrell, as part of their marketing efforts, pharmaceutical companies made direct payments of almost \$2.2 million to prescribers in Vermont, including consulting fees and travel expenses in 2005. Estimates of total costs of marketing to prescribers in Vermont are \$10 million or more, excluding free samples and direct-to-consumer advertising.

(17) In 2004, the pharmaceutical industry spent \$27 billion marketing pharmaceuticals in the United States, and spent more than any other sector in the United States on its sales force and media advertising. Over 85 percent of these marketing expenditures are directed at the small percentage of the population that practice medicine. Pharmaceutical manufacturers spend twice as much on marketing as on research and development.

(18) Coincident with the rise of physician identity data mining, the pharmaceutical industry increased its spending on direct marketing to doctors by over 275 percent and doubled its sales force to over 90,000 drug representatives. It is estimated that there is a pharmaceutical sales representative for every five office-based physicians.

(19) A significant portion of prescriber time is spent meeting with pharmaceutical representatives. According to a survey recently published in the New England Journal of Medicine, family practitioners reported the highest frequency of meetings with representatives – an average of 16 times per month. To the extent that this meeting time comes at the expense of time spent with patients, quality of care will be negatively affected.

(20) Some doctors in Vermont are experiencing an undesired increase in the aggressiveness of pharmaceutical sales representatives and a few have reported that they felt coerced and harassed. The Vermont Medical Society, an organization representing two-thirds of Vermont doctors, unanimously passed a resolution stating "the use of physician prescription information by sales representatives is an intrusion into the way physicians practice medicine."

(21) Several studies suggest that drug samples clearly affect prescribing behavior in favor of the sample. The presence of drug samples may influence physicians to dispense or prescribe drugs that differ from their preferred drug source according to a study by Chew et al. in the Journal of General Internal Medicine in 2000.

(22) Prescriber-identifiable prescription data show details of physicians' drug use patterns, both in terms of their gross number of prescriptions and their inclinations to prescribe particular drugs.

(23) Prescriber identity data mining allows pharmaceutical companies to track the prescribing habits of nearly every physician in Vermont and link those habits to specific physicians and their identities.

(24) Monitoring of prescribing practices also allows the sales representatives to assess the impact of various gifts and messages on a particular physician to help them select the most effective set of rewards.

(25) Prescriber-identified data increase the effect of detailing programs. They support the tailoring of presentations to individual prescriber styles, preferences, and attitudes.

(26) Prescriber identified databases of prescribing habits encourage pharmaceutical companies to increase the quid pro quo nature of relations between pharmaceutical sales representatives and prescribers. Pharmaceutical companies use prescriber identity data-mining to target increased attention and manipulative practices toward those doctors that they find would lead to increased prescriptions and profitability, including high prescribers, brand loyal prescribers, doctors that show themselves willing to prescribe new medicines, and doctors who are shown to be especially susceptible to sales messages.

(27) Added and unwanted pressure occurs when doctors are informed by sales representatives that they are being monitored – through messages of

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appreciation for writing prescriptions, or messages of disappointment that they are not prescribing what was implicitly promised.

(28) As with the use of consumer telephone numbers for marketing, the trading of prescriber identities linked to prescription data can result in harassing sales behaviors by pharmaceutical sales representatives toward doctors.

(29) Health care professionals in Vermont who write prescriptions for their patients have a reasonable expectation that the information in that prescription, including their own identity and that of the patient, will not be used for purposes other than the filling and processing of the payment for that prescription. Prescribers and patients do not consent to the trade of that information to third parties, and no such trade should take place without their consent.

(30) The physician data restriction program offered by the American Medical Association (AMA) is not an adequate remedy for Vermont doctors, because many physicians do not know about the program and other health care professionals who prescribe medications may not avail themselves of the AMA program. In addition, approximately 23 percent of Vermont physicians belong to the AMA, which is one of the lowest rates in the nation. Finally, data-mining companies could use other identifiers, including state licensing numbers, to track prescribing patterns.

(31) This act is necessary to protect prescriber privacy by limiting marketing to prescribers who choose to receive that type of information, to save money for the state, consumers, and businesses by promoting the use of less expensive drugs, and to protect public health by requiring evidence-based disclosures and promoting drugs with longer safety records.

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

§ 1998. PHARMACY BEST PRACTICES AND COST CONTROL PROGRAM ESTABLISHED

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

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

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

~~(B) The commissioner of human resources shall use the preferred drug list in the state employees health benefit plan only if participation in the program will provide economic and health benefits to the state employees health benefit plan and to beneficiaries of the plan, and only if agreed to through the bargaining process between the state of Vermont and the authorized representatives of the employees of the state of Vermont. The provisions of this subdivision do not authorize the actuarial pooling of the state employees health benefit plan with any other health benefit plan, unless otherwise agreed to through the bargaining process between the state of Vermont and the authorized representatives of the employees of the state of Vermont. No later than November 1, 2004, the commissioner of human resources shall report to the health access oversight committee and the senate and house committees on health and welfare on whether use of the preferred drug list in the state employees health benefit plan would, in his or her opinion, provide economic and health benefits to the state employees health benefit plan and to beneficiaries of the plan.~~

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

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

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

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

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

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

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

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

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

* * *

(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

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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, workers' compensation, and any other state or publicly funded purchaser of prescription drugs.

* * *

(f)(1) The drug utilization review board shall make recommendations to the director for the adoption of the preferred drug list. The board's recommendations shall be based upon evidence-based considerations of clinical efficacy, adverse side effects, safety, appropriate clinical trials, and cost-effectiveness. "Evidence-based" shall have the same meaning as in section 4622 of Title 18.

* * *

(6) The director shall encourage participation in the joint purchasing consortium by inviting representatives of the programs and entities specified in subdivision (c)(1) 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 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.

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

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

(4) The following shall be exempt from disclosure:

* * *

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

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

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

* * *

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

Sec. 5. 33 V.S.A. § 2005a(d) is amended to read:

(d) As used in this section:

* * *

(2) "Pharmaceutical manufacturing company" is defined by subdivision 2005(e)(5) 4632(c)(5) of this title.

(3) "Pharmaceutical marketer" is defined by subdivision 2005(e)(4) 4632(c)(4) of this title.

* * * Price Disclosure and Certification * * *

Sec. 6. 33 V.S.A. § 2010 is added to read:

§ 2010. ACTUAL PRICE DISCLOSURE AND CERTIFICATION

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

(1) the prices required to be provided to the Medicaid program under federal law, including prices defined in 42 U.S.C. § 1396r-8; and

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

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

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

(d) When a manufacturer of prescription drugs dispensed in this state reports the 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.

(e) Notwithstanding any provision of law to the contrary, information submitted to the office under this section is confidential and is not a public record as defined in subsection 317(b) of Title 1. Disclosure may be made by the office to an entity providing services to the office under this section; however, that disclosure does not change the confidential status of the information. The information may be used by the entity only for the purpose specified by the office in its contract with the entity. Data compiled in aggregate form by the office for the purposes of reporting required by this section are public records as defined in subsection 317(b) of Title 1, provided they do not reveal trade information protected by state or federal law.

(f) The attorney general shall enforce the provisions of this section under the Vermont consumer fraud act in chapter 63 of Title 9. The attorney general has the same authority to make rules, conduct civil investigations, and bring civil actions with respect to acts and practices governed by this section as is provided under the Vermont consumer fraud act.

* * * Healthy Vermonters * * *

Sec. 7. 33 V.S.A. § 2003 is amended to read:

§ 2003. PHARMACY DISCOUNT PLANS

(a) The director of the office of Vermont health access shall implement pharmacy discount plans, to be known as the "Healthy Vermonters" program and the ~~"Healthy Vermonters Plus"~~ program, for Vermonters without adequate coverage for prescription drugs. The provisions of ~~section 1992 of~~

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~~this title subchapter 8 of this chapter shall apply to the director's authority to administer the pharmacy discount plans established by this section.~~

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

* * *

(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~~ 350 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 household income or whose total unreimbursed medical expenses, including insurance premiums, equal 15 percent or more of household income.~~

* * *

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*** PBM Regulation ***

Sec. 8. 18 V.S.A. chapter 221, subchapter 9 is added to read:

Subchapter 9. Pharmacy Benefit Managers

§ 9471. DEFINITIONS

As used in this subchapter:

(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.

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

(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.

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

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

(A) mail service pharmacy;

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

(C) clinical formulary development and management services;

(D) rebate contracting and administration;

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

(F) disease or chronic care management programs.

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

§ 9472. PHARMACY BENEFIT MANAGERS; REQUIRED PRACTICES

(a) A pharmacy benefit manager that provides pharmacy benefit management for a health plan shall discharge its duties with reasonable care and diligence and be fair and truthful under the circumstances then prevailing that a 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.

(b) A pharmacy benefit manager shall provide notice to the health insurer that the terms contained in subsection (c) of this section may be included in the contract between the pharmacy benefit manager and the health insurer.

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

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

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

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

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

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

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

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

(3) With regard to the dispensation of a substitute prescription drug for a prescribed drug to a beneficiary in which the substitute drug costs more than the prescribed drug and the pharmacy benefit manager receives a benefit or payment directly or indirectly, disclose to the health insurer the cost of both drugs and the benefit or payment directly or indirectly accruing to the pharmacy benefit manager as a result of the substitution.

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

(5) Disclose to the health insurer all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefit manager and any prescription drug manufacturer that relate to benefits provided to beneficiaries under or services to the health insurer's health plan, including formulary management and drug-switch programs, educational support, claims processing, and pharmacy network fees charged from retail pharmacies and data sales fees. A pharmacy benefit manager providing information under this subsection may designate that material as confidential.

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Information designated as confidential by a pharmacy benefit manager and provided to a health insurer under this subsection may not be disclosed by the health insurer to any person without the consent of the pharmacy benefit manager, except that disclosure may be made by the health insurer:

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

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

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

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

(d) 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.

§ 9473. ENFORCEMENT

(a) Except as provided in subsection (d) of this section, in addition to any remedy available to the commissioner under this title and any other remedy provided by law, a violation of this subchapter shall be considered a violation of the Vermont consumer fraud act in subchapter 1 of chapter 63 of Title 1. Except as provided in subsection (d) of this section, all rights, authority, and remedies available to the attorney general and private parties to enforce the Vermont consumer fraud act shall be available to enforce the provisions of this subchapter.

(b) In connection with any action for violation of the Vermont consumer fraud act, the commissioner's determinations concerning the interpretation and administration of the provisions of this subchapter and any rules adopted hereunder shall carry a presumption of validity. The attorney general and the commissioner shall consult with each other prior to the commencement of any investigation or enforcement action with respect to any pharmacy benefit manager.

(c) The commissioner may investigate, examine, or otherwise enforce a

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violation of this subchapter by a pharmacy benefit manager under section 9412 of this title as if the pharmacy benefit manager were a health insurer.

(d) The commissioner shall have the exclusive authority to investigate, examine, and otherwise enforce the provisions of this subchapter relating to a pharmacy benefit manager in connection with the pharmacy benefit manager's contractual relationship with, and any other activity with respect to, a health insurer defined by subdivision 9471(2)(A) of this title.

(e) Notwithstanding the foregoing, the commissioner and the attorney general may bring a joint enforcement action against any person or entity for a violation of this subchapter.

Sec. 9. 18 V.S.A. § 9421 is added to read:

§ 9421. PHARMACY BENEFIT MANAGEMENT; REGISTRATION; AUDIT

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

(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) 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:

(1) 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 the contract;

(2) 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 the contract; and

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

(d) The department's reasonable expenses in administering the provisions of this section may be charged to pharmacy benefit managers in the manner provided for in section 18 of Title 8. These expenses shall be allocated in proportion to the lives of Vermonters covered by each pharmacy benefit manager as reported annually to the commissioner in a manner and form prescribed by the commissioner. The department shall not charge its expenses to the pharmacy benefit manager contracting with the office of Vermont health access if the office notifies the department of the conditions contained in its contract with a pharmacy benefit manager.

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

(f) As used in this section:

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

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

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

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

Sec. 10. APPLICATION

Secs. 8 and 9 of this act apply to contracts executed or renewed on or after September 1, 2007. For purposes of this section, a contract executed pursuant to a memorandum of agreement executed prior to September 1, 2007 is deemed to have been executed prior to September 1, 2007 even if the contract was executed after that date.

Sec. 11. 8 V.S.A. § 4088d is added to read:

§ 4088d. NOTICE OF PREFERRED DRUG LIST CHANGES

On a periodic basis, no less than once per calendar year, a health insurer as defined in subdivisions 9471(2)(A), (C), and (D) of Title 18 shall notify beneficiaries of changes in pharmaceutical coverage and provide access to the preferred drug list maintained by the insurer.

Sec. 12. 18 V.S.A. chapter 91 is amended to read:

CHAPTER 91. GENERIC DRUGS PRESCRIPTION DRUG
COST CONTAINMENT

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

Subchapter 1. Generic Drugs

Sec. 14. 18 V.S.A. chapter 91, subchapter 2 is added to read:

Subchapter 2. Evidence-Based Education Program

§ 4621. DEFINITIONS

For the purposes of this subchapter:

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

(2) "Evidence-based" means based on criteria and guidelines that reflect high-quality, cost-effective care. The methodology used to determine such guidelines shall meet recognized standards for systematic evaluation of all available research and shall be free from conflicts of interest. Consideration of the best available scientific evidence does not preclude consideration of experimental or investigational treatment or services under a clinical investigation approved by an institutional review board.

§ 4622. EVIDENCE-BASED EDUCATION PROGRAM

(a)(1) The department, in collaboration with the attorney general, the University of Vermont area health education centers program, and the office of Vermont health access, shall establish an evidence-based prescription drug education program for health care professionals designed to provide information and education on the therapeutic and cost-effective utilization of prescription drugs to physicians, pharmacists, and other health care professionals authorized to prescribe and dispense prescription drugs. To the extent practicable, the program shall use the evidence-based standards developed by the blueprint for health. The department may collaborate with other states in establishing this program.

(2) The program shall notify prescribers about commonly used brand-name drugs for which the patent has expired within the last 12 months or will expire within the next 12 months. The department and the office of Vermont health access shall collaborate in issuing the notices.

(3) To the extent permitted by funding, the program may include the distribution to prescribers of vouchers for samples of generic medicines used for health conditions common in Vermont.

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

(c) The department may contract for technical and clinical support in the development and the administration of the program from entities conducting independent research into the effectiveness of prescription drugs.

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

Sec. 15. GENERIC DRUG VOUCHER PILOT PROJECT

(a) As part of the evidence-based education program established in subchapter 2 of chapter 91 of Title 18, the department of health, in collaboration with the office of Vermont health access and the University of Vermont area health education centers program, shall establish a pilot project

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to distribute vouchers for a sample of generic drugs equivalent to frequently prescribed prescription drugs that are used to treat common health conditions.

(b) The office of Vermont health access shall fund the vouchers from the fee established in section 1998b of Title 33 and shall provide payment to the pharmacy dispensing the prescription drugs in exchange for the voucher. The office shall establish a payment rate, including a dispensing fee, using the rules and procedures for the Medicaid program.

Sec. 15a. GENERIC DRUG VOUCHER PILOT; REPORT

(a) By January 15, 2009, the office of Vermont health access, the department of banking, insurance, securities, and health care administration, the area health education centers, and the joint fiscal office shall provide a report to the house committee on health care and the senate committee on health and welfare describing and evaluating the effects of the generic drug voucher pilot program.

(b) The report shall describe how the pilot project is implemented, including which health conditions were targeted, the generic drugs provided with the vouchers, and the geographic regions participating. The report shall compare the distribution of prescribing among generic drugs provided through the vouchers and brand-name drugs before and after the first year of the generic drug sample pilot project and will review a year of prescribing data prior to the implementation of the pilot project to a year of prescribing data during the first year of the pilot project's implementation. The data shall be adjusted to reflect how and where the pilot was implemented.

Sec. 16. PRESCRIPTION DRUG PRICING; FEDERALLY QUALIFIED HEALTH CENTERS

No later than January 1, 2008, the department of health shall create a plan to inform Vermonters of the availability of health services provided by federally qualified health centers (FQHC) and FQHC look-alikes, including information about prescription drug pricing, focusing on 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 for whom the cost of prescription drugs is likely to be higher than prices under Section 340B of the Public Health Service Act.

*** Prescription Drug Data Confidentiality ***

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Sec. 17. 18 V.S.A. chapter 91, subchapter 3 is added to read:

Subchapter 3. Information Requirements

§ 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

(a) It is the intent of the general assembly to advance the state's interest in protecting the public health of Vermonters, protecting the privacy of prescribers and prescribing information, and to ensure costs are contained in the private health care sector, as well as for state purchasers of prescription drugs, through the promotion of less costly drugs and ensuring prescribers receive unbiased information.

(b) As used in this section:

(1) "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.

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

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

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

(5) "Marketing" shall include advertising, promotion, or any activity that is intended to be used or is used to influence sales or the market share of a prescription drug, influence or evaluate the prescribing behavior of an individual health care professional to promote a prescription drug, market prescription drugs to patients, or evaluate the effectiveness of a professional pharmaceutical detailing sales force.

(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) "Promotion" or "promote" means any activity or product the intention of which is to advertise or publicize a prescription drug, including a brochure, media advertisement or announcement, poster, free sample, detailing visit, or personal appearance.

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

(c)(1) The department of health and the office of professional regulation, in consultation with the appropriate licensing boards, shall establish a prescriber data-sharing program to allow a prescriber to give consent for his or her identifying information to be used for the purposes described under subsection (d) of this section. The department and office shall solicit the prescriber's consent on licensing applications or renewal forms and shall provide a prescriber a method for revoking his or her consent. The department and office may establish rules for this program.

(2) The department or office shall make available the list of prescribers who have consented to sharing their information. Entities who wish to use the information as provided for in this section shall review the list at minimum every six months.

(d) A health insurer, a self-insured employer, an electronic transmission intermediary, a pharmacy, or other similar entity may use regulated records which include prescription information containing prescriber-identifiable data for marketing or promoting a prescription drug only if:

(1)(A) a prescriber has provided consent for the use of that data as provided in subsection (c) of this section; and

(B) the entity using the regulated records complies with the disclosure requirements in subsection (f) of this section; or

(2) the entity meets one of the exceptions provided in subsection (e) of this section.

(e) 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;

(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; and

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

(f) When a pharmaceutical marketer engages in any form of prescription drug marketing directly to a physician or other person authorized to prescribe prescription drugs as provided for under this section, the marketer shall disclose to the prescriber evidence-based information as provided for by rule describing the specific health benefits or risks of using other pharmaceutical drugs, including drugs available over the counter; which patients would gain from the health benefits or be susceptible to the risks described; the range of prescription drug treatment options; and the cost of the treatment options. As necessary, the office of Vermont health access, in consultation with the department of health, the area centers on health education, the office of professional regulation, and the office of the attorney general, shall develop

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rules for compliance with this subsection, including the certification of materials which are evidence-based as defined in section 4621 of this title and which conditions have evidence-based treatment guidelines. The rules shall be consistent with the federal Food and Drug Administration's regulations regarding false and misleading advertising. To the extent practicable, the rules shall use the evidence-based standards developed by the blueprint for health.

(g) 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. 18. 1 V.S.A. § 317(c)(38) and (39) are added to read:

(38) records held by the agency of human services, which include prescription information containing prescriber-identifiable data, that could be used to identify a prescriber, except that the records shall be made available upon request for medical research, consistent with and for purposes expressed in sections 4621, 4631, 4632, 4633, and 9410 of Title 18 and chapter 84 of Title 18, or as provided for in chapter 84A of Title 18 and for other law enforcement activities.

(39) records held by the agency of human services or the department of banking, insurance, securities and health care administration, which include prescription information containing patient-identifiable data, that could be used to identify a patient.

Sec. 19. 18 V.S.A. § 9410(g) is amended to read:

(g) Any person who knowingly fails to comply with the requirements of this section or rules adopted pursuant to this section shall be ~~fin~~ed subject to an administrative penalty of not more than \$1,000.00 per violation. The commissioner may impose an administrative penalty of not more than \$10,000.00 each for those violations the commissioner finds were willful. In addition, any person who knowingly fails to comply with the confidentiality requirements of this section or confidentiality rules adopted pursuant to this

section and uses, sells, or transfers the data or information for commercial advantage, pecuniary gain, personal gain, or malicious harm shall be subject to an administrative penalty of not more than \$50,000.00 per violation. The powers vested in the commissioner by this subsection shall be in addition to any other powers to enforce any penalties, fines, or forfeitures authorized by law.

Sec. 20. 33 V.S.A. § 2004 is added to read:

§ 2004. MANUFACTURER FEE

(a) Annually, each pharmaceutical manufacturer or labeler of prescription drugs that are paid for by the office of Vermont health access for individuals participating in Medicaid, the Vermont Health Access Program, Dr. Dynasaur, VPharm, or Vermont Rx shall pay a fee to the agency of human services. The fee shall be 0.5 percent of the previous calendar year's prescription drug spending by the office and shall be assessed based on manufacturer labeler codes as used in the Medicaid rebate program.

(b) Fees collected under this section shall fund collection and analysis of information on pharmaceutical marketing activities under sections 4632 and 4633 of Title 18, analysis of prescription drug data needed by the attorney general's office for enforcement activities, and the evidence-based education program established in subchapter 2 of Title 18. The fees shall be collected in the evidence-based education and advertising fund established in section 2004a of this title.

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

Sec. 20a. 33 V.S.A. § 2004a is added to read:

§ 2004a. EVIDENCE-BASED EDUCATION AND ADVERTISING FUND

(a) The evidence-based education and advertising fund is established in the treasury as a special fund to be a source of financing for activities relating to fund collection and analysis of information on pharmaceutical marketing activities under sections 4632 and 4633 of Title 18, analysis of prescription drug data needed by the attorney general's office for enforcement activities, and for the evidence-based education program established in subchapter 2 of Title 18. Monies deposited into the fund shall be used for the purposes described in this section.

(b) Into the fund shall be deposited:

(1) revenue from the manufacturer fee established under section 2004 of this title; and

(2) the proceeds from grants, donations, contributions, taxes, and any other sources of revenue as may be provided by statute, rule, or act of the general assembly.

(c) The fund shall be administered pursuant to subchapter 5 of chapter 7 of Title 32, except that interest earned on the fund and any remaining balance shall be retained in the fund.

* * * Consumer Protection; False Advertising * * *

Sec. 21. 9 V.S.A. § 2466a is added to read:

§ 2466a. CONSUMER PROTECTIONS; PRESCRIPTION DRUGS

(a) A violation of section 4631 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 if that advertisement does not comply with the requirements concerning drugs and devices and prescription drug advertising in 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. A warning or untitled letter issued by the U.S. Food and Drug Administration shall be prima facie evidence of a violation of federal law and regulations.

(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).

(B) "Regulated advertisement" means:

(i) 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; or

(ii) a commercial message regarding a prescription drug or biological product by a manufacturer of prescription drugs or its representative that is conveyed:

(I) to the office of a health care professional doing business in Vermont, including statements by representatives or employees of the manufacturer and materials mailed or delivered to the office; or

(II) at a conference or other professional meeting occurring in Vermont.

(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. This subsection shall not apply to information provided to the health care professional about pharmacy reimbursement, prescription drug formulary compliance, and patient care management.

*** Insurance Marketing ***

Sec. 22. 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:

(A)(i) sell, solicit, or negotiate the purchase of health insurance in this state through an advertisement which makes 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.

(ii) Use 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 requests the solicitation, and the products to be discussed are clearly identified to the consumer in writing at least 48 hours in advance of the appointment.

(iii) Solicit the sale of Medicare products door-to-door prior to receiving an invitation from a consumer.

(B) 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. 22a. LITIGATION REPORT; AUDITOR

Beginning January 1, 2008 and annually thereafter, the state auditor shall provide a report to the general assembly with a detailed accounting of all amounts paid by the state with state or federal funds in connection with any litigation challenging the validity of this act or a section of this act. The report shall include costs, fees, damages, amounts paid to expert witnesses, salaries and benefits of state employees who work on the litigation, amounts paid to individuals under contract with the state who work on the litigation, attorney's fees awarded to the other party, any other amounts awarded by the court, and the number of hours spent by state employees involved in the litigation.

Sec. 23. 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.
- (4) Section 2006 shall be section 852 of Title 2.

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Sec. 24. REPEAL

Section 2009 of Title 33 is repealed.

Sec. 24a. APPROPRIATIONS

(a) The amount of \$200,000.00 is appropriated from the evidence-based education and advertising fund to the department of health for a grant to the area health education centers for the evidence-based education program established under subchapter 2 of Title 18.

(b) The amount of \$300,000.00 is appropriated from the evidence-based education and advertising fund to the office of Vermont health access for the evidence-based education program's generic drug sample pilot project as described in Sec. 15 of this act.

(c) The amount of \$50,000.00 is appropriated from the evidence-based education and advertising fund to the office of attorney general fund for the collection and analysis of information on pharmaceutical marketing activities under sections 4632 and 4633 of Title 18 and analysis of prescription drug data needed by the attorney general's office for enforcement activities.

Sec. 24b. EFFECTIVE DATES

Sec. 17 of this act shall become effective no later than January 1, 2008, except that the department of health and the office of professional regulation may begin any necessary rulemaking, revision of forms, or other administrative actions necessary to implement the program, immediately upon passage. The department and office may implement Sec. 17 for prescribers with licenses at the time of passage of this act when the prescriber next requests a renewal of the license.

ATTESTED TO:

David A. Gibson
DAVID A. GIBSON
Secretary of the Senate

Brian J. White

PRESIDENT OF THE SENATE

Carolyn E. Brown

SPEAKER OF THE HOUSE OF REPRESENTATIVES

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John D. Felt

GOVERNOR

6/9/07
Date

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~~