PX 12

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

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

TAB

A

Date: 2/13/07
PX 89 LR 1426-1463
As originally introduced, including a New Hampshire-style ban on prescriber-identifiable data.

B

Date: 3/13/07 (1:57)
PX 81 LC 338-359
Contains the Senate Health and Welfare version of the bill, which removes the prescription drug confidentiality and inserts a legislative counsel report on the result of the NH lawsuit.
(Version LC 000381 contains handwritten notes noting testimony prior to the amendment.)

C

Date: 4/10/07 (handwritten)
PX 89 LR 182-226
Version as passed by the Senate, which includes a New Hampshire-style ban on prescriber-identifiable information.

D

Date: 4/24/07 (5:40)
PX 81 LC 002769-002804]
Contains the House Health Care Committee version of the bill, which includes a New Hampshire-style ban.

E

Date: 5/1/07 (11:26 a.m.)
PX 81 LC 002652-002657
Contains 7 findings regarding Vermont spending on prescription drugs; spending by manufacturers on marketing in Vermont; therapeutic choices have impacts on third-party payers; and marketing impacts on prescriber providing patterns.

F

Date: 5/2/07 (10:14 a.m.)
PX 81 LC 002631-002644
Amendment prepared regarding House Health Care Committee Changes. Contains 24 findings and the prescriber opt-in language.

G

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

H

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

I

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

J

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

K

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

L

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

M

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

TAB A

Introduced by Committee on Finance

Date:

Subject: Health; prescription drugs; pharmaceuticals; pharmacy benefit managers; drug education; preferred drug list; pricing; confidentiality

Statement of purpose: This bill proposes to increase transparency in prescription drug information and pricing by limiting fraudulent advertising of prescription drugs to consumers and health care professionals, requiring increased disclosure to clients by pharmacy benefit managers, strengthening the Medicaid preferred drug list, establishing an evidence-based education program, providing additional pricing information to the Medicaid program from drug manufacturers, and requiring disclosure of education programs funded by drug manufacturers.

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

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

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 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 plan to encourage Vermonters to use federally qualified health centers (FQHC) and FQHC look-alikes, focusing on participants in the

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

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

~~(8)~~(9) 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 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. "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, 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) 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, in collaboration with the department of health, shall enter into a contract with the Oregon Health and Science University Drug Effectiveness Review Project (DERP) to provide technical and clinical support

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

* * * Pharmaceutical Marketer Disclosures * * *

Sec. 3. 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.

* * * Price Disclosure and Certification * * *

Sec. 4. 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); and

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

(b) 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).

(c) When a manufacturer of prescription drugs dispensed in this state reports the average manufacturer price or best price, the president or chief executive officer 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.

(d) 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.

(e) The attorney general shall enforce the provisions of this section under the Vermont Consumer Fraud Act in subchapter 1 of chapter 63 of Title 1. 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 Plus * * *

Sec. 5. 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~~ 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.

* * *

(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. 6. 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. As used in this subchapter, the term includes the state of Vermont and any agent or instrumentality of the state that offers, administers, or provides financial support to state government. It also includes 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 management programs.

(5) "Pharmacy benefit manager" means an entity that performs pharmacy benefit management. The term includes a person or entity acting for a pharmacy benefit manager in a contractual or employment relationship in the performance of 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:

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

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

(2) Provide all financial and utilization information requested by a health plan relating to the provision of benefits to beneficiaries through that health plan and all financial and utilization information relating to services to that health plan. 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 plan under this subsection may not be disclosed by the health plan to any person without the consent of the pharmacy benefit manager, except that disclosure may be made in a court filing under the consumer fraud provisions of chapter 63 of Title 9 or when authorized by that chapter or ordered by a court for good cause shown.

(3) Notify a health plan 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.

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

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

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

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

(5) 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 plan, unless the contract between the pharmacy benefit manager and the health plan provides otherwise.

(6) Disclose to the health plan all financial terms and arrangements for remuneration of any kind that apply between the pharmacy benefit manager and any prescription drug manufacturer, including formulary management and drug-switch programs, educational support, claims processing, 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 plan under this subsection

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

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

Sec. 7. 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 services shall offer health insurance plans 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 insurance plan external sources of revenue and profit, in addition to quotations for any other alternative pricing arrangement. Quotations for an administrative-services-only contract shall include a reasonable fee payable by the health insurance plan which represents a competitive pharmacy benefit profit.

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

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

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

(3) any other verifications relating to the pricing arrangements and activities of the pharmacy benefit manager 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. Such 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.

(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 health insurance plans.

(f) As used in this section:

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

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

(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. 8. APPLICATION

Sec. 6 and 7 of this act applies 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. 9. 18 V.S.A. chapter 91 is amended to read:

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

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

Subchapter 1. Generic Drugs

Sec. 11. 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) The department, in collaboration with the attorney general, 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.

(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) As provided for under subsection 1998(g) of this title, the department shall have technical and clinical support in the development and the administration of the program from 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. 12. 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.

(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; health care research; or as otherwise provided by law;

(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, or clinical trials;

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

(6) 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 rules adopted under this section. The attorney general shall have the same authority to investigate and to obtain remedies as if the action were brought under the consumer fraud act, chapter 63 of Title 9. Each violation of this section or of rules adopted under this section constitutes a separate civil violation for which the attorney general may obtain relief.

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

(e)(1) Records or information protected by the provisions of the physician-patient privilege under subsection 1612(a) of Title 12, 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.

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

Sec. 14. 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. 15. 8 V.S.A. § 4100f is added to read:

§ 4100f. PRESCRIPTION DRUG CO-PAYMENTS

A health insurance or other health benefit plan offered by a health insurer licensed under this chapter or a prescription drug plan offering coverage under Medicare Part C or D 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. 16. 18 V.S.A. chapter 91, subchapter 5 is added to read:

Subchapter 5. Unconscionable Pricing

§ 4651. PURPOSE

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

§ 4652. DEFINITIONS

For purposes of this subchapter:

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

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

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

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

§ 4653. UNCONSIONABLE PRICING OF PRESCRIPTION DRUGS

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

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

§ 4653. SPECIFIED HEALTH CONDITION

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

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

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

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

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

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

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

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

§ 4654. UNCONSCIONABLE PRICING

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

§ 4655. CIVIL INVESTIGATION

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

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

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

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

§ 4656. CIVIL ACTION

(a) Any affected party, including the attorney general on behalf of the state, 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. If the state is the plaintiff, it may seek remedies on its own behalf or on behalf of all residents, or both.

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

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

(c) 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.

§ 4657. REMEDIES

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

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

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

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

(4) 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;

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

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

(b) Any person who violates the terms of an injunction issued under this section shall forfeit and pay to the state a civil penalty of not more than $10,000.00 for each violation. For the purposes of this section, the court issuing such injunction shall retain jurisdiction, and the cause shall be continued, and in such cases, the attorney general or a state's attorney acting in the name of the state may petition for recovery of such civil penalty.

* * * FALSE ADVERTISING * * *

Sec. 17. 18 V.S.A. chapter 82 is amended to read:

CHAPTER 82. LABELING AND ADVERTISING OF FOODS, DRUGS, COSMETICS, AND HAZARDOUS SUBSTANCES

§ 4051. DEFINITIONS

For the purposes of this chapter:

* * *

(25) "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).

(26) "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 or radio from a station 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.

§ 4052. MANUFACTURE, SALE, DELIVERY; PROHIBITIONS

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

* * *

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

(13) 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.

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

* * *

§ 4054. PENALTIES

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

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

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

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

* * *

§ 4068. ADVERTISING REGULATIONS

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

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

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

* * *

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

§ 1998a. MANUFACTURER FEE

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

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

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

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

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

§ 2466a. CONSUMER PROTECTIONS; PRESCRIPTION DRUGS

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

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

(1) 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.

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

Sec. 20. 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.

Sec. 21. REPEAL

Section 2009 of Title 33 is repealed.

TAB B

A-1525

LC 000338

(Draft No. 1 – S.115)
3/13/2007 - RJL - 1:57 pm

TO THE HONORABLE SENATE

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

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

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

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

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

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

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

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

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

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

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

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

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

symbol "* * *" the following:

(c) As used in this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Subchapter 3. Information Requirements

§ 4631. CONFIDENTIALITY OF PRESCRIPTION INFORMATION

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

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.

(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.

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

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

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

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

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

Subchapter 4. Consumer Provisions

§ 4641. CO-PAYMENT PRICING

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

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

§ 4100f. PRESCRIPTION DRUG CO-PAYMENTS

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

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

* * * Unconscionable Pricing * * *

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

Subchapter 5. Unconscionable Pricing

§ 4651. PURPOSE

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

§ 4652. DEFINITIONS

For purposes of this subchapter:

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

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

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

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

§ 4653. UNCONSCIONABLE PRICING PROHIBITED

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

§ 4654. SERIOUS PUBLIC HEALTH PROBLEM

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

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

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

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

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

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

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

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

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

§ 4655. UNCONSCIONABLE PRICING; PRIMA FACIE CASE

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

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

§ 4656. CONSUMER FRAUD ACTION

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

§ 4657. CIVIL ACTION

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

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

§ 4658. REMEDIES FOR CIVIL ACTIONS

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

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

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

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

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

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

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

§ 1998a. MANUFACTURER FEE

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

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

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

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

* * * Consumer Protection; False Advertising * * *

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

§ 2466a. CONSUMER PROTECTIONS; PRESCRIPTION DRUGS

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

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

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

(2) For purposes of this section:

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

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

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

* * * Insurance Marketing * * *

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

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

* * *

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

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

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

* * *

Sec. 21. RECODIFICATION

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

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

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

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

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

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

~~(8)~~(9) 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 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. "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, 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 and Science University Drug Effectiveness Review Project (DERP), to provide technical and clinical support in the development and the administration of the preferred drug list and the evidence-based education program established in subchapter 2 of Title 18.

* * * Pharmaceutical Marketer Disclosures * * *

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

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

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.

* * * 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

Was this in Maine Rx?

(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.

(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 average manufacturer price or best price, 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 Plus * * *

→ ↓300%FPL or whoare up to 400%FPL 65/dis.
→ expanding program 300-350% → complicated receipts
→ just ↑ FPL to 350% [or less]

Sec. 6. 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~~ 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.

* * *

(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:

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

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

(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

Medco - strongly support opt out

ExpressScripts legal confusion n.p / PBM

Caremark too restrictive

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.

(3) 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.

(4) 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.

(5) 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.

(6) 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.

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

(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.

§ 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 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.

(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 [that a quotation for an administrative-services-only contract with full pass through of negotiated prices, rebates, and other such financial benefits which

Medco licensure - what is being protected against? - broad delegation pg 21 Line 13

Medco inconsistency - seems to think it requires a bid & doesn't want to have to issue a bid for that purpose.

would identify to the health insurer external sources of revenue and profit, is available when the pharmacy benefit manager provides a quotation for any other alternative pricing 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.

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

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

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

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

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

(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. Such 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.

(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.

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

(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. 9. APPLICATION

Secs. 7 and 8 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. 10. 18 V.S.A. chapter 91 is amended to read:

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

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

Subchapter 1. Generic Drugs

Sec. 12. 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) The department, in collaboration with the attorney general, 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.

(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, 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 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.

(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;

Medco – add to marketing pg 35

(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.

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

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

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

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

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

Subchapter 4. Consumer Provisions

§ 4641. CO-PAYMENT PRICING

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

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

§ 4100f. PRESCRIPTION DRUG CO-PAYMENTS

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

LC 000409

Susan to email it to me.

BILL AS INTRODUCED
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* * * Unconscionable Pricing * * *

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

Subchapter 5. Unconscionable Pricing

§ 4651. PURPOSE

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

§ 4652. DEFINITIONS

For purposes of this subchapter:

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

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

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

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

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

Susan Gretkowski

VT
- all
- unc = not

DC
- patented
- unc = foreign
- any drug unconif 30% over ↑income country

- notary. drug; serious health problem

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

specific lang DC police power

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

unconscionable pricing → do we have a general provision?

§ 4653. UNCONSCIONABLE PRICING PROHIBITED

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

§ 4654. SERIOUS PUBLIC HEALTH PROBLEM

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

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

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

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

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

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

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

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

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

§ 4655. UNCONSCIONABLE PRICING; PRIMA FACIE CASE

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

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

§ 4656. CONSUMER FRAUD ACTION

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

§ 4657. CIVIL ACTION

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

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

§ 4658. REMEDIES FOR CIVIL ACTIONS

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

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

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

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

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

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

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

§ 1998a. MANUFACTURER FEE

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

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

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

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

* * * Consumer Protection; False Advertising * * *

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

§ 2466a. CONSUMER PROTECTIONS; PRESCRIPTION DRUGS

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

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

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

(2) For purposes of this section:

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

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

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

Medco
- concerned that unsure re: PDL would be prohibited
- input language from Rx confident. ?

PBM language re: not mean formulary comp

* * * Insurance Marketing * * *

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

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

* * *

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

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

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

* * *

Sec. 21. RECODIFICATION

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

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

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

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

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

Sec. 22. REPEAL

Section 2009 of Title 33 is repealed.