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1	S.216
2	Introduced by Senator Mullin
3	Referred to Committee on Finance
4	Date: January 5, 2016
5	Subject: Health; health insurance; prescription drugs; formularies
6	Statement of purpose of bill as introduced: This bill proposes to require health
7	insurance plans to make information about their prescription drug formularies
8	available to enrollees, potential enrollees, and health care providers. It would
9	also require hospitals to provide prescription drug cost-sharing information to
10	hospital-affiliated physicians through the hospital's electronic prescribing
11	system.
12	An act relating to prescription drug formularies
13	An act relating to prescription drugs
14	It is hereby enacted by the General Assembly of the State of Vermont:
15	Sec. 1. 8 V.S.A. § 4089i is amended to read.
16	§ 4089i. PRESCRIPTION DRUG COVERAGE
17	(a) Prescription drugs from Canada. A health insurance or other health
18	benefit plan offered by a health insurer shall provide coverage for prescription
19	drugs purchased in Canada, and used in Canada or reimported legally or
20	purchased through the I-SaveRx program on the same benefit terms and
21	conditions as prescription drugs purchased in this country. For drugs

purchased by mail or through the Internet, the plan may require accreditation 1 2 by the Internet and Mailorder Pharmacy Accreditation Commission 3 (IMPAC/tm) or similar organization. (b) No annual dollar limit. A health insurance or other health benefit plan 4 5 offered by a health insurer or pharmacy benefit manager shall not include an 6 annual dollar limit on prescription drug benefits. 7 (c) Out-of-pocket maximum. A health insurance or other health benefit 8 plan offered by a health insurer or pharmacy benefit manager shall limit a 9 beneficiary's out-of-pocket expenditures for prescription drugs, including specialty drugs, to no more for self-only and family coverage per year than the 10 11 minimum dollar amounts in effect under Section 223(c)(2)(A)(i) of the Internal Revenue Code of 1986 for self-only and family coverage, respectively. 12 13 (d) <u>High-deductible health plans</u>. For prescription drug benefits offered in 14 conjunction with a high-deductible health plan (NDHP), the plan may not provide prescription drug benefits until the expenditures applicable to the 15 16 deductible under the HDHP have met the amount of the minimum annual deductibles in effect for self-only and family coverage under Section 17 223(c)(2)(A)(i) of the Internal Revenue Code of 1986 for self-only and family 18 19 coverage, respectively, except that a plan may offer first-dollar prescription 20 drug benefits to the extent permitted under federal law. Once the foregoing

expenditure amount has been met under the HDHP, coverage for prescription

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1	drug benefits shall begin, and the limit on out of pocket expenditures for
2	prescription drug benefits shall be as specified in subsection (c) of this section.
3	(e)(1) Step therapy. A health insurance or other health benefit plan offered
4	by a health insurer or by a pharmacy benefit manager on behalf of a health
5	insurer that provides coverage for prescription drugs and uses step-therapy
6	protocols shall not require failure on the same medication on more than one
7	occasion for continuously enrolled members or subscribers.
8	(2) Nothing in this subsection shall be construed to prohibit the use of
9	tiered co-payments for members or subscribers not subject to a step-therapy
10	protocol.
11	(f)(1) No off-label drug requirements. A health insurance or other health
12	benefit plan offered by a health insurer or by a pharmacy benefit manager on
13	behalf of a health insurer that provides coverage for prescription drugs shall
14	not require, as a condition of coverage, use of drugs not indicated by the
15	federal Food and Drug Administration for the condition diagnosed and being
16	treated under supervision of a health care professional.
17	(2) Nothing in this subsection shall be construed to plevent a health care
18	professional from prescribing a medication for off-label use.
19	(g) <u>Prescription drug formularies</u> . <u>Each health insurance or other health</u>
20	benefit plan offered by a health insurer or by a pharmacy benefit manager on
21	behalf of a health insurer that provides coverage for prescription drugs shall

1	provide notice to enrollees in the certificate of coverage regarding whether the
2	plan uses a prescription drug formulary. The notice shall include an
3	explanation of what a formulary is, how the plan determines which
4	prescription drugs are included or excluded, and how often the plan reviews
5	the contents of the formulary. The health insurer or pharmacy benefit manager
6	shall also do all of the following:
7	(1) Post the formulary for each health insurance or other health benefit
8	plan on the plan's website in a manner that is accessible to and searchable by
9	enrollees, potential enrollees, and providers. The formulary shall either be
10	displayed in a standard format established by the Department of Financial
11	Regulation or through a web-based search tool that allows enrollees, potential
12	enrollees, and providers to enter the name of a drug and receive plan-specific
13	information regarding whether the drug is covered and the cost-sharing range,
14	if applicable.
15	(2) Update each posted formulary within 72 hours after making any
16	changes to the formulary.
17	(3) Include all of the following on any published formulary for each
18	plan, including the formularies posted pursuant to subdivision (1) of this
19	subsection:
20	(A) any prior authorization, step therapy, or utilization management
21	requirements for each drug included in the formulary;

1	(B) if the plan uses a tier based formular	v. the specific tier the drug
2	occupies and a list of the specific co-payments for	each tier; and
3	(C) for drugs subject to cost-sharing, the	dollar range of coinsurance
4	typically paid by an enrollee for each specific drug	included in the formulary,
5	using the following ranges and symbols:	
6	(i) \$100.00 or less:	"\$"·
7	(ii) from \$100.01 to \$250.00:	<u>"\$\$":</u>
8	(iii) from \$250.01 to \$500.00:	<u>"\$\$\$";</u>
9	(iv) from \$500.01 to \$1,000.00:	"\$\$\$\$"; and
10	(v) over \$1,000.00:	<u>"\$\$\$\$\$."</u>
11	(4) If mail order pharmacy is permitted under	er the plan, provide separate
12	coinsurance ranges for potential enrollees if they p	urchase the drug through a
13	mail order facility, using the same ranges and sym	bols as provided in
14	subdivision (3) of this subsection.	
15	(5) For drugs covered under a plan's medica	al benefit and typically
16	administered by a health care professional, provide	e a list of all covered drugs
17	and any cost-sharing imposed on the drugs, either	posted on the plan's website
18	or through a toll-free telephone number that is staf	fed at least during normal
19	business hours.	
20	(6) Provide a description of the criteria by w	which medications are
21	specifically included in or excluded from the dedu-	ctible.

1	(h) Definitions. As used in this section:
2	(1) "Health care professional" means an individual licensed to practice
3	medicine under 26 V.S.A. chapter 23 or 33, an individual certified as a
4	physician assistant under 26 V.S.A. chapter 31, or an individual licensed as an
5	advanced practice registered nurse under 26 V.S.A. chapter 28.
6	(2) "Health insurer" shall have the same meaning as in 18 V.S.A.
7	§ 9402.
8	(3) "Out-of-pocket expenditure" means a co-payment, coinsurance,
9	deductible, or other cost-sharing mechanism.
10	(4) "Pharmacy benefit manager" shall have the same meaning as in
11	section 4089j of this title.
12	(5) "Step therapy" means protocols that establish the specific sequence
13	in which prescription drugs for a specific medical condition are to be
14	prescribed.
15	(h)(i) The Department of Financial Regulation shall enforce this section
16	and may adopt rules as necessary to carry out the purposes of this section.
17	Sec. 2. STANDARD PRESCRIPTION DRUG FORMULARY FORMAT;
18	RULEMAKING
19	The Department of Financial Regulation shall adopt rules establishing the
20	standard format for posting online prescription drug formularies pursuant to
21	8 V.S.A. § 4089i(g).

1	Sec. 3. 18 V.S.A. § 0413g is added to read:
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2	§ >413a. COST INFORMATION FOR ELECTRONIC PRESCRIBERS
3	(a) Each hospital providing an electronic prescribing system for use by its
4	affiliated health care providers shall indicate in the system the dollar range of
5	coinsurance typically paid by patients with commercial insurance for each drug
6	included in the electronic prescribing system, using the following ranges and
7	symbols:
8	(1) \$100.00 or less. "\$";
9	(2) from \$100.01 to \$250.00: "\$\$";
10	(3) from \$250.01 to \$500.00: "\$\$\$";
11	(4) from \$500.01 to \$1,000.00. "\$\$\$\$"; and
12	(5) over \$1,000.00: "\$\$\$\$\$."
13	(b) Annually on or before July 1, each health insurer with more than 200
14	covered lives in this State shall provide to each hospital in this State an
15	updated copy of its formulary, including the ranges and symbols set forth in
16	subsection (a) of this section.
17	Sec. 4. EFFECTIVE DATES
18	(a) Sec. 1 (8 V.S.A. § 4089i) shall take effect on January 1, 2017.
19	(b) Sec. 2 (rulemaking) and this section shall take effect on passage.
20	(c) Sec. 3 (18 V.S.A. § 9413a) shall take effect on January 1, 2017, except
21	that health insurers shall provide a copy of their formularies to each hospital on

1 er before July 1, 2016 to enable the hospitals to update their electronic

prescribing systems on or before January 1, 2017

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Sec. 1. PRESCRIPTION DRUG FORMULARIES, RULEMAKING

On or before January 1, 2017, the Commissioner of Financial Regulation shall adopt rules pursuant to 3 V.S.A. chapter 25 to require all health insurers that offer health benefit plans to Vermont residents through the Vermont Health Renefit Exchange to provide information to enrollees, potential enrollees, and health care providers about the plans' prescription drug formularies. The rules shall ensure that the formulary is posted online in a standard format established by the Department of Financial Regulation; that the formulary is updated frequently and is searchable by enrollees, potential enrollees, and health care providers; and that it includes information about the prescription drugs covered, applicable cost-sharing amounts, drug tiers, prior authorization, step thereby, and utilization management requirements.

Sec. 2. 33 V.S.A. § 2011 is added to read:

§ 2011. 340B DRUG PRICING; REIMBURSEMENT FORMULA

The Department of Vermont Nealth Access shall use the same dispensing fee in its reimbursement formula for 340B prescription drugs as the Department uses to pay for non-340B prescription drugs under the Medicaid program.

Sec. 3. 340B REIMBURSEMENT; REPORT

The Department of Vermont Health Access shall determine the formula used by other states' Medicaid programs to reimburse covered entities that use 340B pricing for dispensing prescription drugs to Medicaid beneficiaries. On or before January 15, 2017, the Department shall report to the House Committee on Health Care and the Senate Committees on Health and Welfare and on Finance regarding its findings, its recommendations for modifications to Vermont's 340B reimbursement formula, if any, and the financial implications of implementing any recommended modification.

Sec. 4. 18 V.S.A. § 4631a(b) is amended to read:

- (b)(1) It is unlawful for any manufacturer of a prescribed product or any wholesale distributor of medical devices, or any agent thereof, to offer or give any gift to a health care provider or to a member of the Green Mountain Care Board established in chapter 220 of this title.
- (2) The prohibition set forth in subdivision (1) of this subsection shall not apply to any of the following:

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(K) The provision of coffee or other, snacks, or other refreshments at a booth at a conference or seminar.

Sec. 5. EFFECTIVE DATE

This act shall take effect on passage

Sec. 1. FINDINGS

The General Assembly finds that:

- (1) The costs of prescription drugs have been increasing dramatically without any apparent reason.
- (2) Containing health care costs requires containing prescription drug costs.
- (3) In order to contain prescription drug costs, it is essential to understand the drivers of those costs, as transparency is typically the first step toward cost containment.
- Sec. 2. 18 V.S.A. § 4635 is added to read:

§ 4635. PHARMACEUTICAL COST TRANSPARENCY

(a) As used in this section:

- (1) "Manufacturer" shall have the same meaning as "pharmaceutical manufacturer" in section 4631a of this title.
 - (2) "Prescription drug" means a drug as defined in 21 U.S.C. § 321.
- (b)(1) The Green Mountain Care Board, in collaboration with the Department of Vermont Health Access, shall identify annually up to 15 prescription drugs on which the State spends significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or by 15 percent or more over the past 12 months, creating a substantial public interest in understanding the development of the drugs' pricing. The drugs identified shall represent different drug classes.
- (2) The Board shall provide to the Office of the Attorney General the list of prescription drugs developed pursuant to this subsection and the percentage of the wholesale acquisition cost increase for each drug and shall make the information available to the public on the Board's website.
- (c)(1) For each prescription drug identified pursuant to subsection (b) of this section, the Office of the Attorney General shall require the drug's manufacturer to provide a justification for the increase in the wholesale acquisition cost of the drug in a format that the Attorney General determines

to be understandable and appropriate. The manufacturer shall submit to the Office of the Attorney General all relevant information and supporting documentation necessary to justify the manufacturer's wholesale acquisition cost increase, which may include:

- (A) all factors that have contributed to the wholesale acquisition cost increase;
- (B) the percentage of the total wholesale acquisition cost increase attributable to each factor; and
- (C) an explanation of the role of each factor in contributing to the wholesale acquisition cost increase.
- (2) Nothing in this section shall be construed to restrict the legal ability of a prescription drug manufacturer to changes prices to the extent permitted under federal law.
- (d) The Attorney General, in consultation with the Department of Vermont Health Access, shall provide a report to the General Assembly on or before December 1 of each year based on the information received from manufacturers pursuant to this section. The Attorney General shall also post the report on the Office of the Attorney General's website.
- (e) Information provided to the Office of the Attorney General pursuant to this section is exempt from public inspection and copying under the Public Records Act and shall not be released in a manner that allows for the identification of an individual drug or manufacturer or that is likely to compromise the financial, competitive, or proprietary nature of the information.
- (f) The Attorney General may bring an action in the Civil Division of the Superior Court, Washington County for injunctive relief, costs, and attorney's fees, and to impose on a manufacturer that fails to provide the information required by subsection (c) of this section a civil penalty of no more than \$10,000.00 per violation. Each unlawful failure to provide information shall constitute a separate violation. In any action brought pursuant to this section, the Attorney General shall have the same authority to investigate and to obtain remedies as if the action were brought under the Consumer Protection Act, 9 V.S.A. chapter 63.

Sec. 3. PRESCRIPTION DRUG FORMULARIES; RULEMAKING

On or before January 1, 2017, the Commissioner of Financial Regulation shall adopt rules pursuant to 3 V.S.A. chapter 25 to require all health insurers that offer health benefit plans to Vermont residents through the Vermont Health Benefit Exchange to provide information to enrollees, potential enrollees, and health care providers about the Exchange plans' prescription

drug formularies. The rules shall ensure that the formulary is posted online in a standard format established by the Department of Financial Regulation; that the formulary is updated frequently and is searchable by enrollees, potential enrollees, and health care providers; and that it includes information about the prescription drugs covered, applicable cost-sharing amounts, drug tiers, prior authorization, step therapy, and utilization management requirements.

Sec. 4. 340B DRUG DISPENSING FEES

- (a) The Department of Vermont Health Access shall use the same dispensing fee in its reimbursement formula for 340B prescription drugs as the Department uses to pay for non-340B prescription drugs under the Medicaid program.
- (b) Notwithstanding the provisions of subsection (a) of this section, the Department is authorized to modify the dispensing fee or reimbursement formula provided to federally qualified health centers and Title X family planning clinics for dispensing 340B prescription drugs to Medicaid beneficiaries.

Sec. 5. 340B DRUG REIMBURSEMENT; REPORT

- (a) The Department of Vermont Health Access shall:
- (1) determine the formula used by other states' Medicaid programs to reimburse covered entities that use 340B pricing for dispensing prescription drugs to Medicaid beneficiaries;
- (2) evaluate the advantages and disadvantages of using the same dispensing fee in its reimbursement formula for 340B prescription drugs as the Department uses to pay for non-340B prescription drugs under the Medicaid program; and
- (3) identify the benefits, if any, of 340B drug pricing to consumers, other payers, and the overall health care system.
- (b) On or before March 15, 2017, the Department shall report to the House Committee on Health Care and the Senate Committees on Health and Welfare and on Finance regarding its findings and recommendations, including recommended modifications to Vermont's 340B reimbursement formula, if any, and the financial implications of implementing any recommended modifications.
- Sec. 6. OUT-OF-POCKET PRESCRIPTION DRUG LIMITS; 2018 PILOT; REPORTS
- (a) The Department of Vermont Health Access shall convene an advisory group to develop options for bronze-level qualified health benefit plans to be

offered on the Vermont Health Benefit Exchange for the 2018 plan year, including:

- (1) one or more plans with a higher out-of-pocket limit on prescription drug coverage than the limit established in 8 V.S.A. § 4089i; and
- (2) two or more plans with an out-of-pocket limit at or below the limit established in 8 V.S.A. § 4089i.
 - (b) The advisory group shall include at least the following members:
 - (1) the Commissioner of Vermont Health Access or designee;
- (2) a representative of each of the commercial health insurers offering plans on the Vermont Health Benefit Exchange;
 - (3) a representative of the Office of the Vermont Health Advocate;
- (4) a member of the Medicaid and Exchange Advisory Board, appointed by the Commissioner;
 - (5) a representative of Vermont's AIDS services organizations;
 - (6) a consumer appointed by Vermont's AIDS services organizations;
 - (7) a representative of the American Cancer Society;
 - (8) a consumer appointed by the American Cancer Society; and
 - (9) a Vermont Health Connect navigator.
- (c)(1) The advisory group shall meet at least six times prior to the Department submitting plan designs to the Green Mountain Care Board for approval.
- (2) In developing the standard qualified health benefit plan designs for the 2018 plan year, the Department of Vermont Health Access shall present the recommendations of the advisory committee established pursuant to subsection (a) of this section to the Green Mountain Care Board.
- (d)(1) Prior to the date on which qualified health plan forms must be filed with the Department of Financial Regulation pursuant to 8 V.S.A. § 4062, a health insurer offering qualified health benefit plans on the Vermont Health Benefit Exchange shall seek approval from the Green Mountain Care Board to modify the out-of-pocket prescription drug limit established in 8 V.S.A. § 4089i for one or more nonstandard bronze-level plans. In considering an insurer's request, the Green Mountain Care Board shall provide an opportunity for the advisory group established in subsection (a) of this section, and any other interested party, to comment on the recommended modifications.
- (2)(A) Notwithstanding any provision of 8 V.S.A. § 4089i to the contrary, the Green Mountain Care Board may approve modifications to the

out-of-pocket prescription drug limit established in 8 V.S.A. § 4089i for one or more bronze-level plans for the 2018 plan year only.

- (B) For the 2018 plan year, the Department of Vermont Health Access shall certify at least two standard bronze-level plans that include the out-of-pocket prescription drug limit established in 8 V.S.A. § 4089i, as long as the plans comply with federal requirements. Notwithstanding any provision of 8 V.S.A. § 4089i to the contrary, the Department may certify one or more bronze-level qualified health benefit plans with modifications to the out-of-pocket prescription drug limit established in 8 V.S.A. § 4089i for the 2018 plan year only.
- (e)(1) For each individual enrolled in a bronze-level qualified health benefit plan for plan years 2016 and 2017 who had out-of-pocket prescription drug expenditures during the 2016 plan year that met the out-of-pocket prescription drug limit established in 8 V.S.A. § 4089i, the health insurer shall, absent an alternative plan selection or plan cancellation by the individual, automatically reenroll the individual in a bronze-level qualified health benefit plan for plan year 2018 with an out-of-pocket prescription drug limit at or below the limit established in 8 V.S.A. § 4089i.
- (2) Prior to reenrolling the individual in a plan pursuant to subdivision (1) of this subsection, the health insurer shall notify the individual of the insurer's intent to reenroll automatically the individual in a bronze-level plan for plan year 2018 with an out-of-pocket prescription drug limit at or below the limit established in 8 V.S.A. § 4089i and of the availability of bronze-level plans with higher out-of-pocket prescription drug limits.
- (f)(1) The Director of Health Care Reform in the Agency of Administration, in consultation with the Department of Vermont Health Access and the Office of Legislative Council, shall determine whether the Secretary of the U.S. Department of Health and Human Services has the authority under the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, as amended by the federal Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152 (ACA), to waive annual limitations on out-of-pocket expenses or actuarial value requirements for bronze-level plans, or both. On or before October 1, 2016, the Director shall present information to the Health Reform Oversight Committee regarding the authority of the Secretary of the U.S. Department of Health and Human Services to waive out-of-pocket limits and actuarial value requirements, the estimated costs of applying for a waiver, and alternatives to a waiver for preserving the out-of-pocket prescription drug limit established in 8 V.S.A. § 4089i.
- (2) If the Director of Health Care Reform determines that the Secretary has the necessary authority, then on or before March 1, 2017, the

Commissioner of Vermont Health Access, with the Director's assistance, shall apply for a waiver of the cost-sharing or actuarial value limitations, or both, in order to preserve the availability of bronze-level qualified health benefit plans that meet Vermont's out-of-pocket prescription drug limit established in 8 V.S.A. § 4089i.

- (g) On or before February 15, 2017, the Department of Vermont Health Access shall provide to the House Committee on Health Care and the Senate Committees on Health and Welfare and on Finance:
- (1) an overview of the cost-share increase trend for bronze-level qualified health benefit plans offered on the Vermont Health Benefit Exchange for the 2014 through 2017 plan years that were subject to the out-of-pocket prescription drug limit established in 8 V.S.A. § 4089i;
- (2) detailed information regarding lower cost-sharing amounts for selected services that will be available in bronze-level qualified health benefit plans in the 2018 plan year due to the flexibility to increase the out-of-pocket prescription drug limit established in 8 V.S.A. § 4089i pursuant to subdivision (d)(2) of this section;
- (3) a comparison of the bronze-level qualified health benefit plans offered in the 2018 plan year in which there will be flexibility in the out-of-pocket prescription drug limit established in 8 V.S.A. § 4089i with the plans in which there will not be flexibility;
- (4) information about the process engaged in by the advisory group established in subsection (a) of this section and the information considered to determine modifications to the cost-sharing amounts in all bronze-level qualified health benefit plans for the 2018 plan year, including prior year utilization trends, feedback from consumers and health insurers, Health Benefit Exchange outreach and education efforts, and relevant national studies;
- (5) cost-sharing information for standard bronze-level qualified health benefit plans from states with federally facilitated exchanges compared to those on the Vermont Health Benefit Exchange; and
- (6) an overview of the outreach and education plan for enrollees in bronze-level qualified health benefit plans offered on the Vermont Health Benefit Exchange.
- (h) On or before February 1, 2018, the Department of Vermont Health Access shall report to the House Committee on Health Care and the Senate Committees on Health and Welfare and on Finance:
- (1) enrollment trends in bronze-level qualified health benefit plans offered on the Vermont Health Benefit Exchange; and

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(2) recommendations from the advisory group established pursuant to subsection (a) of this section regarding continuation of the out-of-pocket prescription drug limit established in 8 V.S.A. § 4089i.

Sec. 7. EFFECTIVE DATE

This bill shall take effect on passage.