Roche Hemophilia Drug Lowers Costs Despite High Price: ICER

Reuters

January 26, 2018

A costly new Roche Holding AG drug to treat the bleeding disorder hemophilia A could significantly reduce healthcare expenses for certain patients, a draft report from an independent U.S. nonprofit organization that evaluates clinical and cost effectiveness of new medicines said on Friday.

The drug, Hemlibra, or emicizumab, was approved by the Food and Drug Administration in November as a once-weekly injection for adults and pediatric patients with hemophilia A who have developed inhibitors, or resistance, to other treatments. Roche's medicine is required to carry a black box warning, the most serious, about the risk of blood clots.

The Institute for Clinical and Economic Review (ICER) found that, for such patients aged 12 years and older, emicizumab at current wholesale prices would reduce spending by around $1.85 million per patient annually. In patients under 12 years of age, emicizumab would reduce costs by about $720,000 per patient annually.

Hemophilia is a rare bleeding disorder in which a clotting protein is missing or does not function normally. Roche plans to charge about $482,000 for the first year of treatment and $448,000 a year after that.

To avoid joint damage and other complications, patients with severe hemophilia need regular infusions of very expensive clotting factors. About 25 percent of people with severe hemophilia A develop factor antibodies, called inhibitors, at some point, making it difficult to control bleeding without very high doses of clotting factors or other expensive treatments known as bypassing agents.

Hemlibra is an antibody designed to activate the natural coagulation cascade and restore the blood clotting process for hemophilia A.

ICER noted in its analysis that hemophilia is a lifelong disease that creates substantial burdens for patients.

CASE STUDY

Manufacturer-payer hepatitis C negotiations

What Payers Claimed Would Happen

"What they have done with this particular drug will break the country.... It will make pharmacy benefits no longer sustainable. Companies just aren't going to be able to handle paying for this drug."

–EXPRESS SCRIPTS (APRIL 2014)

"This pricing, which Gilead attempts to justify as the cost of medical advancement, will have a tsunami effect across our entire health care system."

–AMERICA'S HEALTH INSURANCE PLANS (JULY 2014)

What Actually Happened

"The price is sufficiently low that we can go to our clients and say that they can treat every patient with hepatitis C."

–EXPRESS SCRIPTS (JANUARY 2015)

"We are receiving market-leading rates from both companies. Neither company wanted to be left off the formulary."

–PRIME THERAPEUTICS (JANUARY 2015)

"Competitive market forces and hard-nosed bargaining" make 'tremendously effective' new hepatitis C medicines not just more accessible to ailing patients – but also offer good value to the U.S. health care system."

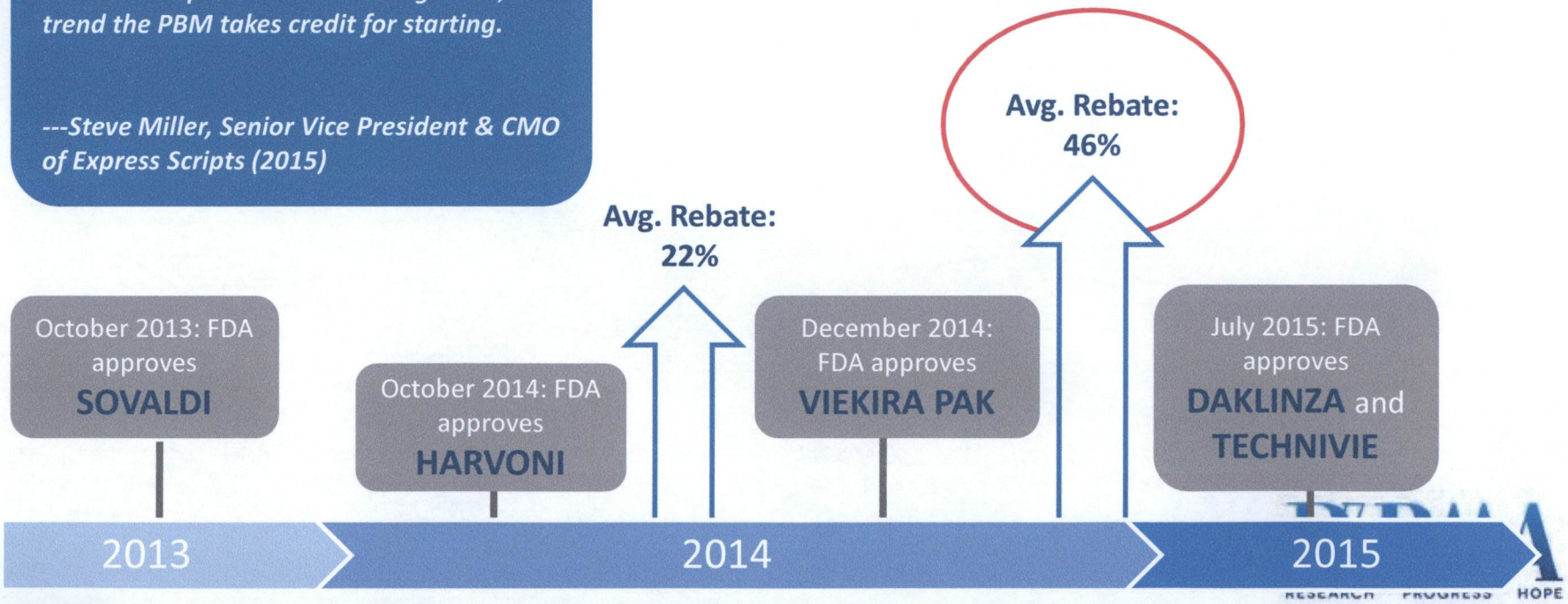
–THE NEW YORK TIMES EDITORIAL BOARD (SEPTEMBER 2015)

Competition and Aggressive Payer Negotiations Reduce Net Drug Costs

Discounts and rebates significantly reduce the net prices of brand medicines. This is particularly true when new medicines enter the market. Payers and PBMs leverage competition and negotiate lower prices through the aggressive use of formulary restrictions and the threat of coverage exclusions.

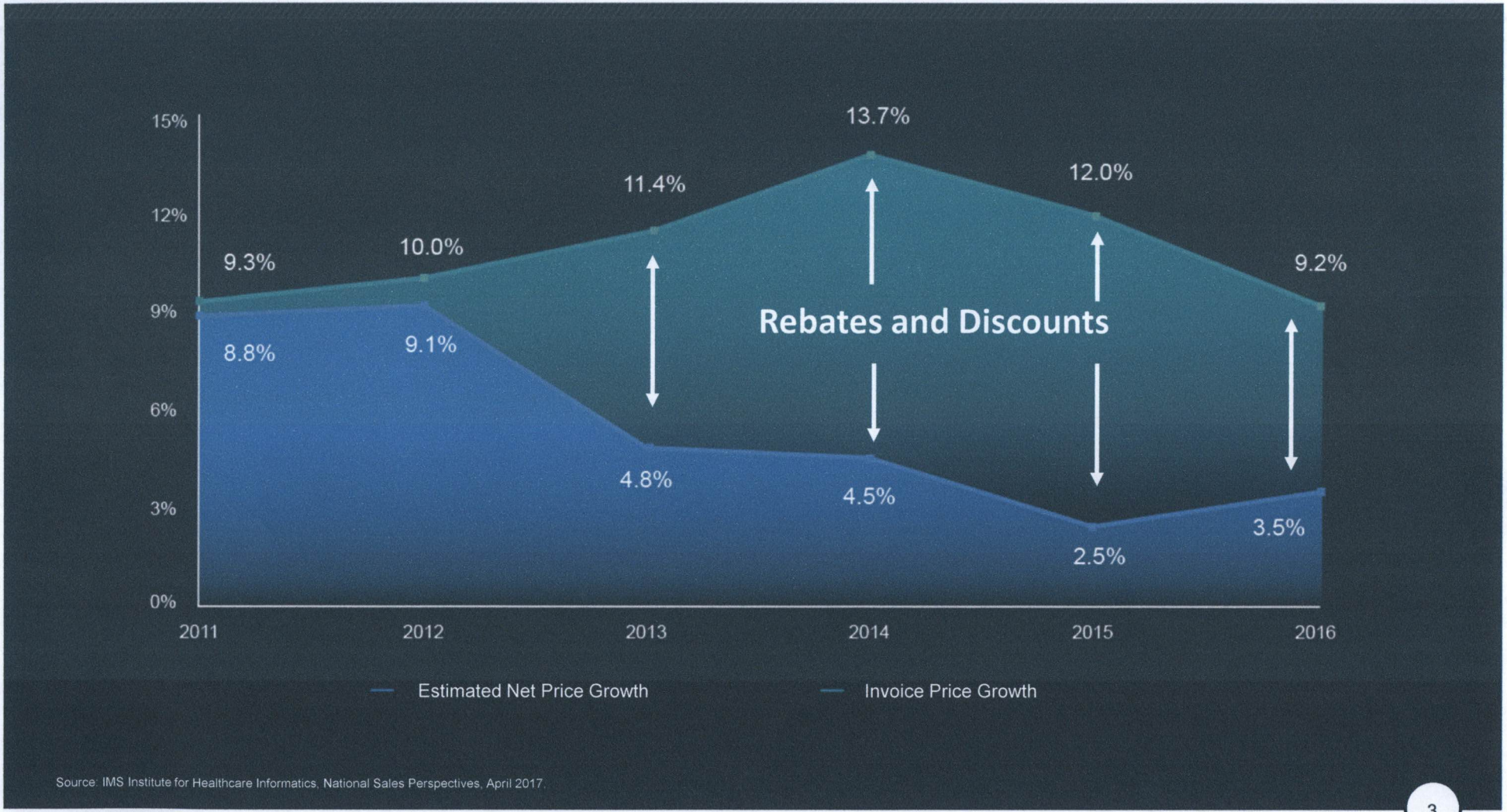
U.S. payers will save $4 billion this year thanks to hepatitis C cost-cutting deals, a trend the PBM takes credit for starting.

---Steve Miller, Senior Vice President & CMO of Express Scripts (2015)



Sources: E. Wasserman. "Gilead Zooms Past AbbVie in Hep C Race With UnitedHealth Deal." *FiercePharma*. January 29, 2015; A. Fein. "What Gilead's Big Hepatitis C Discounts Mean for Biosimilar Pricing." *Drug Channels*. February 5, 2015.

In fact, after discounts and rebates, brand medicine prices grew just 3.5% in 2016



Source: IMS Institute for Healthcare Informatics, National Sales Perspectives, April 2017.

Brand manufacturers realize 63% of gross brand prescription medicine spending

GROSS BRANDED DRUG EXPENDITURES BY COMPONENT (IN BILLIONS)				
TYPE OF COMPONENT	COMPONENT	2013	2014	2015
Initial Gross Drug Expenditures[1]		**$264.9**	**$306.3**	**$349.1**
Statutory Rebates and Fees	Medicaid Drug Rebate Program[2]	$19.1	$23.0	$28.3
	Part D Coverage Gap Discounts	$4.2	$5.1	$5.8
	TRICARE Rebates & Federal Supply Schedule Discounts	$3.5	$4.6	$4.7
	Excise Fee[3]	$2.8	$3.0	$3.0
Market Access Rebates and Discounts	Negotiated Health Plan and PBM Rebates and Fees[4]	$33.2	$43.5	$57.7
	Patient Cost Sharing Assistance	$4.2	$5.4	$6.9
Supply Chain Entities	Pharmacy/Provider Margin[5]	$17.5	$18.5	$20.4
	Wholesaler Margin[6]	$2.3	$2.7	$3.1
	GPO Administrative Fees	$0.6	$0.6	$0.7
Net Amount Realized by Brand Manufacturer ($)		**$177.5**	**$199.9**	**$218.6**
Net Amount Realized by Brand Manufacturer (%)		**67.0%**	**65.3%**	**62.6%**

Source: Berkley Research Group

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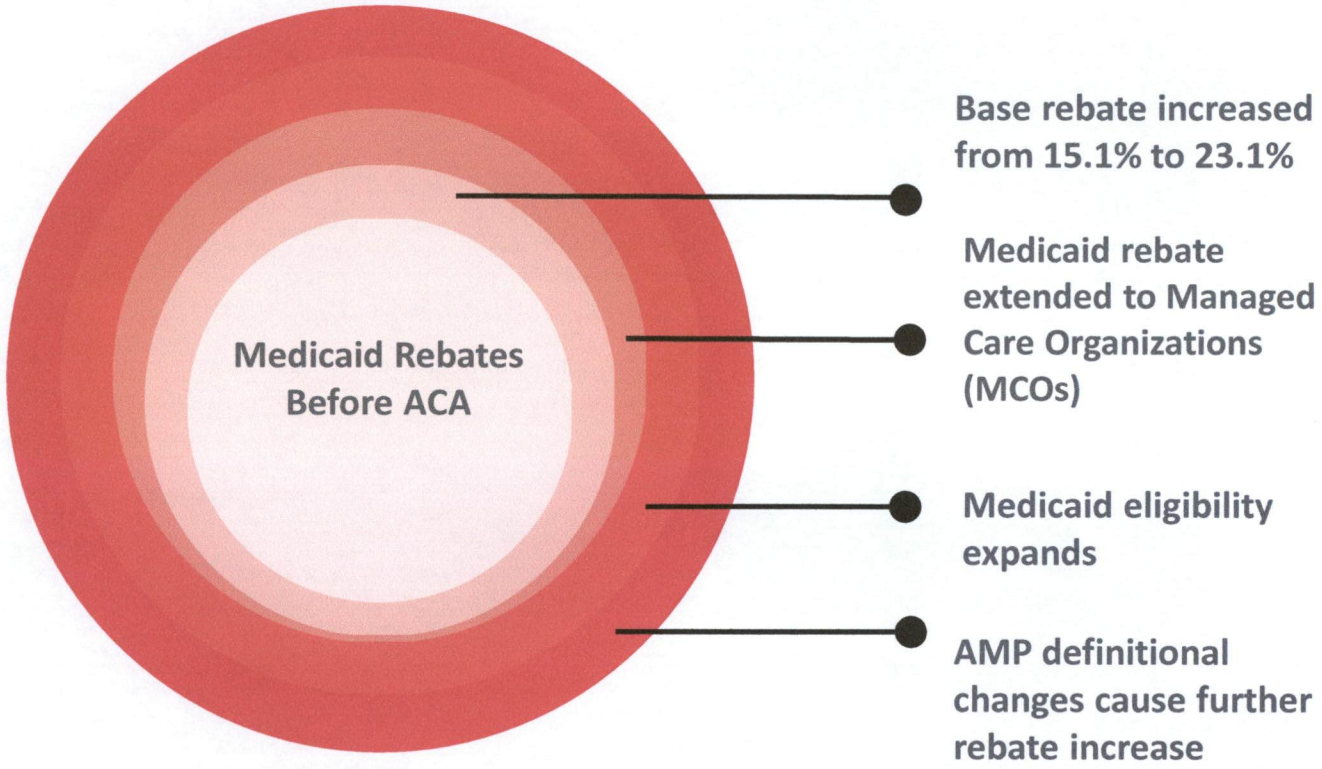
Medicaid Rebates on Prescription Medicines Increase Substantially Under ACA

Independent analysts estimate the expansion of Medicaid prescription drug rebates in the Affordable Care Act could increase brand manufacturers' costs by more than $40 billion over 10 years (2012-2021).[10]



Note: Graphic is Illustrative only.
Sources: PwC Health Research Institute[10]; Medicaid.gov[11]

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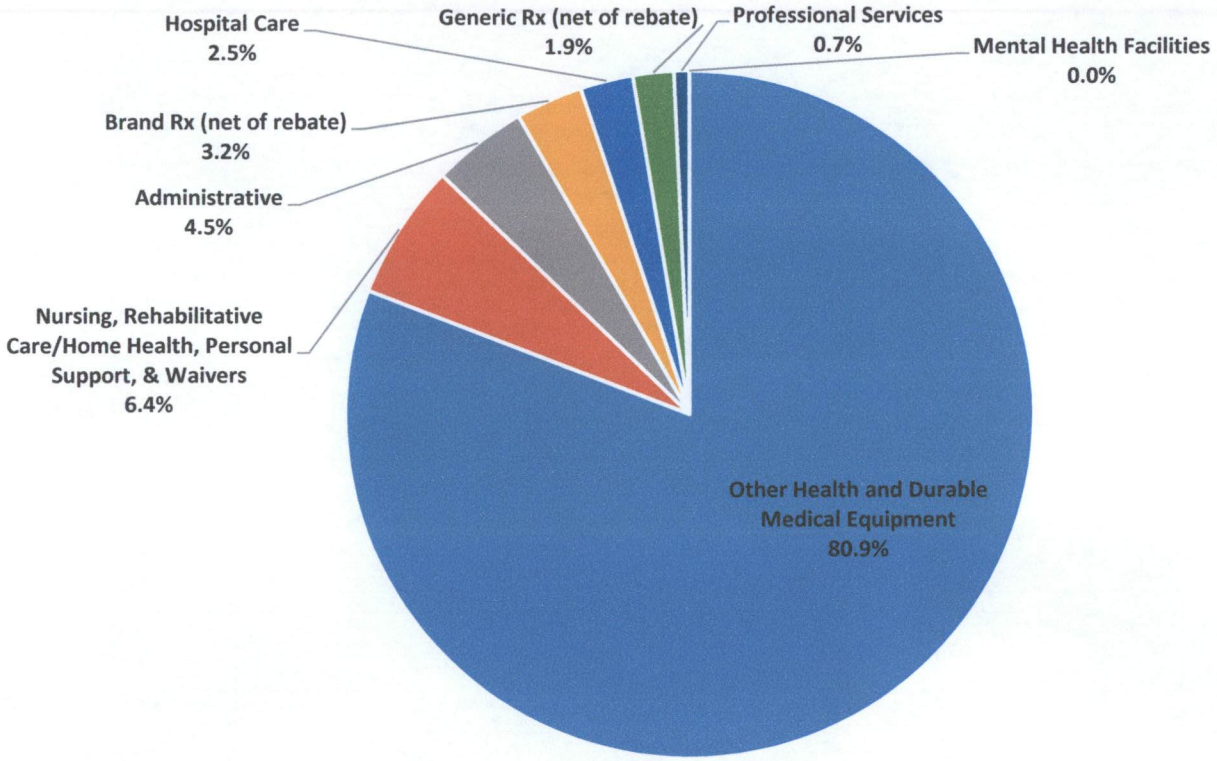
Brand Prescription Drugs Account for Approximately 3.2% of Total 2016 Vermont Medicaid Spending

Vermont Medicaid Spending, 2016



TOTAL $1.98 B

Note: Professional services include physician and clinic, dental, and other professional services. Administration costs include federal and state administration and net cost of private insurance. Other health, residential, and personal care includes school health, work site, residential mental/substance abuse, some ambulance, and Medicaid home/community waivers.

Source: PhRMA analysis of data from CMS, HHS OIG, and The Lewin Group[1]

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Medicaid Expansion & Price Controls

As a condition of a drug being covered by Medicaid, drug manufacturers pay a rebate to the states and the Centers for Medicare & Medicaid Services based on a statutory formula.

Price Controls in Medicaid Are Manifested Through the Rebate Program

THE BASE REBATE FOR BRAND MEDICINES
is the greater of **23.1%** of the Average Manufacturer Price (AMP) or the difference between AMP and a manufacturer's best price for the drug.*

AN ADDITIONAL REBATE
is paid by brand manufacturers if their AMP increases more than inflation.

ADDITIONAL STATE SUPPLEMENTAL REBATES
are also often required on brand medicines.

GENERIC MANUFACTURERS
also pay a statutory rebate of **13.0%** of AMP.

In FFY2016, manufacturers paid Vermont Medicaid rebates totaling $100.7 million.

Drug purchases by beneficiaries in Medicaid Managed Care Organizations became eligible for statutory rebates in 2010. Beginning in 2014, the Medicaid expansion allowed states to expand Medicaid to more adults, further increasing the number of people whose prescriptions are eligible for rebates.

*Certain brand medicines are subject to a different rebate percentage.

Example

THEN & NOW

How Prescription Drug Prices Fall Significantly Over Time

Biopharmaceutical companies invest in pioneering research to bring new treatments to patients, and over time those medicines become available as lower-cost generic copies.

MEDICINE		BRAND NAME THEN	VS.	GENERIC NOW	% CHANGE
DIOVAN HCT® *Hypertension*	2010	$87		$13	-85%
LIPITOR® *Cholesterol*	2010	$85		$4	-95%
PLAVIX® *Blood Thinner*	2011	$166		$5	-97%
SEROQUEL® *Schizophrenia*	2010	$87		$3	-97%
ZYPREXA® *Schizophrenia & Bipolar Disorder*	2010	$393		$8	-98%

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Figures represent the average annual price for 30 pills of the most commonly dispensed form and strength.
"Then" price represents the average price in the year prior to generic entry. "Now" price represents the average price in CY 2014.
Source: IMS analysis for PhRMA, May 2015

There are two provisions of law that address the issue of patients paying copayment that is higher than the cost of the drug and pharmacists informing them of this option. Legislation addressing PBM conduct in this context is becoming increasingly common. Language addressing the payment itself is often referred to as "copay clawback" and language ensuring pharmacists are able to communicate options with patients is often referred to as an "anti-gag" clause.

Vermont has currently enacted language addressing the "copay clawback." This is found in Title 18, section 9473(b) [included below]. While the existing law does not explicitly include "anti-gag" language, 9473(b) could be amended to include a new (4) that reads:

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

…

(4) contractually prohibit or penalize a pharmacy or pharmacist for:

a. Disclosing to a Health Plan enrollee information regarding:
   i. the cost-sharing amounts that the enrollee must pay for a particular prescription drug (i) under his or her Health Plan prescription drug benefit, and/or (ii) outside his or her Health Plan prescription drug benefit, without requesting any Health Plan reimbursement; and/or
   ii. the existence and clinical efficacy of a therapeutically equivalent drug that would be less expensive to the enrollee (i) under his or her Health Plan prescription drug benefit, and/or (ii) outside his or her Health Plan prescription drug benefit, without requesting any Health Plan reimbursement, than the drug that was originally prescribed; or

§ 9473. Pharmacy benefit managers; required practices with respect to pharmacies

(a) Within 14 calendar days following receipt of a pharmacy claim, a pharmacy benefit manager or other entity paying pharmacy claims shall do one of the following:

(1) Pay or reimburse the claim.

(2) Notify the pharmacy in writing that the claim is contested or denied. The notice shall include specific reasons supporting the contest or denial and a description of any additional information required for the pharmacy benefit manager or other payer to determine liability for the claim.

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

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

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

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

(c) For each drug for which a pharmacy benefit manager establishes a maximum allowable cost in order to determine the reimbursement rate, the pharmacy benefit manager shall do all of the following:

(1) Make available, in a format that is readily accessible and understandable by a pharmacist, the actual maximum allowable cost for each drug and the source used to determine the maximum allowable cost.

(2) Update the maximum allowable cost at least once every seven calendar days. In order to be subject to maximum allowable cost, a drug must be widely available for purchase by all pharmacies in the State, without limitations, from national or regional wholesalers and must not be obsolete or temporarily unavailable.

(3) Establish or maintain a reasonable administrative appeals process to allow a dispensing pharmacy provider to contest a listed maximum allowable cost.

(4) Respond in writing to any appealing pharmacy provider within 10 calendar days after receipt of an appeal, provided that a dispensing pharmacy provider shall file any appeal within 10 calendar days from the date its claim for reimbursement is adjudicated. (Added 2013, No. 144 (Adj. Sess.), § 14; amended 2015, No. 54, § 3, eff. June 5, 2015.)