



**Program Report:
Pharmacy Best Practices and
Cost Control Program
SFY 2015**

Report to: Health Reform Oversight Committee
Pursuant to 33 V.S.A. § 2001(c)

**Agency of Human Services
Department of Vermont Health Access
Pharmacy Unit**

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Section I – Executive Summary

The purpose of this legislative report is to provide an overview of the scope of DVHA’s Pharmacy Benefit programs, including a description of the pharmacy programs provided to DVHA members; a financial summary of current drug spend, both gross and net; clinical and cost strategies that DVHA employs to manage drug utilization; and future pharmacy trends.

The Agency of Human Services (AHS) has the widest reach in state government and one of the most critical missions: to improve the conditions and well-being of Vermonters today and tomorrow, and protect those who cannot protect themselves.

The Department of Vermont Health Access assists beneficiaries in accessing clinically appropriate health services; administers Vermont's public health insurance system efficiently and effectively; and collaborates with other health care system entities in bringing evidence-based practices to Vermont Medicaid beneficiaries. In support of the Agency and Department goals, the Pharmacy Benefit Management Program goal is to ensure that beneficiaries receive medically necessary medications in the most efficient and cost-effective manner. With the fiscal challenges facing the state over the next few years, at stake is preserving, to the greatest extent possible, the benefits that have evolved in Vermont’s programs.

The Patent Cliff

The last several years have seen a shift in the prescription drug marketplace that has made it particularly challenging for states to manage the cost and utilization of prescription drugs. One significant change is the levelling off of the “patent cliff”. During the period between 2011 and 2014, a large number of so-called “blockbuster” drugs lost

their patents, allowing more cost-effective generic drugs to enter the market and compete for market share. Some drugs that had a large impact on lowering cost for DVHA include several widely used psychiatric drugs such as Zyprexa®, Geodon®, Seroquel®, Lexapro®, and Cymbalta® as well as Singulair® for Asthma, Plavix®, Lipitor®, Protonix®, and Nexium®. This “patent cliff” helped to moderate growth and contributed to a lower trend in prescription drug spending. While the so-called patent cliff will always exist as drugs continue to lose their patent protection, fewer “blockbuster” drugs will be losing patent protection over the next several years and therefore will moderate savings attributable to the influx of generic drugs.

Specialty Drugs

In addition, the impact of new and specialty drugs is beginning to have an ever-larger impact on drug spend. Specialty drugs treat complex or life-threatening health conditions and are typically made using “advanced biotechnology methods and are referred to as “biologics” or “large molecules.” Specialty drugs are defined as having one or more of the following characteristics:

- “Complex to manufacture, requiring special handling and administration
- Injectable or oral, self-administered or administered by a health care provider
- Costly, both in total and on a per-patient basis; taken by a relatively small share of the population who have complex medical conditions
- Difficult for patients to take without ongoing clinical support; also challenging for providers to manage.”

(UnitedHealth Center for Health Reform & Modernization, 2014)

At the end of CY2013, DVHA witnessed the introduction of Sovaldi®, the well-publicized first “all-oral” treatment of Hepatitis C at a cost of \$1,000 per capsule, and \$84,000 per each 12-week course of treatment. Shortly thereafter, Harvoni® entered the Hepatitis C market with an annual cost of \$96,000 per 12-week course of treatment. By the first quarter of SFY2015, Sovaldi® had become Vermont Medicaid’s third highest drug spend by cost, exceeded only by Suboxone®, a drug used to treat opiate addiction, and Abilify®, used for various psychiatric conditions.

In 2012, Kalydeco®, a drug that reduces thick mucus secretions by improving the movement of chloride and water into cells, entered the Cystic Fibrosis (CF) market at a cost of \$300,000 per year, per patient. It was approved to treat only about 4% of the roughly 32,000 CF patients nationwide who have a particular genetic mutation. Then in July 2015, Orkambi®, which is a combination of Kalydeco® and another drug which has a similar mechanism of action, entered the market to treat a different genotype that is prevalent in nearly 45% of CF patients, at a cost of \$250,000 per year, per patient. If effective, this drug is continued for the duration of a CF patient’s treatment lifetime. In company trials, patients treated with Orkambi® for six months reported a 2.5 to 3 percent improvement in lung function (FEV1), a key measure for cystic fibrosis patients. That improvement was statistically significant, but was not as large an improvement as results seen with Kalydeco®, which improved lung function by about 10 percent. More studies are needed to determine what the impact of these drugs is on survival and long-term reductions in overall health care costs. (Newsmax Health, 2015) (Vertex Pharmaceuticals, 2015) (Vertex Pharmaceuticals - 2, 2015)

There have also been large increases in the number of oral drugs used to treat cancer, some at a cost of more than \$10,000 per month. Nationally, about half of all spending for specialty drugs is for cancer, rheumatoid arthritis, and multiple sclerosis. In Medicaid health plans, HIV drugs represent a significant portion (around 18%) of

specialty pharmacy spend. (UnitedHealth Center for Health Reform & Modernization, 2014)

Nationally, spending on specialty drugs in 2012 was about \$87 billion, with estimates suggesting that could quadruple by 2020, reaching about \$400 billion (or 9.1 percent of national health care spending). “Unit price growth is driving spending increases but utilization growth plays a strong role for certain therapies. Specialty drug prices increased by an average of twenty-two percent during 2012. About half of spending for specialty drugs is funded as a pharmacy benefit; the other half is funded as a medical benefit, leading to challenges in integrated clinical management.” (UnitedHealth Center for Health Reform & Modernization, 2014).

DVHA has seen its specialty drug spend as a percent of total drug spend increase from 9% to 16% from SFY2013 to SFY2015. As more of these extremely expensive drugs reach the market, it will be necessary to monitor patient’s health outcomes and changes in overall health care costs to truly evaluate a drug’s benefits.

Increase in Cost of Generic Drugs

Another pressure on drug trend has been an increase in the cost of generic drugs. Historically, generics have proven to be more cost effective for Medicaid programs once the six-month “generic exclusivity” period has expired and a generic is available from multiple manufacturers.

However, recently there have been many older and established generic drugs whose prices have risen 100% to more than 1000%, such as captopril 12.5mg, which is used to treat hypertension and heart failure. The price for captopril 12.5MG increased by more than 2800% between November 2012 and November 2013, from 1.4 cents to 39.9 cents per pill. Similarly, clomipramine 25 mg, a tricyclic antidepressant, increased

from 22 cents to \$8.32 per pill, and the price of doxycycline hyclate 100 mg, a broad-spectrum antibiotic that has been on the market since 1967, increased from 6.3 cents to \$3.36 per capsule. (Alpern, Stauffer, & Kesselheim, 2014)

More recently, some manufacturers have been under fire from for dramatic price increases on their products. For example, Valeant Pharmaceuticals has increased prices on 54 medications this year, and last year it raised prices on 62 drugs by an average of fifty percent. Also, Turing Pharmaceuticals recently came under fire for increasing the price of the drug daraprim by more than 5000%. Daraprim is a drug used to treat a parasitic infection, toxoplasmosis, to which immune compromised individuals such as those with HIV or cancer, are more susceptible. This drug has been on the market for sixty-two years and now costs \$750 per tablet. (Helfand, 2015)

A variety of reasons are thought to contribute to the rapid rise of generic drug costs, but the primary reason is attributed to consolidation among generic drug companies, which has resulted in fewer manufacturers and less competition. In addition, a shortage of raw materials, gaps in production schedules, supply and demand, and regulatory issues have all been cited as reasons. (Generic Drug Price Increases: Causes and Impact, 2015)

While the significant increase in the cost of some generic products has rightfully gained the attention of payers and lawmakers, these increases don't have as much of an impact on overall net expenditures as it might seem at first glance. In many cases, Medicaid can transition utilization away from high-cost generic drugs to lower-cost therapeutic alternatives or low net-cost brands. Thus, while several hundred percent increases in the cost of certain generics can and do increase expenditures to some extent, they are not as significant as other cost drivers when looking at overall pharmacy expenditures.

Outlook for SFY 2016

Despite these pressures on drug spend, CMS' National Health Expenditures Projections estimates that during SFY16, U.S. net Medicaid expenditures for prescription drugs will increase by approximately 8% compared to SFY15.

This is significantly lower than the 14-18% trend seen over the previous two years. This trend is projected to be even lower after SFY16, averaging 5-6% over the next five fiscal years (SFY17-SFY21). (Centers for Medicare and Medicaid Services)

Medicaid: Major Findings

- “Total Medicaid spending is reported to have grown 12.0 percent in 2014 due to increased enrollment of 7.6 million beneficiaries. Primarily driving the increase in enrollment are states that chose to expand coverage to adults up to 138 percent of the federal poverty level.
- The newly insured for Medicaid are believed to have required less medical care than the currently insured, thereby decreasing per beneficiary Medicaid spending from 3.8 percent in 2013 to a projected -0.8 percent in 2014.
- For 2015 to 2024, Medicaid spending growth is projected to be 5.9 percent per year on average, reflecting more gradual growth in enrollment as well as increased spending per beneficiary due to aging of the population.”
(Centers for Medicare and Medicaid Services)

Prescription Drugs – Industry-Wide Drivers of Growth

“Prescription drug spending was projected to have grown 12.6 percent in 2014 to \$305.1 billion. Driving growth were new specialty drugs designed to treat conditions such as hepatitis C, coupled with increased prescription drug use among people who were newly insured and those who moved to more generous insurance plans as a result of the premium and cost-sharing subsidies offered by the Affordable Care Act.

Prescription drug spending growth is projected to average 6.3 percent annual growth from 2015 through 2024, due to improving economic conditions; changes in benefit management designed to encourage better drug adherence for people with chronic health conditions; and anticipated changing clinical guidelines designed to encourage drug therapies at earlier stages of treatment.”

(Centers for Medicare and Medicaid Services)

Projections for Specific Therapeutic Areas

According to Steve Liles, PharmD, Senior Director of Pharmacy Services at DVHA’s contracted pharmacy benefits manager, Good Health systems:

The increase in pharmacy expenditures will continue to be driven by specialty pharmaceuticals. Net expenditures for traditional pharmaceuticals are expected to increase by only 2-4% each of the next two fiscal years (SFY16 and SFY 17). This low rate of increase is due to the fact that low cost generics are available in many traditional

drug classes and with the exception of drugs for diabetes, there are not many innovator products in the traditional drug pipeline over that time period.

Expenditures for diabetes drugs are projected to increase by 18% in each of the next two years. This increase is due to higher utilization of newer diabetes therapies, including longer acting SGLT2 inhibitors and GLP-1 receptor agonists. This increased utilization will stem from a more aggressive approach to the treatment of type 2 diabetes and a shift away from older, less costly therapies.

Pharmacy expenditures for specialty drugs are expected to increase by about 22% in both SFY16 and SFY17. This increase will be led by several classes of specialty drugs that are expected to have increases in expenditures greater than 20% each year. In both SFY16 and SFY17, hepatitis C drugs are expected to continue to lead the way, primarily due to an increase in the number of patients treated. Expenditures for hepatitis C drugs could increase by more than 50-60% in each of the next two years before leveling off as patients with this infection are identified and treated.

Pharmacy expenditures for cancer drugs are likely to increase 20-25% each year for the next several years. This increase is the result of many factors but, in general, is due to the recent and near-term launch of oral cancer drugs that are better tolerated and more effective than previously existing injectable drugs. Many of these new drugs treat cancers for which previously there were no effective (or, at best, minimally effective) treatments. Thus, the availability of these new drugs will increase overall utilization due to expanded indications. Another result of the improved effectiveness of newer cancer drugs is that cancer chemotherapy has, in many cases, become a chronic therapy as progression free survival rates become increasingly longer.

While increases in utilization and net cost of the newer agents are drivers in the overall increases in expenditures for cancer drugs, it should be noted that some of the projected increase in pharmacy expenditures is the result of a shift from utilization of

older, injectable drugs covered under the medical benefit to the newer, oral products covered under the pharmacy benefit. Thus, not all of the projected 20% increase in pharmacy expenditures represents “new” costs but, rather a shift in costs from one benefit to another.

Pharmacy expenditures for drugs used for the treatment of inflammatory conditions (such as rheumatoid and psoriatic arthritis, Crohn’s disease and psoriasis) are projected to increase over 20% each of the next two years. Similar to the cancer drugs, some of this increase will be due to a shift from utilization of drugs covered under the medical benefit. Much of this projected increase, however, will be due to the release of new biologic and non-biologic drugs for the treatment of these conditions, expanded indications for existing products and increased utilization as more patients are diagnosed with an inflammatory disorder. The availability of effective, non-injectable, non-biologic agents will also result in at least some shift away from preferred, higher rebated biologics.

Expenditures for HIV drugs could increase by 15-20% each of the next two years, but some states have increasingly used effective utilization management tools such as inclusion of the class on the Preferred Drug List and non-preferring some of the newer products, which are predominantly single pills containing a combination of existing lower cost drugs. These efforts can largely blunt the increase in expenditures that might otherwise occur. (Lisle, 2015) (Centers for Medicare and Medicaid Services) (ExpressScripts, 2015) (Bruen & Young, 2014)

Vermont statute prohibits Medicaid from placing stricter limits on HIV drugs than the HIV program, the Vermont AIDS Medication Assistance Program (VMAP), therefore we do not currently manage HIV drugs (Vermont General Assembly), but this should be a consideration for the future.

Several other drug classes, including anticoagulants and hereditary angioedema, are expected to have 20-25% increases in pharmacy expenditures in SFY16 that will be, at least in part, due to a shift in utilization away from injectable drugs currently covered under the medical benefit. From a broader budgetary standpoint, it will be important to track this cost-shifting from medical to pharmacy benefits.

Net expenditures for pain medications are likely to increase by about 10% per year as utilization shifts to new, higher-cost, abuse-deterrent formulations. A 10% annual increase in expenditures for asthma drugs is also expected as at least some utilization shifts to new inhalers. Expenditures for growth hormone are also likely to increase by 10% in each of the next two years as new long-acting products and, potentially, an oral agent for adults are launched. (Lisle, 2015)

Section II: Overview of DVHA's Pharmacy Benefit Management Programs

Pharmacy Benefit Administration

The DVHA Pharmacy Unit is responsible for managing all aspects of Vermont's publicly funded pharmacy benefits program. Responsibilities include but are not limited to: processing pharmacy claims; making drug coverage determinations; assisting with drug appeals and exception requests; overseeing federal, state, and supplemental drug rebate programs and the manufacturer fee program; resolving drug-related pharmacy and medical provider issues; overseeing and managing the Drug Utilization Review (DUR) Board; managing of the Preferred Drug List (PDL); and assuring compliance with state and federal pharmacy and pharmacy benefits regulations.

The Unit also has responsibility for overseeing the contract with DVHA's prescription benefit manager (PBM) Goold Health Systems (GHS), which encompasses many clinical and operational services in addition to managing a call center in South

Burlington, Vermont, for pharmacies and prescribers. The Pharmacy unit manages over \$185 million in gross drug spend, and routinely analyzes national and DVHA drug trends, reviews drug utilization, and seeks innovative solutions to delivering high-quality customer service, assuring optimal drug therapy for DVHA members, and managing drug utilization and cost.

During SFY 2015, the DVHA Pharmacy Unit continued its focus on ensuring that members receive high-quality, clinically appropriate, evidence-based medications in the most efficient and cost-effective manner possible. In addition, the unit focused on improving health information exchange through e-prescribing, automated prior authorizations, and other efforts related to administrative simplification for DVHA and our providers.

The Pharmacy Best Practices and Cost Control Program

The Pharmacy Best Practices and Cost Control Program was authorized in 2000 and established in SFY 2002 by Act 127. This program encompasses the following operational strategies:

- Partnering with a vendor with skills and expertise in pharmacy benefit administration
- Managing and processing claims
- Managing benefit design
- Monitoring and managing utilization through retrospective and prospective drug utilization review

- Evaluating new-to-market drug and preferred drug list placement
- Procuring supplemental rebates on drugs used
- Managing reimbursement
- Responding to change

Pharmacy Benefit Management (PBM) Services

The DVHA procured a new PBM contract in May 2014. Goold Health Systems (GHS), an Emdeon company, was chosen as the new Pharmacy Benefit Manager (PBM) effective January 1, 2015. GHS is a national leader in Medicaid health care management services with over 40 years of experience in developing Medicaid Pharmacy Benefit Management (PBM) solutions and provides Medicaid services in sixteen (16) other states.

GHS' expertise includes clinical management, account management, analytics, pharmacy cost management strategies, claims processing, formulary management, and rebate processing. It operates a local Call Center in a South Burlington, Vermont, location, servicing DVHA providers and staffed by Vermont pharmacists and pharmacy technicians. A new provider portal being launched in SFY16 allows pharmacists and prescribers access to a secure, web-based application that offers features such as a pharmacy and member eligibility and drug queries, electronic submission of prior authorizations (PA), uploading of clinical documentation into a document management system, and status updates for submitted PA requests.

Pharmacy benefit management (PBM) services support the program in the following areas:

- Claims processing platform and operational support
- E-prescribing support

- Drug benefit management
- Drug utilization review activities
- Preferred Drug List management
- Drug Prior Authorization programs
 - Manual PA
 - Auto PA
 - EMR PA (SFY16)
- Drug Utilization Review Board coordination
- Federal, State, and Supplemental Rebate management
- Analysis and reporting
- Provider Portal (SFY16)
- Pharmacy and Provider Call Center
- Medication Therapy Management Program (SFY16)

Drug Benefit Program Designs

For the DVHA programs that include full health insurance coverage, all included a pharmacy benefit in SFY 2015. These programs are described on the following page.

DVHA Pharmacy Programs for Members Eligible for Medicare

Overview of Green Mountain Care and Vermont Health Connect Programs as of 1/1/2015 – Last Revised 5/1/15 Created by Vermont Legal Aid’s Office of Health Care Advocate 1-800-917-7787			
PROGRAM	WHO IS ELIGIBLE	BENEFITS	COST-SHARING
MABD Medicaid¹ Medicaid Working Disabled MCA² (Expanded Medicaid)	Aged, blind, disabled at or below the PIL ³ . Disabled working adults at or below 250% FPL ⁴ . Vermonters at or below 138% of FPL who are: <ul style="list-style-type: none"> • Parents or caretaker relatives of a dependent child; or • Adults under age 65 and not eligible for Medicare 	<ul style="list-style-type: none"> • Covers physical and mental health, dental (\$510 cap/yr), prescriptions, chiro (limited), transportation (limited). • Not covered: eyeglasses (except youth 19-20); dentures. • Additional benefits listed under Dr. Dynasaur (below) covered for youth 19-20. • Covers excluded classes of Medicare Part D drugs for dual-eligible individuals. 	<ul style="list-style-type: none"> • No monthly premium. • \$1/\$2/\$3 prescription co-pay if no Medicare Part D coverage. • \$1.20 -\$6.60 co-pays if have Part D. Medicare Part D is primary prescription coverage for dual-eligible individuals. <ul style="list-style-type: none"> • \$3 dental co-pay. • \$3/outpatient hospital visit.
Dr. Dynasaur	Pregnant women at or below 213% FPL.	Same as Medicaid, but with full dental.	No premium or prescription co-pays.
Dr. Dynasaur	Children under age 19 at or below 317% FPL.	Same as Medicaid but covers eyeglasses, full dental, & additional benefits.	<ul style="list-style-type: none"> • Up to 195% FPL: no premium. • Up to 237% FPL: \$15/family/month. • Up to 317% FPL:

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			<p>\$20/family/month . (\$60/family/mo. w/out other insurance)</p> <ul style="list-style-type: none"> • No prescription co-pays.
<p>VPharm1 150% FPL</p> <p>VPharm2 175% FPL</p> <p>VPharm3 225% FPL</p>	<p>Medicare Part D beneficiaries</p>	<ul style="list-style-type: none"> • VPharm1 covers Part D cost-sharing & excluded classes of Part D meds, diabetic supplies, eye exams. • VPharm 2&3 cover maintenance meds & diabetic supplies only. 	<ul style="list-style-type: none"> • VPharm1: \$15/person/mo. pd to State • VPharm2: \$20/person/mo. pd to State • VPharm3: \$50/person/mo. pd to State • \$1/\$2 prescription co-pays. • VPharm1 must apply for Part D Low Income Subsidy.
<p>Medicare Savings Programs:</p> <p>QMB 100%FPL Qualified Medicare Beneficiaries</p> <p>SLMB 120% FPL Specified Low-Income Beneficiaries</p> <p>QI-1 135% FPL Qualified Individuals</p>	<ul style="list-style-type: none"> • QMB & SLMB: Medicare beneficiaries w/ Part A • QI-1: Medicare bens. who are not on other fed. med. benefits e.g. Medicaid (LIS for Part D OK). 	<ul style="list-style-type: none"> • QMB covers Medicare Part B (and A if not free) premiums; Medicare A & B cost-sharing. • SLMB and QI-1 cover Medicare Part B premiums only. 	<p>No cost / no monthly premium.</p>
<p>Healthy Vermonters 350% FPL/ 400% FPL if aged or disabled</p>	<p>Anyone who has exhausted or has no prescription coverage</p>	<ul style="list-style-type: none"> • Discount on medications. (NOT INSURANCE) 	<p>Beneficiary pays the Medicaid rate for all prescriptions.</p>
<p>Qualified Health Plan (QHP)</p>	<p>Legally present Vermonters who do not have Medicare</p> <p>Legally present Vermonters</p>	<p>Choice of QHPs on Vermont Health Connect (VHC)</p> <p>Covers all or part of</p>	<p>Individual pays full premium unless s/he qualifies for tax credits, or employer pays a portion</p>

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<p>[Advance] Premium Tax Credits (APTC / PTC)</p>	<p>from 100-400% FPL⁵ who do not have an offer of affordable⁶ MEC.⁷</p>	<p>premium on VHC.</p>	
<p>Cost-Sharing Reduction (CSR)</p>	<p>Legally present Vermonters up to 300% FPL who do not have an offer of affordable⁵ MEC.⁶ Must purchase silver plan on VHC.</p>	<p>Reduces cost-sharing burden.</p>	

¹ MABD: Medicaid for the Aged, Blind, and Disabled. MABD is the only program w/ resource limits: \$2000/person, \$3000/couple (Medicaid for the Working Disabled is \$5000/person, \$6000/couple). Long Term Care Medicaid (nursing home care; waiver services) is not included in this chart.

¹ MCA: Medicaid for Children and Adults

¹ PIL: Protected Income Limit.

¹ FPL: Federal Poverty Level

¹ Lawfully present non-citizens with FPL below 100% are also eligible for APTC, since they are not eligible for Medicaid until they have lived in the United States for at least 5 years. Their FPL will be treated as 100% FPL for the purposes of determining APTC eligibility.

¹ "Affordable": employee's contribution for a self-only plan is less than 9.56% of household's MAGI (Modified Adjusted Gross Income).

¹ MEC: Minimum Essential Coverage. Vermont Health Connect (VHC) will disregard offers of certain insurance, including student health plans, TRICARE, and Medicare coverage that requires the beneficiary to pay a Part A premium.

(Vermont Legal Aid's Office of Health Care Advocate, 2015)

Section III: Strategies Utilized to Manage the Pharmacy Benefit

Preferred Drug List

DVHA's Preferred Drug List (PDL) includes a list of preferred and non-preferred drugs that are covered by DVHA's drug benefit programs. Currently, DVHA's PDL manages over 175 different therapeutic categories representing thousands of drugs. The PDL is designed to reduce the cost of providing prescription drugs, and is one of the most effective tools used to assure clinically appropriate and cost-effective prescribing. If a drug is not listed as "preferred" in a particular category on the PDL, it requires prior authorization for the drug to be covered. Prescribers can and do refer to the PDL to identify which drugs are most appropriate to prescribe for DVHA members.

The PDL features clinically appropriate, low-cost options including:

- Generics (nearly 79% of DVHA's overall drug use is generic drugs-see Table below);
 - Most do not require PA
- Preferred brand drugs (approximately 70% of DVHA's brand drug utilization-see Chart below);
 - Brand drugs that have clinical superiority to other drugs in the class, or in some cases for which only one drug is available to treat a medical condition
 - Brands where manufacturers pay a level of federal Medicaid rebates that makes the net cost of the drug lower compared to other products in the drug's therapeutic class; and
 - Brands where manufacturers pay Vermont rebates supplemental to required federal Medicaid rebates to make their products more affordable.

- A limited number of preferred brands require PA for clinical reasons
- Non-Preferred brand drugs (approximately 30% of DVHA's brand drug utilization- see #1 chart below);
 - Brand drugs that do not have clinical superiority to other drugs in the class, have similar clinical efficacy and/or offer no clinical advantage
 - Brands where manufacturers pay a lower level of federal Medicaid rebates that makes the net cost of the drug higher compared to other products in the drug's therapeutic class; and the manufacturer does not offer rebates supplemental to the required federal rebates
 - All non-preferred brands require prior authorization

Within all of these categories there may be drugs or even drug classes that are subject to Quantity Limit parameters.

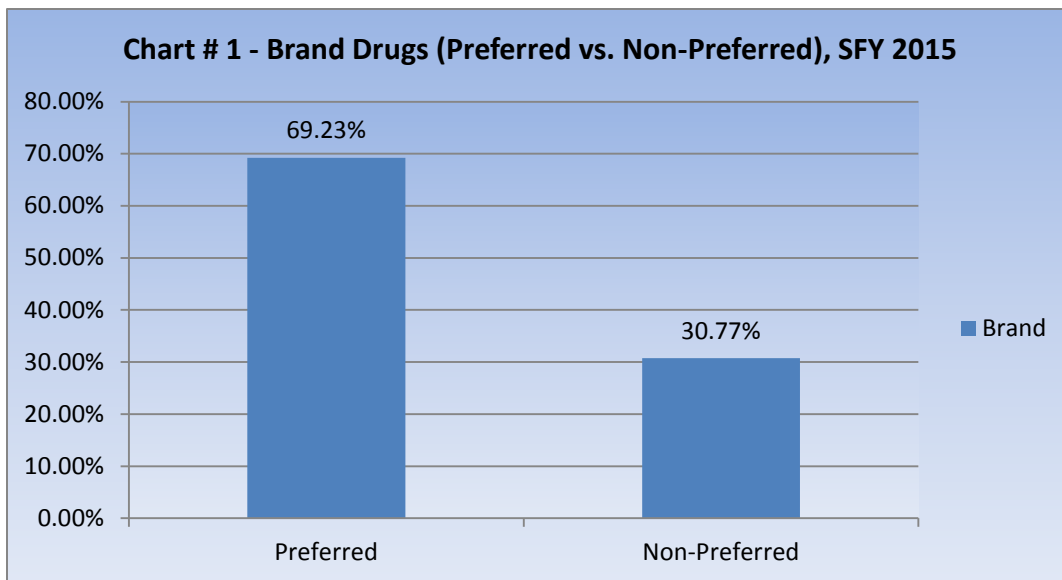


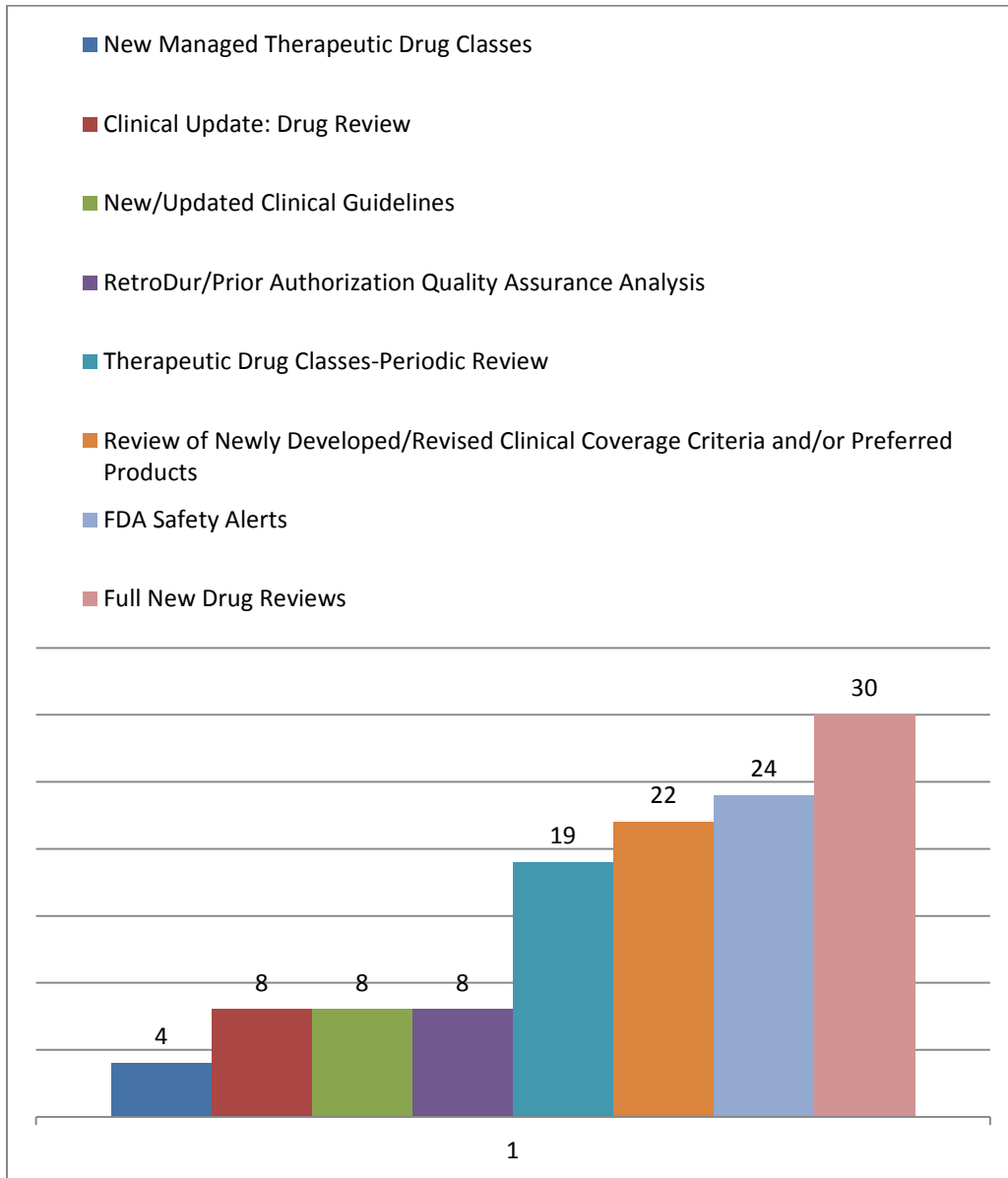
Chart #3: Generic Usage Rate (SFY 2013-2015)			
Generic Indicator	2015	2014	2013
Generic use as a percentage of prescriptions for all drugs dispensed	78.79%	77.19%	76.60%
Generic use as a percentage of prescriptions when a generic equivalent is available	89.26%	88.10%	88.15%

Drug Utilization Review (DUR) Board

The Drug Utilization Review (DUR) Board of the Department of Vermont Health Access (DVHA) is a committee composed of Vermont physicians and pharmacists. In SFY 2015 the Board membership included five physicians, one Nurse Practitioner and five pharmacists. The DUR Board meets approximately every six weeks, and there are eight meetings per year with a robust agenda composed of drug utilization review and analyses, reviews of new drugs, new indications and dosage forms, therapeutic class reviews including recently published treatment guidelines and best practices that may influence clinical criteria, safety information, and other drug information pertinent to managing the drug benefit programs for DVHA.

The Board also routinely reviews therapy by examining patterns in prescribing, dispensing and consumption of medications. The Board may help DVHA select the most relevant drugs to target for review to ensure that clinical criteria and prescribing patterns are appropriate. As an outcome of these reviews, the Board identifies specific therapeutic and clinical behaviors that, if altered, may improve patient outcomes and lower costs. These activities allow DVHA, with the Board's guidance, to optimize the pharmaceutical care received by our members. The chart below describes some of the SFY2015 activities of the DUR Board:

Chart #4, DUR Board Activities, SFY 2015



Some topics of discussion at DUR Board meetings in SFY 2015 included drug utilization reviews of skeletal muscle relaxants, sleep agents, concomitant opioids and benzodiazepines, long-term use of diazepam, and Hepatitis C drugs and viral load testing.

DVHA also creates and distributes provider communications when certain changes are made to clinical criteria or dosing limitations, or if an educational communication is appropriate based on a drug utilization review. For example, if a preferred drug is changed to a non-preferred status and specific beneficiaries are affected, prescribers are provided with a list of all the patients who were prescribed the specific drug that is being changed and a profile unique to each patient with the drug change listed. This creates a record for use in the patient's file and advance notice to provider offices of the upcoming change. DVHA's pharmacy unit uses various forms of communication including letters to providers, "fax blasts", banners on the provider payment statements, website postings, and in SFY 2016 the provider portal will offer an excellent option for direct provider communication.

Prior Authorization Program

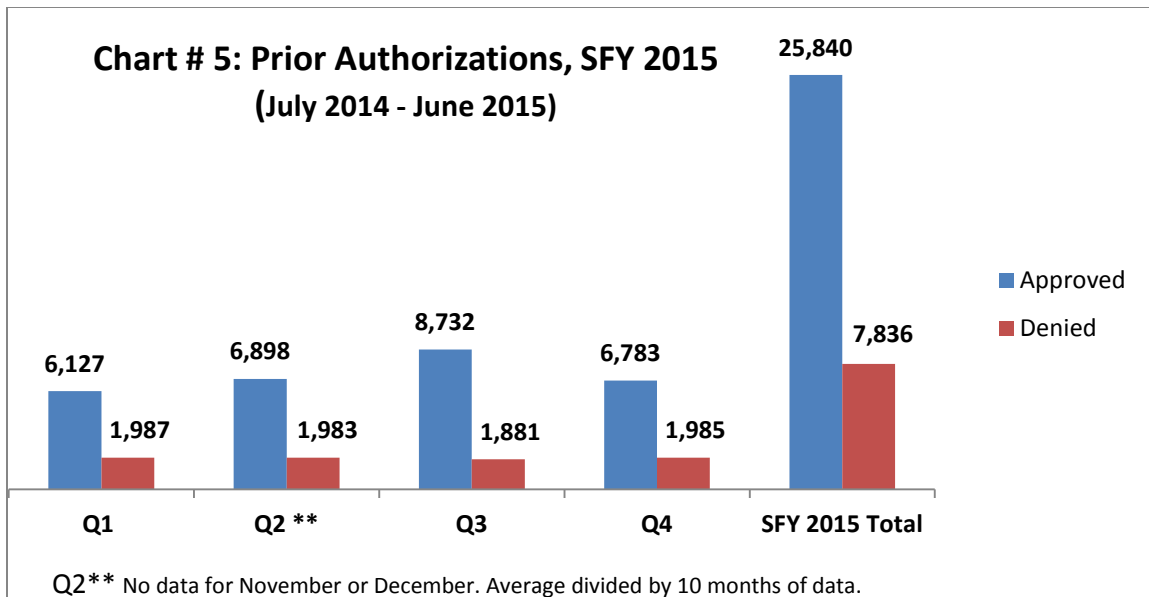
DVHA's prior authorization program is an extremely important tool in managing cost and clinical appropriateness of drug use. While most insurers can utilize high copays, high premiums, multiple drug tiers, and other forms of member cost sharing to shift utilization to preferred products, DVHA is limited in that capacity, and therefore a prior authorization program becomes an even more important tool in managing utilization.

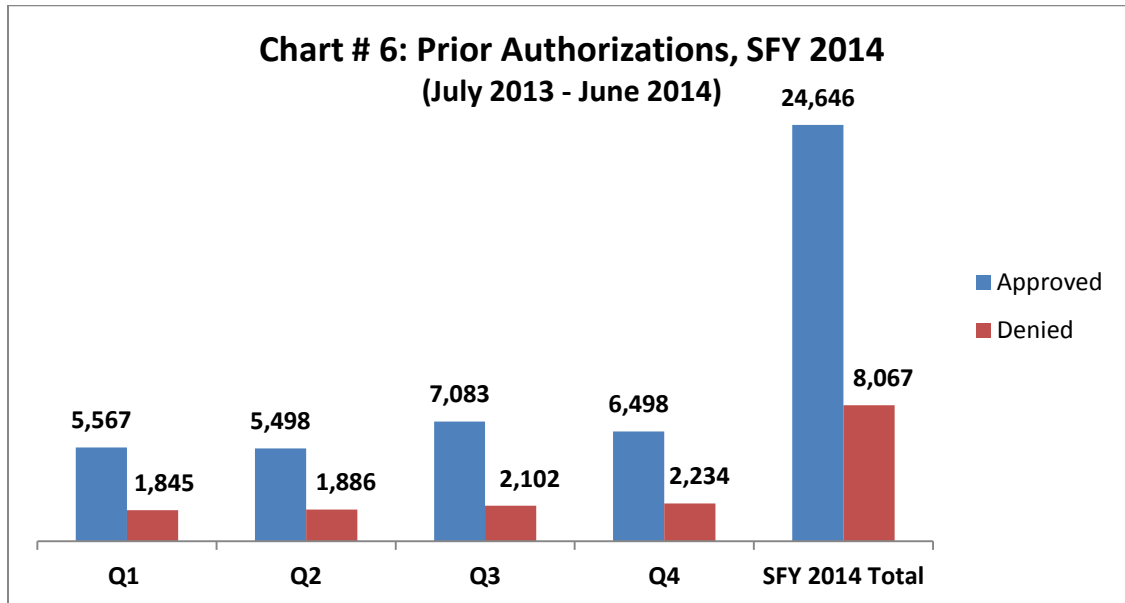
Prescribers can submit a prior authorization to request coverage of a non-preferred drug on the PDL. Many drugs have specific criteria, such as a specific

diagnosis or lab test result, while other drugs have more general criteria and simply require a “step-through” a preferred drug. Other drugs are set up with automated criteria, where the system is able to identify previous drug therapy, or a pre-existing diagnosis and the PA process is completed by the POS system and is invisible to the providers.

Goold Health System (GHS) staff, including physicians and clinical pharmacists, helps DVHA structure and manage the application of the criteria. As explained above, the DUR Board helps DVHA create new criteria as new drugs enter the market or new classes are selected for management. All criteria and therapeutic classes are reviewed at least biennially. New criteria and proposed changes are reviewed, modified, and approved by the DUR Board.

The following charts reports the incidence of prior authorization requests in SFY 2015:





State Maximum Allowable Cost (SMAC) Program

Vermont's state MAC or "SMAC" program is modeled after the Centers for Medicare & Medicaid Services (CMS) Federal Upper Limit (FUL) program. The intent is to provide a maximum price the State of Vermont will pay for a given generic pharmaceutical regardless of its package size or manufacturer. The MAC program is designed to promote the efficient purchasing of generic pharmaceuticals within the pharmacy provider network to ensure that the Medicaid program is a frugal payer of prescription drugs.

In developing the state MAC pricing list the State of Vermont utilizes its PBM Gould Health Systems (GHS) to determine the appropriate "average" price for a generic drug. GHS utilizes multiple sources for determining accurate pricing information, some sources are based on actual acquisition cost data from pharmacy submitted invoices and GHS also reviews both state-specific and national industry data. Some examples of

the benchmarks used include wholesale acquisition cost (WAC), federal upper limit (FUL), post-Affordable Care Act FULs, and national average drug acquisition cost (NADAC) prices.

A full review of the SMAC pricing list is done on a monthly basis. These reviews include reviewing any new generics that have entered the market and obtaining acquisition cost to determine if a MAC can be applied or needs to be adjusted on a drug. GHS also monitors changes in product availability & drug shortages for the State of Vermont, which may affect the price of drug products so we can proactively adjust SMAC pricing to assure fair and accurate reimbursement to Vermont pharmacies.

Effective July 1, 2015, Title 18 of the Vermont Statutes requires pharmacy benefit managers, including DVHA to make available the maximum allowable cost (MAC) listing in a readily accessible format. Vermont's MAC list has always been and is currently available on the DVHA pharmacy provider website. Pharmacy providers who wish to appeal reimbursement on a claim may submit a special request form found on the DVHA website. Appeals must be received within 10 calendar days of the claim adjudication date and DVHA responds within 10 calendar days of receipt of a timely appeal request.

Section IV: Pharmacy Program Statistics

**Chart #6: Gross Pharmacy Claims and Spend
 (prior to application of rebates), SFY 2013-2015)**

All Claims						
SFY	CLAIM_COUNT	Year to Year Difference	GROSS AMOUNT PAID	Year to Year Difference	GROSS COST/CLAIM	Year to Year Difference
2015	2,118,287	3.18%	\$187,482,670	16.58%	\$89	13.93%
2014	2,053,032	-0.72%	\$156,389,616	9.74%	\$76	10.39%
2013	2,067,911		\$141,155,930		\$68	
Medicaid						
SFY	CLAIM_COUNT		GROSS AMOUNT PAID		GROSS COST/CLAIM	
2015	1,626,364	7.98%	\$179,340,168	17.42%	\$110	10.83%
2014	1,506,119	-0.26%	\$148,092,540	10.09%	\$98	10.32%
2013	1,510,004		\$133,156,177		\$88	
Vpharm						
SFY	CLAIM_COUNT		GROSS AMOUNT PAID		GROSS COST/CLAIM	
2015	380,216	-12.39%	\$6,546,586	-4.47%	\$17	8.48%
2014	433,998	-5.51%	\$6,838,920	3.45%	\$16	8.77%
2013	459,283		\$6,602,708		\$14	
Dual Eligibles						
SFY	CLAIM_COUNT		GROSS AMOUNT PAID		GROSS COST/CLAIM	
2015	111,707	-1.07%	\$1,595,916	8.63%	\$14	9.61%
2014	112,915	14.49%	\$1,458,156	4.19%	\$13	-9.69%
2013	98,624		\$1,397,045		\$14	

NOTE:

Dual-Eligibles: DVHA only pays for non-Part D drugs, primarily over-the-counter (OTC) drugs

VPharm: DVHA pays secondary to Part D, and for non-Part D drugs, primarily OTC drugs

**Chart #7: Net Pharmacy Claims Cost – Medicaid Only
(after application of rebates), SFY 2013-2015**

Medicaid										
SFY	CLAIM_COUNT	GROSS AMOUNT PAID	COST/CLAIM	TOTAL REBATES INVOICED*	NET AMOUNT PAID	Year-to-year Difference	Eligible Member Count	Year-to-year Difference	NET SPEND PMPM	Year-to-year Difference
2015	1,626,364	\$179,340,168	\$110	\$94,113,866	\$85,226,302	12.88%	167890	2.44%	\$42.30	11.16%
2014	1,506,119	\$148,092,540	\$98	\$73,840,061	\$74,252,479	7.89%	163796	11.27%	\$37.78	-4.33%
2013	1,510,004	\$133,156,177	\$88	\$64,761,793	\$68,394,383		145334		\$39.22	

* estimated invoiced amount

CHART #8A, Top Drugs by Spend, SFY 2015

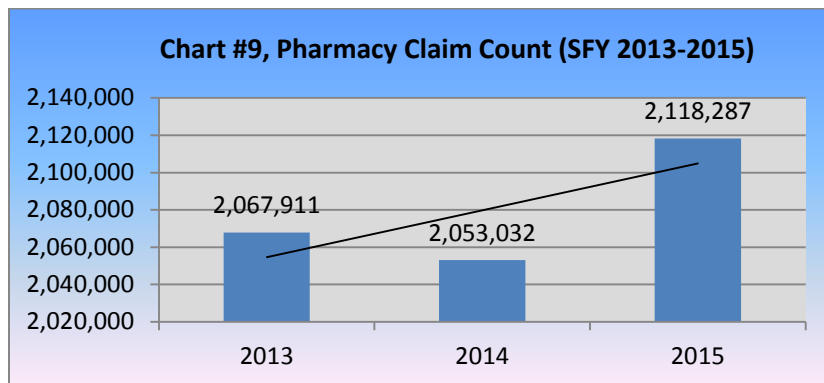
DRUG NAME	UNIQUE RECIPIENTS	RX COUNT	AMOUNT PAID	AVERAGE PAYMENT PER CLAIM
HARVONI TAB 90-400MG	70	234	\$5,869,568.40	\$25,083.63
SUBOXONE MIS 8-2MG	1891	22687	\$2,642,262.40	\$116.47
LANTUS INJ SOLOSTAR	1152	2857	\$1,843,298.44	\$645.19
HUMIRA PEN INJ 40MG/0.8	118	486	\$1,682,432.47	\$3,461.80
PROAIR HFA AER	11924	19123	\$1,225,371.87	\$64.08
SUBOXONE MIS 12-3MG	631	7238	\$963,747.56	\$133.15
ENBREL SRCLK INJ 50MG/ML	78	276	\$941,797.45	\$3,412.31
ABILIFY TAB 5MG	315	905	\$926,391.84	\$1,023.64
NOVOLOG INJ FLEXPEN	592	1293	\$884,093.28	\$683.75
SPIRIVA CAP HANDIHLR	738	1528	\$866,108.78	\$566.83

CHART # 8B, Top Drugs by Volume, SFY 2015

DRUG NAME	UNIQUE RECIPIENTS	RX COUNT	AMOUNT PAID
SUBOXONE MIS 8-2MG	1891	22687	\$2,642,262.40
PROAIR HFA AER	11924	19123	\$1,225,371.87
SUBOXONE MIS 12-3MG	631	7238	\$963,747.56
SUBOXONE MIS 2-0.5MG	753	6148	\$370,695.41
HYDROCO/APAP TAB 5-325MG	3231	5009	\$74,625.95
GABAPENTIN CAP 300MG	1929	4608	\$93,297.72
IBUPROFEN TAB 800MG	2845	4585	\$38,161.00
FLUTICASONE SPR 50MCG	3036	4412	\$123,543.83
TRAMADOL HCL TAB 50MG	1435	3440	\$36,515.63
LORATADINE TAB 10MG	1360	3183	\$44,953.16

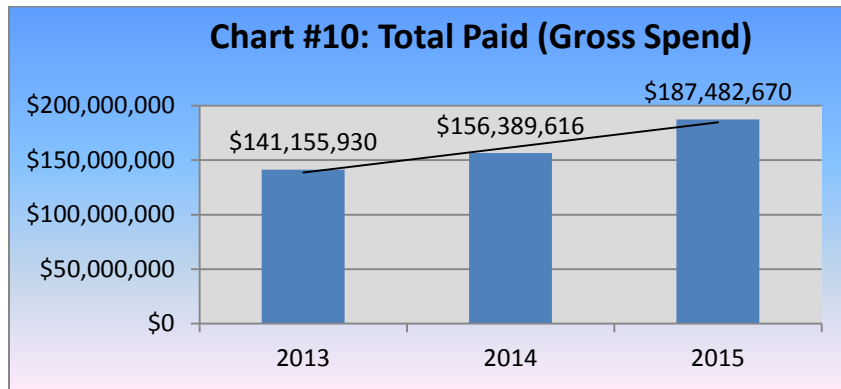
Pharmacy Claims

A total of 2,118,287 pharmacy drug claims were paid for all of Vermont’s publicly funded pharmacy programs during SFY 2015. This represents a 3.2% increase in the number of pharmacy claims paid in SFY 2014.



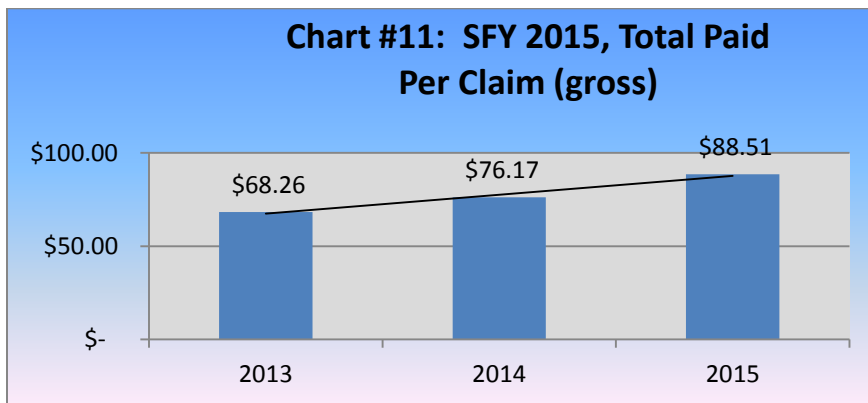
Gross Spend – SFY 2015

Gross spending prior to rebates for pharmacy drug claims was \$187.5 million for SFY 2015. This represents a 16.5% increase in gross spending on pharmacy claims from SFY 2014.



Gross Cost Per Claim – SFY 2015

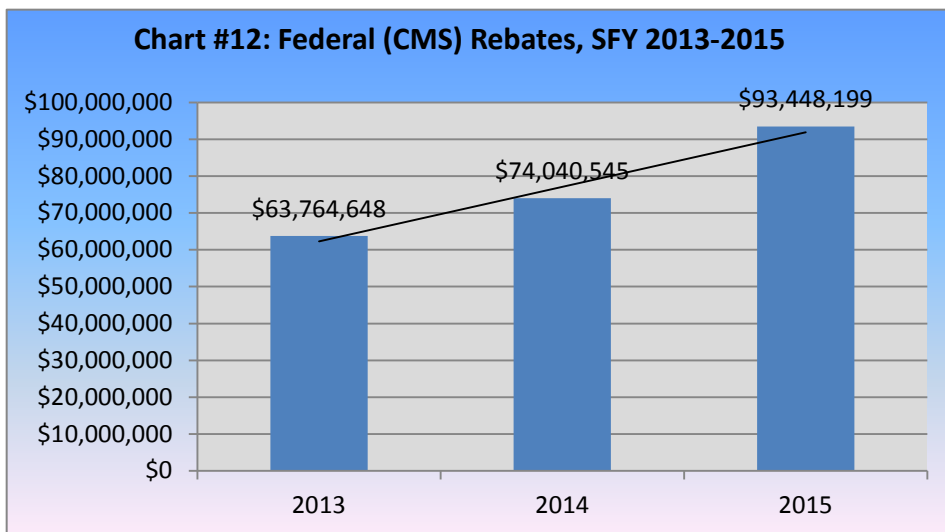
The average gross cost per claim increased from \$76 in SFY 2014 to \$88.5 in SFY 2015, a year-to-year increase of 13.9%.



Federal Rebates

Federal rebates that manufacturers pay to states are calculated based on prices manufacturers set, and financial concessions manufacturers make available to all entities that purchase their drugs. The two prices used in the calculation are “best price” and the “average manufacturer price” (AMP). The DVHA does not directly influence the amount of Federal rebate for a particular drug. Drugs that have large Federal rebates may be preferred based on their lower net cost to the State. In general, Federal rebate collection increases as overall drug utilization increases. Also, generally, the longer a drug is on the market the larger its federal rebate due to the rebates being based in part on the Consumer Price Index to account for inflation.

Federal rebates invoiced in SFY 2015 totaled \$93.5 million. This represents a 20.8% increase from SFY 2014.

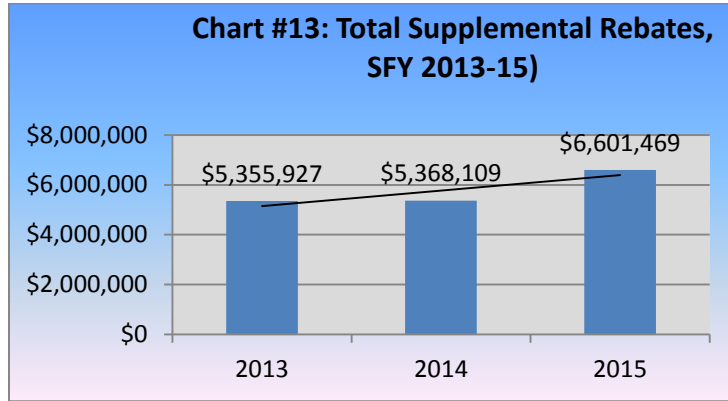


Supplemental and Diabetic Supplies Rebates

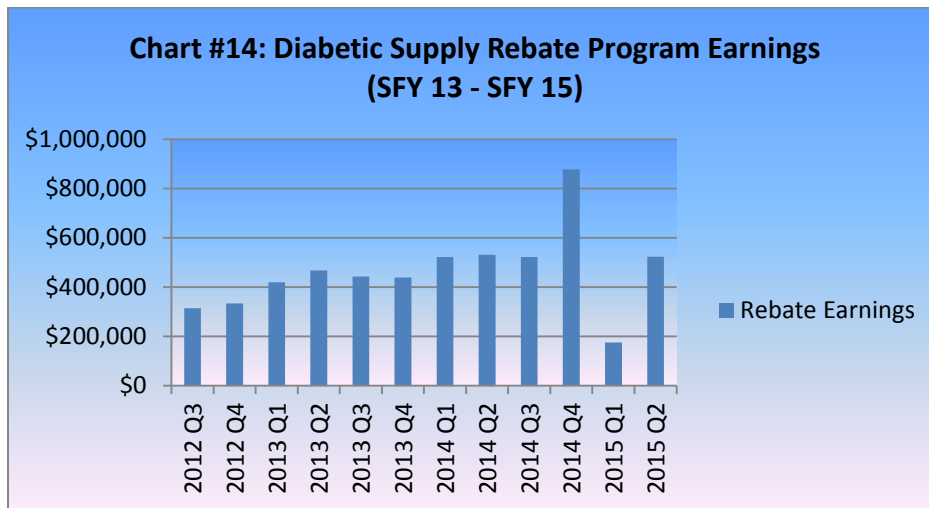
Supplemental rebates are negotiated by the State through its participation in the Sovereign States Drug Consortium (SSDC). Supplemental rebates are those rebates in addition to the required federal rebates on a drug, while Diabetic supply rebates are state-only rebates on Diabetic Supplies for which we do not get federal rebates. Both programs provide substantial rebate value to the State. The SSDC is the only state-administered Medicaid supplemental drug rebate pool. Vermont contracts for SSDC-negotiated supplemental rebates via its own Supplemental Rebate Agreement, enabling us to retain control and flexibility in the management of our preferred drug list while taking advantage of the additional leverage provided by the large number of members covered by the SSDC pool.

Now in its tenth year of operation, the SSDC was first authorized by the Centers for Medicare and Medicaid Services (CMS) in 2006 in the approvals of the supplemental rebate State Medicaid Plan amendments of the founding Member States - Iowa, Maine, and Vermont. Since 2006, the states of Utah, Wyoming, West Virginia, Oregon, and Mississippi have joined the SSDC and received CMS approval of their plans. In 2015, the states of North Dakota and Delaware joined the SSDC and are seeking CMS approval. In 2015, a total of 2,593,682 members and \$1,746,704,426 in drug expenditures is represented by the 10 participating states providing substantial leverage in manufacturer negotiations.

Supplemental rebates invoiced in SFY 2015 totaled \$6.6 million, representing a 23% increase over SFY 2014.

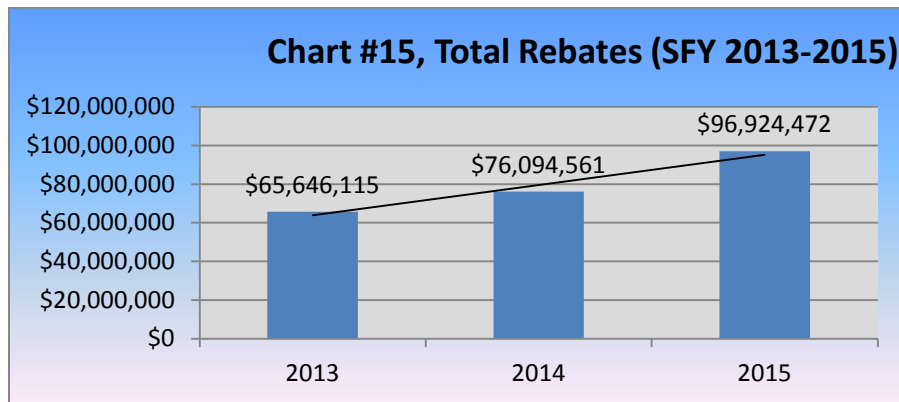


These increases are due to an improvement in rebate contracting on a variety of drug products as well as increases in utilization. In some cases, the Sovereign States Drug Consortium (SSDC) aggressively negotiated more substantial supplemental rebates. For other drugs, new drug categories were added to the Preferred Drug List for drug management in order to be able to accept and realize the supplemental rebates being offered. Rebate amounts for Diabetic Supplies totaled \$2,097,490 in SFY 2015.



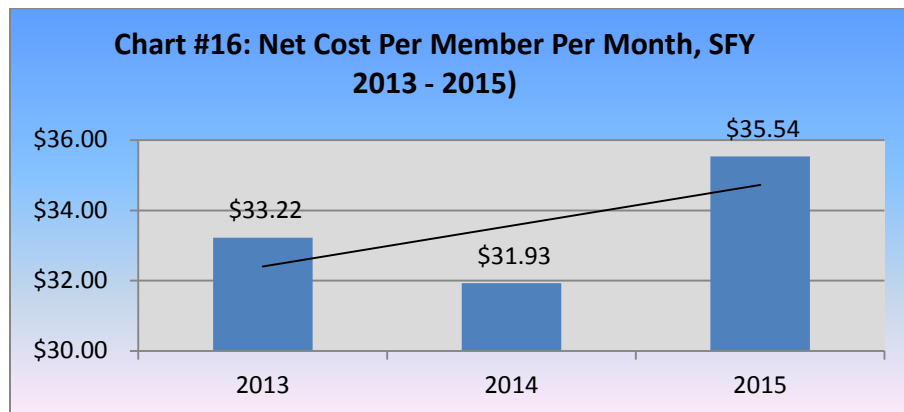
Total Rebates

Total rebates for all rebate programs have grown 20.6% from SFY 2014 to SFY 2015.



Total Net Cost

Net of all rebates, the total program spend was \$87.4 million compared to \$76.9 million in 2014, a 12.8% increase in SFY 2015 compared to SFY 2014. Net of all rebates, per-member, per-month spending increased 10.1%.



Generic Dispensing Rates

The rate of generic dispensing reflects the use of generics as a percentage of all drugs dispensed. The rate of generic substitution reflects the percentage of time generics are utilized when a generic equivalent is available for a drug. Unlike commercial insurance and Part D plans, Medicaid generic utilization rates are typically lower since brands that lose patent protection are often more cost-effective for the State for a period of time after generics enter the market. This is especially true for the first six months to a year after patent expiration, and is reflected in the “brand-preferred” products on our PDL. This is a result of the impact of the federal rebate program.

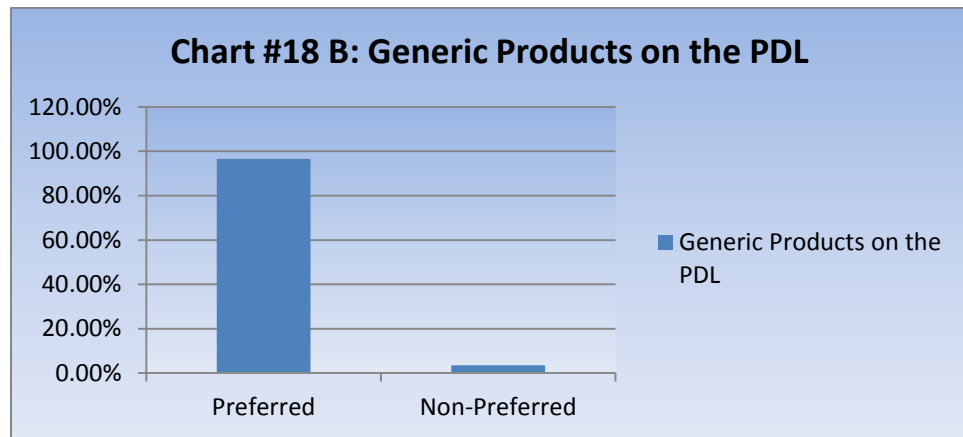
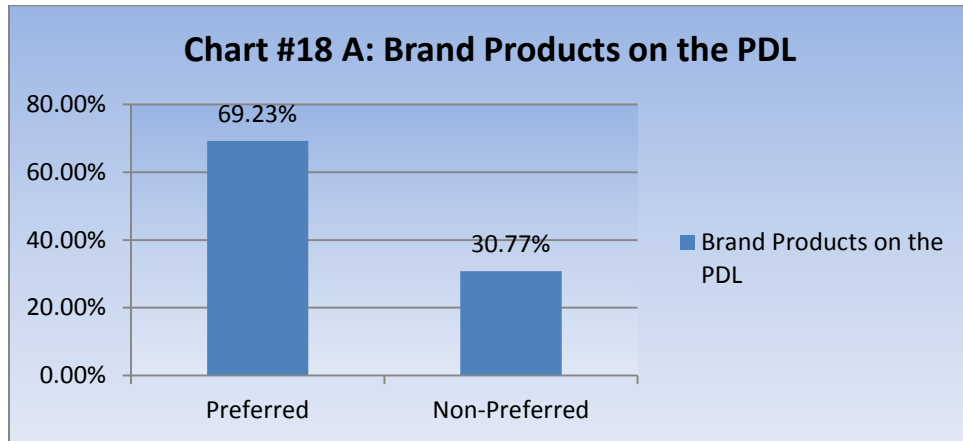
The following chart illustrates this observation for state fiscal years 2013 through 2015 for Medicaid versus our VPharm and Dual Eligible (Medicare) populations:

Chart #17: Generic Dispensing Rates, SFY 2013 - 2015

	Medicaid			Vpharm and Duals		
	2015	2014	2013	2015	2014	2013
Generic use as a percentage of prescriptions for all drugs dispensed	78.8%	77.2%	76.6%	83.7%	83.7%	83.1%
Generic use as a percentage of prescriptions when a generic equivalent is available	89.3%	88.1%	88.2%	93.0%	91.5%	90.4%

Preferred Drug List Compliance

The following charts display the percentage of time a preferred brand or generic is used compared to a non-preferred product.



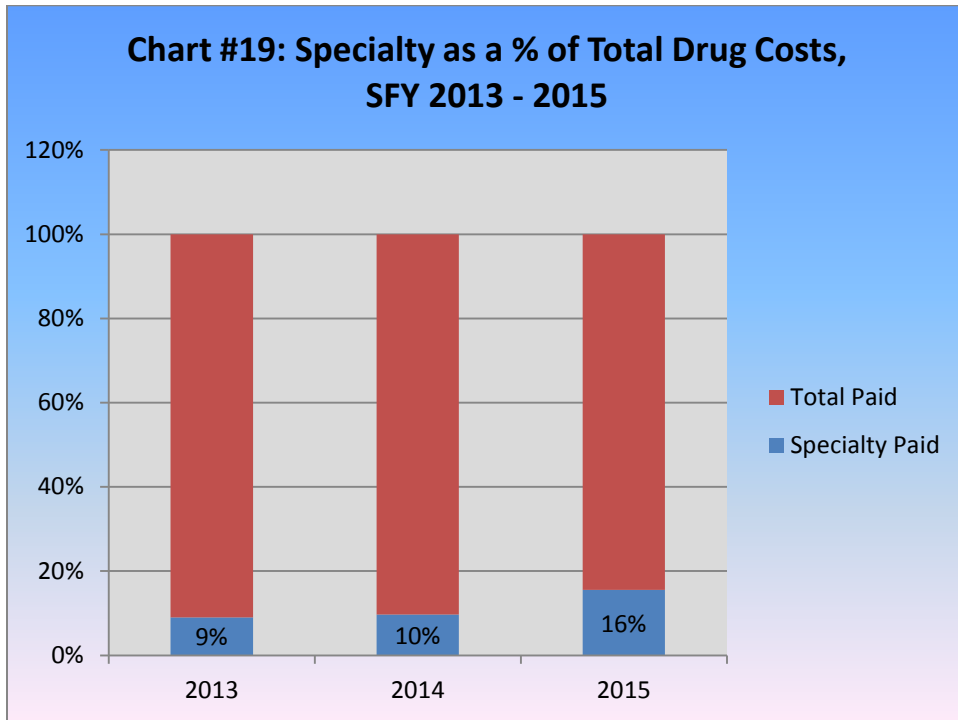
Specialty Pharmacy

In SFY 2015, Vermont Medicaid utilized the services of two specialty pharmacies. Wilcox Medical is a home infusion pharmacy and home medical equipment supplier owned by BioScrip®, and BriovaRx® is a full-service specialty pharmacy located in South Portland, Maine partnering with our pharmacy benefits manager, Goold Health Systems (GHS).

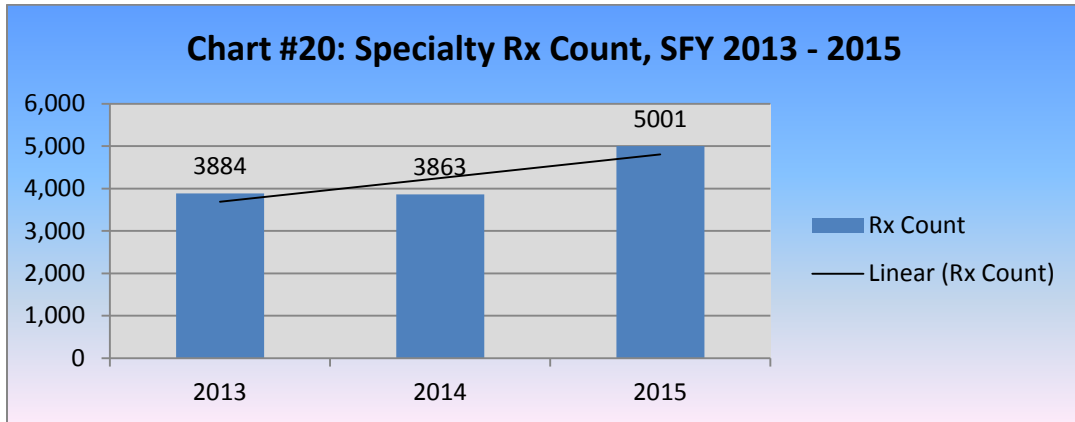
Wilcox Medical is the specialty pharmacy for the specialty drug Synagis® used to prevent respiratory syncytial virus (RSV) in at-risk infants, and BriovaRx™ is the specialty pharmacy for most other specialty drugs.

Some examples of specialty drugs managed by BriovaRx include drugs used to treat multiple sclerosis; hepatitis C; cancer; rheumatoid, psoriatic and juvenile arthritis; psoriasis; Crohn's Disease; ankylosing spondylitis; growth hormone deficiencies; and ulcerative colitis. Dispensing of identified specialty medications is limited to these pharmacies for Medicaid beneficiaries where Medicaid is the primary insurer. Both providers were selected based on a combination of the quality and the value of the services they offered and the competitive pricing of the products involved.

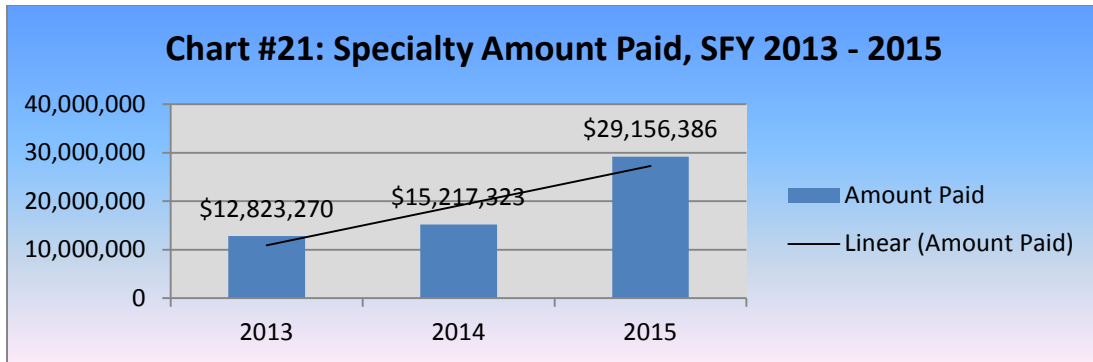
In SFY 2015, specialty drugs represented 16% of DVHA's overall drug spend. This was a 60% increase over SFY 2014, when specialty drug spend represented 10% of DVHA's drug spend.



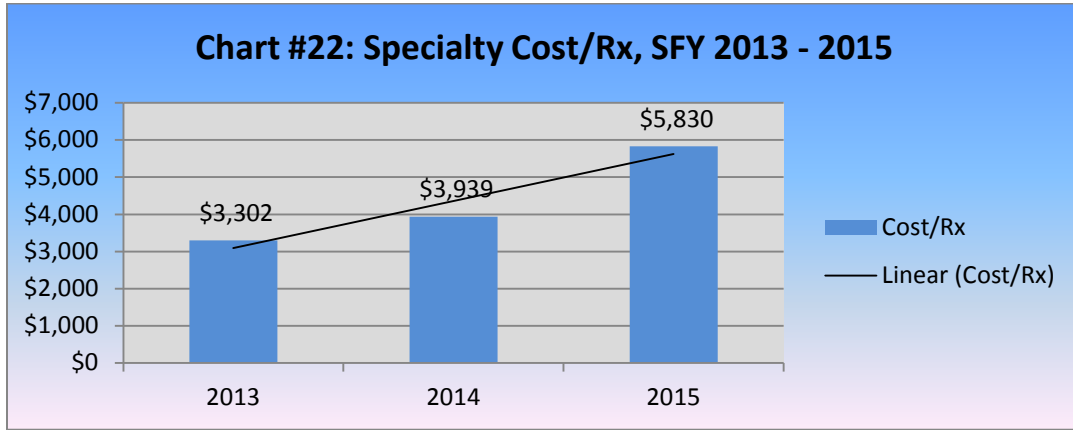
In SFY2015, DVHA paid 5,001 specialty prescriptions. This was a 29% increase over SFY 2014, when DVHA paid 3,863 specialty prescriptions.



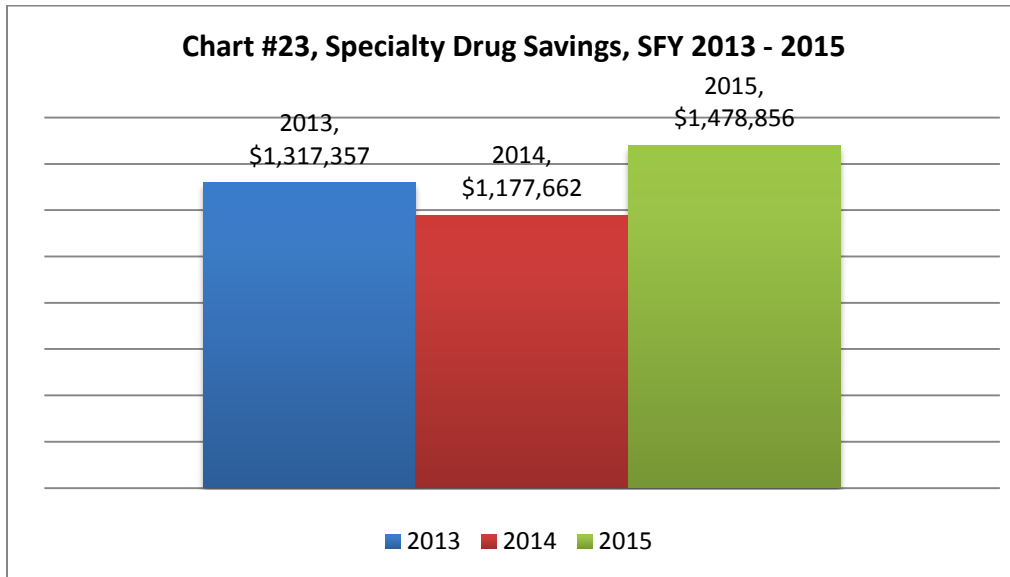
In SFY 2015, DVHA spent \$29,156,386 on specialty drugs. This is a 92% increase over SFY2014, when specialty costs were \$15,217,323.



In SFY 2015, DVHA spent an average cost of \$5,830 per specialty drug prescription. This is a 48% increase over SFY, when the average specialty prescription cost was \$3,939.



In SFY2015, savings attributable to DVHA's preferred specialty pharmacies totaled \$1,478,856, a 20% increase over SFY 2014.



Section IV:

Works Cited

- Alpern, D., Stauffer, W., & Kesselheim, A. (2014, November 13). *High-Cost Generic Drugs — Implications for Patients and Policymakers*. Retrieved October 9, 2015, from New England Journal of Medicine: <http://www.nejm.org/doi/full/10.1056/NEJMp1408376?af=R&rss=currentIssue&>
- Bruen, B., & Young, K. (2014, December 2019). *What Drives Spending and Utilization on Medicaid Drug Benefits in States?* Retrieved October 20, 2015, from The Henry J. Kaiser Family Foundation: <http://kff.org/medicaid/issue-brief/what-drives-spending-and-utilization-on-medicaid-drug-benefits-in-states/>
- Centers for Medicare and Medicaid Services. (n.d.). *National Health Expenditure Data, Projected*. Retrieved October 5, 2015, from <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>
- ExpressScripts. (2015, March). *Express Scripts 2014 Drug Trend Report*. Retrieved October 20, 2015, from lab.express-scripts.com/~media/PDFs/Drug%20Trend%20Report/ExpressScripts_DrugTrendReport.ashx
- Generic Drug Price Increases: Causes and Impact*. (2015). Retrieved October 8, 2015, from Elsevier Clinical Solutions: http://www.ncpa.co/pdf/elsevier_wp_genericdrug.pdf
- Helfand, C. (2015, October 5). *Valeant's price-hike strategy goes far beyond two high-profile increases*. Retrieved October 8, 2015, from FiercePharma: <http://www.fiercepharma.com/story/valeants-price-hike-strategy-goes-far-beyond-two-high-profile-increases/2015-10-05>
- Lisle, S. (2015, October 8). *Projections for Specific Therapeutic Areas*. Augusta: Goold Health Systems, Inc.
- Newsmax Health. (2015, May 15). *New Cystic Fibrosis Treatment OKd by FDA*. Retrieved October 9, 2015, from Newsmax Health: <http://www.newsmax.com/Health/Health-News/Orkambi-cystic-fibrosis-drug/2015/05/12/id/644161/>
- UnitedHealth Center for Health Reform & Modernization. (2014, April). *The Growth of Specialty Pharmacy, Current trends and future opportunities*. Retrieved October 5, 2015, from

Unitedhealthgroup.com: <http://www.unitedhealthgroup.com/~media/uhg/pdf/2014/unh-the-growth-of-specialty-pharmacy.ashx>

Vermont General Assembly. (n.d.). *The Vermont Statutes Online*. Retrieved October 8, 2015, from Title 33: Human Services, Chapter 19, Medical Assistance:
<http://legislature.vermont.gov/statutes/chapter/33/019>

Vermont Legal Aid's Office of Health Care Advocate. (2015, May 1). Overview of Green Mountain Care and Vermont Health Connect Plans. Burlington, Vermont.

Vertex Pharmaceuticals - 2. (2015). *KALYDECO(TM)*. Retrieved October 12, 2015, from HIGHLIGHTS OF PRESCRIBING INFORMATION: http://pi.vrtx.com/files/uspi_ivacaftor.pdf

Vertex Pharmaceuticals. (2015, July 20). *ORKAMBI(TM), HIGHLIGHTS OF PRESCRIBING INFORMATION*. Retrieved October 8, 2015, from http://pi.vrtx.com/files/uspi_lumacaftor_ivacaftor.pdf