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Title Page Photo Source – McGill University Faculty of Medicine
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Executive Summary

Despite a recent slowdown, spending on healthcare in the United States continues to grow faster than the rate of inflation. Consumers, employers, and public insurance programs are all impacted by this continued growth, as spending on healthcare consumes an ever-greater proportion of budgets. State Medicaid Agencies have been particularly interested in understanding the underlying drivers of this growth, given that Medicaid programs now comprise 27.4% of the average state’s total expenditures.

Total spending on prescription drugs has recently gained national attention as a major factor in cost increases. The introduction of several specialty drugs in the past year, including the new Hepatitis C drug, Sovaldi, has contributed significantly to this cost growth. With an estimated 8% annual pharmacy cost growth expected over the next few years, many states have turned to their prescription drug policies and reimbursement programs to analyze whether cost savings might be possible. ¹

MassHealth, the agency within the Commonwealth of Massachusetts that administers its Medicaid program, experienced a significant increase in spending in 2014 (+$2.4 billion, or a 19% increase) due to greater than expected enrollment and costs associated with the introduction of several high-cost specialty drugs. While MassHealth has instituted numerous initiatives to control its pharmaceutical costs, new policy solutions are necessary to curb the continued rise in the cost of medications while ensuring broad access to treatment.

This report analyzes nine potential strategies to address the cost primary drivers within the Medicaid pharmacy program. This includes several supply-side strategies to achieve savings from drug manufacturers and pharmacies, as well as demand-side strategies to improve patient adherence.

We establish an evaluation framework to assess these strategies using a standardize set of criteria. These criteria include estimated cost savings, operational burden, political feasibility, impact on access, and impact on quality.

Based upon this assessment, we recommend four strategies to reduce costs within MassHealth’s pharmaceutical budget:

1. Continue to Expand the Supplemental Rebate Program
2. Establish Differential Reimbursement Rates for Specialty Drugs
3. Join a Multi-State Purchasing Cooperative
4. Pilot a Medication Therapy Management (MTM) Program

Together, these recommendations may generate up to $50 million in annual savings for the MassHealth pharmacy budget. These strategies help to ensure that the MassHealth pharmaceutical program expenditures grow at a sustainable rate, while also continuing to provide the highest-quality pharmaceutical care to all MassHealth members.

¹ Interview with MassHealth Pharmacy Officials, March 2016
Section I - Increasing Cost of Health Care

Over the past several years, the U.S. had experienced historically low rates of annual growth in health care spending, with health expenditures rising at approximately 3% annually from 2008 through 2013. This trend reversed course in 2014, the first full year that Medicaid expansions and mandatory health insurance coverage established by the Patient Protection and Affordable Care Act (ACA) took effect. Total national health care expenditures increased by 4.7% in 2014, and are projected to increase by an average rate of 4.9% per year from 2014 to 2024. As these increases are greater than that of inflation, a higher overall proportion of economic activity will be devoted to health care services in the years ahead.

In 2012, the Massachusetts legislature enacted a law requiring medical expenditures in the state to grow at a rate less than or equal to the growth rate of the state domestic product, the current benchmark is set at 3.6%. This law included a penalty meant to incentivize health care entities to slow their spending growth. Despite the enactment of this law, medical expenditures outpaced the state economic growth at a rate of 4.8% in 2014, raising total expenditures to $8,010 per capita. Medicaid expenditures were a major factor in the Commonwealth’s aggregate growth, with MassHealth expenditures increasing by 19%, an additional $2.4 billion in costs. This increase in total MassHealth expenditures outpaced the national Medicaid average of a 16% increase in spending.

Increases in Medicaid expenditures can have a substantial impact on state budgets, with Medicaid programs comprising, on average, 27.4% of state total expenditures. At present, MassHealth accounts for more than 30% of the Commonwealth’s budget, leading many Massachusetts officials and legislators to take an interest in understanding the drivers of growth. While the Federal government reimburses 50% of all MassHealth’s costs, the state must initially allocate these resources “up front” in order to reimburse providers for their services. In fiscal year (FY) 2015 MassHealth was allocated $13.6 billion, increasing to $14.8 billion in FY16.

Continued growth in Medicaid expenditures has a “crowding out” effect on state budgets that leaves less flexibility in the Commonwealth’s budget for other priorities and obligations, including investments in transportation, infrastructure, or education - absent further revenue increases. Analyzing, and accounting for, current and future growth trends will allow states to alter their Medicaid programs and/or reimbursement models to incentivize more efficient spending.

Much of the recent growth in health care spending has been attributed to two primary factors:

1) A significant increase in Medicaid enrollment, and
2) Rapid growth in pharmacy costs.

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2 KFF, Peterson Health System Tracker (A)
4 KFF-Peterson Health System Tracker (B) – How Much is Health spending Expected to Grow?
6 CHIA (2015)
7 CBO (2016)
8 National Association of State Budget Officers (2015)
9 Massachusetts Medicaid Policy Institute (2015)
Coverage Expansions
Recent analysis attributes much of the national spending growth to the major coverage expansions under the ACA. This includes increased insurance coverage through the individual marketplaces, mandates for employer-sponsored insurance, and an expansion in state-based Medicaid programs, each of which contribute to higher rates of utilization of health care services.

Nationally, Medicaid enrollment grew by 13.2% in 2014 (compared to 1.7% in 2013), due to the expansion of coverage for new eligibility groups under the ACA. This increase is also due to the “woodwork effect,” in which previously eligible individuals also chose to enroll in the Medicaid program.

In Massachusetts, enrollment grew by an unanticipated 23% in 2014, despite having expanded coverage prior to the ACA. This was primarily due to a malfunctioning of the state health care exchange website. From October 2013 until December 2014, all individuals that applied for subsidized exchange coverage were automatically enrolled as a temporary MassHealth member regardless of whether they were eligible for MassHealth or the Connector. As a result, enrollment of an additional 379,000 temporary members cost the Commonwealth an estimated $658 million. Between 2014 and 2015, many were routed back to the exchange and MassHealth enrollment decreased by 15%.

Pharmaceutical Spending
The other primary contributor to increased health care spending is rise in prescription drugs costs, growing by 12.2% nationally in 2014 (compared to 2.4% in 2013).

Massachusetts’s Health Policy Commission (HPC) reported an estimated 14.1% growth in overall drug spending in MA in 2014, increasing from $6.4 billion to $7.3 billion. The Massachusetts Center for Health Information and Analysis (CHIA) estimated that increases in drug spending contributed to one-third of the increase in total state health care spending.

Based upon our analysis, MassHealth provided $640,369,760 in pharmacy reimbursements for the cost of prescription drugs and pharmacist dispensing fees in FY 2015. However, this amount only include those members enrolled within the MassHealth fee-for-service program and in-house managed care populations, and does not include pharmaceutical spending among Medicaid contracted Managed Care Organizations.

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10 Martin et al. (2016)
11 Ibid.
12 CHIA (2015)
13 Ibid
14 HPC (2015)
15 Ibid.
(MCOs), federal cost sharing from the federal medical assistance percentage (FMAP), or federal or supplemental drug rebates. Figure 1 shows the growth in MassHealth total spending by quarter over time – from 2011 through the end of 2014 – for its FFS and MCO programs. The dramatic rise in spending, starting in 2014, can be seen in the figure below.

**Figure 1, MassHealth Pharmacy Budget (2011-2014, By Quarter)**

![MassHealth Pharmacy Budget (by Quarter)](image)

*Source – CMS State Drug Utilization Data*

The dramatic growth in MassHealth drug expenditures has been attributed to the introduction of several new, aggressively priced “specialty drugs”, as well as increases in the average price of generic drugs, and a slowdown of brand name drugs moving off-patent.

It is estimated that the share of spending on specialty drugs grew from 26% of all drug spending in 2010 to 34% of drug spending in 2014.¹⁶ In addition, highly complex therapies, such as biologics, are becoming increasingly common in physician prescribing practices and clinical guidelines, raising concerns regarding the ability to manufacturers to bring therapeutically equivalent off-brand products to market.

In addition to expensive novel therapies, the average per-unit cost of brand and generic drugs have increased in cost over the past several years.¹⁷ Spending on oncology drugs increased by 12.3%, while spending on insulin increased 19.8% from 2013-2014 in Massachusetts.¹⁸ In a highly publicized price increase, the manufacturer Turing Pharmaceuticals acquired the rights to market the 62-year old generic drug Daraprim, ¹⁶ Ibid.
¹⁷ Ibid.
¹⁸ Ibid.
raising the price of the product from $13.50 to $750 per pill, a nearly 5000% increase.19

While the Daraprim price hike represents an extreme example, it is emblematic of a larger issue regarding cost increases for medications that have been on the market for many years. In addition to price hikes, experts have attributed these increases to a general consolidation of suppliers, a lack of therapeutically equivalent drugs, disruptions in the supply of ingredients, and drug shortages.20

In 2014, few drug patents expired, leading to a higher share of high cost, brand name drugs with no generic equivalents. In 2012, there was an estimated reduction of $11.9 billion in national spending on brand name drugs because of expiring patents.21 FY 2014 experienced only one third of those savings due to patent expirations.

**Medicaid Programs and Prescription Drug Costs**

Medicaid spending on all prescription drugs grew by 24.3% in 2014, as compared to 4.3% in 2013.22 As described above, while much of this growth can be attributed to Medicaid expansion and resulting increases in spending on new enrollees, the growth in per-unit pharmaceutical costs – among novel therapies, as well as existing brand and generic drugs – has also driven higher expenditures. The increase in pharmaceutical cost is acutely felt by Medicaid agencies, given that their covered population is, on average, sicker than the average insured.

Hepatitis C Virus (HCV) provides a striking example of the different medical needs of Medicaid beneficiaries when compared to the U.S. at-large. One study estimated HCV prevalence of 1.13% among Medicaid beneficiaries.23 Another study found that the prevalence of HCV was 7.5 times higher in Medicaid than in commercial insurance.24 Treatment for HCV greatly impacts Medicaid budgets across the country. The HPC reported that MassHealth covered 20% of all prescriptions for Hepatitis C drugs in Massachusetts in 2014.25

Further, Medicaid agencies have limited tools with which to manage benefits or offset losses, as compared to private insurers - as discussed further in *Section II*.

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19 Forbes (2015)
20 Alpern (2014)
21 IMS Institute for Healthcare Informatics (2015)
22 Martin (2016)
23 Johnson et al. (2015)
24 Senate Finance Committee, Medicaid Spending Data (2015)
25 HPC (2015)
A Call to Action
Recent consumer reaction to the growing cost of prescription drugs, including high-cost drugs like Sovaldi and Daraprim, has been strong, prompting calls for government intervention.26

A Kaiser Family Foundation Health Tracking Poll found that 73% of those polled believe that the cost of prescription drugs is unreasonable, with a majority blaming pharmaceutical manufacturers for setting unreasonable prices.27 A subsequent poll in October 2015 found that 77% believe that it is important to “[make] sure that high-cost drugs for chronic conditions, such as HIV, hepatitis, mental illness and cancer, are affordable to those who need them”. Further, 63% support “government action to lower prescription drug prices”.28

In response, officials at both the federal and state levels are exploring options to mitigate such public and fiscal concerns.

Figure 2, Majority of Public Finds Drugs Costs Unreasonable

![Figure 2](image)


On the federal level, the U.S. Senate Finance Committee conducted an 18-month investigation on “The Price of Sovaldi and Its Impact on the U.S. Healthcare System”, releasing its findings in December 2015. These findings detailed the impact on states’ budgets and strategies states were taking to reduce costs related

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26 WSJ (2016)
27 Peterson-KFF(a) (2015)
28 Peterson-KFF(b) (2015)
to HCV treatment. In February 2016, the House Committee on Oversight and Government Reform conducted hearings on the same issue.

The U.S. Department of Health and Human Services (HHS) has also publically weighed in on these concerns. It convened a Pharmaceutical Forum with health care and pharmaceutical experts in November 2015 that explored issues in innovation, access, and affordability. Within HHS, the Centers for Medicare and Medicaid Services (CMS) have taken solicited input from stakeholders on what actions might be taken to curb the cost of growth. Administrator Andy Slavitt sent letters to four major drug companies – AbbVie, Gilead Sciences Inc., Johnson & Johnson, and Merck & Company – and state Medicaid agencies, requesting information on existing pharmaceutical purchasing and contract arrangements, and soliciting other ideas to assist states address the affordability of new “unbudgeted pharmaceuticals”.29,30

In Massachusetts, Attorney General Maura Healey has also signaled her concern for recent cost increases, sending a public letter to Gilead in January 2016.31 In the letter, Healey “urge[s] Gilead to adjust its pricing strategy in a way that continues to generate substantial profits for the company, while also providing a clear pathway to the eradication of this life-threatening disease in the United States”.32 Attorney General Healey goes on to cite the access limitations many Medicaid agencies across the country have had to employ to contain costs. This letter further announced her office’s intent to investigate Gilead’s pricing strategies as violations of Massachusetts’s law on unfair trade practices.

Finally, the Assistant Majority Leader in the Massachusetts Legislature is the lead sponsor and advocate for Senate Bill 1048, which would increase drug production cost transparency and pricing strategies and cap excessive drug prices.33

While many of the preceding examples are specific to Sovaldi or Harvoni, they are indicative of greater public rhetoric and government momentum towards addressing the larger issue of the growing costs of prescription drugs. The high costs of these life-saving therapies speak to current system’s failures in addressing affordability, allowing for unabated cost increases of brand and generic drugs that unduly burden government agencies and patients.

State Medicaid agencies are capitalizing on the public pressure to reassess whether further cost savings might be possible through reforms to prescription drug reimbursement and management programs.

Although potential cost-saving strategies may incur political or stakeholder opposition, the strong public support for action will be crucial in moving forward with reforms.

29 HHS-CMS, HCV Communication (2015)
31 Massachusetts Attorney General, Letter to John C. Martin, Gilead Sciences, January 22, 2016
32 Ibid.
33 Massachusetts Senate Bill 1048
Section II – Medicaid Pharmaceutical Regulations

Overview of Federal versus State Regulatory and Oversight Authorities
The Centers for Medicare and Medicaid Services (CMS), within the U.S. Department of Health and Human Services (HHS) is the executive agency charged with regulating and overseeing several federal health care programs, including Medicare, Medicaid, and the Children’s Health Insurance Program (CHIP).

CMS and state governments jointly administer Medicaid. CMS sets minimum standards for benefits, cost-sharing, and reimbursement policies for Medicaid programs. States have flexibility within these standards to apply more generous policies or to tailor their programs to their beneficiaries.

The following sections describe the federal regulation of Medicaid drug benefits and reimbursement, including the federal government’s recent Final Rule on Covered Outpatient Drugs (CMS-2345-FC), released January 21, 2016. This rule provides further clarity to changes made to Medicaid’s covered outpatient drug policy by the ACA. CMS projects that this rule will save federal and state governments over $2.7 billion over a five-year period, given lower payments to pharmacy providers. However, the Final Rule requires states to come into full compliance no later than April 2017, a challenging deadline for many state Medicaid agencies, including MassHealth.

Regulation of Prescription Drug Benefits
State Medicaid agencies are not required by federal law to cover outpatient prescription drugs, however all states have elected to offer this benefit to their beneficiaries. Once a Medicaid agency elects to offer beneficiaries prescription drugs, the state must abide by the CMS regulatory standards. For instance, states are not permitted to deny access to medically necessary prescription drugs, although they may implement a variety of strategies to manage drug utilization and contain costs. There are several classes of drugs that are exempt from the coverage requirements, including drugs for the cosmetic purposes, fertility, obesity management, sexual dysfunction, or experimental and investigational drugs. All other classes of drugs must be covered if deemed medically necessary, according to federal and Massachusetts’s regulations.

Drug benefit programs may differ if a beneficiary is enrolled through a managed care organization (MCO), through fee-for-service (FFS), or among other coverage variants, due to federal regulatory differences. Except as noted, this Section will cover federal regulation of the FFS program, as many of the FFS requirements are waived for MCO plans.

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34 42 CFR Part 447
35 Ibid.
36 CMS Finalizes ACA Final Rule (2016)
37 CMS Letter to State Medicaid Directors, February 11, 2016
38 MACPAC (2015)
39 Ibid.
40 130 CMR § 406.413(B)
41 42 CFR § 1396r-8
Regulation of Cost-Sharing for Prescription Drugs
The federal government limits the amount of cost-sharing for prescription drugs that states can impose on Medicaid beneficiaries. Copayments of up to $4.00 are allowed for preferred drugs, and up to $8.00 for non-preferred drugs. Consumers with incomes above 150% of the federal poverty level (FPL) may be required to contribute up to 20% of the cost of the drug to the Medicaid agency.\(^{42}\) 40 states and the District of Columbia employ some type of cost-sharing for prescription drug benefits.\(^{43}\) However, few states require the maximum copayment amount. Copays typically range from $0.50 to $3.00 depending on brand and preferred status. MassHealth currently charges a range from $1 - for generics that have preventative and cost saving value for diabetes and hypertension – to $3.65 for all other drugs covered. It has also set a maximum cost-sharing amount at $250 per year.\(^{44}\)

Regulation of Prescription Drug Reimbursement
Prescription drug reimbursement is a complex process involving financial transactions between the federal government, Medicaid agencies, pharmaceutical manufacturers, wholesalers, pharmacies, and the Medicaid beneficiary. The federal government manages the federal drug rebate program with drug manufacturers, while states manage pharmacy reimbursement, and may pursue additional cost-containment mechanisms. See Figure 3 for a diagram displaying the relationship between these stakeholders in pharmacy reimbursement.

Figure 3, Medicaid Fee-for-Service Drug Payment and Rebate Flow

Adapted from MACPAC (2015)

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\(^{42}\) MACPAC (2015)
\(^{43}\) Ibid.
\(^{44}\) 130 CMR 450.130(B)
The true cost of drugs is often hidden, due to the multiple negotiations, rebates, and markups that occur throughout the pharmacy supply chain. For example, manufacturers negotiate with wholesalers to supply their products to consumers. Wholesalers then sell these drugs to pharmacies, where consumers can then purchase them. Consumers are insured by public or private payers, which negotiate reimbursement rates with the pharmacies, based on estimates of the ‘true’ cost of drugs. Public and private insurers, seeking cost savings, also negotiate discounts or rebates with manufacturers in exchange for inclusion or preferential status on formularies.

The rebate structure creates additional financing concerns for insurers, as the full “up front” cost of the drug is owed to the pharmacy before rebates are received.45

Added to this complexity is the fact that drug prices are set by manufacturers according to their perceived market value and demand, which may or may not bear a relationship to the drug’s estimated clinical effectiveness or overall value.

**Manufacturer Rebates**

The National Drug Rebate Program was established through the Omnibus Reconciliation Act of 1990, and is authorized by section 1927 of the Social Security Act.46 Manufacturers must enter into rebate agreements with the Secretary of HHS in order for their drugs to be offered through the Medicaid program. By law, any drug that offers this federal rebate must be made available to Medicaid beneficiaries in any state. The ACA expanded coverage of these rebates drugs dispensed to members in Medicaid MCOs.

The ACA also updated the federal rebate percentages applied to outpatient drugs. The rebate percentages are applied to a newly defined Average Manufacturer Price (AMP), the price paid to manufacturers by wholesalers or pharmacies.47 These new rates will be applied to the adjusted AMP for more accurate assessments of the cost of drugs to manufacturers and greater cost-savings for the federal and state governments. In general, participating manufacturers must provide:

- **Branded drugs**: the greater of either a 23% rebate off of the AMP per unit or the difference between the AMP and the “best price” per unit.
- **Generics**: 13% off of the AMP per unit.48

States collect drug utilization from pharmacy claims and calculate the federal drug rebate amount, which is split between the federal and state governments.

The federal drug rebate program helps to offset a significant proportion of total Medicaid prescription drug spending. In fiscal year 2010, the federal rebate alone saved the federal and state governments approximately

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45 Note - Section V will discuss strategies to mitigate financing concerns and allow for expenditure smoothing.
46 42 USC 1396r-8, Section 1927 of the Social Security Act
47 42 CFR Part 447
48 HHS-CMS, Medicaid Drug Rebate Program (2016)
40% of nearly $27 billion in pre-rebate Medicaid drug costs. The Office of the Inspector General (OIG) found that from 2010-2012, the rebate program saved Medicaid an average of $15 billion each year.

States may also negotiate supplemental rebates with manufacturers for additional discounts. These supplemental rebates are generally negotiated by the state, or by a pharmacy benefit manager (PBM). The ACA also authorized states to expand their supplemental rebates to MCOs. Previously, MCOs negotiated their own additional rebates with manufacturers or wholesalers, limiting direct state or federal savings. The rebate extension aligns the built-in cost-savings in the FFS Medicaid program with the MCO programs.

Combined federal and state supplemental rebate agreements result in a national average of 45% savings off the total cost of claims, substantially improving the affordability of pharmacy programs amidst continued increases in prices and utilization.

The HPC reports that MassHealth has higher rebate levels than the national average, recouping 50.1% of pharmacy spending for the FFS and primary care clinician (PCC) programs in FY 2015. This additional savings is likely to due to MassHealth’s current drug management policies, including its efforts to collect federally required rebates and its recently implemented supplemental rebates. See Section V for further discussion of supplemental rebates.

Pharmacy Reimbursement
There are two main components to the cost of drugs that are paid by Medicaid agencies: the ingredient cost and the dispensing fee. CMS and state governments both play a role in setting reimbursement rates for each. The following sections apply to Medicaid FFS, as Medicaid MCOs negotiate their own reimbursement rates that cover ingredient cost and dispensing fees for participating pharmacies.

Ingredient Costs
The ingredient cost is the amount that pharmacies pay to acquire a drug from manufacturers or wholesalers.

Through the recent Final Rule on Covered Outpatient Drugs, CMS now requires that state Medicaid agencies reimburse pharmacies based on the Actual Acquisition Cost (AAC) of drugs. Though States have discretion to determine their AAC rates they are instructed to base this calculation on the actual amount that pharmacies pay to acquire drugs. This is determined using surveys of retail community pharmacies. CMS assists with this collection effort by performing national surveys of pharmacies. CMS publishes this data as part of its National Average Drug Acquisition Costs (NADAC) file, as a proxy for the AAC for each drug. States may choose to either use the NADAC rates or to survey pharmacies within the state to assess costs.

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49 Bruen et al. (2014)
50 OIG (2014)
51 See Section V, Strategy 1 for further discussion of supplemental rebates.
52 Bruen et al. (2014)
53 HPC (2015)
54 Ibid.
55 CMS-2345-FC, 42 CFR Part 447
56 Ibid.
Importantly, the NADAC list does not include cost estimates for every drug, including most specialty drugs. CMS therefore allows states to continue using their current reimbursement rates for specialty drugs (for a full discussion, see Section V, Strategy #5). States that have already adopted the AAC use either the wholesale acquisition cost (WAC) or reimburse using a “usual and customary charge” (U/C) when there is no AAC/NADAC for a drug.

The AAC is a departure from the previous standard of reimbursement, which used an estimated acquisition cost (EAC) for covered drugs. Given the difficulty in measuring the true costs of acquisition, EACs would often range widely among states. States benchmark the EAC using the average wholesale price (AWP) of a drug, or the WAC of a drug, among others. This final reimbursement rate therefore differs from state to state given variations in pharmacy costs, political pressure, and states’ ability to collect accurate information of the true acquisition costs of drugs from pharmaceutical manufacturers or wholesalers. When adopted nationwide, AAC may alleviate some variance in state reimbursement amounts stemming from difficulties in measuring estimated acquisition costs.57

The federal government also sets a federal upper limit (FUL) for multiple-source drugs, which caps that amount that state Medicaid agencies will pay for a drug. Recently, the FUL was set at 175% of the weighted average of the most recently updated AMP. Many states also use a maximum allowable cost (MAC), which also places a ceiling on the amount that states will pay to reimburse for a multiple-source drug on a state MAC list.58 These MAC lists are generally more expansive than drugs subject to the federal upper limit and can be used as an additional cost-saving tool.

MassHealth currently uses a WAC + 5% to reimburse participating pharmacies for all single-source drugs, excluding those billed under the federal 340B program (See below for a discussion on 340B program).59 MassHealth uses a MAC formula for multiple-source drugs. MassHealth is currently assessing options to align with the CMS requirement to reimburse pharmacies using AAC, or a proxy when unavailable for a certain drug, by April 2017.

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57 Bruen et al. (2014)
58 MACPAC (2015)
Dispensing Fees
The dispensing fee aims to reimburse pharmacies for the cost of overhead and labor in dispensing each drug.

Dispensing fees to pharmacies currently ranges state-by-state, based on independent state-determined dispensing rates. The magnitude of this fee varies, but can be loosely tied to the benchmark used to reimburse pharmacies for ingredient costs, as states with the most generous dispensing fees tend to use less generous ingredient benchmarks. For example, Alabama was the first state to employ the AAC, but also has one of the highest current dispensing fees, at $10.64.  

However, the CMS Final Rule on Covered Outpatient Drugs revises the methodology that states can use to determine a professional dispensing fee, which is intended to more accurately reflect the cost of dispensing drugs to beneficiaries. As part of the implementation of the Final Rule, states must determine this cost and submit justification for their set dispensing fee to CMS for approval. MassHealth currently provides pharmacies with a $3.00 dispensing fee per unit for all drugs except 340B drugs, which have a $10.00 dispensing fee. The dispensing fee paid by MassHealth is expected to increase with the conversion to AAC, which has ranged from $10 - $12 in states that have already made the conversion.  

340B Programs
The Office of Pharmacy Affairs within the Health Resources and Services Administration (HRSA) at HHS administers a national drug discount program known as 340B. The program was created in 1992 as part of the Veterans Health Care Act and requires drug manufacturers to provide discounts to medical providers that meet the definition of ‘covered entities,’ which includes Disproportionate Share Hospitals (DSH), federally qualified health centers (FQHC), and specialized clinics for HIV/AIDS, tuberculosis, cancer, and family planning. In general, patients that receive regular care at these covered entities are eligible for 340B discounts. According to the National Conference on State Legislatures, 340B prices are estimated to be 51% lower than AWP, 39% lower than AMP, and 19% lower than the Medicaid net price.  

Since 2001, covered entities have been permitted to contract with outside pharmacies, enabling independent pharmacies that are not associated with or integrated within the covered entity to dispense drugs as part of the 340B program. Between 2010-2014, there was a 29% increase in the number of contracted pharmacies covered through the 340B program nationwide and, by 2014, nearly 1 in 4 retail pharmacies were part of the program. In 2014, there were 213 approved contracted pharmacies in the 340B program across the state of Massachusetts. While contracting with third party pharmacies may have improved access for low-income patients, it has also yielded operational difficulties to tracking 340B eligible discounts. Neighborhood retail pharmacies that see many different types of patients are not able to differentiate between patients who are eligible for 340B discounts and those who are not (see Section V, Strategy 7).

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60 HHS-CMS, Medicaid Prescription Reimbursement by State (2015)  
61 HHS-CMS, Final Rule Fact Sheet (2016)  
62 Ibid.  
63 NCSL, 340B (2016)  
64 Clark et al. (2014)  
65 NCSL, 340B (2016)  
66 Ibid.  
67 HRSA (2016)
Section III – Methodology and Evaluation Criteria

The purpose of this paper is to provide a set of actionable recommendations for MassHealth to reduce drug cost growth while maintaining the agency’s high standard of patient care.

Methodology
We used four methods to inform our analyses: (1) literature review, (2) interviews with Medicaid and pharmaceutical policy experts, (3) case studies of policy interventions and best practices, and (4) data analysis using MassHealth claims data and state drug utilization data available through Medicaid.gov.

Literature Review
This document incorporates research based on a review of public MassHealth documents, peer-reviewed articles on pharmaceutical benefits and reimbursement policies, and analysis conducted by the Massachusetts Health Policy Commission and Center for Health Information and Analysis.

Interviews
We conducted interviews with individuals representing a range of organizations and perspectives, including Massachusetts’s officials, other state officials, community advocacy groups, health policy research organizations, and health policy researchers. The following is a list of organizations with which we spoke:

- MassHealth, Office of Clinical Affairs
- Joint Committee on Health Care Financing at the Massachusetts Statehouse.
- State of Vermont, Department of Health Care Access
- State of Minnesota, Department of Human Services
- Massachusetts Medicaid Policy Institute
- Massachusetts Health Policy Commission, Research and Cost Trends
- Health Care For All
- Community Catalyst, Pharmaceutical Access Project
- Kaiser Commission on Medicaid and the Uninsured
- National Association of Medicaid Directors
- Institute for Clinical and Economic Review
- National Academy for State Health Policy
- Harvard University, Faculty of Arts and Sciences, Department of Economics
- Harvard University, Harvard Kennedy School, Malcolm Weiner Center for Social Policy
- Harvard University, Harvard T.H. Chan School of Public Health, Department of Health Policy and Management
- Harvard University, Harvard Medical School, Department of Health Care Policy
- Harvard University, Harvard Medical School, Drug Policy Research Group
- George Washington University, School of Public Health and Health Services, Department of Health Policy
Data Analysis
We used STATA 14.1 for our data analysis and QGIS for mapping visualizations. For our analysis, we used the following four data sets:

**MassHealth Claims Data (July 2012 – June 2015):** These data include all members enrolled in contracted Managed Care Plans, Fee-For-Service, and the MassHealth Primary Care Clinician plans. These data exclude those who receive their primary coverage through another payer and are enrolled in MassHealth as a secondary insurer. The data set also exclude most Medicaid-eligible seniors enrolled in Senior Care Plans, and childless adults enrolled in CarePlus plans.

These data represent 1.9 million unique individuals and 17 million claims between FY 2012-2015. While not the complete MassHealth population, these data allowed us to map trends in utilization and spending for these specific populations across the state of Massachusetts.

**CMS State Drug Utilization Data:** These data give a more complete snapshot of the total drug spends and utilization counts for the full MassHealth program. We used these data for our total spending charts, identify biggest drugs in the MassHealth budget, and to determine the Wholesale Acquisition Costs (and potential savings) for one our strategy on differential pricing.

**National Drug Code Directory:** These data are publically available through the Federal Drug Administration website. Using these data, we were able to match drug utilization in Massachusetts to drug manufacturers to identify MassHealth’s largest drug contracting agreements.

**Healthcare Effectiveness Data and Information Set:** These data are publically available through the National Committee for Quality Assurance (NCQA) website. These data include lists of drugs broken into disease-specific categories (diabetes, asthma, and mental health), and allowed us to flag MassHealth members based on their condition. Unfortunately, we were unable to distinguish MassHealth members using disease specific drugs for “off-label” purposes. However, using this data, we were able to target high cost, high utilization individuals with specific chronic conditions.

In the following section we analyze the current status quo of the MassHealth pharmacy program. This includes an analysis of the specific drugs and therapeutic classes that are driving spending increases, and descriptive characteristics of patients with the highest pharmaceutical costs (e.g., geographical location, demographics).
**Evaluation Criteria**

This report puts forward a series of potential strategies and policies that MassHealth can take to contain pharmaceutical costs. Many of these strategies have been studied or implemented by public and private payers. In an effort to assess these strategies using a standardized set of criteria, we established the evaluation framework below that includes many of the relevant considerations and trade-offs that MassHealth will confront in implementing a cost-containment policy.

The evaluation framework is structured as follows:

<table>
<thead>
<tr>
<th>Evaluation Criteria</th>
<th>Questions for Consideration</th>
</tr>
</thead>
</table>
| **Cost Savings**      | • What are the potential cost savings for MassHealth?  
                       • Has this strategy produced cost savings among other public or private health insurers?  
                       • What is the likelihood that costs will be shifted to enrollees? To other stakeholders?                                                             |
| **Operational Burden**| • What resources are necessary to implement this policy?  
                           • Does MassHealth have the existing authority to implement this strategy?  
                           • Can this strategy be scaled throughout the state of Massachusetts?  
                           • Is compliance required among Managed Care Organizations (MCOs)?                                                                                   |
| **Political Feasibility** | • What stakeholders (if any) would resist the cost containment strategy?  
                                • Will this require a waiver or state plan amendment from CMS? What is the likelihood of approval?  
                                • Will this require legislative authorization from the Massachusetts state legislature? What is the likelihood of approval? |
| **Impact on Access**   | • What are the impacts on MassHealth members’ access to pharmaceuticals and health services?  
                           • Will this require additional time, co-sharing, or other resources from members?  
                           • Does this have the potential to cost-shift to MassHealth members?  
                           • Will this strategy affect MassHealth members’ access to health care services?                                                                  |
| **Impact on Quality**  | • How will this strategy impact enrollees’ quality of care?  
                           • Does this strategy improve care coordination between providers?  
                           • Is there evidence of improved clinical outcomes from implementation?                                                                                  |

This report concludes by making a series of recommendations based upon our evaluation of the cost-containment strategies.
Section IV – The MassHealth Pharmacy Program

Background
Currently, the MassHealth program covers 1.8 million low-income adults, children, pregnant women, and seniors in the Commonwealth of Massachusetts. Low-income adults are eligible for MassHealth up to 133% of the Federal Poverty Level (FPL), which sets an income threshold of $16,260 annually for an individual or $33,480 annually for a family of four. Children and pregnant women are eligible for MassHealth at higher income levels (150% and 200% of the FPL respectively), whereas seniors are only eligible up to 100% of the FPL. Since the inception of the Massachusetts universal health care reform law that was signed by Governor Romney in 2006, the MassHealth program has grown from 1.02 million enrollees to 1.8 million enrollees.

One third of those eligible for MassHealth are enrolled in one of six Managed Care Organizations (MCOs). Seniors eligible for MassHealth are mostly enrolled in Senior Care Option Plans (or SCOs) that are jointly funded through Medicare and Medicaid. Seniors who are not eligible for Medicare are in the fee-for-service plan. Childless adults who are eligible for MassHealth are covered through CarePlus, which receives a smaller funding match from the Federal Government. MassHealth administers a Primary Care Clinician (PCC) plan and a Fee-For-Service (FFS) plan.

Figure 4, MassHealth Enrollment by Payer Type, 2015

Source: Massachusetts Joint Committee on Health Care Financing, 2015
The average per-member-per-month (PMPM) spending for all medical and drug services in 2014 was $436 for members covered through an MCO, as compared to $678 for those enrolled in the PCC plan. These variations in PMPM payments are largely attributable to differences between the covered patient populations. There is a higher proportion of persons with disabilities and multiple chronic conditions in the MassHealth PCC plan, which contributes to higher overall expenditures.

Table 1, Summary Statistics of MassHealth Beneficiaries

<table>
<thead>
<tr>
<th>2014 Plan Summary Statistics</th>
<th>Unique Individuals</th>
<th>Age (Mean)</th>
<th>Drug Count (Mean)</th>
<th>Psychotics Flag</th>
<th>Asthma Flag</th>
<th>Diabetes Flag</th>
</tr>
</thead>
<tbody>
<tr>
<td>MassHealth PCC Plan</td>
<td>86,838</td>
<td>30.47</td>
<td>1.86</td>
<td>12%</td>
<td>20%</td>
<td>5%</td>
</tr>
<tr>
<td>MassHealth Fee-For-Service</td>
<td>259,468</td>
<td>43.50</td>
<td>1.49</td>
<td>9%</td>
<td>13%</td>
<td>6%</td>
</tr>
<tr>
<td>Manage Care Organizations</td>
<td>192,187</td>
<td>30.69</td>
<td>1.49</td>
<td>4%</td>
<td>11%</td>
<td>2%</td>
</tr>
</tbody>
</table>

*These numbers only reflect those individuals in our claims analysis of MassHealth MCOs, FFS, and PCC plans.

The Status Quo: MassHealth Drug Management Programs
MassHealth manages the pharmacy benefit for its members in the PCC and FFS plan. MassHealth staff manage the formulary (known as the MassHealth Drug List), prior authorization, and the pharmacy network. MassHealth contracts with Xerox State Healthcare, a national pharmacy benefits manager (PBM), for its claims and rebate invoicing and other administrative services.

The MassHealth MCO plans administer their own drug benefit, negotiating additional rebates through contracts with PBMs, which negotiate on their behalf. Major PBMs include Express Scripts, CVS Caremark, Magellan, Goold, and United Health Group.

Since 2001, the MassHealth Pharmacy program has implemented several management strategies aimed at containing drug costs and ensuring clinically appropriate treatment. Central to the pharmacy program’s drug management strategy is the MassHealth Drug List (MHDL), commonly referred to as the preferred drug list, which designates drugs that are recommended as the first line of treatment and serves as the framework for other management strategies, such as prior authorization. Major components of the MassHealth drug management program are highlighted below:

- **Prior Authorization**: MassHealth approval is required prior to dispensing of certain drugs, which has helped to ensure clinically appropriate prescribing and cost-effective treatment.
- **Step Therapy**: Drugs that are designated as the “first line” of treatment options. These drugs are often the lower-cost alternatives.
- **Generic Drug Promotion**: Structuring the MHDL to promote generic drugs as the first drug of choice and implementing a mandatory generic substitution policy within pharmacies.

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68 MassHealth Report to the Legislature Concerning Cost Savings on Prescription Drugs (2016)
69 Ibid.
70 Thomas (2009)
71 Ibid.
72 Ibid.
- **Quantity Limits**: Limiting the quantity of drugs per prescription (e.g., long-acting opioids), limiting the dosage, and restricting access to early refills.\(^{73}\)
- **Maximum Allowable Cost (MAC)**: Imposing a maximum reimbursement for multiple-source drugs (set at 130% of the lowest publicly available price).\(^ {74}\)
- **Prescriber Education and Outreach**: Providing evidence-based information on pharmaceuticals to providers.

A 2009 review of the agency’s use of the MassHealth drug management program suggests that the agency has generated significant cost savings from these drug management programs, while also avoiding many of the stricter drug controls that have been put in place by other state Medicaid agencies (e.g., monthly limits on number of medications dispensed). MassHealth has reported that in the first full year of implementation, these strategies generated $99 million in cost savings, largely attributed to savings from prior authorization ($43 million), limited access to early refills ($29 million), and frequent updates to the MAC generic pricing formula ($12 million).\(^ {75}\) In 2014, MassHealth projected savings of $230,510,948 through intensive care management for at-risk populations, especially those with HCV.\(^ {76}\)

Still, despite its many cost control and drug management strategies, drugs costs in both the MassHealth administered plans and the MCOs continue to rise.

*Figure 5, MassHealth MCO versus FFS spending*

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\(^{73}\) Ibid.
\(^{74}\) 130 CMS Part 406
\(^{75}\) Thomas et al. (2009)
There are several high spending ‘hotspots’ in Massachusetts, as can be seen in Figure 6, including along the I-91 corridor stretching from Springfield up through Greenfield in Western Massachusetts, the New Bedford region, South Worcester County, and the Northwest corner of the state. As the state considers cost control strategies, they must consider parts of the state that have particularly high levels of drug spending and how to manage the care for those patients.

Appendix A-1 includes a list of MassHealth’s top drugs by cost for reference.

Figure 6, High Cost Spending Areas in Massachusetts by Zip
Section V – Potential Strategies for Cost Containment

This section provides detailed descriptions of nine potential strategies to mitigate the growing cost of pharmaceuticals. These nine strategies address cost drivers across the Medicaid drug purchasing and reimbursement spectrum – including supply-side strategies to realize savings from drug manufacturers or pharmacies, and demand-side strategies to improve patient adherence.

Table 2 – List of Potential Strategies for Cost Containment

<table>
<thead>
<tr>
<th>Target Stakeholder</th>
<th>Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug Manufacturers</td>
<td>1. Expand Use of Supplemental Rebates</td>
</tr>
<tr>
<td></td>
<td>2. Contract with a Third Party to Negotiate Supplemental Rebates</td>
</tr>
<tr>
<td></td>
<td>3. Establish Pay-for-Performance Contracts</td>
</tr>
<tr>
<td></td>
<td>4. Consolidate Drug Purchasing among Massachusetts Agencies</td>
</tr>
<tr>
<td>Pharmacies</td>
<td>5. Establish Differential Reimbursement Rates for Specialty Drugs</td>
</tr>
<tr>
<td></td>
<td>6. Implement Specialty Pharmacy Networks</td>
</tr>
<tr>
<td></td>
<td>7. Enforce 340B Drug Discount Program Rebates</td>
</tr>
<tr>
<td></td>
<td>8. Reimburse for Medication Therapy Management Services</td>
</tr>
<tr>
<td>Patients</td>
<td>9. Apply Value-Based Insurance Designs to Co-Payments</td>
</tr>
</tbody>
</table>
Drug Manufacturers

1. Expand Use of Supplemental Rebates

Massachusetts currently has several supplemental rebates in place with pharmaceutical manufacturers. One potential cost containment strategy is to expand the use of supplemental rebates by:

1) Implementing additional rebate agreements for the PCC/FFS programs
2) Expanding the use of supplemental rebates to include members covered through MCOs.

Overview
States may enter into supplemental rebates with drug manufacturers, provided they share any savings with the federal government.77 45 states have negotiated supplemental agreements with pharmaceutical manufacturers for their FFS programs, saving millions in drug costs.78 Some states have implemented single-state agreements (31 states), while others have joined together with other states for additional negotiating power through multi-state purchasing agreements (27 states).79,80

The ACA authorized states to expand their supplemental rebates to include drugs dispensed to members covered through MCOs, which generally establish their own discount agreements with manufacturers.81 Of the 32 Medicaid agencies that that contracted with MCOs in 2013, only six collected or intended to collect supplemental rebates on drugs covered through their MCOs, though they do capture savings through the federal rebate.82 Furthermore, states require MCOs to report theirnegotiated rebates in advance of determining a capitated rate for the program. MCO rebates are included in the capitated rate agreed on for the program in the initial contract. Expanding the state’s supplemental rebates to include MCO enrollees will provide states with direct savings.

Negotiating Supplemental Agreements
States commonly use their status as a major purchaser of prescription drugs to negotiate with pharmaceutical manufacturers for additional discounts. State Medicaid agencies may target agreements with manufacturers on particular drugs by leveraging the needs and composition of their beneficiary population. For example, several states have negotiated with Gilead Sciences to discount the price of Harvoni or Sovaldi, including MassHealth.83

In addition, states use preferred drug lists (PDL) or require prior authorization (PA) for non-preferred drugs as leverage in negotiations with manufacturers of therapeutically-equivalent, or competing, drugs. Studies demonstrate that drugs subject to prior authorization lose significant market share.84 Even though consumers may retain access to the non-preferred drugs, the additional step required of physicians to request prior

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77 Social Security Act Section 1927
78 HHS-CMS, Medicaid Pharmacy Supplemental Rebate Agreements (2015)
79 Ibid.
80 Note - Strategy #2 will explore the multi-state purchasing option in more detail.
81 Ibid.
82 HHS-OIG (2014)
84 Mello (2004)
authorization results in modifications to prescribing behavior. This potential for reduced market share helps incentivize manufacturers to negotiate. Improving (or maintaining) market share through a preferred drug may offset reduced revenues due to negotiated rebates. MassHealth employs a preferred drug list, the MHDL, for its PCC/FFS Program.

Evidence of Cost Savings
The OIG found that 44 states had supplemental rebates in place in 2011 and 2012, saving a total of $1.7 billion. Accounting for their shared savings with the federal government, these states saved a total of $656 million in 2011 and 2012.

Michigan implemented a series of drug cost-containment initiatives for their dual eligible population between 2001-2004, including a PDL, joint and multistate purchasing arrangements, and a Maximum Allowable Cost (MAC) list. The state used the PDL to derive supplemental rebates from manufacturers. Drugs placed on the PDL saw increased market share and the state experienced reduced daily costs.

Florida first established a list of preferred drugs for its Medicaid program based on clinical effectiveness, offering manufacturers of therapeutically equivalent drugs the chance to provide the state with a supplemental rebate in exchange for an exemption from prior authorization. The state reported savings of $500 million over two years from a combination of its PDL and other related initiatives.

MassHealth and Supplemental Rebates
Massachusetts first received CMS approval for its single-state SRA in 2004 for its PCC/FFS program, and subsequently implemented three supplemental rebates for its PCC/FFS program. However, as these products lost their patent exclusivity, and amid a rise in the quantity of available generic drugs, MassHealth chose not to engage in further rebate agreements. Instead, for the next several years it leaned on its generic-first strategy to gain maximum savings from generics.

With the recent rise in the cost of pharmaceuticals, MassHealth revisited the supplemental rebate program and implemented four supplemental agreements with manufacturers in 2015. Combined, these supplemental rebates are projected to save MassHealth approximately $25 million annually, once fully operational. These rebates range from savings on medical equipment to specialty drugs, indicating the variety of product opportunities to obtain savings. As of February 2015, MassHealth is evaluating responses from a fifth solicitation and is preparing five additional bid solicitations; these promise to result in further cost savings for the PCC/FFS plans.

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85 Soumerai (2004)  
86 HHS-OIG (2014)  
87 Ibid.  
88 Kibicho (2012)  
89 NGA (2003)  
90 Note - A report by Community Catalyst from 2009 provides a separate perspective on the decision made by MassHealth officials to limit use of supplemental rebates. Officials had “doubts regarding the true long-term savings of this policy” and felt that the rebates would “undermine the clinical credibility of the drug list”.  
91 MassHealth Report to the Legislature Concerning Cost Savings on Prescription Drugs (2016)  
92 Ibid.  
93 Ibid.
MassHealth does not currently participate in supplemental rebate collections for MCOs, but does require that MCOs disclose their private rebate deals as a factor in setting the capitated rate in their contracts. The February 2016 report, however, states that MassHealth is updating its SRA template to include rebates for drugs covered through MCO plans. If implemented, the Commonwealth would negotiate rebate agreements with manufacturers with greater leverage given the increased purchasing power of combining the PCC/FFS and MCO populations. Any supplemental rebate savings would be shared between the Commonwealth and the federal government.

MassHealth does not currently belong to any multi-state purchasing agreements.

Opportunities
Federal and supplemental rebates have resulted in significant cost savings, with a reduction of 50.1% off total pharmacy expenditures. Additional supplemental rebate agreements for the PCC/FFS plans would likely result in further savings for the state and for the federal government. Expanding supplemental rebates to drugs covered through MCOs would allow the state to capture savings for a significant additional proportion of its beneficiaries.

Challenges
MassHealth faces several challenges in implementing further supplemental rebates with the PCC/FFS and MCO plans. The main challenges of this strategy are outlined below.

Negotiating supplemental rebates may be more difficult when there are limited therapeutically equivalent, competing drugs on the market. New, innovator, or brand-name drugs still on patent likely do not yet have competitors, and are therefore able to demand high prices. Similarly, high prices for generic drugs like Daraprim are also difficult to counter if there are no competitors.

Massachusetts state procurement procedures may limit MassHealth’s capacity to establish several agreements at once or to rapidly develop and implement agreements. Due to the agreements’ fiscal and legal implications, there are lengthy procedures that must be followed when completing negotiated agreements. This process requires significant resource investment from MassHealth and other state official staff.

Expanding supplemental rebates to MCOs entails additional challenges given MCOs are independent, contracted entities with separate administrative processes and differing profit motivations. Extending supplemental rebates to the MCO program might limit MCOs’ ability to enact their own discount rates with manufacturers. As MassHealth’s supplemental agreements are expanded to the MCOs, any duplicative rebate agreements would have to be vacated by the MCO, resulting in reduced revenues for the MCO. In turn, the capitated rate MassHealth reimburses its MCOs will likely increase to offset the MCOs’ reduced pharmaceutical savings.

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94 Ibid.
2. Contract with a Third Party to Negotiate Supplemental Rebates

While MassHealth negotiates directly with manufacturers to secure supplemental rebates for pharmaceutical products, other states have chosen to contract with third parties in an effort to obtain additional savings. Below we highlight two main strategies other state Medicaid agencies have undertaken: joining a multi-state purchasing cooperative and/or contracting with a Prescription Benefits Manager (PBM).

Multi-State Drug Purchasing Cooperatives

Overview

Many states participate in multi-state cooperatives that leverage their joint market power to negotiate supplemental rebates from manufacturers. Massachusetts may be able to obtain additional savings by joining a multi-state cooperative. However, joining a cooperative may considerably limit MassHealth’s ability to negotiate its own supplemental deals with manufacturers.

Joining a purchasing cooperative is not a new policy for the Commonwealth. In 1999, Massachusetts joined with six other New England states, New York, and Pennsylvania to develop possible strategies for collective purchasing. Massachusetts dropped out of the coalition after changes in state leadership.95

In May of 2015, MA Senate President Stan Rosenberg advocated for Massachusetts to join a purchasing cooperative, attaching a section to a FY16 budget that requires MassHealth to investigate joining a multi-state purchasing cooperative (Section 182). 96, 97 In February of 2016, MassHealth submitted a report to the Massachusetts legislature describing the initial results of their investigation and intent to continue exploring the potential for savings.98

Evidence of Cost Savings

As of December 2015, more than half of state Medicaid agencies participate in a pharmaceutical purchasing cooperative.99 There are three major state cooperatives that purchase pharmaceuticals for Medicaid programs: (1) The National Medicaid Pooling Initiative (NMPI), (2) The Optimal PDL Solution (TOP$), and (3) The Sovereign State Drug Consortium (SSDC). Two other purchasing cooperatives—the Northwest Prescription Drug Consortium and The Minnesota Multi-State Contracting Alliance for Pharmacy—purchase collectively for other state and commercial entities, but not specifically on behalf of the Medicaid programs.

The February 2016 MassHealth report to the state legislature cited claims by cooperatives that the cooperative-negotiated rebate agreements could save members between 3-6% of their total pharmacy spend.100

95 NCSL, Bulk Purchasing (2016)
97 Massachusetts FY2016 Budget (2016)
98 MassHealth Report to the Legislature Concerning Cost Savings on Prescription Drugs (2016)
99 NCSL, Bulk Purchasing (2016)
100 MassHealth Report to the Legislature Concerning Cost Savings on Prescription Drugs (2016)
As a striking example of collective state bargaining power – in 2015 twenty-four states negotiated a rebate with the manufacturer AbbVie for their Hepatitis C medication, Viekira Pak, which was expected to save states 20-30% off of the list price. Missouri alone expected $4.2 million in savings.

The Minnesota Multi-State Contracting Alliance for Pharmacy provides another example of savings from participation in a purchasing cooperative. By law, Minnesota requires that the Alliance undergo a competitive procurement process for prospective cooperatives every five years. The selected cooperative then negotiates with the manufacturers on behalf of its members. Each manufacturer submits a bid to become the preferred agent, with an associated rebate. States have autonomy within the cooperative to accept and reject bids. Each member of the cooperative pays a flat monthly fee based on the state pharmacy budget. Clinical pharmacists at the state serve as the liaison to the cooperative. Minnesota estimates that they received around $11-12 million in supplemental rebates, equivalent to approximately 3-4% of their pharmacy budget.

Opportunities

Savings from MassHealth’s current and expected supplemental rebates equate to 4.4% of their projected pharmacy spend. If a purchasing cooperative can help MassHealth save an additional 1-2%, the option should be further considered. MassHealth should evaluate which of the cooperatives will provide the greatest breadth of additional rebate opportunities with maximum additional savings. Joining a cooperative will allow MassHealth to retain their current supplemental rebates for the duration of their contract periods while gaining the advantage of new rebate opportunities to sign on to. Unfortunately, as a member of a cooperative, MassHealth would lose the ability to extend or negotiate future supplemental agreements on its own, but would instead benefit from the cooperative’s existing rebates.

Challenges

Unfortunately, there is limited information to assist in determining whether joining a multi-state purchasing cooperative will generate sufficient savings for MassHealth. The amount of supplemental rebates negotiated between the manufacturer and the cooperatives remains proprietary, and as such is only available to cooperative members. The only figures available are the ranges published by cooperatives as potential savings of total spend.

In order to become a member, the agency will need to join the purchasing cooperative and pay the associated membership fees. These membership fees vary, but one cooperative charges a $12,000 one-time fee, plus $20,000 per year, according to the MassHealth legislative report. While the costs for joining the cooperative may be more than offset by savings through additional rebates, there is limited evidence of total cost effectiveness to draw on prior to establishing membership.

Lastly, as mentioned above, the state would lose the ability to continue its current supplemental rebates or to enact new agreements independent of the cooperative, possibly limiting its negotiating and savings potential.

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101 St. Louis Today (2015)
102 Interview notes with Minnesota Department of Human Services (2016)
103 MassHealth Report to the Legislature Concerning Cost Savings on Prescription Drugs (2016)
Prescription Benefits Manager (PBM)

Overview
MassHealth can also consider shifting supplemental rebate negotiations to a Pharmacy Benefit Manager (PBM). States generally contract with PBMs for administrative or managerial elements of their pharmacy benefits, including claims processing and rebate invoicing, as well as pharmacy network, formulary management, and prior authorization services.

PBMs contend they can extract greater savings from manufacturers on rebates than states might be able to attain on their own, given their enhanced purchasing power. Further, the PBMs manage some of the administrative aspects of the contracting process, potentially saving state resources. National PBMs like Magellan Health and Goold Health Systems also manage supplemental rebates for many of the multi-state cooperative initiatives.

As noted earlier, MassHealth currently contracts with Xerox State Healthcare for its claims and rebate invoicing services. MassHealth manages its pharmacy network and formulary management, as well as its prior authorization services, in-house. MassHealth officials note they have been successful at using their purchasing clout to negotiate several supplemental rebate agreements within the past year. The most significant challenge identified related to Massachusetts’s time and resource intensive procurement process, which would not be wholly alleviated even if a PBM were used.

Opportunities
Advocates argue that PBMs can leverage their substantial coverage pool to generate larger supplemental rebates than states might be able to obtain on their own. One study placed the range of rebates between 4-20% below the AMP. Similar to multi-state purchasing cooperatives, the extent and magnitude of cost savings from supplemental rebates are proprietary, making cost-benefit comparisons between MassHealth and PBMs difficult.

However, there are potential savings from collectively outsourcing the supplemental rebate negotiating and management processes along with the other pharmacy management services that MassHealth already outsources. Further, PBMs, similar to purchasing cooperatives, might provide MassHealth with a broader set of rebate opportunities, providing greater potential for cost-savings. In an effort to determine whether PBMs can offer additional savings through supplemental rebates, MassHealth could consider submitting a Request for Information from interested parties to better assess the costs and benefits of such a strategy.

Challenges
Contracting with a PBM may save MassHealth through additional rebates on a wide range of products, however it is not clear just how much savings are possible. Many of the cooperatives retain confidentiality regarding their agreements and savings rates, though they posit that states may expect to save 3-6% of their total pharmacy spend through their services.

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104 Chandra (2015)
105 Interview with MassHealth Pharmacy Officials - March 7, 2016
106 Ibid.
107 Donahue et al. (1995)
108 MassHealth Report to the Legislature Concerning Cost Savings on Prescription Drugs (2016)
Further, any decision to pursue a supplemental rebate as negotiated through a PBM would still have to go through the full procurement process as required by MassHealth and Massachusetts state law. This would require lengthy reviews by budget and legal analysts and review by the Drug Use Review Board, among other Massachusetts entities. Therefore, while a PBM might provide some overarching management of the process or additional opportunities for rebates, the remaining resource investment from the Commonwealth is not insignificant.

Lastly, as mentioned in the previous section, there is reason to believe that MassHealth has been successful than other states in securing supplemental rebates on its own, and given it just began its supplemental rebate program in 2015, there is still significant room for it to grow on its own.
3. Establish Pay-for-Performance Contracts

Overview
A growing number of public and private health plans have implemented pay-for-performance (P4P) contracts that aim to link health care spending to improved quality, efficiency, and overall value. Pay-for-performance agreements typically include financial incentives for health care providers to improve upon a set of quality measures and achieve optimal health outcomes.

In 2008, MassHealth was one of the first Medicaid agencies to launch a large-scale P4P program, which included physician incentive payments for quality indicators relating specifically to pneumonia and surgical infection prevention.¹⁰⁹

Pay-for-Performance for Drugs
In contrast to the rapid growth of P4P agreements for in-patient and physician care, P4P arrangements have been slow to develop for pharmaceuticals. However, the recent rise in high-cost specialty drugs has caused commercial and government-sponsored health plans to reexamine the potential value of linking patient outcomes to the cost of novel pharmaceuticals.

While clinical trials performed as part of the FDA approval process provide critical evidence on the safety and efficacy of the drug, uncertainties exist regarding the true clinical effect of the drug or value of a treatment in real-world settings. For example, factors such as lack of patient adherence and heterogeneous patient populations can have a meaningful impact on the clinical effectiveness across the health system. Pay-for-performance agreements can therefore reduce uncertainty or risk in covering novel therapies.¹¹⁰

In a pay-for-performance arrangement, drug manufacturers agree to share in the risk of a treatment outcome along with the payer. Under such a contract, MassHealth and a drug manufacturer would agree to a reimbursement rate that corresponds to pre-established patient outcomes and performance measures (see Case Study: Pay-for-Performance in Massachusetts). Potential pricing strategies include:

- **Outcomes-based pricing**: Uses a measurable clinical outcome (e.g., a valid biomarker) to assess the efficacy of a drug in achieving its therapeutic objective.
- **Process-based pricing**: Incentivizes manufacturers to provide and improve certain clinical services, such as patient medication adherence or prescriber outreach and education.¹¹¹

The specifics of the reimbursement agreement would need to be established at the outset of coverage. Reimbursement can be structured numerous different ways, including a manufacturer providing the initial therapy reimbursement reconciliation based upon a patient outcome, or an up-front payment by MassHealth followed by certain rebates from the manufacturer if an outcome is (or is not) achieved.

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¹⁰⁹ James (2012)
¹¹⁰ Neumann et al (2011)
¹¹¹ Ibid.
Opportunities
Increasingly, payers are facing additional scrutiny on whether the high-cost of brand name drugs reflect the true value of a true in bringing about improvement to patient outcomes. P4P provides MassHealth with an opportunity to tie the price of drug to the value that it provides for a patient. Moreover, P4P contracts are consistent with overarching efforts underway at MassHealth to re-align payment toward value-based care. In addition, this strategy provides an opportunity for MassHealth to target both cost savings and quality improvement strategies through a single administrative contract.

Increasingly, the federal government has signaled support for state agencies to incorporate pharmaceutical P4P contracts as a strategy to control costs and improve patient outcomes. In November 2015, CMS sent a letter to the CEOs of four major drug manufacturers expressing concern regarding access to medications for Hepatitis C patients. In the letter, CMS asked that the drug manufacturers provide information regarding performance-based purchasing arrangements that state Medicaid agencies might be able to participate in for the Hepatitis C drug. Specifically, CMS asked what types of performance-based arrangements, if any, are currently being offered to commercial or other government-sponsored health insurance plans.112,113

Additionally, in a letter addressed to state Medicaid agencies, CMS reiterated Medicaid’s obligation to provide access to HCV when medically necessary, while encouraging Medicaid directors to explore alternate pricing arrangements with manufacturers.

Lastly, the Medicaid Covered Outpatient Drug rule released by CMS in January 2016 (see Section II for details) indicates that the agency is considering more

CASE STUDY:
Pay-for-Performance in Massachusetts
In November 2015, Harvard Pilgrim Health Care and the drug manufacturer Amgen announced a pay-for-performance agreement for the cholesterol-lowering pharmaceutical Repatha. This contract is significant in that it incorporates both a pay-for-performance element and a substantial discount from the manufacturer. While the specifics of the agreement remain confidential, the parties acknowledge that Amgen will be at risk financially for the cholesterol levels of the Harvard Pilgrim enrollees that utilize the drug.

Repatha is the second FDA-approved therapy in a new drug class known as PCSK9 inhibitors. The other cholesterol-lowering drug, known as Praluent, is marketed by Sanofi Aventis and was approved in the summer of 2015. Both drugs represent a significant cost to public and commercial insurers, with retail prices for Repatha at $14,100 and Praluent at $14,600 annually. The fact that these two drugs are within the same therapeutic class provides Health Pilgrim with additional negotiating power in striking a discounted price. As part of the contract, Harvard Pilgrim will place Repatha on its preferred formulary, while Praluent will not receive preferential coverage status for its members.

The high retail prices of the PCSK9 inhibitors have called into question to the cost-effectiveness of this new class of drugs. In fact, a recent analysis by the Institute for Clinical and Economic Review (ICER) has determined that the both Repatha and Praluent are extremely overpriced, estimating that the true value of these drug are around $2,520 annually. In light of these relative low-value drugs, pay-for-performance represents a potential path forward for both commercial and public payers.


112 HHS-CMS, HCV Communication (2015)
specific guidance on performance-based pricing for agencies and manufacturers. This will likely include further clarity on how these agreements may be constructed in Medicaid, and how such relations may affect Medicaid’s “best price” calculations.\textsuperscript{114}

**Challenges**

Pay-for-performance contracts for pharmaceuticals have proven difficult to design and implement in the U.S.\textsuperscript{115} As such, the specifics of the arrangements and the ultimate impact on patient health outcomes have not been well characterized, particularly among public payers. There are also concerns regarding how “success” would be characterized or measured. While previous agreements have used biomarker measurements (e.g., cholesterol level) to determine clinical outcomes, not all drugs will be well suited for an outcomes-based reimbursement scheme. In addition, the MassHealth and manufacturers will need to address how outcomes can be influenced by numerous other factors outside the scope of a drug’s performance (e.g., socioeconomic factors) to adjust the contracts appropriately.

In addition, there are likely to be high transaction costs and administrative burdens in establishing and implementing a P4P contract. It is likely that each contract will require drug-specific negotiations that take into account the unique benefits, risks, and clinics evidence of each drug. In addition, there will be challenges in the data collection for outcomes-based measures, potentially including patient-collected data, laboratory results, and claims processing.\textsuperscript{116,117} MassHealth would need to ensure that adequate data systems and infrastructure are in place to accurately capture this information. Obtaining reliable and timely measurements within the Medicaid population poses its own challenges, as enrollees may dis-enroll from the program, switch coverage, or lose eligibility.\textsuperscript{118}

Lastly, depending upon how a contract is structured, there is a potential that a payer can be liable for increased overall costs, as compared to the traditional reimbursement rate. However, any increase in the overall pharmaceutical spend would be need to balanced against the improved outcomes for MassHealth members and the potential for downstream cost savings.

\textsuperscript{114} AmerisourceBergen (2015)
\textsuperscript{115} Patel (2015)
\textsuperscript{116} Ibid.
\textsuperscript{117} Neumann (2011)
\textsuperscript{118} Ibid.
4.  Consolidate Drug Purchasing among Massachusetts Agencies

Overview
Consolidated, or “bulk”, purchasing attempts to leverage the purchasing power of multiple agencies within a state to form a single administrative contract or negotiation for all purchased prescription drugs. Advocates of consolidated purchasing argue that by enlarging the pool of enrollees, the state will be better able to secure favorable financial agreements with drug manufacturers.

Consolidated Purchasing in Massachusetts
Proposals to utilize consolidated purchasing as a pharmaceutical cost containment strategy have resurfaced repeatedly in Massachusetts. In fact, Section 271 of the 1999 Budget Bill directed the Secretary of Administration and Finance to establish an aggregated drug purchase program.\textsuperscript{119,120} However, no statewide agency drug-purchasing program has been implemented to date.

In 2004, the Massachusetts Office of Health and Human Services solicited a Request for Information (RFI) from PBMs regarding a potential statewide pharmaceutical purchasing program. This program would have consolidated pharmaceutical purchasing between MassHealth, the Group Health Commission, and the State Office for Pharmacy Services.\textsuperscript{121,122} Based on these responses and subsequent independent analysis, there is reason to believe that a consolidating drug purchasing across multiple agencies will have only a modest effect on savings for both MassHealth and the Commonwealth of Massachusetts.\textsuperscript{123}

Despite the limited progress of these large-scale efforts, smaller-scale bulk purchasing programs have been implemented within the Commonwealth. For example, the FY 2016 Budget established a “Municipal Naloxone Bulk Purchase Trust Fund,” to be administered by the Massachusetts Department of Public Health.\textsuperscript{124} This trust fund enables municipalities to purchase the drug Naloxone at a discounted rate that is negotiated by the Attorney General of Massachusetts. Naloxone is administered by emergency responders (e.g., police and firefighters) and is used to reverse the effects of an overdose from heroin or other opioids.

In August 2015, Attorney General Healey announced a negotiated agreement with the manufacturer of Naloxone, Amphastar Pharmaceuticals, to secure $325,000 for the Trust Fund. This payment helped to lower the cost of Naloxone for municipalities participating in the Trust Fund and offset a more than doubling in the price of the drug (from $15 per dose to more than $30) in late 2014.\textsuperscript{125}

While successful, it is important to note that the bulk purchase of Naloxone was a drug-specific strategy that was aimed at increasing the negotiating strength of municipalities, which remain relatively small purchasers of drugs, rather than statewide agencies such as MassHealth.

\textsuperscript{119} Lewis (2011)
\textsuperscript{120} Day (2007)
\textsuperscript{121} Note - GIC is the health plan for Massachusetts state employees, retirees, survivors, and dependents.
\textsuperscript{122} Note - The State Office for Pharmacy Services is the pharmacy program for the Commonwealth’s inmate population.
\textsuperscript{123} Day (2007)
\textsuperscript{124} Commonwealth of Massachusetts, FY2016 Budget Outside Section 48. (2015)
\textsuperscript{125} Attorney General of Massachusetts (2015)
Opportunities
For administrative purposes, statewide bulk purchasing may be conducted under a single entity, such as the Governor’s office, Department of Public Health, or through a Pharmacy Benefits Manager (PBM). In addition, statewide agencies would need to unify their formularies to fully leverage the state’s negotiating power. Analysis suggests that there may be indirect savings stemming from streamlined processes in administration and improved pharmacy management. A 2001 report estimated the indirect savings stemming increased efficiency at $1.8 - 3.5 million for Massachusetts annually.126

Challenges
With several hundred thousand covered lives within PPC and FFS plans, MassHealth already possesses substantial purchasing power to negotiate with manufacturers. In general, while increasing the total volume of drugs purchased can provide leverage in negotiations with manufacturers, these effects are diminishing. It is not clear that increasing the volume alone will generate additional savings for MassHealth.127 As mentioned in earlier sections, more relevant for these negotiations is the ability of the purchaser to influence prescribing and dispensing patterns through placement on the MassHealth Drug List and other forms of drug utilization management strategies (e.g., prior authorization, step therapy).

In addition, a 2001 report that analyzed consolidated drug purchasing program in the Commonwealth found that MassHealth would not generate any direct savings in the form of lower dispensing fees, claims processing, supplemental rebates, or other discounts from participating in a consolidated purchasing program.128 This is due, in part, to existing state and federal law that provide MassHealth with preferential purchasing rates (e.g., federal mandatory rebates, federal upper limit) compared to other agencies, as well as certain restrictions on how dispensing fees and ingredient costs can be lowered.

Lastly, there are likely a number of technical and programmatic complications in the implementation of a consolidated purchasing program. Implementing a unified, “one size fits all,” formulary approach would reduce the regulatory flexibility of all agencies participating agencies in determining their own drug management strategies and preferred pharmaceutical products.

126 Lewis (2011)
128 Ibid.
**Pharmacies**

5. Establish Differential Reimbursement Rates for Specialty Drugs

**Overview**

Several Medicaid agencies have instituted heavily discounted pharmacy reimbursement rates for certain specialty medications. These discounts can take the form of an across-the-board reduction in the reimbursement for medications that are designated on a state-based specialty drug list. For example, the State of Maine provides a reimbursement rate for specialty pharmacy providers at a fixed discount off the Average Wholesale Price (AWP). Specifically, these drugs are reimbursed at AWP minus 17%, as compared to the typical AWP minus 16% for all other brand name drugs and AWP minus 13% for generics.\(^{129}\)

States have also implemented specialty drug discount rates that vary depending on the specific characteristics and price of the drug. For example, the State of Tennessee’s Medicaid Agency – TennCare – has established a Specialty Pharmaceutical Pricing List, which implements discounts that range from AWP minus 16% to AWP minus 40% (e.g., for certain oncology therapies).\(^{130}\) By comparison, TennCare’s reimbursement rate is AWP minus 15% for brand name drugs and AWP minus 13% for generic drugs.\(^{131}\) As with other states, Tennessee utilizes a “lesser than” reimbursement methodology, by which the state reimburses based on the lowest-cost of multiple reimbursement methodologies (see text box at right).

**Implications from the Recent Federal Rule on Covered Outpatient Drugs**

As described in Section II of this report, CMS finalized the Medicaid Covered Outpatient Drugs rule in January 2016, which will have a substantial impact on Medicaid drug reimbursement rates. As a result of this rule, Medicaid agencies will transition to a reimbursement rate that is based on the AAC for the ingredient cost of the drug and dispensing fee for the pharmacy.

CMS provides states with some flexibility in establishing an AAC reimbursement rate. States have the option of using the CMS NADAC files as a pricing benchmark, but may also conduct their own surveys of retail pharmacy providers to establish their AAC. If a state chooses to estimate their own AAC, CMS requires that the process be transparent, comprehensive, and provide adequate reimbursement to Medicaid pharmacy providers. MassHealth will be required to submit their methodology to CMS as part of a state plan amendment by no later than April 1, 2017.

\(^{129}\) MaineCare Benefits Manual (2015)

\(^{130}\) Magellan (2016)

\(^{131}\) Gordon (2016)

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**Specialty Pharmaceutical Reimbursement in the State of Tennessee**

Medications included on the State of Tennessee’s Specialty Pharmaceutical Pricing List are reimbursed using the lowest-cost option of four separate reimbursement methodologies:

1. AWP minus the discounted rate for the medication listed on the Specialty Pharmaceutical Pricing List.
2. The pharmacy’s usual and customary charge.
3. Maximum Allowable Cost (MAC) plus a $1.50 dispensing fee.
4. Federal Upper Limit plus a $1.50 dispensing fee.

Source: Gordon (2016)
The NADAC survey only includes retail community pharmacies. Importantly, the statutory definition of retail community pharmacies excludes specialty pharmacies that dispense medications to patients and physicians primarily through the mail. Community pharmacies are unequipped to store, dispense, or provide the clinical outreach necessary for certain specialty medications, therefore many specialty medications are not included within the NADAC survey. This has important implications, as certain specialty drugs and physician-administered drugs will not have a pricing benchmark in the same manner that other drugs have through NADAC.

CMS has sought to address this issue by providing states with the ability to establish separate reimbursement rates for specialty and physician-administered drugs. As a result, states have the ability to maintain differential reimbursement rates for specialty drugs (e.g., the Specialty Pharmaceutical Pricing List for Tennessee). Establishing this reimbursement rate presents an opportunity to generate cost savings provided the methodology reimburses Medicaid pharmacy providers adequately.

Opportunities

With the release of the final Covered Outpatient Drug rule, MassHealth has a timely opportunity to reevaluate how the state reimburses for specialty drugs.

Implementing a lower reimbursement rate for specialty drugs is relatively straightforward for an operational standpoint, as MassHealth is already required to submit for CMS approval the reimbursement methodologies for specialty drugs. This has a distinct advantage over other cost control strategies presented in this paper, as it has the potential for significant cost savings while leveraging existing regulatory requirements and MassHealth authority.

States can take a number of different routes in establishing a differential reimbursement rate for specialty medications. Fortunately, several states have already made the transition to AAC in advance of the CMS final rule and have confronted the issue of reimbursement for specialty products with no NADAC benchmark. Many states have chosen to utilize the Wholesale Acquisition Cost (WAC) based formula as a proxy for AAC, a methodology that CMS permits to be used under the new regulations.

Use of a WAC-based reimbursement for specialty drugs has a number of distinct advantages. First, as mentioned in previous sections, MassHealth already has in place a reimbursement rates of WAC plus 5% for single-source drugs, allowing the agency to continue with existing methodologies while adjusting the percentages as appropriate. Second, analysis suggests that there is a consistent relationship between the WAC and NADAC measurement for single-source drugs. For example, one analysis suggests that there is an average difference of 2% between the two measures (WAC vs. NADAC), with a WAC minus 2% being roughly equivalent to the NADAC benchmark for branded drug. Other analyses recommended states adopt a WAC + 0% for drugs without a NADAC price benchmark.

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133 National Association of Chain Drug Stores. (2016)
134 Myers and Stauffer – Texas (2014)
135 Bruin (2014)
136 Myers and Stauffer – Texas (2014)
137 Myers and Stauffer – Maryland (2014)
Lastly, it is important to note that MassHealth has the option of conducting a state-based survey of pharmacies and potential specialty pharmacies to establish a reimbursement methodology that is specific to Massachusetts. Such surveys have already been conducted in Alabama, Colorado, Idaho, Iowa, Louisiana, and Oregon, among others. However, it is not clear at this point how a Massachusetts-based pharmacy survey may compare to cost estimates provided by NADAC or WAC benchmarks.

**Challenges**

In implementing this strategy, MassHealth will need to determine a reimbursement threshold that is both adequate for Medicaid pharmacy providers and achieves the desired amount of cost savings. If the agency proposes to set a rate that is too low, there is a potential that the reimbursement methodology will not be approved by CMS. In addition, a lower specialty pharmacy rate has the potential for specialty pharmacy providers to discontinue participation in the Medicaid program, however this has not occurred within states that have already lowered their reimbursement rates for specialty pharmaceuticals.\textsuperscript{139}

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\textsuperscript{138} Bruen (2014)
\textsuperscript{139} Texas (2015)
6. Implement Specialty Pharmacy Networks

Overview
Establishing a preferred network of health care providers is a common strategy to reduce costs for health insurers. In the private sector, health insurance plans such as health maintenance organizations (HMOs) and preferred provider organization (PPOs) establish contracts with providers to establish a “network” from which covered individuals receive their health care. Providers, incentivized to be included in the preferred or exclusive network, compete with one another to offer price discounts to the health plan.140

With the rise in pharmaceutical costs, health insurance plans have increasingly engaged in selective contracting with retail pharmacies as a means of reducing drug reimbursement and dispensing fees. Similar to the market for physicians, hospitals, and other health care providers, pharmacies will compete to offer discounts and/or additional member services for inclusion within a pharmacy network.

Evidence suggests that the more exclusive the network (i.e., the narrower the network), the greater the potential price discount for the insurer.141 Typically, health insurers use PBMs to negotiate contracts with retail pharmacies regarding discounts and inclusion within the pharmacy network.

Insurers must balance the advantages of drug discounts with the potential drawbacks of selective contracting. Critics of selective pharmacy networks typically point to access issues from limiting consumer choice of pharmacies, exclusion of smaller and independent pharmacies from the network, and potential violations of “any willing provider” or “freedom of choice” laws, as applicable.

Establishing Specialty Pharmacy Networks
Medicaid agencies can contract with specialty pharmacy chains to serve as Medicaid’s preferred or sole source for certain specialty drugs through a competitive bidding process. This is the strategy used by both Pennsylvania and Vermont in establishing a “specialty pharmacy network”. In Pennsylvania, two specialty pharmacy chains serve as the sole source of specialty medications statewide, and are responsible for the dispensing and delivery of medication to patients and providers. As a condition of the exclusive contract, the Pennsylvania Department of Health requires that the specialty pharmacies provide care management services

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140 Klick and Wright (2012)
141 Sherpherd (2013)
and employ nurse case managers to ensure appropriate clinical management of the specialty medications. The state re-negotiates the ingredient cost of a drug twice annually on a drug-by-drug basis.142

Opportunities
Evidence from Pennsylvania’s implementation of the Specialty Pharmacy Drug Program suggests that cost savings can be obtained both through lower negotiated drug ingredient costs and improved clinical management, generating cost savings from avoidance of adverse events and inpatient hospital visits. (For a full discussion, see Case Study: Specialty Pharmacy Networks in the State of Pennsylvania).143

Challenges
Medicaid agencies implementing a Specialty Pharmacy Drug Program will face regulatory challenges, as approval is contingent upon approval of a waiver from CMS. The Section 1915 B Waiver would allow the state to require beneficiaries to use certain preferred providers (i.e. specialty pharmacies). In addition, the Massachusetts State Plan Amendment would need to be revised and approved by CMS.

Concerns may also be raised regarding how specialty pharmacy networks can affect patient access and choice of pharmacy provider. However, the extent to which this is a significant issue will depend on the scope of the specialty pharmacy network. For example, many specialty pharmaceuticals are currently provided to patients and physicians through mail delivery, and such a feature would likely be incorporated into a contract. However, the specialty pharmaceutical network may also incorporate drugs that are commonly dispensed at retail community pharmacies, thereby altering a patient’s pharmaceutical purchasing behavior. This may generate criticism from patients that would prefer to use their pharmacy and/or pharmacist of choice. In addition, MassHealth may face political resistance from retail pharmacies and specialty pharmacies that are excluded from the Specialty Pharmacy Network.

Lastly, this strategy will likely also increase the operational complexity and burden of reimbursing specialty drugs for MassHealth. Among the tasks required to establish a specialty pharmacy network include:

- Designing and evaluating a Request for Proposals (RFP) for specialty pharmacies;
- Establishing a criteria by which drugs will be considered “specialty” for the purpose of these networks;
- Designing and implementing a Specialty Drug List;
- Negotiating ingredient costs with the specialty pharmacies; and
- Managing and overseeing the specialty pharmacy contracts on an ongoing basis.

142 Smith et al. (2011)
143 Ibid.
CASE STUDY: Specialty Pharmacy Networks in the State of Pennsylvania

Overview: In 2009, the Pennsylvania State Department of Health (DOH) contracted with two specialty pharmacy chains to serve as the exclusive providers of specialty drugs under a newly established Specialty Pharmacy Drug Program. In launching this preferred network, the Pennsylvania DOH sought to obtain cost savings through lower reimbursement rates for specialty drugs, provide more effective clinical management for patients using specialty medications, and improve care coordination between providers.

Scope of the Program: Pharmacies within the Specialty Pharmacy Network agree to provide a wide range of specialty drugs and physician-administered medications (for a full list of specialty drugs included in the Specialty Pharmacy Network see Appendix A-3). Pharmacies dispense these medications primarily through mail orders, which are delivered to beneficiaries’ homes, physician offices, clinics, and treatment centers.

Clinical Services and Care Coordination: Specialty pharmacies within the network provide a host of clinical services to ensure safe and optimal use of specialty medications. This includes using nurse case managers to evaluate and assess patients with certain conditions (e.g., multiple sclerosis, depression), call centers for phone-based consultations, and other clinical management services to coordinate care between providers. Preferred pharmacies also provide clinical outreach to health professionals to ensure proper use of the drugs and compliance monitoring. In addition, participating specialty pharmacy work to integrate medical, laboratory, and hospital data into a prescription treatment regimen that is shared with providers.

Impact on Beneficiaries: Medicaid beneficiaries enrolled in the Fee-for-Service (FFS) system are required to obtain all specialty medications from one of the state’s two preferred pharmacy chains. In 2011, this included approximately 2,000 Medicaid beneficiaries throughout the state. As an added benefit for Medicaid beneficiaries, Pennsylvania waived all co-payments for specialty drugs included in the Specialty Pharmacy Drug Program and provided free supplies for administration (e.g., syringes).

Cost Savings: Pennsylvania reported a 21% decrease in the overall per-member-per-month (PMPM) expenditures among beneficiaries using specialty drugs as part of the Specialty Pharmacy Drug Program. These cost savings stemmed from two primary factors:
1) 16% discount on the ingredient cost of the specialty drug; and
2) 56% decrease in inpatient hospital expenditures, resulting from clinical outreach.

Sources: Smith (2011) and Kittridge (2011)
7. Enforce the 340B Drug Discount Program Rebates

Overview
According to the federal law, MassHealth cannot receive both the Medicaid federal drug rebate and the 340B discount, a violation that is commonly referred to as ‘double dipping.’ The 340B discount is applied at the point-of-purchase of the drug (i.e., at the dispensing pharmacy), while the Medicaid rebate is refunded to MassHealth after billing. When approved providers contract with outside pharmacies, it may be difficult for pharmacists (and subsequently MassHealth officials) to monitor which prescriptions are eligible for the 340B discount. Pharmacies may also inadvertently ‘divert’ 340B discounts to ineligible patients.

The ultimate liability lies with the 340B provider, or ‘covered entity’. In 2010, HRSA released guidance recommending that entities provide quarterly audits of the pharmacies with which they contract to ensure that they meet federal regulations. Since the GAO released its report in September 2011, HRSA has stepped up its audits of the 340B program.

In 2011, New York State audited its 340B program and found that the state Department of Health was not sufficiently tracking 340B prescriptions, at an estimated cost of $24.3 million in savings. The problems were attributed to flaws in the computer tracking system and claims process at the provider level for administered drugs. In response, the New York State Department of Accountability recommended a formal reminder to all 340B pharmacies about the drug claims process, monitoring high risk providers for physician-administered drugs, and revamping their electronic tracking system to capture relevant claims.

Given the complexity of the process, it is possible that MassHealth does not receive the full 340B rebate from contract pharmacies. Without enforcement of the 340B program, MassHealth may be missing out on savings. To ensure maximum savings, MassHealth could create a clear tracking system so that pharmacies can flag 340B claims more easily. It could also make efforts to remind 340B entities that they are required to track 340B claims and that failure to comply will end in exclusion from the MassHealth network. MassHealth could further monitor the 340B pharmacies could exclude from the network those that do not comply. Only with strict monitoring will MassHealth be able to obtain full savings from the program.

Obtaining the full rebates through the 340B program requires that MassHealth, (1) revamp the state’s electronic claims process with eligible pharmacies, (2) heighten monitoring of the program, and (3) report pharmacies that fail to comply with 340B requirements to the federal government. If the problems persist, MassHealth can consider terminating contracts with pharmacies that fail to comply—although this may compromise access for MassHealth members.

Opportunities
MassHealth may be able to achieve cost savings through stricter monitoring of the 340B program. While it is currently unclear the extent to which eligible prescriptions may not be “flagged” as 340B and thus heavily discounted, MassHealth may be able to conduct an audit to determine the extent to which this is a problem.

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144 NCSL (2016)
145 Rosebush (2015)
146 New York State Dept. of Accountability (2012)
Challenges
As the Federal government is tasked with overseeing the 340B program, MassHealth does not have the authority to penalize non-compliant pharmacies, beyond eliminating the Medicaid pharmacy agreement. Strict enforcement also has political consequences, as pharmacists under scrutiny can appeal to legislators since the current process is somewhat burdensome.
8. Reimburse for Medication Therapy Management (MTM) Services

Overview
Lack of health literacy and poor medication adherence remains a significant barrier to effectively managing patient health. When medications are missed or not taken as prescribed, conditions can worsen, leading to adverse health outcomes and higher overall costs. In addition, issues can arise if providers are not fully aware of all medications that a patient may be taking – which can include over-the-counter drugs, supplements, and additional therapies that have the potential to result in harmful drug interactions. Pharmacists often play an important role in identifying these potential medication issues and helping patients to actively manage their medications.

One formalized approach, known as Medication Therapy Management (MTM), fosters collaboration between pharmacists and primary care providers, allowing each to better identify and resolve medication related problems that might occur during drug treatment. Specifically, MTM aims to supports patients in optimizing drug therapy and improving therapeutic outcomes through a set of five core services, including:

- Performing a comprehensive Medication Therapy Review (MTR) to identify and resolve potential medication-related problems;
- Establishing a Personal Medication Record (PMR) that records a patient’s medications, including prescription, nonprescription, herbal products, and dietary supplements;
- Creating a Medication-Related Action Plans (MAP) to assist patients in self-management and progress tracking;

<table>
<thead>
<tr>
<th>State Medicaid Agency</th>
<th>Patient Population</th>
<th>Cost Savings (Per Patient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minnesota147</td>
<td>Patients with hypertension and hyperlipidemia.</td>
<td>$3,768</td>
</tr>
<tr>
<td>North Carolina148</td>
<td>Patients using 12 or more medications each month.</td>
<td>$107</td>
</tr>
<tr>
<td>California149</td>
<td>Patients with HIV/AIDS.</td>
<td>No significant differences in cost.</td>
</tr>
<tr>
<td>Texas150</td>
<td>Patients with hypertension and taking at least four maintenance medications.</td>
<td>$8,600</td>
</tr>
<tr>
<td>Connecticut151</td>
<td>Patients with at least one chronic condition taking three or more prescription medications.</td>
<td>$1,595</td>
</tr>
<tr>
<td>Iowa152</td>
<td>Patients using four or more medications.</td>
<td>No significant differences in cost.</td>
</tr>
</tbody>
</table>

Sources: Barner (2015), Isetts (2003), Smith (2011)
• Providing interventions and/or referrals as necessary, including consultative services to address medication-related problem; and
• Documenting services and scheduling follow-up on a patient’s medication-related needs and/or ensuring a patient is properly transitioned between care settings.\footnote{154} 

Numerous studies have demonstrated improved clinical outcomes associated with pharmacist-directed MTM interventions, including among Medicaid populations. Typically, these MTM programs have targeted a chronic condition (e.g., diabetes, hypertension, asthma) or a high-risk patient population (e.g., patients taking 4 or more medications) that would benefit from additional care management.

In addition to improving health outcomes, MTM programs have demonstrated the potential for overall cost savings. These savings commonly result from improving medication adherence and administration for complex drug regimens, identifying insufficient or excessive dosages, and avoidance of additional physician visits, additional prescription orders, hospitalizations, or other costly interventions. Evidence of cost savings from MTM services has been well documented by multiple Medicaid state agencies conducting MTM program and pilot studies (see table 3). For example, in September 2015, the Texas Department of Health and Human Services issued a report on the effectiveness on a pilot MTM program that targeted adult enrollees with hypertension taking four or more maintenance medications. Using Medicaid claims data, Texas found that receipts of MTM services resulted in a mean total cost savings of approximately $8,600 per patient, when factoring in savings associated with cost avoidance fewer physician visits, prescription drugs, labs, and emergency department and hospital visits.\footnote{155}

**Opportunities**

MassHealth does not currently reimburse for MTM services. However, the agency can initiate MTM reimbursement to incentivize pharmacists to provide these services to Medicaid beneficiaries. While reimbursing pharmacists for these services will result in an initial up-front cost for the MassHealth pharmacy program, evidence from existing Medicaid-based MTM reimbursement programs show a positive return-on-investment and positive health outcomes for Medicaid beneficiaries.

<table>
<thead>
<tr>
<th>Medicaid Agency</th>
<th>New Patient Consultation</th>
<th>Returning Patient Consultation</th>
<th>Additional 15-minute Consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iowa</td>
<td>$75</td>
<td>$40</td>
<td>$25</td>
</tr>
<tr>
<td>Minnesota</td>
<td>$52</td>
<td>$34</td>
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<tr>
<td>Missouri</td>
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<td>$10</td>
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<tr>
<td>Oregon</td>
<td>$28.22</td>
<td>$26.34</td>
<td>$13.17</td>
</tr>
</tbody>
</table>

*Table 4. Medicaid Reimbursement for MTM Services*  


While the scope and nature of these MTM programs vary by state, Medicaid agencies typically reimburse between $15 and $75 per pharmacist for MTM consultation services (see table 4).\footnote{156} Medicaid agencies often reimburse on a 15-minute consultation basis, with large upfront reimbursement for new patients and a reduced rate for established patients. This larger up-front payment helps to incentivize pharmacists to provide

\footnote{154}Bluml (2005)  
\footnote{155}Barner (2015)  
\footnote{156}Cauchi (2010)
MTM services for Medicaid beneficiaries, as well as reimburse for additional workload in reviewing a patient’s medication history for the first time.

Challenges
Authorization for MassHealth to reimburse pharmacists for MTM services will require legislative action from the Massachusetts legislature. In general, legislators may be wary of providing additional reimbursement for pharmacists that will increase the pharmacy budget. While long-term cost savings can accrue through better health outcomes, improved clinical management, and reduced hospitalizations, this does not change the fact that additional up-front costs associated with pharmacist reimbursement would need to be budgeted. Recent efforts by Massachusetts Legislature to provide additional reimbursement for pharmacist services and pharmacy clinical management – such as Collaborative Drug Therapy Management (CDTM) – have stalled.157,158

158 Note - In 2015, the Massachusetts Legislature considered legislation (H.2041) that would require MassHealth to provide coverage for CDTM services for patients with one or more chronic diseases. Under this bill, registered pharmacists that have entered into collaborative practice agreements with patients’ physicians would be eligible to receive reimbursement for MTM services. As part of a collaborative practice agreement, pharmacists are take on additional responsibilities to work with patients’ care team to manage drug therapy, which can include initiating, altering, and terminating medications to enable the best health outcome. Though distinct from MTM, legislative approval for CDTM faces many of the same political and operational challenges.
9. Apply Value-Based Insurance Designs to Co-Payments

Value based insurance designs (VBID) are increasingly used by commercial carriers to incentivize utilization of high value drugs. In this model, co-pays for drugs are determined by the clinical value of the drug. Consumers receiving drugs with low clinical value are charged higher co-pays, whereas consumers receiving highly effective drugs have low co-pays (or no co-pays at all). This model is often used for drugs that manage chronic diseases—like asthma, diabetes, and hypertension—and can both keep members out of the hospital through improved adherence to their medication, while at the same time discourage use of high cost, low value drugs.

VBID is currently being pioneered by Michigan and New Mexico through their Medicaid expansions. In addition, CMS issued a RFP for innovative VBID designed plans in both Medicare Advantage and Medicaid Managed Care in October 2014.

Identifying High-Value Drugs

It is important that drugs are defined as ‘high value’ based on their clinical value, not simply because of their price tag. The Institute for Clinical Effectiveness and Economic Review (ICER) was established in 2007 and is charged with evaluating the therapeutic value of a given drug in relation to its costs. ICER found that the new PCSK9 inhibitors were priced 60-70% more than the Value-Based Price benchmark. Entresto, for congestive heart failure, was priced 9% above the Price Benchmark. Health carriers, like MassHealth, should reflect the value of these drugs in their cost-sharing schedules for its members. In a VBID model, drugs like PCSK9 or Entresto would have higher copays to discourage use.

In a Health Affairs systematic review of VBID, researchers found a demonstrated improvement in medication adherence as a result of VBID. They did not, however, find any strong evidence of cost savings as a result of the program. The model was particularly effective for those patients with chronic illnesses, especially diabetes and managing cholesterol.

Opportunities

At a national level, Medicaid rules allow varying co-pays for drugs from $0-$4 for preferred drugs, and up to $8 on non-preferred drugs. In reality, Medicaid programs do not list their drugs for more than $4. As reported earlier, MassHealth lists most drugs for $3.65, although there are limited high value drugs for diabetes, hypertension, and cholesterol with a co-pay of $1.

MassHealth has already lowered co-pays for certain high value drugs as determined by their clinical board in their evaluation of the Preferred Drug List. They could, however, pilot a demonstration with the attention on

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159 Center for Value Based Insurance Design (2014)
160 HHS - CMS Value Based Insurance Design (2014)
161 Fendrick (2013)
162 Weisman (2015)
163 “Interview with Sarah Emond at ICER” Personal Interview; (2015.)
164 Note - MassHealth can also use ICER reports to construct pay for performance contracts for drugs with uncertain results.
165 Lee et al. (2013)
specific patient populations who may see improved health outcomes through strengthened medication adherence. At present, Massachusetts legislators in both the House and the Senate are considering legislation (H. 984/S. 606)\textsuperscript{166} that would eliminate co-pays for high value care.

**Challenges**

Through VBID, payers provide a ‘carrot’ to patient through free or discounted medications to improve health outcomes. MassHealth will have to decide if they want to use a ‘stick’ as well: pricing up low value drugs for its members to discourage utilization. There is clear evidence that low-income individuals are especially price elastic when it comes to high pharmaceutical prices.\textsuperscript{167} If MassHealth decides to raise co-pays for low-value drugs, it will likely discourage utilization (as intended). Clearly, there are additional concerns regarding the use of VBID among Medicaid beneficiaries, as members may face additional financial barriers to care, as compared to those who are privately insured.

Furthermore, in Massachusetts, MassHealth members are not required to pay their co-pay if they cannot afford it. Anecdotal evidence demonstrates that many MassHealth members waive their co-pays altogether because of their inability to pay.\textsuperscript{168} In these circumstances, VBID would be ineffective.

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\textsuperscript{166} Farley-Bouvier (2015)
\textsuperscript{167} Chernew (2008)
\textsuperscript{168} “Interview with Kate Segel at Health Care For All,” Personal Interview; December 2015
Section VI – Evaluation of Strategies

Overview
This section aims to assess each of the strategies by evaluating them against five key criteria:

1. Cost Savings for MassHealth
2. Operational Burden
3. Political Feasibility
4. Impact on Access to Necessary Medications or Treatments
5. Impact on Quality of Medications or Treatments

The Policy Decision Matrix, as shown in Table V on the following pages, outlines each of the nine policies as assessed against these five criteria. As described below, there are four recommendations that fail to meet the majority of the selected criteria, two recommendations that meet some criteria, and four recommendations that meet most of the criteria.

Strategies that Fail to Meet Most of the Criteria
Four strategies fail to meet most of the five criteria outlined, and are clearly dominated by other potential strategies.

- **Status Quo**: This option fails to adequately address the growing cost of pharmaceuticals. Given that the agency projects an annual 8% annual growth in pharmaceutical costs, additional actions are necessary to bring the MassHealth pharmacy budget to a sustainable level. MassHealth will need to develop and expand its already successful pharmacy management programs to rein in this cost growth.

- **Statewide Consolidated Drug Purchasing**: This strategy would require significant investment and coordination across a multitude of state agencies, while generating only minimal return in savings. As mentioned earlier, previous initiatives and investigations into statewide bulk purchasing have suggested that MassHealth will not likely to generate significant cost savings for the agency.

- **Enforce 340B Drug Discount Rebates**: There are significant operational burdens required in effectively enforcing the 340B drug discount rates, potentially outweighing any savings the state might realize. Further, stricter enforcement might require the state to take action against entities that fail to comply, raising concerns regarding reduced access to pharmacies for MassHealth’s most vulnerable beneficiaries.

- **Value-Based Insurance Design (VBID)**: While this strategy has demonstrated the potential to provide savings for certain therapies, the effect of VBID in Medicaid has not been well established. Given the nature of VBID in modifying pricing and cost-sharing structures, concerns persist that this strategy has the potential to reduce access, given the cost barriers that many Medicaid beneficiaries face in purchasing medications.
Strategies that Meet Some of the Criteria
Two strategies meet some of the selected criteria, but failed to meet others.

- **Specialty Pharmacy Networks**: Specialty pharmaceutical networks have the potential to yield significant savings and improved health outcomes. However, these advantages must be balanced against the potential for high operational and political challenges. First, establishing and managing the Specialty Pharmacy Network will require a substantial commitment of MassHealth staff resources and time. Second, MassHealth may face a political challenge in proposing to “narrow” the pharmacy network. While this is unlikely to have a meaningful impact on patients, there may nevertheless be political pushback from patients concerning access issues and complaints among independent pharmacies that are not included within the network. Lastly, the potential benefits of this strategy may also be achieved by establishing the ‘differential pharmacy reimbursement rate’ (discussed below), while avoiding many of the potential operational and political challenges.

- **Pay-for-Performance (P4P) Contracting**: P4P contracting remains a promising, yet highly resource intensive, strategy for MassHealth. While CMS has signaled its support of P4P in recent regulations, there are multiple aspects of P4P that will benefit from additional regulatory guidance to inform the contracting of these programs. Moreover, given the propriety nature of many existing P4P contracts within the commercial sector, it may be prudent for agency to wait until best practices have been established before adopting a risk-based contract. While we recommend the agency wait on implementing a P4P contract in the near term, MassHealth may consider exploring P4P models with manufacturers that have previously implemented P4P with commercial health insurers. This may also include establishing Memorandum of Understanding (MoU) with manufacturers to facilitate future P4P contracting. Additionally, the operational burdens associated with contracting might be better facilitated through a multi-state cooperative purchasing organization, rather than one-off agreements established by MassHealth staff.

Strategies that Meet Most of the Criteria
The following four strategies meet most of our selected criteria for evaluation. These strategies work across the spectrum of the pharmaceutical reimbursement system and promise to provide significant cost-savings for MassHealth. As such, these strategies are the basis for our recommendations to MassHealth, and will be discussed further in *Section VII*.

- **Expand Supplemental Rebates**: MassHealth is projected to save $25 million annually given its current foray into supplemental rebates. Because this is a new program, there is likely substantial room to increase the number of supplemental rebates MassHealth undertakes, providing substantial potential savings. The state’s efforts to expand the program to include drugs covered through MCOs should provide significant savings as well. This policy enjoys broad support from most stakeholders, and because it generally requires competing therapeutically-equivalent drugs, would not result in limited access or quality of care.

- **Contract with a Third-Party to Negotiate Supplemental Rebates**: MassHealth already contracts out some of its pharmacy management activities to a third-party, and may benefit from also contracting with a third-party to negotiate its supplemental rebates. Contracting with a cooperative
will provide maximum flexibility, while allowing MassHealth to realize savings from additional rebates that would be made available through a third-party. There would be no impact on access or quality, and given the legislature required MassHealth to explore this option in the last session, it enjoys moderate political feasibility.

- **Differential Pharmacy Reimbursement Rates for Specialty Drugs**: The release of the Covered Outpatient Drug Final Rule provides a valuable opportunity for MassHealth to revise the specialty drug reimbursement rate and generate cost savings for many of the most expensive therapies. Fortunately, this strategy does not require a large time or resource commitment from MassHealth, as it capitalizes on an existing reimbursement rate (Wholesale Acquisition Cost) and utilizes specialty pharmacy providers already participating in the MassHealth system. Establishing the new pharmacy reimbursement rate can occur alongside other regulatory requirements of the recent CMS Final Rule.

- **Medication Therapy Management**: Reimbursing for MTM services has the potential to generate moderate cost savings for the Commonwealth while improving patient health outcomes. As an added benefit, is likely to enjoy a high degree of political feasibility, given that it has proven effective in other Medicaid programs. While operationalizing the program might require upfront investment of MassHealth staff time and administrative costs, there are potentially significant benefits for increasing access and quality of care for beneficiaries.
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Cost Savings</strong></td>
<td><strong>Low.</strong> The state has had minimal success using current strategies.</td>
<td><strong>Moderate.</strong> MassHealth has already seen significant savings and has room to establish more. Expanding to MCOs will expand purchasing power, providing more direct savings.</td>
<td><strong>Low to Moderate.</strong> Multi-state cooperatives or PBMs may save Medicaid agencies between 3-6% of total claims – potentially tens of millions.</td>
<td><strong>Very Low.</strong> Analysis suggests that MassHealth will generate very little cost savings from a consolidated drug purchasing program.</td>
<td><strong>Low.</strong> Precise amount will vary by contract and drug, however little evidence is publically available regarding the true effect of cost-savings.</td>
</tr>
<tr>
<td><strong>Operational Burden</strong></td>
<td><strong>None.</strong> All existing drug management policies will remain in effect.</td>
<td><strong>High.</strong> Securing a supplemental rebate is a resource intensive process that requires a substantial time commitment from MassHealth staff in contracting an agreement with the manufacturer.</td>
<td><strong>Medium.</strong> This strategy will require a regular procurement and contracting process and may restrict MassHealth’s agility in additional supplemental contracting.</td>
<td><strong>High.</strong> This strategy will require a significant investment of staff time in coordinating across multiple state agencies.</td>
<td><strong>Very High.</strong> Establishing suitable contracts and clear measurements for pay-for-performance is extremely time intensive.</td>
</tr>
<tr>
<td><strong>Political Feasibility</strong></td>
<td><strong>Possibly negative.</strong> Public and political concern over rising drug costs and the impact on state budgets is high.</td>
<td><strong>Positive.</strong> There is substantial political support for generating additional supplemental rebates. However, MCOs may resist having to use the terms of MassHealth supplemental rebates agreements</td>
<td><strong>Positive.</strong> There is political support for this strategy, particularly for joining a multi-state purchasing cooperative.</td>
<td><strong>Possibly Positive.</strong> A consolidated purchasing program has resurfaced repeatedly within the Massachusetts Legislature as a cost saving strategy.</td>
<td><strong>Positive.</strong> P4P contracts generally receive support, however there may be concerns with as P4P an “untested” in the Medicaid pharmaceutical arena.</td>
</tr>
<tr>
<td><strong>Impact on Access</strong></td>
<td><strong>Possibly negative.</strong> Continued increases in spending may result in downstream coverage limitations.</td>
<td><strong>None.</strong> This strategy will not have a significant impact on access.</td>
<td><strong>None.</strong> This strategy will not have a significant impact on access.</td>
<td><strong>None.</strong> This strategy will not have a significant impact on access.</td>
<td><strong>None.</strong> This strategy will not have a significant impact on access.</td>
</tr>
<tr>
<td><strong>Impact on Quality</strong></td>
<td><strong>Possibly negative.</strong> Continued increases in spending may result in downstream coverage limitations.</td>
<td><strong>None.</strong> This strategy will not have a significant impact on quality.</td>
<td><strong>None.</strong> This strategy will not have a significant impact on quality.</td>
<td><strong>None.</strong> This strategy will not have a significant impact on quality.</td>
<td><strong>Possible Improvements.</strong> Improved care coordination and management may improve clinical outcomes.</td>
</tr>
</tbody>
</table>
### Strategies for Cost Containment

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td><strong>Cost Savings</strong></td>
<td><strong>Medium to Large.</strong> Specialty Pharmacy Networks have the potential to generate savings from drug discounts and the avoidance of costly services from improved patient health outcomes.</td>
<td><strong>Large.</strong> Establishing a specialty drug reimbursement rate (WAC -2%) can generate significant cost savings, as compared to the current MassHealth reimbursement rate for high-cost drugs.</td>
<td><strong>Low.</strong> The potential savings from enforcing 340B are low. MassHealth needs to invest in audits and improve the electronic claims tracking, which is a significant up front investment.</td>
<td><strong>Low to Moderate.</strong> Medicaid MTM services have demonstrated the potential for a range of cost savings. Specific savings will depend upon the target population and/or clinical disease management area.</td>
<td><strong>Very Low.</strong> While there is some evidence that VBID can improve health outcomes to offset future medical spending, the evidence is weak and inconsistent.</td>
</tr>
<tr>
<td><strong>Operational Burden</strong></td>
<td><strong>Medium to High.</strong> This will require a significant time and resource commitment from MassHealth in establishing contracts and reviewing bids from specialty pharmacies.</td>
<td><strong>Low.</strong> This strategy has a low operational burden for MassHealth, as it capitalizes on existing reimbursement methodologies and regulatory deadlines.</td>
<td><strong>High.</strong> Auditing, monitoring, and enforcing the 340B drug discount program rebates will require a substantial commitment from MassHealth staff.</td>
<td><strong>Medium.</strong> Establishing an MTM reimbursement program will likely require contracting, pharmacist training, claims adjudication processes, and patient recruitment.</td>
<td><strong>Medium.</strong> MassHealth will need to define and categorize all drugs by their ‘value.’</td>
</tr>
<tr>
<td><strong>Political Feasibility</strong></td>
<td><strong>Possibly Negative.</strong> Consumers may pushback against the establishment of a “narrow network,” as will pharmacies excludes from the network.</td>
<td><strong>Possibly Positive.</strong> Lowering the reimbursement rate for specialty drugs retains political popularity, though pharmacies will pushback to low rates.</td>
<td><strong>Possibly Negative.</strong> Pharmacies may retaliate that the law is too burdensome.</td>
<td><strong>Possibly Positive.</strong> Obtaining funding for the costs for pharmacist reimbursement will be challenging, however MTM remains a popular patient-focused program.</td>
<td><strong>Possibly Negative.</strong> It would be politically difficult for MassHealth to raise co-pays for medication that was deemed ‘low value.’</td>
</tr>
<tr>
<td><strong>Impact on Access</strong></td>
<td><strong>Potentially Negative.</strong> Dependent on how the contract structured, this may result in a “narrow network” or delivery-based dispensing system.</td>
<td><strong>None.</strong> This strategy will not have a significant impact on access.</td>
<td><strong>Negative.</strong> If MassHealth eliminates those pharmacies that do not comply with 340B, it can have a negative impact on access.</td>
<td><strong>Positive.</strong> As part of MTM services pharmacists will routinely conduct patient consultations and follow-up.</td>
<td><strong>Potentially Negative.</strong> VBID is designed to actively discourage use of ‘low value’ drugs. This could impact access for MassHealth members.</td>
</tr>
<tr>
<td><strong>Impact on Quality</strong></td>
<td><strong>Possible Improvements.</strong> Contracts may include requirements for pharmacies to provide clinical services and care coordination.</td>
<td><strong>None.</strong> This strategy will not have a significant impact on quality.</td>
<td><strong>None.</strong> This strategy will not have a significant impact on quality.</td>
<td><strong>Positive.</strong> Medicaid MTM services have demonstrated substantial improvement in clinical outcomes in multiple therapeutic areas.</td>
<td><strong>Potentially Negative.</strong> Patients may not be able to afford the medication they need.</td>
</tr>
</tbody>
</table>
Section VII – Recommendations to MassHealth

Based on our analysis of the nine strategies discussed in this paper, we recommend that MassHealth pursue the following four strategies to reduce costs.

These strategies can largely be bucketed into short-term, actionable items, and long-term strategies that the Commonwealth should evaluate further and begin to implement. Each intends to address various points in the pharmaceutical purchasing and reimbursement system, aiming to obtain maximum cost savings without sacrificing access or quality of care for beneficiaries.

Short-Term
1. Continue to Expand the Supplemental Rebate Program.
2. Establish Differential Reimbursement Rates for Certain Specialty Drugs

Long-Term
4. Pilot a Medication Therapy Management (MTM) Program

Together, these recommendations have the potential to generate up to $50 million in annual savings for the MassHealth pharmacy budget. The following pages provide additional information regarding our rationale for each strategy, as well as estimates of cost savings, an implementation timeline, and whether federal approval or regulatory or legislative action is needed for each proposed strategy.

<table>
<thead>
<tr>
<th>Recommended Strategy</th>
<th>Estimated Annual Savings</th>
<th>Implementation Timeline</th>
<th>Regulatory or Legislative Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expand the Supplemental Rebate Program</td>
<td>New Supplemental: $8 million</td>
<td>New Supplemental: Ongoing</td>
<td>New Supplemental: None</td>
</tr>
<tr>
<td></td>
<td>Expand to MCOs: $12 million</td>
<td>Expand to MCOs: 6-12 months</td>
<td>Expand to MCOs: State Plan Amendment</td>
</tr>
<tr>
<td>Establish a Differential Reimbursement Rate for Specialty Drugs</td>
<td>$15-20 million</td>
<td>1 year</td>
<td>State Plan Amendment</td>
</tr>
<tr>
<td>Join a Multi-State Purchasing Cooperative</td>
<td>$10 million</td>
<td>2 years</td>
<td>State Plan Amendment</td>
</tr>
<tr>
<td>Pilot a Medication Therapy Management (MTM) Program</td>
<td>&lt;$1 million</td>
<td>2-3 years</td>
<td>Legislative approval and appropriation of funds</td>
</tr>
</tbody>
</table>
1. Continue to Expand the Supplemental Rebate Program.
We recommend MassHealth continue to implement additional supplemental rebates and expand the program to cover Managed Care Organization (MCO) plans.

Rationale
MassHealth is projected to annually save approximately $25 million through its recently negotiated supplemental rebates with manufacturers. We believe additional savings are possible through additional rebates with manufacturers given MassHealth’s relatively recent use of rebates. MassHealth already has a recently negotiated supplemental rebate agreement (SRA) in place, has legislative support, and likely has a strong bargaining position with manufacturers given public pressure and concern regarding recent perceived abuses by the pharmaceutical industry. Additionally, MassHealth will receive more direct savings by expanding their supplemental rebates to include drugs covered through the MCO plans.

Regulatory and Operational Requirements
MassHealth has a Supplemental Rebate Agreement in place that was last approved by CMS in 2012. The SRA authorizes MassHealth to pursue supplemental rebates for drugs covered through its PCC/FFS programs; any additional rebates would not require additional CMS approval. A revision to the SRA to include MCOs in the supplemental rebate program, however, would require approval from CMS. There are no additional regulatory actions needed to comply with Massachusetts’s law. Additional supplemental rebates will require sufficient staffing and resources to manage the bid solicitation and contracting process.

Timeline for Implementation
Based on conversations with MassHealth, we believe that the development, bidding and implementation process for the supplemental rebates requires between six months to a year of time. Continuing to add supplemental rebates or modifying the current rebate agreements will require an investment of about a year and could be completed by early 2017.

Updating the SRA to include drugs covered by MCOs in the supplemental rebate agreements will likely take an additional six months, but may occur concurrently with the process of expanding the number of supplemental rebates.

Cost Savings Estimate
MassHealth already has 4 supplemental rebate agreements in place totaling a projected $25 million in annual savings; 6 additional agreements will be implemented in the next several months and are worth an unspecified amount of savings. While in the short-term, there is likely significant opportunity for cost savings, we believe there are diminishing marginal returns to this strategy as MassHealth continues to implement agreements. We estimate potential additional savings of roughly $8 million per year.

Expanding the supplemental rebates to the MCO program may result in significant cost savings for the state, despite likely increases in the MCOs’ capitation rates. Expanding the supplemental rebate program to the MCOs would expand the covered population by 40%, which corresponds to $10 million saved under the current supplemental rebate agreements. This value will decrease moderately, with increased capitation rates, but will also grow as more supplemental rebate agreements are established. Therefore, we estimate potential additional savings of $12 million per year. In total, expansion of supplemental agreements and expanding them include drugs covered through MCOs may save MassHealth $20 million annually.
2. Establish a Differential Reimbursement Rate for Specialty Drugs.

We recommend that MassHealth reimburse specialty and physician-administered drugs at a rate of Wholesale Acquisition Cost (WAC) minus 2%.

**Rationale**

The release of the Covered Outpatient Drugs Final Rule provides a timely opportunity for MassHealth to establish a new reimbursement rate for specialty medications. In particular, MassHealth has the flexibility to determine a separate reimbursement rate for specialty and physician-administered drugs that are not dispensed within a community retail pharmacy setting. **For these drugs, we recommend that MassHealth adjust its reimbursement rate to a level of WAC minus 2%.** This adjustment will generate significant cost savings for MassHealth, while remaining within the regulatory guidelines that CMS has established in ensuring adequate reimbursement to Medicaid pharmacy providers. Moreover, independent analysis has found that a reimbursement rate of WAC minus 2% bares a consistent relationship to that of the reimbursement from drugs in the NADAC files. This helps to ensure that reimbursement levels for specialty medication are roughly consistent with those reimbursed under the AAC methodology.

**Regulatory and Operational Requirements**

Implementation of the differential reimbursement rate for specialty drugs will require approval of CMS through a revision to a state plan amendment. Approval for this methodology can be completed alongside other regulatory requirements for the Final Rule.

**Timeline for Implementation**

In order to comply with the requirements of the Final Rule, MassHealth will need to submit a state plan amendment by **April 1, 2017.** This allows MassHealth with approximately **12 months** to finalize the reimbursement methodology. This includes:

- **1-3 months:** Identifying specialty drugs to be included in this reimbursement rate.
- **1-3 months:** Surveying Massachusetts specialty pharmacies, as necessary to validate or revise proposed WAC minus 2% reimbursement methodology.
- **1-3 months:** Soliciting stakeholder feedback on proposed changes to the state plan amendment.
- **1-3 months:** Incorporating and drafting state plan amendment for submission to CMS.

**Cost Savings**

Implementing a WAC -2% reimbursement rate has the potential to generate significant savings for the MassHealth program. **We provide a rough estimate of estimated savings at between $15 and $20 million annually,** though the true amount will depend a wide range of factors, including the drugs deemed “specialty,” the variability in the WAC price, and overall utilization trends.

As an example of potential cost savings, we provide an analysis of the revised reimbursement rates for a subset of Oncology medications, Hepatitis C medications, and Injectable Anti-Psychotic medications (highly costly therapeutic areas). At the modified reimbursement rate of WAC -2%, we estimate that approximately $7.4 million in cost savings will result from these three therapeutic categories of drugs.

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169 Oncology and Hepatitis C medications selected from the Pennsylvania Specialty Drug List (also provided in Appendix A-3).
We recommend MassHealth join a multi-state purchasing cooperative for increased savings.

Rationale
MassHealth has successfully implemented several supplemental rebate agreements with manufacturers. However, each agreement requires significant administrative investment to develop and execute, limiting the quantity the Commonwealth can process at any one time. Joining a multi-state cooperative may moderately alleviate some of the in-house resource procurement burden. Further, these organizations may provide a wider range of product opportunities for supplemental agreements than MassHealth might be able to negotiate independently.

Regulatory and Operational Requirements
Joining a multi-state cooperative will require:
- Continued assessment of the costs and benefits of joining the cooperative versus continued individual negotiated with manufacturers;
- A State Plan Amendment and CMS approval.

Timeline for Implementation
We estimate it will take approximately 2 years to join and realize savings from a multi-state cooperative.
- 12 months to continue to research the relative value of various cooperative services, given the current influx of supplemental rebate agreements
- 12-18 months to amend and get approval for a multi-state supplemental rebate agreement with CMS.

Cost Savings Estimate
A MassHealth report cites that joining a multi-state purchasing cooperative might provide savings ranging from 3-6% of gross pharmacy spend, depending on the cooperative.

MassHealth estimates it will save 4.4% of its projected spend for its PCC/FFS programs in FY17 through its existing and pending supplemental rebates. This figure places it in the middle of the savings range for cooperatives, allowing for a potential additional savings of 1.6% of spend.

In addition to the potential savings from expanding the use of supplemental rebates to the MCOs described in the Supplemental Rebate recommendation, MassHealth can save an additional $10M per year by contracting with a multi-state cooperative, reaching total savings of 6% of its total PCC/FFS spend.

Administrative Costs: Contracting with a cooperative would provide a greater range of products for rebates. However, a MassHealth report argues that because there is a requirement that MassHealth would still have to establish its own individual contracts with each product, there may be minimal administrative savings. Further, the cooperative require annual fees for membership.
4. Pilot a Medication Therapy Management (MTM) Program

We recommend MassHealth implement a pilot program that reimburses pharmacists for providing MTM services to a subset of high-risk patients. In particular, we recommend that this pilot target adult FFS MassHealth members that are diagnosed with diabetes or asthma, and are currently prescribed four or more prescription medications.

**Rationale**

Piloting a MTM reimbursement program will allow MassHealth to explore the potential clinical and economic benefits that these services have on a subset of high-risk, high-cost MassHealth members. While previous efforts to reimburse pharmacists for drug management services for all chronic conditions have stalled in the Massachusetts Legislature, piloting an MTM program can provide an opportunity to demonstrate the potential cost savings of this approach. For a full discussion on patient selection within the MTM pilot, see Appendix A-4.

**Regulatory and Operational Requirements**

This pilot will require legislative approval and appropriation of funds from the Massachusetts Legislature. This pilot may also require a revision to the MassHealth state plan amendment, however CMS has recognized the role of pharmacists as providers of MTM services since 2005.170

**Timeline for Implementation**

Based upon MTM programs that have been piloted in other states, it is feasible that MassHealth can operationalize a statewide pilot **within 12 months** of enactment. This includes:

- **1-3 months:** Pilot program design.
- **3-6 months:** Pharmacist recruitment and training.
- **3-6 months:** Patient recruitment and enrollment.

Once implemented, the provision of MTM services under the pilot program should place over **18 months**.

**Cost Savings**

Based upon the relatively small patient population of interest, we estimate that cost savings stemming from this pilot program will be less than $1 million in total. While these cost savings are marginal, they represent only a very narrow subset of MassHealth members that may be able to benefit from MTM services. If the pilot proves successful, expanding this program to include all patients with one or more chronic condition will achieve far greater cost savings statewide.

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170 CMS (2005)
Section VIII – Conclusion and Next Steps

Nationwide, health care payers are facing new challenges in addressing the rapid increase in pharmaceutical costs. In confronting these issues, payers need to develop innovative cost control strategies that are capable of adjusting to an ever-evolving marketplace of new therapies and price fluctuations. For MassHealth, it is essential that the agency balance cost containment for its drug budget while also maintaining the highest standard of care for its members.

In our analysis, we recommend several strategies for MassHealth to implement over the next several years. In the near term, we recommend that MassHealth continue entering into supplemental rebate negotiations with drug manufacturers to secure discounts, expand the supplemental rebate program to include members covered by Managed Care Organizations, and adjust the current reimbursement rate for specialty pharmaceuticals. Over the long term, we recommend that MassHealth begin the process for contracting with a multi-state purchasing cooperative, as well as implement a Medication Therapy Management pilot program to incentive pharmacists to provide this high-value service to beneficiaries. Taking these steps will help to ensure that the MassHealth pharmaceutical budget grows within a sustainable rate, while also continuing to provide the highest-quality pharmaceutical care to all MassHealth members.
## APPENDICES

Appendix A – Supporting Materials

### 1. Top Drugs in Massachusetts (2010-2014)

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Manufacturer</th>
<th>Medicaid Amount Reimbursed</th>
<th>No. of Prescriptions</th>
<th>Units Reimbursed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abilify</td>
<td>Otsuka America Pharmaceutical, Inc.</td>
<td>$224,426,639</td>
<td>389,885</td>
<td>11,895,298</td>
</tr>
<tr>
<td>Seroquel</td>
<td>AstraZeneca Pharmaceuticals LP</td>
<td>$132,387,688</td>
<td>407,084</td>
<td>16,984,884</td>
</tr>
<tr>
<td>Atripla</td>
<td>Bristol Myers Squibb &amp; Gilead Sciences, LLC</td>
<td>$96,823,966</td>
<td>52,756</td>
<td>1,627,671</td>
</tr>
<tr>
<td>Truvada</td>
<td>Gilead Sciences, Inc</td>
<td>$77,679,425</td>
<td>65,962</td>
<td>2,003,545</td>
</tr>
<tr>
<td>Sovaldi</td>
<td>Gilead Sciences, Inc</td>
<td>$74,540,994</td>
<td>2,681</td>
<td>73,808</td>
</tr>
<tr>
<td>Flovent</td>
<td>GlaxoSmithKline LLC</td>
<td>$70,071,742</td>
<td>449,872</td>
<td>6,039,722</td>
</tr>
<tr>
<td>Advair</td>
<td>GlaxoSmithKline LLC</td>
<td>$62,453,489</td>
<td>237,169</td>
<td>14,614,405</td>
</tr>
<tr>
<td>Lantus</td>
<td>sanofi-aventis U.S. LLC</td>
<td>$50,110,947</td>
<td>230,406</td>
<td>3,704,627</td>
</tr>
<tr>
<td>Dextroamphetamine</td>
<td>Barr Laboratories Inc.</td>
<td>$49,977,315</td>
<td>304,493</td>
<td>10,955,666</td>
</tr>
<tr>
<td>Saccharate</td>
<td>Eli Lilly and Company</td>
<td>$49,810,300</td>
<td>179,514</td>
<td>3,483,963</td>
</tr>
<tr>
<td>Humalog</td>
<td>AbbVie Inc.</td>
<td>$48,849,173</td>
<td>20,819</td>
<td>48,976</td>
</tr>
<tr>
<td>Humira</td>
<td>Indivior Inc.</td>
<td>$46,546,773</td>
<td>254,777</td>
<td>6,756,760</td>
</tr>
<tr>
<td>Suboxone</td>
<td>Immunex Corporation</td>
<td>$42,763,518</td>
<td>20,265</td>
<td>88,760</td>
</tr>
<tr>
<td>Enbrel</td>
<td>Eli Lilly and Company</td>
<td>$41,547,898</td>
<td>69,895</td>
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2. Cost Estimate: Updated Reimbursement Methodology for Oncology, Hepatitis C, and Injectable Anti-Psychotic Specialty Drugs

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Units Reimbursed</th>
<th>No of Prescriptions</th>
<th>Medicaid Amount Reimbursed (WAC+5%)</th>
<th>WAC + 2%</th>
<th>WAC + 0%</th>
<th>WAC -2%</th>
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<tbody>
<tr>
<td>Oncology Specialty Drug List</td>
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<tr>
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<td>Quantity</td>
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<td>2015</td>
<td>2016</td>
<td>2017</td>
</tr>
<tr>
<td>---------------------</td>
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<td>-------</td>
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<td>Pegasis 18</td>
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<td>$1</td>
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<td>$1</td>
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<tr>
<td><strong>Injectable Anti Psychotics Specialty Drug List</strong></td>
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<td></td>
</tr>
<tr>
<td>Abilify Ma</td>
<td>503</td>
<td>501</td>
<td>$734,595</td>
<td>$713,606</td>
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<td>Invega Sus</td>
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<td><strong>Total</strong></td>
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<td>$111,654,225</td>
<td>$108,464,104</td>
<td>$106,337,357</td>
<td>$104,210,610</td>
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</table>

**Total Amount Saved on Specialty Drugs**

<table>
<thead>
<tr>
<th></th>
<th>Quantity</th>
<th>PCE</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
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<td>$3,190,121</td>
<td>$5,316,868</td>
<td>$7,443,615</td>
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*Utilization and cost data gathered from FY2014 claims provided by MassHealth (see methodology section)

**These figures assume a consistent dispensing fee

*** Oncology, Hepatitis C, and Injectable Anti-Psychotics medications selected from the Pennsylvania Specialty Drug List (also provided in Appendix A-3).
### Specialty Drug List in the State of Pennsylvania

<table>
<thead>
<tr>
<th>Specialty Pharmacy Drug Program</th>
<th>Effective September 26, 2011</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Specialty</th>
<th>Drug Name</th>
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</thead>
<tbody>
<tr>
<td>Cancer (continued)</td>
<td>Taceva, Hemophilia, Advate, Immune Deficiency (continued)</td>
</tr>
<tr>
<td>Blood Cell Deficiency</td>
<td>Aranesp, Epogen, Granix, Leukine, Nplate, Promacta, Zanzar</td>
</tr>
<tr>
<td>Botulinum Toxins</td>
<td>Botox, Dysport, Myobloc, Xeomin</td>
</tr>
</tbody>
</table>
4. **Patient Selection: Medication Therapy Management (MTM) Program**

For the MTM pilot, we recommend that MassHealth target a subset of high-risk, high-cost members. For the purpose of our analysis, we analyzed the feasibility of MTM for **MassHealth members with diabetes or asthma that are currently taking four or more medications.**

Using 2014 MassHealth claims data, we identified clusters of patients around the state (in total numbers) with flags for diabetes and asthma (using the NCQA data set). Within that population, we were able to extract the number of patients that are also on four or more prescription medications. These patients are often some of the most complex and costly, requiring more intensive care management.

<table>
<thead>
<tr>
<th></th>
<th>MassHealth members dispensed medications</th>
<th>MassHealth members also on 4+ medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>25,415</td>
<td>605</td>
</tr>
<tr>
<td>Asthma</td>
<td>72,692</td>
<td>321</td>
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</table>

Though a relatively small subset of the overall MassHealth population, patients with these characteristics are particularly well suited to pharmacist intervention as part of the disease management of chronic conditions. Analyzing the impact of MTM within these populations will help policymakers determine the clinical and economic value of proving MTM services more broadly.
Clusters of Patients with Diabetes (by zipcode)

Clusters of Patients with Asthma (by zip)

Number of Individuals with Diabetes
- 41–128
- over 128

Number of Individuals with Asthma
- 94–277
- 277–505
- over 505
Appendix B – Glossary of Terms
Adapted from MACPAC (2015) and MassHealth Regulations at 130 CMR 406.402

340B-Covered Entities. Facilities and programs eligible to purchase discounted drugs through a program established by Section 340B of Public Health Law 102-585, the Veterans Health Act of 1992.

340B Drug-Pricing Program. A program established by Section 340B of Public Health Law 102-585, the Veterans Health Act of 1992, permitting certain grantees of federal agencies access to reduced cost drugs for their patients.

340B Entity Dispensing Fee. A fee paid to a 340B-covered entity, in addition to the actual acquisition cost of the drug, for dispensing a 340B drug to a MassHealth member. This dispensing fee is paid to the 340B-covered entity in accordance with Division of Health Care Finance and Policy (DHCFP) regulations at 114.3 CMR 31.00: Prescribed Drugs.

Actual acquisition cost (AAC). Actual price paid by a pharmacy to acquire drug products marketed or sold by specific manufacturers.

Average manufacturer price (AMP). The average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies and retail community pharmacies that purchase drugs directly from the manufacturer. The calculation of AMP excludes the prices paid by certain payers (e.g., Department of Veterans’ Affairs, Department of Defense, or Federal Supply Schedule) and providers (e.g., hospitals, long-term care facilities, mail order pharmacies, or managed care organizations) and certain discounts to wholesalers (e.g., prompt pay or bona fide service fees). In the February 2012 proposed Medicaid drug rule [CMS-2345-P], CMS provides technical guidance related to the calculation of AMP, but these provisions have yet to be finalized as of September 2015.

Average wholesale price (AWP). List price from a wholesaler to a pharmacy. AWPs for drugs are reported by pharmaceutical manufacturers and published in commercial clearinghouses such as Redbook, Medi-Span, First DataBank, and Elsevier Gold Standard.

Best price. The lowest price available to any wholesaler, retailer, provider, or paying entity excluding certain governmental payers such as the Indian Health Service, Department of Veterans’ Affairs, Department of Defense, Public Health Service (including 340B), Federal Supply Schedule and Medicare Part D plans.

Brand name drug. A drug that is produced or distributed under an original new drug application approved by the Food and Drug Administration (FDA), covered by a patent, and marketed and sold under a proprietary, trademark-protected name. A brand name drug may be a single source drug or an innovator multiple source drug.

Dispensing fee. Professional fee that pays for costs in excess of the ingredient cost of an outpatient prescription drug each time a drug is dispensed. The dispensing fee covers the pharmacy’s costs associated with the professional services required by the pharmacist to dispense the prescription and overhead.

Estimated acquisition cost (EAC). Defined in federal regulations (42 CFR 447.502) as a state Medicaid agency’s best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size most frequently purchased by providers.
Federal upper limit (FUL). Federal upper limit that caps the federal financial contribution toward state expenditures for certain multiple source drugs. A FUL price is established by CMS for innovator multiple source drugs and non-innovator multiple source drugs for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent. The ACA established the FUL amount as no less than 175 percent of the utilization-weighted average of the most recently reported monthly AMP for equivalent multiple source drug products (FUL group) purchased by retail community pharmacies. States can pay above or below the FUL amount for individual prescription drugs, as long as the aggregate expenditures for drugs with FULs do not exceed the amounts that would be spent by applying the FUL limit, plus a reasonable dispensing fee.

Generic drug. A drug that is distributed by multiple manufacturers and is rated therapeutically equivalent to a brand name drug by the FDA. Drug products evaluated as therapeutically equivalent can be expected to have equal effect and no difference when substituted for the brand name product.

Innovator multiple source drug. A multiple source drug that was originally marketed under an original new drug application approved by the FDA as a brand name drug. A brand name drug (i.e., single source drug) becomes an innovator multiple source drug as it loses its patent protection and generic equivalents become available.

MassHealth Drug List. A list of commonly prescribed drugs and therapeutic class tables published by MassHealth. The MassHealth Drug List specifies the drugs that are payable under MassHealth. The list also specifies which drugs require prior authorization. Except for drugs and drug therapies described in 130 CMR 406.413(B), any drug that does not appear on the MassHealth Drug List requires prior authorization, as otherwise set forth in 130 CMR 406.000.

Maximum allowable cost (MAC). Payment limit on certain multiple source drugs and select other drugs set by state Medicaid agencies.

Multiple source drug. A drug that is distributed by multiple manufacturers who provide a therapeutically equivalent product having the same active ingredient(s), strength, and dosage form. For purposes of the Medicaid Drug Rebate Program, a multiple source drug means, with respect to a rebate period, a covered outpatient drug for which there is at least one other drug product that is rated as therapeutically equivalent.

Non-innovator multiple source drug. A multiple source drug that is not originally marketed under an original new drug application (i.e. multiple source drug not distributed by the original manufacturer). Non-innovator multiple source drugs are frequently called generic drugs.

Non-preferred drug. Drugs that are not preferred drugs as defined in federal regulations (42 CFR 447.51).

Over-the-counter drug. A drug that may be obtained without a prescription.

Outpatient prescription drug. Drug obtained with a prescription and typically dispensed from a retail or other outpatient pharmacy. Outpatient prescription drugs do not include drugs provided as part of or incident to and in the same setting as inpatient and outpatient hospital services, hospice services, dental services, nursing facility and intermediate care facility services, and physician services (e.g., physician administered drugs).

Preferred drug. Defined in federal regulations (42 CFR 447.51) as drugs that the state has identified on a publicly available schedule as being determined by a pharmacy and therapeutics committee for clinical efficacy as the most cost effective drugs within each therapeutically equivalent or therapeutically similar class of drugs, or all drugs within such a class if the agency does not differentiate between preferred and non-preferred drugs.
**Single source drug.** A drug that is produced or distributed under an original new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application. Single source drugs are brand name drugs that are still under patent and are available only from the manufacturer(s) listed on the application.

**Usual and Customary Charge.** The lowest price that a Provider charges or accepts from any payer for the same quantity of a drug on the same date of service, in Massachusetts, including but not limited to the shelf price, sale price, or advertised price for any drug including an over-the-counter drug. If an insurer and the Eligible Provider have a contract that specifies that the insurer will pay an average or similarly computed fixed amount for multiple therapeutic categories of drugs with different acquisition costs, the fixed amount will not be the Provider’s usual and customary charge.

**Wholesale acquisition cost (WAC).** Price paid by a wholesaler for a drug purchased from the wholesaler’s supplier, typically the manufacturer of the drug. WAC amounts may not reflect all available discounts, such as prompt-pay (cash) discounts.
Appendix C – Citations

304 F.3d 1197, Pharmaceutical Researchers and Manufacturers of America v. M Meadows.


42 U.S.C. §1396c–8 (1990), Social Security Act Section 1927

56 F.R. 7049 (1991), Federal Drug Rebate Program

42 CFR Part 447, Payments for Services


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