Washington State Health Care Authority

Review of Prescription Drug Costs and Summary of Potential Purchasing Strategies

A Report to Washington Legislators

November 15, 2016

Jointly sponsored and organized by the Washington State Health Care Authority and Office of Financial Management

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Executive Summary

In March 2016 a group of legislators requested the Directors of the Office of Financial Management (OFM) and the Washington State Health Care Authority (HCA) to convene the medical directors of all state agencies that purchase or reimburse for prescription drugs to address the impacts of unpredictable, rising pharmaceutical pricing on the state budget. The legislators' main interest centered on (1) analyzing potential strategies to promote and improve drug pricing transparency and (2) exploring value-based drug purchasing approaches for state programs designed to maximize their purchasing power to the extent possible under current federal law. The agency directors convened two meetings of the Prescription Drug Price and Purchasing Summit during the summer. Over 100 stakeholders attended the meetings (held in SeaTac), including drug manufacturers, consultants, an official from the Centers for Medicare and Medicaid Services (CMS), insurers, staff from the State's agency purchasers (DSHS, DOC, L&I and HCA), and several nationally recognized academics. Presentations and transcripts from both meetings are available online.

Findings showed how prescription drugs play a vital role in saving lives, keeping people healthy and improving quality of life, and that rapidly rising costs place an economic burden on consumers, employers and public programs. There is general agreement that long-term solutions to rapidly escalating prescription drug prices require federal action because, in the U.S. market, drug manufacturers set prices based on what the market can bear. Most recently, "specialty drugs"—prescription drugs that require special handling, administration or monitoring that are used to treat complex, chronic and often costly conditions (e.g. multiple sclerosis, rheumatoid arthritis, hepatitis C, and hemophilia)—are rapidly driving up spending.

In part as a result of specialty drug spending Washington experienced significant prescription drug cost increases in Calendar Year (CY) 2015. The Department of Social and Health Service's drug spending for Western and Eastern State Hospitals combined with the Developmental Disabilities Administration was just upwards of $10 million, and Department of Correction's spending was about $20 million; HCA's spending was closer to $1.3 billion.

One of the newer value-based methods for controlling drug spending uses alternative payment models (APMs) which are agreements with manufacturers that link the cost of a prescription drug to agreed-upon measures that are financial-based or health outcome-based. At the summit meetings, HCA learned that, in practice, there are limitations, challenges, and barriers to the implementation of a successful APM contract. Health outcome-based APMs pose the biggest challenge as the desired outcome must be clinically relevant and occur within a timeframe that meets programs' short-term budget needs. Moreover, the way APMs are structured may unevenly

distribute risk of losses toward the state due to the various sources of uncertainty. Based on engagement with multiple stakeholders through the summit meetings, leadership from HCA and OFM identified the following steps for the state to consider to address escalating drug prices:

- Pursue strategies that increase both the number of drug classes subject to rebates, as well as the dollar value of each rebate. A comprehensive study of this nature could be completed by January 1, 2018.
- Explore potential strategies and make recommendations that leverage multi-state purchaser consortiums, beginning with the existing NW consortium.
- HCA should consider, for Medicaid and UMP, implementing one or two alternative payment models.
- With technical support provided from participating in SMART-D, HCA should investigate and identify potential options to obtain access to the 340B Drug Discount Program, either through MCO contracts or centers of evidence, with a primary focus on specialty drugs.

Background

On March 11, 2016, 32 members of the Washington State Legislature sent a letter to the Directors of the Office of Financial Management (OFM) and the Health Care Authority (HCA) requesting they convene the medical directors of all state agencies that purchase or reimburse for prescription drugs to address the impacts of rising and unpredictable pharmaceutical pricing on the state budget.[1] The legislators' main interest centered on (1) analyzing potential strategies to promote and improve drug pricing transparency and (2) exploring value-based drug purchasing approaches for state programs designed to maximize their purchasing power to the extent possible under current federal law.

On March 22, 2016, the Directors of OFM and HCA responded to their request. In a joint letter, the leadership of HCA and OFM committed to identifying actions that could be taken to manage the state's pharmaceutical budget; and, in consultation with other states, purchasers, insurers, pharmacy benefit managers and research organizations, to explore best practice purchasing strategies that ensure quality while constraining cost growth. They also made a commitment to share the results of the work with the Legislature by November 15, 2016.[2]

Introduction

Prescription drugs play a vital role in saving lives, keeping people healthy and improving quality of life. The rapidly rising cost of prescription drugs, however, places an economic burden on consumers, employers and public programs. Public programs, such as state Medicaid programs, are often the payer of last resort for high users of pharmaceuticals, including the mentally ill, permanently disabled and others with high medical needs.

Pharmacy spending has now joined the ranks of physician services and hospital care as a major cost driver in the U.S. health care market. If unabated, the accelerating growth in prescription drug and other health care spending will further erode spending for other important state priorities like education and transportation, and limit consumers' access to needed drugs as a result of prohibitive out-of-pocket expenses (Prescription Drug Price and Purchasing Summit - Part 1, 2016).

The structure of the U.S. drug market is frequently cited as the main driver of rising pharmacy costs. In short, drug pricing is not subject to price controls and lacks transparency, which allows manufacturers to set prices based on what the market can bear. Manufacturers generally point to the rebates that are negotiated by health plans and PBMs as a remedy (Daniel, n.d.). Some reports suggest that the rising list prices for some drugs are being offset, if not outright lowered, by sizable manufacturer rebates (Bailin J, 2005). However, since rebates and discounts are not disclosed publicly and only the list price is published, this claim is difficult to confirm. Additionally, research

[1] The legislative request letter is shown as Appendix A.

[2] The agency response to the request letter is shown as Appendix B.

on drug prices over time suggests that the rebates and discounts offered do not significantly offset price increases.

Until recently, prescription drug spending had not been a big part of the nation's health care cost-control reform discussions. Historically, the focus has been on the more traditional U.S. health care cost drivers—hospitals, and professional and clinical services—that now confront a new and evolving reimbursement landscape. Led by Medicare, health care purchasers nationally—including Washington, the largest health care purchaser in Washington State's market—are moving away from volume-based, fee-for-service payment arrangements and requiring the provider community to adopt new payment models that reward quality, not volume. These legacy big market players, like insurers and hospitals, have responded to the changes in their business' risk exposure with horizontal mergers and vertical integration strategies. In fact, consolidation by health plans and provider delivery systems hit a record high in 2014 mainly in response to these new value-based payment approaches.

Pharmacy Costs: Historical Context

In 2015 the Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE) estimated national expenditures on prescription drugs at $457 billion dollars or approximately 16.7% of the $2.7 trillion spent on health care in the United States (ASPE, 2016). Factors contributing to the increased drug spending include increases in utilization, a shift toward use of newer more expensive drugs, and drug price increases.

Washington State has experienced similar prescription drug cost increases. The Department of Social and Health Services (DSHS) "facility-based" drug spending for Western State Hospital, Eastern State Hospital, and the Developmental Disabilities Administration combined was just upwards of $10 million in Calendar Year (CY) 2015. The Department of Corrections (DOC), another facility-based purchaser, spent roughly twice that amount—about $20 million in the same year.

HCA spent nearly $1.3 billion on prescription drugs in CY 2015. HCA's drug spending constitutes the lion's share of state drug purchasing (Washington Health Care Authority, June 2016). The PEB program accounted for 30% of HCA's $1.3 billion drug spend, while the Medicaid program accounted for the remaining 70%. Just over half (61%) of the Medicaid drug purchasing in 2015, was incurred by the contracted managed care organizations (MCOs). Medicaid's traditional fee-for-service drug spending comprised 18% of the total state Medicaid program's drug spend in 2015 and 21% of the Medicaid prescription drug costs in 2015 are attributed to the Medicare Part-D "claw-back" payments to CMS. These claw-back payments are a result of the Medicare Modernization Act that established the Medicare Part-D program to cover prescription drugs for Medicare beneficiaries. Prior to 2006, Medicaid covered the cost of prescription drugs for members that were dually eligible for both Medicaid and Medicare. These claw-back payments reflect a percentage of what the state would have paid had it continued to pay for prescription drugs for the dually eligible members.

Table 1 (next page) summarizes HCA's prescription drug expenditures (total, all funds) from Calendar Year 2013 through Calendar Year 2015. Overall HCA's spending on prescription drugs

increased 39% from 2013 ($915 million) to 2015 ($1.3 billion). During this period Medicaid experienced a 45% increase. Although a substantial portion of the increased drug expenditure is attributable to the implementation of the Affordable Care Act, which increased Medicaid enrollment beginning January 1, 2014, the PEB program—with a relatively stable population—experienced a 27% increase in drug costs over the same period. Both PEB and Medicaid experienced a 14% increase in calendar year 2015 over calendar year 2014.

Table 1: Health Care Authority Prescription Drug Expenditures, Net of Rebates

Prescription drug expenditure in thousands	CY2013	CY2014	CY2015
Medicaid FFS[1]	$ 129,817	$ 150,260	$ 162,241
Medicaid MCO[1]	$ 296,816	$ 454,994	$ 544,654
Medicare Part-D Claw-back Payments	$ 190,988	$ 183,909	$ 189,979
Medicaid Total	**$ 617,621**	**$ 789,163**	**$ 896,874**
PEB MCO[2]	$ 91,876	$ 105,879	$ 117,404
PEB UMP[3]	$ 205,662	$ 226,693	$ 261,599
PEB Total	**$ 297,538**	**$ 332,572**	**$ 379,003**
Grand Total (all funds)	**$ 915,159**	**$ 1,121,735**	**$ 1,275,877**

[1] Net of federal and supplemental rebates; includes drugs dispensed through retail pharmacies, physicians, clinics, and outpatient hospital settings.

[2] Net of rebates with the exception of Kaiser which is only 3% of PEB MCO spend; includes drugs dispensed through retail pharmacies, physicians, clinics, and outpatient hospital settings.

[3] Net of rebates; includes drugs dispensed through retail pharmacies only.

This is not the first time that the United States has experienced annual double digit prescription drug price increases. In the late 1990's annual increases on prescription drug spending ranged from 11% to17% and overtook the cost increases in hospital and physician expenditures (LaFluer J, 2008). This historical increase in prescription drug spending was primarily due to the introduction of novel blockbuster therapies in five leading therapeutic classes: lipid-lowering drugs, proton pump inhibitors, respiratory drugs, antidepressants, and oral diabetes drugs. Between 1999 and 2001 the FDA approved, on average, 35 new drug products per year (Aitken M, 2009). In 1995, 21 drugs reached blockbuster status, defined as a branded drug with average annual sales exceeding $1 billion; in 2010, 123 drugs achieved this status (Jacquet P, 2011).

Growth in prescription drug spending peaked around 2001 and then began to slowly decline. In 2004 the annual increase in drug expenditures reached single digits (8.2%) for the first time in over ten years (Smith C, 2006). Growth in prescription drug expenditures continued to slow through 2005 due to increased use of generic drugs, changes in insurance benefit designs, and fewer new drug approvals (Kaiser Family Foundation, 2008). Although there was an increase in prescription drug expenditures nationally in 2006 due to the implementatin of Medicare Part-D, the rate of growth in prescription drug spending continued to decline through 2008 and remained level through 2013 (Schumock GT, 2016). Much of this decline in overall prescription drug spending can be attributed to the "patent cliff" which is the five year period starting in 2009 when major blockbuster drugs began to lose their patent protection and generic alternatives were introduced to

the market. The patent cliff continued through 2014, with a peak impact in 2011-2012. Drugs that lost their patent protection during this period include: Actos®, Cozaar®, Cymbalta®, Diovan® Lexapro®, Lipitor®, Nexium®, Plavix®, Risperidal®, Seroquel®, Singulair®, and Zyprexa® (Giambrone, 2016).

After several years of low growth in prescription drug spending nationally, there was a significant 12.6% increase in prescription drug spending in 2014 and this increase persisted in 2015. This was, in large part, due to the approval of two new direct acting antiviral drugs Sovaldi® and Harvoni® to treat hepatitis C infection (ASPE, 2016). But the costs of other specialty drugs, such as those targeting inflammatory disorders (e.g. rheumatoid arthritis) also contributed. Utilization of prescription drugs remained unchanged during this period which suggests that price increases and the high cost of new drugs is now driving the upward growth in prescription drug expenditures.

Medicaid, which provides health care coverage to 70 million people, is the largest purchaser of prescription drugs in the country, spending $27 billion on pharmaceuticals in 2014 (National Academy For State Health Policy, 2016). This figure is net of rebates and includes drug spend within managed care plans. Prescription drug expenditures net of rebates now account for 5% of the total Medicaid spend on health care (Medicaid and CHIP Payment and Access Commission, 2016). Medicaid is limited in what it can do to manage the growth of prescription drug costs, in part due to federal legislation and the Medicaid Drug Rebate Program.

Overview of the Medicaid Drug Rebate Program

The Medicaid prescription drug program is an optional benefit; however, all states provide this coverage. In 1990 Congress passed the Omnibus Budget Reconciliation Act (OBRA-90) which created the Medicaid Drug Rebate Program (MDRP). The MDRP is codified in section 1927 of the Social Security Act (42 U.S.C. §1396r-8) and ensures that all Medicaid programs get a discount off the average manufacturer price (AMP), and pay no more than the manufacturer's "best price" for prescription drugs within the U.S. pharmaceutical market. Best price is generally defined as the lowest price a manufacturer receives for a drug, and is net of rebates that might be provided to purchasers such as pharmacy benefit managers (PBMs). In exchange for the guaranteed best price, Medicaid programs must cover all drugs for which the manufacturer has entered into a federal rebate agreement with the Secretary of the Department of Health and Human Services. The MDRP rebate amount is the greater of (1) a percentage discount off the average manufacturers price (AMP) for that drug, or (2) the difference between the AMP and the best price. Best price and AMP are confidential; drug manufacturers report them to CMS directly and they can only be disclosed in certain situations (SSA§ 1927(b) (3) (D)).

In addition to the federal statutory rebates, state Medicaid programs are also able to negotiate additional "supplemental" rebates with manufacturers. These supplemental rebates, like those provided at the federal level, are not disclosable. States typically use preferred drug lists and prior authorization to negotiate better supplemental rebates. In 2010 the Affordable Care Act extended the MDRP to prescription drugs covered under Medicaid managed care organizations. Since the Medicaid best price provisions do not apply to the Medicaid program itself, the supplemental

rebates negotiated by individual states are not considered in the best price determination (CMS, 2016).

Efforts to Control Prescription Drug Spending in Washington State

In FY 1999, Washington State agencies spent approximately $520 million on prescription drugs (Washington Health Care Authority, June 2001). Purchases made through the DSHS Medical Assistance Administration (MAA) and HCA accounted for 90% of state agency spending on prescription drugs. Furthermore, in 1999, several Washington State agencies experienced increases in prescription drug expenditures well above the national average of 15%. In 1999, the HCA Uniform Medical Plan (HCA-UMP) saw a 26% increase over 1998 expenditures, while the DSHS-MAA fee-for-service drug program had an increase of approximately 21%. Agencies with smaller prescription drug programs experienced similar increases as well.

In April 2001, Governor Gary Locke convened an inter-agency Prescription Drug Workgroup under the auspices of HCA to analyze state-purchased care programs and explore options for cost containment and service delivery alternatives, such as more effective drug purchasing strategies (RCW 41.05.021(1) (b)(ii). The interagency workgroup included representatives from HCA, Department of Health (DOH), DOC, Department of Veterans Affairs, DSHS, and Labor and Industries (L&I), the Office of the Attorney General, Department of General Administration, State Board of Health, and the Office of the Insurance Commissioner. The full report from the Washington State Prescription Drug Project can be found in Appendix C.

In 2001 the Prescription Drug Workgroup conducted a comprehensive study of the prescription drug programs and purchasing mechanisms of the agencies listed above and provided the following recommendations:

1. Establish a statewide Pharmacy and Therapeutics (P&T) Committee to develop, implement and maintain a Washington State Preferred Drug List. The P&T Committee shall, where appropriate, seek additional expertise to address issues concerning special populations.

2. Establish a statewide Drug Utilization Review Board to develop treatment guidelines and criteria for appropriate drug use.

3. Explore the feasibility of consolidating claims processing, claims adjudication, and other pharmacy management and information services.

4. For agencies and/or programs that directly purchase drugs, explore the feasibility of implementing and maintaining a consolidated rebate program.

In 2003 UMP, L&I, and Medicaid created the Washington Prescription Drug Consortium and released a joint procurement to obtain consolidated pharmacy benefit management services for the three programs. As a result, a single contractor (Express Scripts Inc.) was selected to provide services. UMP participated in the contract for full pharmacy benefit management services; L&I

participated for the negotiation and management of rebates marking the first time L&I received rebates on covered drugs.

Washington Preferred Drug List

Also in 2003 the Legislature passed Senate Bill 6088, establishing an evidence-based prescription drug program. This program creates and administers the Washington Preferred Drug List (PDL) and the Therapeutic Interchange Program (TIP). The purpose of this legislation was to control state prescription drug costs while maintaining the quality of care, and to increase public awareness of safe and cost-effective drug use. The PDL is currently used by HCA's UMP, the Medicaid fee-for-service program (FFS) and L&I's Worker's Compensation program. Other state agencies may also use the PDL at their own discretion. The Therapeutic Interchange Program for endorsing practitioners allows pharmacists to automatically exchange a non-preferred drug with a therapeutically equivalent preferred drug on the PDL, unless the endorsing practitioner has specified "dispense as written."

A key component of the PDL development is participation in the multi-state Drug Effectiveness Review Project coordinated by the Oregon Health & Science University. HCA receives reports summarizing evidence on drug effectiveness for over 30 drug classes that cover a large portion of pharmaceutical spending by the state. A Pharmacy and Therapeutics (P&T) committee made up of physicians, pharmacists, a registered nurse, and a physician's assistant, reviews the reports and convenes about every two months to evaluate the evidence for a chosen drug class. Other stakeholders may also get the reports and participate in the meetings. The committee makes recommendations on drugs that are "equally safe and effective," without considering their cost. Washington's PDL program is completely transparent. Open public meetings build the trust and confidence of stakeholders and the public-at-large in the process, and increase their understanding of the basis for including selected drugs on the PDL.

NW Prescription Drug Consortium

In 2005, building upon the evidence-based prescription drug program, the Legislature passed Substitute Senate Bill 5471, creating the Prescription Drug Purchasing Consortium. This legislation compelled state health care programs to purchase prescription drugs through the consortium unless they could demonstrate to the HCA administrator that they received greater discounts as a result of their access to federal programs or other purchasing arrangements.

In 2006, Washington State joined forces with the state of Oregon to further expand both states' purchasing power through the creation of the Northwest Prescription Drug Consortium (NW Consortium). As a result, the consortium contract, which up to this time included only Washington, went through a new procurement process and selected a new contractor (the ODS Companies, now called Moda Health). Moda Health continues to administer the NW Consortium in partnership with the Washington and Oregon Prescription Drug Programs. Services offered include a prescription discount card for uninsured Washington residents and comprehensive pharmacy benefit management services for UMP, as well as numerous small private plans throughout Washington State. The Consortium provides rebate management services and mail order pharmacy services to L&I; it also provides DOC with access to its Group Purchasing Organization (GPO).

While rebates with pharmaceutical companies and reimbursements to pharmacies that are negotiated by PBM's often lack transparency (Barlas, 2015), the NW Consortium provides a fully transparent contract for prescription drug purchasers in Washington and Oregon. The NW Consortium contract also provides all member-groups access to competitive retail pharmacy discounts; the entire discount is passed through to member-groups for a fixed administrative price per paid claim. As the Consortium grows, that fixed administrative cost per claim falls. All drug manufacturer rebates are passed through in full to participating member-groups (including rebates on specialty drugs). Contracts are all performance-based with a guaranteed ceiling price on spend that puts the vendor at financial risk for exceeding contractually specified pricing discounts. Consortium drug prices have consistently proven better than commercial rates currently available to other large groups in either state and are audited annually by a third party. This guarantees results to members that are favorable when compared to what other large employer groups receive in the Northwest. Consortium groups have access to a second audit to assure actual group payments conform to the contracted price guarantees. Both the annual market price assessment and the program benefit audits are performed by a third party but are paid by the Contractor. Total consortium drug spending is currently approaching $1 billion annually for nearly one million members in Oregon and Washington, including programs for public employee benefits, K-12 educators, worker's compensation, uninsured discount cards, corrections, and small employers.

Current Cost Drivers

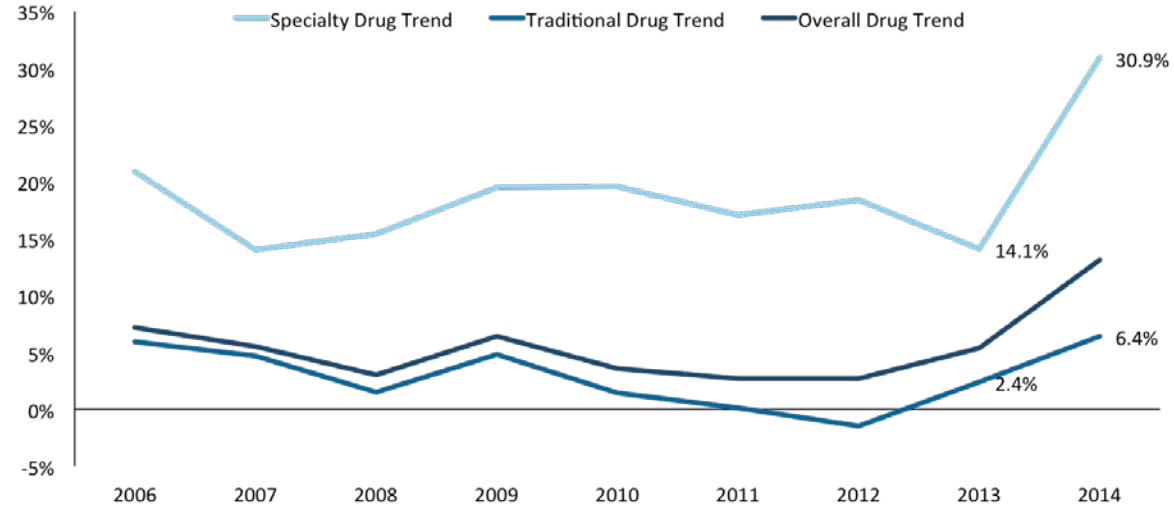
Specialty Drugs

Specialty drugs are prescription drugs that require special handling, administration or monitoring and are used to treat complex, chronic and often costly conditions (e.g. multiple sclerosis, rheumatoid arthritis, hepatitis C, and hemophilia). For example, in commercial plans, when new drugs for the treatment of hepatitis C were approved in late 2013, the cost was approximately $95,000 per course of treatment (Nueman T, 2014). While additional hepatitis C drugs with lower prices have subsequently been approved, these medications remain extraordinarily expensive. Cancer drugs are yet another example of the high cost of specialty medications. The average monthly cost for cancer drugs is $7,158 per month or approximately $86,000 per year, with some types of cancer requiring life-long treatment (Mills, 2016).

Specialty drugs are often developed and used for medical conditions under the U.S. Orphan Drug Act. The intent of this act was to encourage the development of drugs for rare diseases where traditional therapy was inadequate or nonexistent (US Food and Drug Administration, 1983, January 4). Many specialty drug manufacturers claim their products offer significant improvement in treating these rare or orphan conditions; these claims are used to justify the high costs associated with these drugs. Specialty drugs are also entering the market more quickly through four FDA programs that are intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions (US Food and Drug Administration, 2014 May). For example, a new immunotherapy medication for bladder cancer was approved based on a performance measure of tumor shrinkage (a "surrogate" outcome), but no information on survival outcomes or comparative effectiveness with other

existing therapies has been provided. This new specialty drug is expected to cost $12,500 per month (Goozner, 2014).

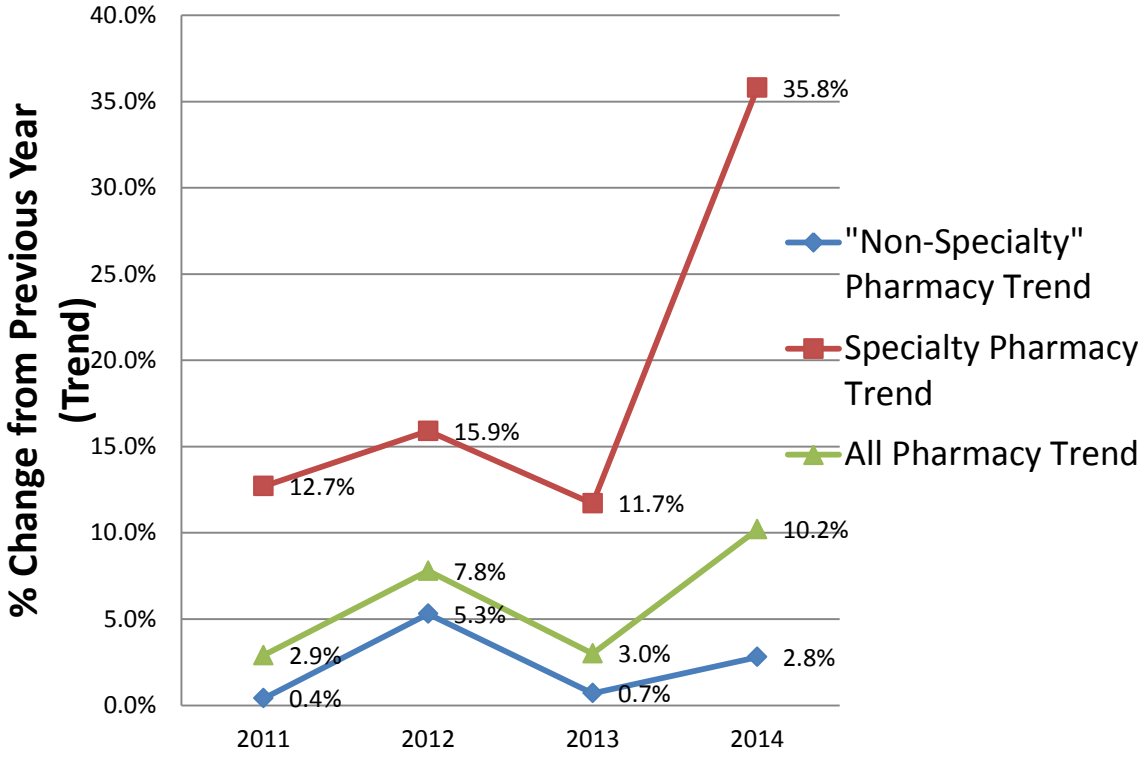
Chart 1: Costly new specialty drugs are a major driver of increased health spending



Source: Express Scripts 2014 Drug Trend Report and Year in Review.

From 2014 to 2015, specialty drug spend increased 17.8% for the commercial market, 27.9% for Medicare, and 10.1% for Medicaid. By comparison, traditional drug spending decreased -0.1% for the commercial market, and increased 4.8% and 3.3%, respectively, for Medicare and Medicaid (Cho, 2016). The costs are highly concentrated among a small set of plan participants. It is estimated that specialty pharmaceuticals will soon account for 1% to 2% of all prescriptions but will comprise 50% of total drug spending by 2018 (Johansen ME, 2016).

Chart 2: Overall national Medicaid trend by pharmacy class from 2011 to 2014



Sources: Express Scripts, 1) "The 2014 Drug Trend Report Medicaid" Mar 2015; 2) "The 2013 Drug Trend Report" Apr 2014; 3) "The "Research & New Solutions Lab Drug Trend Report Medicaid" Oct 2013; 4) "The Express Scripts Research & New Solutions Lab 2011 Drug Trend Report" Apr 2012.

Consolidation of Manufacturers

Consolidation of manufacturers and associated pricing strategies is diluting the high value of traditionally affordable generic medications (Johansen ME, 2016). New generic options that enter the market are priced similarly to brand-name counterparts because of short-term (6 months) market exclusivity under federal law. As a result, drug costs do not immediately fall until other generic manufacturers enter the market and create competition. In addition, there are other forces at work that keep drug prices high. For example, "evergreening"—a tactic manufacturers use to extend patents on drug products that are about to expire, and limited distribution of pharmaceuticals by brand-name manufacturers, prevent generic manufacturers from accessing or releasing generic versions of medications. The delay in entry and additional costs associated with these tactics has significant cost implications for payers and consumers (Collier, 2013).

Long-term Use of Expensive Drugs

New therapies are approved for treatment of chronic medical conditions that patients must take for the remainder of their lives. For example, many cancers are now being treated as chronic diseases, much like high blood pressure or high cholesterol, and require long-term use of newer, expensive pharmaceuticals, leading to increased drug spending. Recent research shows substantial increases in the average per patient monthly costs of oral anti-cancer medications over the last few years (Bennette CS, 2016).

Manufacturer Pricing Effects on State Drug Spending

Drug manufacturers set their own prices. And manufacturers' drug pricing market strategies are constantly changing which makes it difficult for states and other payers to accurately forecast drug spending. The 600% price increase of EpiPen over the last 8 years was an unwelcome surprise that made recent headlines. Prescription drug pricing is becoming increasingly volatile as more and more new drugs are approved and manufacturers adapt and change their pricing strategies in a changing market. Pharmaceutical manufacturers are aggressively marketing and selling their latest high-cost treatments to highly targeted patient populations (Birrell, 2016). Additionally, using the practice of "shadow pricing", manufacturers may raise their price to follow the price increase of a similar product from another manufacturer. For example, SSR Health, a market researcher, recently reported on the price increases of two insulin products in which the manufacturers matched each other's price increases three times in two years (Langreth, 2015). These types of pricing practices have been rapidly evolving over the last decade; as a result, it has become increasingly difficult to accurately predict the costs of pharmaceuticals from one year to the next.

Strategies to Slow the Rate of Prescription Drug Spending

Purchaser Strategies

A large number of states—California, Colorado, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, New Jersey, New York, North Carolina, Pennsylvania, South Dakota, Vermont, Virginia, and Washington—introduced legislation in 2015-16 regarding prescription drug price transparency (National Conference of State Legislatures, 2016). Massachusetts has taken a further step by proposing to place a pricing cap on how much manufacturers can charge for drugs, especially specialty drugs (Massachusetts Senate Bill 1048). Also several states, including Washington and California, introduced but did not enact legislation that would forbid state agencies from paying more for a prescription drug than the lowest price paid by the U.S. Department of Veterans Affairs (VA) for the same drug.

State Medicaid programs, including Washington, have tried to set limits on hepatitis C drug coverage, but these policies have been challenged and, in several cases, overturned in court (United States District Court Western District of Washington at Seattle). In New York, the Attorney General investigated private insurers' policies restricting access to hepatitis C drugs. As a result, private insurers voluntarily agreed to change their policies, and the state Medicaid program followed suit (Lee JJ, 2016).

Public and private employers and purchasers are investigating and implementing a variety of strategies to manage drug costs and utilization, including:

- Demanding more transparency from pharmacy benefit managers (PBMs) including 100% return of drug manufacturer rebates,
- Tighter performance guarantees,
- Requiring "pass-through pricing" to avoid PBMs from keeping the "spread" between what the pharmacy is paid and what the purchaser is charged,
- Independent third-party market checks of local retail pharmacy market rates, and
- More routine third-party audits in general (Stevenson JG, 2015).

Policy Strategies

The high cost of prescription drugs has become a national focus. Organizations are convening work groups and obtaining grants to investigate options to contain growth in prescription drug expenditures. The National Academy for State Health Policy (NASHP) is one such organization. Washington State participated in NASHP's *Pharmacy Costs Work Group* which consisted of state leaders from governors' staff, state legislatures, Medicaid, public employees health insurance programs, offices of attorneys general, state-based insurance exchanges, comptrollers' offices, and corrections departments. The work group carefully weighed the unpredictable costs of prescription drugs against the value those drugs provide, as well as the impact that pharmaceutical manufacturers have on the economy as a prominent employer group. The work group identified a wide range of policy options for states to consider which are detailed in the full report (Appendix D).

The specific policy options suggested were:

- Increasing price transparency to create public visibility and accountability;
- Creating a public utility model to oversee in-state drug prices;
- Bulk purchasing and distribution of high-priced, broadly-indicated drugs that protect public health;
- Utilizing state unfair trade and consumer protection laws to address high drug prices;
- Seeking the ability to re-import drugs from Canada on a state-by-state basis;
- Pursuing Medicaid waivers and legislative changes to promote greater purchasing flexibility;
- Enabling states to operate as pharmacy benefit managers to broaden their purchasing and negotiating powers, including expanding purchasing pools that unify around a single preferred drug list;

- Pursuing return on investment pricing strategies to allow flexible financing based on long-term, avoided costs;
- Ensuring state participation in Medicare Part D through Employer Group Waiver Plans;
- Protecting consumers against misleading marketing; and
- Using shareholder activism through state pension funds to influence pharmaceutical company actions.

Washington is also participating in the *State Medicaid Alternative Reimbursement and Purchasing Test for High-Cost Drugs* (SMART-D) initiative administered by the Center for Evidence-based Policy at the Oregon Health & Science University.[3] The overarching goal of SMART-D is to strengthen the ability of participating Medicaid programs to provide access to clinically valuable prescription drugs, improve patients' health outcomes and better manage prescription drug spending through the use of alternative payment models. The program also aims to provide Medicaid leaders with opportunities to shape the national conversation on prescription drug innovation, access, and affordability. Phase I of the SMART-D initiative consisted of four components: a review of current Medicaid prescription drug coverage and purchasing methodologies, an analysis of prescripton drug spending in Medicaid programs, identification of alternative payment models used in U.S. and international pharmaceutical markets, and review of federal and state laws governing Medicaid programs. The final reports from these components can be found in Appendix E.

Controlling Prescription Drug Costs in Washington State

Washington State Drug Price and Purchasing Summits

The agency directors convened two meetings of the *Prescription Drug Pricing and Purchasing Summit* during the summer. The summit approach was specifically orchestrated to spark an interactive dialogue among participants and presenters to enhance broader understanding of the drug pricing and purchasing issues facing the state, and identify potential strategies for reducing the impact of prescription drug costs on the State's budget. Leading academics, regional purchasers, providers, payers and drug manufacturers were invited to participate in an open-ended public discussion on how to address soaring drug costs. Because of the broad scope of the topic and the wide variety of stakeholders, the agency directors decided to hold two separate meetings. The primary goals of the summit series were to understand the current state of prescription drug prices and explore the evolving options with a focus on value-based purchasing practices used elsewhere that might be adapted by Washington State. Thus, the meetings would examine markets, pricing, and cost drivers, and impacts on consumers. The main objective was to investigate all existing and new or novel drug purchasing strategies with the singular goal of identifying potential strategies to

[3] Funded through a grant from the Laura and John Arnold Foundation.

address the accelerating cost of prescription drugs within the Washington State budget environment.

Over 100 stakeholders attended two summit meetings on June 14, 2016 and September 22, 2016 in SeaTac.[4] Presenters included: drug manufacturer consultants, a CMS official, insurers, staff from the State's agency purchasers (DSHS, DOC, L&I and HCA), and several nationally recognized academics.[5] Their presentations are available online, along with a complete transcript of both summit meetings.[6]

To encourage dialogue between stakeholders in attendance, the meeting organizers strictly enforced a rule that presenters leave 15 minutes for stakeholder questions and audience discussion at the end of each presentation. Meeting planners also encouraged audience participation by placing two roving meeting helpers with handheld microphones in the audience for the question and answer period, and invited all summit attendees to answer three key questions in writing at the end of the day:

1. What is the most important lesson you will take away from the summit, and why?
2. What potential next steps for Washington State do your take-away points suggest, and why?
3. What additional topics should HCA investigate around prescription drug pricing?

Written responses to these questions were collected at the end of the meeting. Stakeholders' answers to these three questions are included in Appendix F.

The theme that consistently permeated the presentations and discussion at the summit is best summarized in this quote from one of the presenters, Bill Ely, Vice President of Actuarial Services at Kaiser Permanente Northwest:

> *The current market for drugs in the U.S. is broken. It's time for a new drug pricing model that rewards biomedical innovation at prices patients can afford.*

[4] Lists of attendees from both Drug Summits are included as Appendix G.

[5] Lists of the presenters from both Drug Summits and their biographies are included as Appendix H.

[6] Both Drug Summit presentations and full transcripts are available at http://www.hca.wa.gov/about-hca/clinical-collaboration-and-initiatives/washington-prescription-drug-price-and-purchasing

Discussion of Various Policy Options

A full description and analysis of the policy options identified by NASHP and SMART-D can be found in Appendixes D and E, respectively. This section will focus on specific policy options that appear most viable for Washington State programs.

Alternative Payment Models

Alternative payment models (APM) are agreements with manufacturers that link the cost of a prescription drug to agreed-upon measures (Cho Y, 2016). These types of arrangements can be grouped in two major categories, financial-based and health outcome-based.

Financial-based APMs are designed to reduce the risk associated with over-utilization of a drug. These types of agreements may be based on a particular population or executed at a patient level. Population based agreements are currently used in France and typically have a budget ceiling to control prescription drug expenditures. If the amount spent on a drug exceeds this budget threshold then the manufacturer reimburses the payer for the additional costs, often through a rebate.

Patient level APMs link drug costs to an individual patient's drug utilization. Examples of these types of arrangements include an agreement between AstraZeneca and the United Kingdom (U.K.) health authorities. In this agreement the U.K. pays for Lynparza®, a novel ovarian cancer drug for the first 15 months of therapy. If the patient continues to take the medication for more than 15 months then AstraZeneca is responsible for the additional costs.

Health outcomes-based APMs link drug costs to clinical outcomes. There are two major types of health outcome-based APMs, conditional coverage and performance-based. Currently CMS uses "conditional coverage with evidence development" to reimburse new treatments for Medicare patients while data is still being collected to determine their effectiveness. In another type of conditional coverage arrangement, the manufacturer covers the cost of a drug for an initial period to determine if it will work in the individual patient; if the outcome is favorable, the payer is responsible for the ongoing cost of the drug. Performance-based health outcome APMs link the cost of the drug to a predetermined health outcome such as lowering cholesterol or preventing hospitalization.

HCA learned from an expert panel discussion at the second Prescription Drug Price and Purchasing summit meeting that, in practice, there are limitations, challenges, and barriers to the implementation of a successful APM contract. Health outcome-based APMs pose the biggest challenge as the desired outcome must be clinically relevant and occur within a timeframe that meets programs' short-term budget needs. In addition, this type of APM requires the ability to measure the health outcomes of the disease state being treated and both parties must agree upfront on how missing data or patient adherence to the medication will impact the agreement.

The way APMs are structured may unevenly distribute uncertainty and risk toward the payer. The payer needs to consider the uncertainty and risk associated with drug effectiveness and safety for a particular disease state; the possibility that missing data will confound analyses; the increased costs

to monitor and comply with such contracts; the potential loss of rebates with other drugs; and the time and resources necessary to manage the APM.

Supplemental Rebates Using a Single Preferred Drug List

Washington State currently has a common preferred drug list consisting of approximately 35 therapeutic drug classes. The PDL is used by three programs: the Uniform Medical Plan, Medicaid fee-for-service (FFS) and Worker's Compensation. While integration of the three state health programs is a hallmark strength of Washington's PDL, it also has challenges. Medicaid, state employee health benefits, and worker's compensation have differing business models, prior authorization requirements, copayment structures, and relationships with pharmacy benefits managers. As a result, the PDL might save some state programs less than it saves others. The National Academy for State Health Policy (NASHP) suggests that if state purchasers of prescriptions drugs were to join together and use the same PDL and utilization management strategies (e.g. prior authorization policies) they could bolster their bargaining position (NASHP, 2016). The inclusion of the Medicaid managed care plans in this purchasing pool might further increase a state's ability to command deeper discounts.

More than 70% of U.S. Medicaid lives are administered by a Medicaid managed care organization (MCO). These MCOs typically contract with national pharmacy benefit managers (PBMs) to obtain deeper discounts (above and beyond the federal rebate) on prescription drugs. However, only a fraction of rebates in Medicaid are delivered through these supplemental arrangements, with the vast majority coming through the mandatory federal drug rebate program. Such discounts are obtained through negotiating rebates with manufacturers, as well as negotiating downward the prices paid to pharmacies.

As discussed earlier, state Medicaid fee-for-service programs are also able to negotiate supplemental rebates in addition to federally mandated rebates; importantly, these supplemental rebates are not restricted by the best price provision (see page 7 of this report for a description of the best price provision). On the other hand, while MCOs are able to obtain rebates on drugs provided to their Medicaid members, these rebates are subject to the best price determination. Therefore, the state is potentially in a better position to negotiate the lowest net cost for prescription drugs for all Medicaid members including those enrolled in an MCO using a single PDL. The Veterans Administration (VA) successfully implemented a single national formulary in 1997 and continues to leverage that single PDL to obtain the lowest prescription drug prices in the country today. Through negotiation of supplemental rebates a state might acquire prices close to those paid by the VA.

The Menges Group released two reports earlier this year examining the use of a single PDL in Texas and Louisiana. In these reports, the authors argue that an MCO's ability to manage its own PDL results in substantial savings to the state (The Menges Group, 2016a; The Menges Group, 2016b). The authors of these reports compare the per prescription drug cost of states that have the highest generic fill rates with those states that have the highest rebate collection. The costs per prescription that are quoted in these reports are not net of federal or supplemental rebates, therefore, the savings the authors assume for MCOs versus State-purchased drugs comes primarily from reduced payments to pharmacies, not lower prices for prescription drugs. Other factors include state laws or

regulations that restrict the FFS program's ability to place restrictions on certain therapeutic classes or that exclude them from placement on a PDL.

Pooled Purchasing Strategies

NASHP suggests that states could strengthen their negotiating power with manufacturers by operating more like a public PBM. The Northwest Prescription Drug Consortium (NW Consortium) discussed earlier is in a prime position to do just that. The NW Consortium already negotiates on behalf of several public payers including state employees, departments of corrections, and worker's compensation programs in both Washington and Oregon. Recently the Eastern Oregon Coordinated Care Organization (CCO) joined the NW Consortium. The Washington Medicaid program could join the NW Consortium in order to align purchasing strategy with other state purchasers and potentially benefit from reduced administrative costs and better prices for prescription drugs using the single PDL method discussed above.

NASHP also advances forward-thinking strategies for states to consider if they take on the role of a public PBM. The suggestions NASHP offers would put a state program like the NW Drug Consortium ahead of commercial PBMs' purchasing strategies by placing new, narrow restrictions on member drug coverage benefit design, as well as strict uniform limits on PDL construction, in order to leverage purchasing power. NASHP's analysis posits that states could further strengthen their negotiating leverage by operating unified PDLs and common benefit structures for all covered members and dependents.

Finally, by using a single agreed-upon approach for treating patients in each therapeutic drug class, states could even require pharmaceutical manufacturers to price drugs based on an agreed-upon return on investment (ROI) to the state within a specified time frame. To date, and to the best of our knowledge, no commercial PBM in the U.S. is doing this type of ROI contracting with drug manufacturers. However, several commercial PBMs have limited customer choice when equally effective therapeutic alternatives are available. In fact, several large PBMs now have "exclusionary lists" for their commercial customers that take certain drugs in a drug class off of the formularies of the employer groups with whom they contract.

Conclusions and Next Steps

Led by the high cost of new specialty drugs, pharmacy prices are again rising after several years of slow growth in the late 2000's.

Historically, the State has used multiple strategies to contain prescription drug costs. These have included: negotiating supplemental rebates for drugs on the Washington PDL; requiring use of cost-effective generic drugs before brand-name drugs, when clinically appropriate; implementing "step therapy" protocols (use of the most cost-effective brand drug before more costly branded drugs when clinically appropriate); and providing care management services for patients on high cost specialty drugs. The State will continue to aggressively deploy these strategies. However, the underlying causes for rising drug costs—including the rapid rate at which newer, novel drugs are coming to market, and the extraordinarily high prices that manufacturers are setting for these drugs—make these strategies less effective than they once were.

Based on its engagement of multiple stakeholders including state agencies, health plans, providers, academics and the pharmaceutical industry, participation in a multi-state initiative aimed at containing drug costs, and review of research literature and recently released authoritative reports on the high cost of prescription drugs, the Washington State Agency Medical Directors' Group, with leadership from HCA and OFM, has identified the following next steps the State should consider to address escalating drug prices:

1. Pursue strategies that increase both the number of drug classes subject to rebates, as well as the dollar value of each rebate. For Medicaid FFS, provided funding is available to contract with an additional evidence vendor, the initial strategy would be to increase the number of drug classes on the FFS PDL. HCA should undertake a comprehensive study and make a recommendation to the legislature regarding the creation of a single PDL across HCA's programs, including Medicaid FFS, Medicaid MCOs and UMP. A comprehensive study of this nature could be completed by January 1, 2018.

2. Explore potential strategies and make recommendations that leverage multi-state purchaser consortiums, beginning with the existing NW consortium. HCA could also convene other states to discuss purchasing strategies that could be built around the concept of a single preferred drug list used by all consortium members. The purchasing pool would initially involve state agencies that purchase prescription drugs directly (e.g. DSHS and DOC) as well as those that reimburse pharmacies for prescription drugs dispensed to their members (e.g. Medicaid, UMP, and Worker's Compensation). The purchasing pool could also be expanded to include other states that agree to follow the purchasing strategy around a single PDL.

3. In conjunction with its work with SMART-D, HCA should identify and possibly test one or two alternative payment models that are outcome or financially based and could be implemented through Medicaid and/or UMP. An example would be to engage a manufacturer of a hepatitis C medication to guarantee a cure rate for patients that take the drug.

4. With technical support provided from participating in SMART-D, HCA should investigate and identify potential options to obtain broader access to the 340B Drug Discount Program either through MCO contracts or centers of evidence with a primary focus on specialty drugs. The 340B drug discount program is a U.S. Federal government program that requires manufacturers to sell prescription drugs at a steep discount to eligible health care organizations serving low-income or indigent patients.

There is general agreement that long-term solutions to rapidly escalating prescription drug prices require federal action (Kesselheim AS, 2016). Nonetheless, the State must continue to actively identify and implement workable strategies than can help moderate the rise in prescription drug costs while maintaining quality of care. In order for HCA to move forward with any of the purchasing strategies discussed in this report, further analysis of feasibility, administrative costs, and potential savings is needed.

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APPENDIX A

Washington State Legislature

11 March 2016

Dorothy Teeter
Director
Washington State Health Care Authority
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Olympia, WA 98504

David Schumacher
Director
Office of Financial Management
P.O. Box 43113
Olympia,

WA 98504 Directors Dorothy Teeter and David Schumacher,

During the 2016 session numerous proposals have been offered to begin addressing the impacts of rising and
unpredictable pharmaceutical drug prices on the state budget. To that end, we would like to request the Office of Financial Management and the Health Care Authority jointly convene the medical directors of all state agencies that purchase or reimburse for prescription drugs for the purpose of analyzing potential strategies to:

i. Promote and improve drug price transparency; and
ii. Implement innovative, value-based drug purchasing approaches for state purchased health care programs that maximize purchasing power, to the extent possible under current federal law.

We would propose that the agency medical directors group would undertake the following steps, in addition to other approaches the group may determine appropriate:

i. Evaluate state and federal regulations regarding the purchase of prescription drugs and examine the current tools and statutory authority for state agencies to leverage the purchase of drugs;
ii. Conduct an environmental scan of best purchasing strategies in other states and seek evidence-based consultation as determined necessary;
iii. Identify current limitations on agency programs to manage drug spend and explore strategies to assure quality and mitigate annual cost increases;

APPENDIX A (cont'd)

iv. Develop recommendations to improve and expand the current tools and statutory authority which focus on innovative value-based approaches to the purchase of prescription drugs and improving drug price transparency; and

v. Communicate with other purchasers, including health insurance carriers, self-insured entities, local governments, and states to share and coordinate prescription drug purchasing strategies, to the extent possible.

In recognition that the legislature has not appropriated dedicated funding for this task, we would request that the OFM and the HCA coordinate with the agency medical directors to develop a work plan to accomplish these tasks and provide periodic progress updates to the Joint Select Committee on Health Care Oversight.

Thank you for your consideration of this request.

Sincerely,

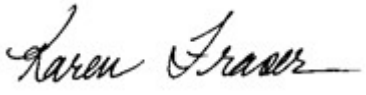
Senator Kevin Ranker 40th District

Representative Eileen Cody 32nd District

Senator Reuven Carlyle 36th District

Senator Annette Cleveland 49th District

Senator Steve Conway 29th District



Senator Karen Fraser 22nd District

Senator Bob Hasegawa 11th District

Senator Karen Keiser 33rd District

APPENDIX A (cont'd)

Senator Marko Liias 21st District

Senator Mark Mullet 5th District

Senator Jamie Pedersen 43rd District

Senator Christine Rolfes 23rd District

Representative Brian Blake 19th District

Representative Judy Clibborn 41st District

Representative Jessyn Farrell 46th District

Representative Mia Gregerson 33rd District

Representative Sam Hunt 22nd District

Representative Laurie Jenkins 27th District

Representative Ruth Kagi 32nd District

Representative Christine Kilduff 28th District

APPENDIX A (cont'd)

Representative Patty Kuderer 48th District

Representative Luis Moscoso 1st District

Representative Gerry Pollet 46th District

Representative June Robinson 38th District

Representative Cindy Ryu 32nd District

Representative Derek Stanford 1st District

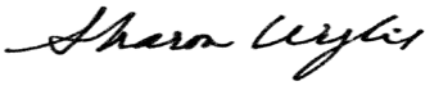
Representative Mike Sells 38th District

Representative Tana Senn 41st Distirct

Representative Steve Tharinger 24th District

Representative Kevin Van De Wege 24th District

Representative Brady Walkinshaw 43rd District



Representative Sharon Wylie 49th District

APPENDIX B

STATE OF WASHINGTON

March 22, 2016

Dear Senators and Representatives:

Thank you for your letter concerning pharmaceutical drug pricing as it relates to state-purchased health care programs. The Health Care Authority and Office of Financial Management believe the state is best served when health care cost drivers are transparent and there is clarity concerning legal, regulatory, and marketplace mechanisms for managing those costs.

Rising pharmacy costs is a very difficult issue with broad implications nationwide. To address your request for further analysis and development of strategies for prescription drug purchasing, we will convene the agency medical directors group to:

- Identify actions that could be taken to manage the state's pharmaceutical drug budget, including recommendations for changes to state and federal regulations that limit flexibility and potential coordination with other purchasers of prescription drugs.

- Consult with other states, purchasers, insurers, pharmacy benefit managers, and the research organizations listed below to explore best practice purchasing strategies that ensure quality while constraining cost growth:

    - Association of Washington Healthcare Plans
    - Drug Effectiveness Review Project
    - Group Health Research Institute
    - Medicaid Evidence-based Decision Project
    - National Academy for State Health Policy
    - National Governors Association
    - National Association of Medicaid Directors
    - Washington Health Alliance

APPENDIX B (cont'd)

We look forward to sharing with you the results of this work by November 15, 2016.

Sincerely,

Dorothy F. Teeter, MHA
Director
Health Care Authority

David Schumacher
Director
Office of Financial Management

APPENDIX C

Washington State

Prescription Drug Project

Phase I Final Report

June 29, 2001

Acknowledgments

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Project Manager
Maggie Baker, Senior Health Policy Analyst, Washington State Health Care Authority

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Department of General Administration
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Raleigh Watts, Program Director, AIDS Prescription Drug Program
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Office of the Attorney General
Christine Gregoire, Attorney General
Joyce Roper, Senior Assistant Attorney General, Agriculture and Health Division

Office of the Insurance Commissioner
Mike Kreidler, Insurance Commissioner
Bill Hagens, Deputy Commissioner

State Board of Health
Don Sloma, Executive Director

Executive Summary

Introduction

Prescription drugs play an increasingly important role in saving lives, keeping people healthy and improving quality of life. The rapidly rising cost of prescription drugs, however, places a burden on consumers, employers and public programs. Public programs, such as state Medicaid programs, are often the payer of last resort for high users of pharmaceuticals, including the mentally ill, frail elderly and others with high medical needs.

In 1998, national health expenditures on prescription drugs totaled $91 billion. By 2008, expenditures are projected to reach $243 billion[1]. Over the last decade, the annual percent change in prescription drug expenditures has exceeded that of hospital care and physician services. In general, three factors are responsible for the upward trend in prescription drug expenditures: increases in utilization, a shift toward use of newer, more expensive drugs and increases in price[2].

In FY 1999, Washington State agencies spent approximately $520 million on prescription drugs (Joint House Health Care Committee, Nov 1999). Purchases made through the Department of Social and Health Services Medical Assistance Administration (DSHS-MAA) and the Washington State Health Care Authority (HCA) accounted for 90% of state agency spending on prescription drugs. Furthermore, in 1999, several Washington State agencies experienced

[1] These expenditures most likely are underestimated, as expenditures were limited to those from retail outlets, such as grocery store and mail order pharmacies, and excluded the value of prescription drugs provided to patients as a part of hospital care, to those in nursing homes as a part of their care, and as provided by physicians during an office visit.

[2] National prescription drug expenditures are commonly defined as the cost of the drug times utilization. Cost is broken down into the price of the drug plus the dispensing fee, minus any payment from others (e.g., discounts or cost share). Utilization is a product of the number of people covered by a benefit times the number of prescriptions per person.

increases in prescription drug expenditures well above the national average of 15%. In 1999, the HCA Uniform Medical Plan (HCA-UMP) saw a 26% increase over 1998 expenditures, while the DSHS-MAA fee-for-service drug program had an increase of approximately 21%. Agencies with smaller prescription drug programs experienced similar increases as well.

The Prescription Drug Project

In April 2001, Governor Gary Locke convened an inter-agency workgroup to begin work on the Prescription Drug Project (PDP). The PDP Workgroup is convened under the Health Care Authority's statutory authority to analyze state-purchased care programs to explore options for cost containment and service delivery alternatives, including state efforts to purchase drugs effectively (RCW 41.05.021(1) (b)(ii). The interagency workgroup includes representatives from the Health Care Authority, Department of Health, Department of Corrections, Department of Veterans Affairs, Department of Social and Health Services, and Labor and Industries, as well as the Office of the Attorney General, Department of General Administration, the State Board of Health and the Office of the Insurance Commissioner.

The Prescription Drug Project (PDP) is supported by a conceptual framework based on value purchasing. The goal of the Prescription Drug Project (PDP) is to enhance the delivery of high-quality health care to Washington State residents by managing pharmacy benefits and prescription drug expenditures through coordinated or consolidated prescription drug purchasing across state agencies within two years.

Phase I of the PDP includes a comprehensive study of current fee-for-service prescription drug programs and purchasing across state agencies and the formulation of recommendations to achieve the overall goal of the Prescription Drug Project. Phase I work focuses on issues related

to current prescription drug programs and practices, legal and regulatory issues, stakeholders, and other prescription drug purchasing models. PDP Phase II entails the design and implementation of a consolidated prescription drug purchasing program across state agencies within two years.

Specific Phase I objectives are:

- To describe, in detail, the agency's current fee-for-service prescription drug program(s) and practice(s)
- To explore the effect of existing or potential federal and state regulations, policies, programs or funding on the development and implementation of a coordinated or consolidated prescription drug purchasing program in the State of Washington
- To identify and anticipate the impact of coordinated or consolidated prescription drug purchasing strategies on stakeholders
- To explore programs from other states or entities that provide positive or negative models or examples for the development and implementation of a coordinated or consolidated prescription drug purchasing program in the State of Washington.

Objective 1: Current Programs and Practices

Six Washington State agencies currently purchase or provide health care benefits, including prescription drugs, to over 1.5 million Washington residents or qualified beneficiaries. These agencies are: the Washington State Health Care Authority (HCA), Department of Health (DOH), Department of Social and Health Services (DSHS), Labor and Industries (L&I), Department of Corrections (DOC), and Washington Department of Veterans Affairs (WDVA).

Of the over 1.5 million individuals served in CY 2000, 902,812 (60%) were served through fee-for-service programs, while the remaining 40% were enrolled in managed care programs.

Of those in fee-for-service programs, 64% were served through DSHS-MAA, 23% through L&I Industrial Insurance, and 10% through the HCA Uniform Medical Plan (HCA-UMP). In total, these three programs accounted for 97% of members served in fee-for-service. DOC, DOH-AIDS Prescription Drug Program (DOH-APDP), L&I Crime Victims Compensation (L&I-CVC) and WDVA comprised the remaining 3%.

In the combined CY 2000 fee-for-service population (902,812), an average of 55% of members used their prescription drug benefit in CY 2000. There was, however, a wide range of users by program. Only 4% of L&I-CVC and 26% of L&I Industrial Insurance beneficiaries used the program's benefits for prescription drugs. In the mid-range of utilization, 60% of members in DOH-APDP, 63% in DSHS-MAA and 70% in HCA-UMP filed claims for prescription drugs. DOC and WDVA utilization rates were reported at 100% for their populations. (DOC considers all drugs provided to inmates to be prescription drugs, since all medications require a prescription and must be dispensed by a pharmacist.) In CY 2000, a total of 11,067,596 prescriptions were filled for this population, yielding approximately 12 prescriptions per member or 22 per user.

Members differed in prescription drug use by age group. Those age 65-and-over comprised 11% of the total population of members and accounted for 15% of total users. Prescription drug use was higher, on average, among those 65-and-over (80%) compared to those less-than-65 years of age (52%).

Members also differed in prescription drug use by gender. Of agencies surveyed for the Prescription Drug Project, females comprised 50% of total members and 57% of total prescription drug users. In CY 2000, 63% of female members used their prescription drug benefit, while 47% of men did so. By age group, 60% of females in the less-than-65 age group used prescription drugs compared to 45% of males. Among those 65-and-over, utilization by females still exceeded that of males (85% vs 72% respectively).

In CY 2000, total health-related expenditures in fee-for-service programs exceeded $2.6 billion. Of this amount, prescription drug expenditures totaled $571,695,513 before rebates, averaging 22% of total combined health-related expenditures. Prescription drug expenditures as a percentage of total health costs *by agency* (before rebates) ranged from 2% for L&I-CVC to 74% for DOH-APDP. Net cost after rebates was $489,438,613.

There is wide variation in agency prescription drug expenditures on a per-member-per-month and per-member-per-year basis. The variance is most likely due to the needs of special populations served by different agencies. For example, DOH-APDP primarily serves patients with HIV/AIDS whose treatment costs are high and for whom few generic drugs are available. L&I Industrial Insurance, on the other hand, primarily serves injured workers whose drug treatment costs are relatively low due to the number of pain medications that have generic alternatives.

Of the state's total drug expenditures *after rebates*, the top 10 drugs comprise 25%, the top 25 drugs make up 39% and the top 100 drugs make up 65%. Expenditures by DSHS-MAA account for 86.9% of total expenditures and 86.1% of Top 100 drug expenditures, but only 64.7% of total members across state agencies. L&I had 22.8% of total members in this survey,

3.4% of total drug expenditures, and 4.1% of Top 100 Drug expenditures. HCA-UMP members comprised 9.7% of the project population but only 7.3% of total drug expenditures and 7.0% of Top 100 drug expenditures. The remaining agencies accounted for less than 3% of total drug expenditures and Top 100 drug expenditures.

Agencies purchase prescription medications either through bulk purchasing, fee-for-service or managed care plans. Bulk purchasing refers to the purchase of large volumes of medications directly from a manufacturer or indirectly through wholesalers. Prescription drugs are then dispensed through in-house pharmacies or other local entities.

The HCA-UMP, DOH-APDP, L&I, and DSHS-MAA programs dispense medications to enrollees through retail pharmacies. Each program's pharmacy network includes many retail pharmacies throughout the state to provide convenient access for plan members. Agencies differ in how they manage their retail pharmacy networks. DOC, WDVA, DOH-Imm, and Eastern and Western State hospitals do not use retail pharmacy networks. They provide access to pharmaceuticals at specific sites (for example, hospital pharmacies, correctional institutions, or local health departments).

Within FFS purchasing, there are several variations in how agencies purchase medications. HCA-UMP, DSHS-MAA and DOH-APDP contract externally for prescription drug claims processing. L&I processes prescription drug claims using in-house staff. DOC and DSHS-JRA receive monthly invoices from Purdy Costless Pharmacy for medications dispensed to program members.

Health plans offered through HCA (PEBB and Basic Health) and DSHS (Healthy Options) contract with several managed care organizations (MCOs) to provide health care

services, including prescription drugs, to individuals eligible for health care benefits. Many MCOs contract with a pharmacy benefit manager to coordinate mail and retail dispensing programs, pharmacy networks, and data management.

Although agencies have different methods for administering and managing prescription drug programs using the FFS method, they all pay contracted pharmacies a predetermined percentage of the drug's Average Wholesale Price (AWP) or the pharmacy's *usual and customary price,* whichever is lower. These discounted rates vary depending on the agency. All agencies pay the pharmacy a dispensing fee for each prescription, ranging from approximately $2.00 to $5.00 per prescription.

In addition to purchasing prescription drugs and processing prescription drug claims, all agencies that administer prescription drug programs provide an array of clinical pharmacy services and member service programs. These services include prospective and retrospective drug utilization review, disease management, and development and management of a prior authorization system. While each agency provides these services to program members, the methods by which they are provided vary. Agencies that provide prescription drugs at specific facilities (DOC, WDVA, DOH-Imm) provide consulting pharmacy services on an in-house basis according to the needs of the facilities.

Although the content of the prescription drug formulary varies among agencies, each agency, except DSHS-MAA, uses a formulary in their prescription drug program. (DSHS-MAA uses a list of covered drugs without prior authorization.) HCA-UMP has a voluntary formulary; L&I only covers drugs routinely used to treat industrial injuries and occupational diseases;

DOH-APDP only covers medications specifically used to treat HIV infection; WDVA follows the Federal VA formulary; and, DOC uses their own formulary.

Federal rules require DSHS-MAA to cover all drugs whose manufacturer has signed a rebate agreement with the Centers for Medicare and Medicaid Services (CMS). However, DSHS-MAA has discretionary authority to list selected drugs as requiring "prior authorization" from MAA if certain criteria are met. Prior authorization requests are granted when the requested drug is medically necessary, as defined in WAC 388-500-0005.

DSHS-MAA and DOH-APDP receive matching federal funds. L&I-CVC receives federal funds for CVC benefits, although these funds are not specific to prescription drugs. L&I's medical aid fund is funded by premiums paid by employers and workers. In addition to adult tetanus-diphtheria and pediatric diphtheria-tetanus vaccines purchased off DOH-negotiated contracts, DOH-Imm receives federal *Vaccines for Children* and *Title 317* funding and state funds to purchase immunizations.

Objective 2: Legal and Regulatory Issues

The PDP Workgroup considered legal and regulatory issues in developing this report. Current federal and state statutes or regulations that define the structure or function of prescription drug programs, including the purchase of prescription drugs (directly or indirectly) by state agencies, are included in the final report. Potential limitations to the implementation of workgroup recommendations were examined, including the need for federal waivers and the adoption of statutory/regulatory changes. Potential limitations related to the fee-for-service or bulk purchasers include:

State Purchased Health Care It appears the authorizing language for exploring state-purchased health care options in RCW 41.05.021(b) and RCW 70.14.050 should be sufficient statutory authority for the recommendations developed by the workgroup. However, there are two issues to be examined:

1) RCW 70.14.050 references RCW 70.14.010 (repealed in 1988) which listed the state agencies authorized to implement cost controls in RCW 70.14.050. The repeal of RCW 70.14.010 has raised an issue about the effect on RCW 41.05.021 (1)(b)(iii) and RCW 70.14.050. The repeal of RCW 70.14.010 is contained in the legislation creating the Health Care Authority, which defines the state agencies included in "state purchased health care." This suggests that RCW 70.14.010 was repealed to eliminate an unnecessary redundancy.

2) Do the provisions in RCW 41.05.026 and RCW 70.47.150 provide the necessary protections from disclosure of proprietary information submitted to the state to implement the workgroup recommendations?

DSHS-MAA It is not clear what waiver(s), if any, would be necessary to implement a coordinated or consolidated prescription drug program, which would include Medicaid, in the State of Washington. It would depend upon how "consolidated or coordinated drug program" is interpreted.

As long as there were no improper delegation of DSHS' "single state agency" authority, Medicaid could participate in a uniform, multi-agency formulary using a prior authorization system to handle requests for non-formulary drugs. If the Medicaid program did not benefit at least as much under a consolidated drug program as it currently does under the Medicaid rebate

program, the consolidated drug program could be vulnerable to challenge. If management and decision-making authority were to be consolidated under one department (other than DSHS), then several waivers might be needed to deal with issues surrounding the single state agency concept. If any of DSHS' discretion to administer the Medicaid drug program were delegated to some other entity without a waiver, that could be challenged by the federal government as improper delegation of the administration of the Medicaid program and, thereby, jeopardize federal funding of the state Medicaid prescription drug program. State legislation and/or new WACs may be needed if the state is looking at implementing a supplemental drug rebate requirement on drug manufacturers.

Industrial Insurance Participation in workgroup recommendations may necessitate statutory and regulatory changes, such as changes to the requirements that purchase of and payment for prescription drugs be consistent with the fee schedule rates established by L&I. This may require changes to RCW 51.04.030, WAC 296-20-015, WAC 296-20-020, WAC 296-20-03012 through WAC 296-20-03024. Participation in an aggregate drug purchasing program should allow L&I to continue ensuring prompt access to proper and necessary prescription drug treatment for injured workers in the most economically efficient manner. It will also ensure that that only qualified providers render prescription drug treatment to injured workers. L&I-CVC regulatory changes would be the same as they are for the Industrial Insurance Program.

DOH-APDP As the federal grantee for Ryan White funds, DOH is the only entity eligible to apply for and receive rebates under this agreement. If DOH-APDP consolidated purchasing with other state agencies, DOH may still need to serve as the fiscal entity for APDP

rebate invoices. This issue requires further research but would not likely be an obstacle to coordinated purchasing.

DOH-Imm Vaccines purchased with VFC or 317 grant funds must be purchased using the Centers for Disease Control federal contracts. There is no federal waiver process.

Department of Corrections DOC would still be required to obtain licensing for our pharmacists and pharmacies under any workgroup recommendations. Both federal and state laws would continue to apply. With these licenses, DOC would be able to participate in a consolidated program without the need for any waiver, exception or regulatory change.

Veterans Affairs WDVA is not aware of any waivers, exceptions or regulatory changes that would be required for the agency to participate in a coordinated or consolidated prescription drug program. WDVA's ability to continue to participate in a resource sharing agreement/contract with the United States Department of Veterans Affairs (USDVA) would be affected if participation were mandated. A concern is whether the benefits will exceed those that the agency is currently able to access through agreement with USDVA. As a provider of services, WDVA is not aware of any federal or state requirements that impede the ability to develop or use a formulary.

Department of General Administration (GA) One of the main issues to be considered relates to the absence of authority under Chapter 43.19 RCW for GA to contract on behalf of private citizens. GA could work jointly with HCA and other agencies to develop a bid and/or contract under HCA's governing statute.

There are a variety of contracting strategies that should be explored by the workgroup in order to determine the best approach to meet the specific needs of the state. One approach would

be to conduct a multi-state solicitation. The approach is generally to choose a lead state in which the procurement is done under that state's procurement statutes. Several states participate in development and award of the contract. GA's Office of State Procurement is a member of the Western States Contracting Alliance (WSCA). The purpose of WSCA is to identify opportunities where multi-state procurements will benefit all participants (because of volume discounts, like requirements, similar distribution networks, etc.) WSCA already has in place a solid foundation of standard contract terms and conditions that have been preappoved by the attorneys for each participating state. WSCA also has written procedures that have been agreed upon by each state on how to conduct multi-state ventures, including the roles and responsibilities of each participant.

Objective 3: Stakeholder Assessment

The design, implementation and maintenance of any prescription drug program includes careful consideration of stakeholder interests. Potential stakeholders related to Washington State prescription drug programs include (but are not limited to): Washington residents and/or beneficiaries served by state agencies, Washington State agencies, retail pharmacists, drug manufacturers, patient advocacy groups, pharmacy benefit managers and special interest groups.

If the State of Washington establishes a coordinated or consolidated prescription drug program, several positive outcomes may be realized. These include:

- Increased access to high quality, cost-effective medications
- Improved clinical management of prescription drugs
- Improved disease management programs
- Improved coordination of benefits for clients covered by more than one agency

- Enhanced customer service
- Increased uniformity of prescription drug programs across agencies
- Improved consistency of drug utilization protocols among agencies
- Integration of quality assurance processes across agencies
- Increased administrative and contracting efficiencies
- Decreased confusion among providers regarding preferred drugs
- Increased rebate collection leading to reduced prescription drug expenditures
- Improved mechanisms to combat fraud and abuse

While pursuing these desired outcomes, suggested PDP Phase II operational tasks include (but are not limited to) consideration of issues related to patient confidentiality, individual program requirements, and agency contracting requirements. In addition, legal, policy and statutory analysis will need to be completed.

Objective 4: Other Prescription Drug Programs or Purchasing Models

Many states are exploring options to control rising prescription drug expenditures. Initiatives include the development of a statewide prescription drug formulary or the formation of multi-state purchasing coalitions. The goal of many initiatives or programs is to become a high volume prescription drug purchaser. Higher volume not only produces better unit pricing, it also provides the "critical mass" needed for effective implementation of sophisticated data management and utilization control strategies. A statewide preferred drug list is pivotal in shifting market share and motivating drug companies to provide their best rebates for all state agencies, including Medicaid.

A common consideration in state consolidation strategies is whether to "make or buy" the complex data systems, provider and supplier contracting, analysis, decision making, negotiating and education functions needed to manage prescription drug use and costs. A handful of pharmacy benefit management companies (PBMs) have pioneered many of the tools now in vogue for prescription drug cost control. PBMs, such as Merck Medco, Express Scripts and Consultec, now manage pharmacy benefits for almost half the US population, including many within the state of Washington.

Several public purchasers (or groups of purchasers) serve as models for the design, implementation, maintenance and evaluation of a prescription drug program in the state of Washington. The progress and outcomes of these programs should be monitored during the development of a consolidated or coordinated prescription drug program in the state of Washington. Such initiatives include the Florida Medical Pharmacy Program, the Georgia Department of Community Health, the Northern New England Tri-States Initiative, the Southern States Purchasing Coalition, and the Oregon Health Plan Formulary.

Phase I: Recommendations

After careful discussion, the Prescription Drug Workgroup puts forth the following recommendations, to be accomplished either through third-party contract(s) or use of existing state resources or structures:

1. Establish a statewide Pharmacy and Therapeutics (P&T) Committee to develop, implement and maintain a Washington State Preferred Drug List. The P&T Committee shall, where appropriate, seek additional expertise to address issues concerning special populations.

2. Establish a statewide Drug Utilization Review Board to develop treatment guidelines and criteria for appropriate drug use.
3. Explore the feasibility of consolidating claims processing, claims adjudication, and other pharmacy management and information services.
4. For agencies and/or programs that directly purchase drugs, explore the feasibility of implementing and maintaining a consolidated rebate program.

Phase II: Next Steps

PDP Workgroup suggestions for tasks in Phase II of the Prescription Drug Project include:

1. Additional analyses for development and refinement of recommendations, including but not limited to:
   - Legal and policy analysis
   - Statutory authority
   - Managed care pharmacy contracts and their relation to Recommendations 1 - 4
2. Consideration of Phase II Operational Issues
   - Project direction and scope
   - Identification of lead agency
   - Administration/Management/Staffing
   - Timeline
   - Resource inventory/assessment
   - Funding
   - Evaluation plan – process and outcomes

- Needed consultations
- Assessment of impact of 340b program changes
- Cost-benefit analysis
- HIPAA considerations
- Marketing
- Stakeholder management
- Exploration of partnerships with other public or private entities

Prescription Drug Expenditures: An Upward Trend

Prescription drugs play an increasingly important role in saving lives, keeping people healthy and improving quality of life. The rapidly rising cost of prescription drugs, however, places a burden on consumers, employers and public programs. While more than half of Americans take prescription drugs on a regular basis, 25% of those surveyed do not have prescription drug coverage through their health insurance plan, 30% report not filling prescriptions because of the cost, and 10% report giving up basic necessities, like food, in order to pay for prescription drugs (KFF Update, 2000). Employers feel the effects as well, with prescription drug benefit costs rising 16.9% in 1999 and 18.3% in 2000 (William M. Mercer, 2001). Public programs, such as state Medicaid programs, may be hardest hit from increases in prescription drug expenditures.

Public programs are often the payer of last resort for high users of pharmaceuticals, including the mentally ill, frail elderly and others with high medical needs. In addition, public programs cannot use the same cost and utilization controls as private payers (NCSL, 2000). Medicaid is the largest source of public coverage for prescription drugs, covering approximately 11% (30 million) of all Americans in 1996. Collectively, government programs (including Medicaid, Medicare, Department of Defense, Veterans Administration, Indian Health Services, public assistance programs, and state and local hospitals, paid approximately 21% of prescription drug expenditures ($91 billion) in 1998, up from 17% of prescription drug expenditures ($38 billion) in 1990 (Kreling, et al., 2000).

Rising Expenditures

In 1998, national health expenditures on prescription drugs totaled $91 billion. By 2008, expenditures are projected to reach $243 billion[3]. While prescription drugs still rank third behind hospital care and physician services in total personal health care expenditures, the annual percent change in prescription drug expenditures has exceeded that of hospital care and physician services. From 1993 to 1998, while the annual percent change in hospital care declined to 3.4% and physician services declined to 5.4%, the annual percentage change in national prescription drug expenditures climbed to 15.4% (Kreling, Mott, Wiederholt, Lundy, & Levitt, 2000).

In general, three factors are responsible for the upward trend in prescription drug expenditures: increases in utilization, a shift toward use of newer, more expensive drugs and increases in price[4]. From 1993 to 1998, utilization accounted for the largest increase in expenditures on prescription drugs (43%) followed closely by expanded use of newer, more expensive drugs (39%). Surprisingly, price increases were only responsible for 18% of the overall increase in spending on prescription drugs. (Kreling, et al., 2000).[5]

[3] These expenditures most likely are underestimated, as expenditures were limited to those from retail outlets, such as grocery store and mail order pharmacies, and excluded the value of prescription drugs provided to patients as a part of hospital care, to those in nursing homes as a part of their care, and as provided by physicians during an office visit.

[4] National prescription drug expenditures are commonly defined as the cost of the drug times utilization. Cost is broken down into the price of the drug plus the dispensing fee, minus any payment from others (e.g., discounts or cost share). Utilization is a product of the number of people covered by a benefit times the number of prescriptions per person.

[5] Additional factors that fuel expenditures are liberal insurance coverage of prescription drugs with little to no cost sharing by the patient and earlier diagnosis of conditions combined with more effective treatment options. (Henneberry, 2000).

Increased Utilization

While the U.S. population grew 6% from 1992 to 1998, the number of prescription drugs purchased increased 37% (KFF, 2000). Multiple factors contribute to increased utilization of prescription drugs, including an aging population, an increased number of prescribers, and aggressive promotion of drugs by manufacturers (Kreling, et al., 2000). Changes in treatment protocols and approaches to medical care, along with the movement of patients into managed care plans, may also be fueling increased utilization.

Increasing age. The incidence of chronic illness increases with advancing age, usually starting at age 45. Many chronic conditions are amenable to treatment with prescription drugs. Between the ages of 45 and 75, prescription drug use triples from an average of 4.3 prescriptions per person annually to 11.4

Increase in prescribers. There has been a gradual increase in the number of core prescribers (MDs or DOs) in the U.S., along with the addition of prescribing privileges to nurse practitioners and physician assistants.

Increase in advertising. In 1998, manufacturers spent $8.3 billion on advertising. The bulk of this ($7 billion) was directed at physicians and other professionals, while the remainder was used for direct-to-consumer (DTC) advertising (KFF, 2000). It is estimated that DTC advertising has led to a 59% increase in patient requests for brand-name drugs (Henneberry, 2000).

Changes in consumer behavior. Today's consumers are more knowledgeable of health conditions and treatment options. They increasingly seek out prescription drug therapy for what ails them, as well as so-called lifestyle drugs for everything from impotence to wrinkles. Fueling

this is the consumer's low cost share for prescription drugs, which have historically not increased at the same rate as drug prices.

Movement into managed care. Although managed care plan benefits may be changing in the future, generous prescription drugs benefits and small out-of-pocket contributions in managed care plans provide an incentive for enrollees to have higher prescription drug use than enrollees in traditional fee-for-service plans (Henneberry, 2000).

Rising Prices

The price of prescription drugs is set by the manufacturer which, in turn, influences prices at the wholesale and retail levels. For every dollar of revenue from a retail prescription, the pharmacy receives 23%, the wholesaler receives 3%, and the manufacturer keeps 74%. Between 1991 and 1998, the average retail price of a brand name drug increased 80%, while the average increase for generic drugs was 55%, reflecting both increased prices of existing drugs and increased use of more expensive drugs. In the same time period, the average annual change in retail prescription prices rose 6.7%, compared to a 2.6% increase in the Consumer Price Index (CPI) and a 4.6% change in the CPI for Medical Care (Kreling, et al., 2000).

Use of Newer, More Expensive Drugs

Research and development have brought many new drugs to the marketplace, either for treatment of diseases or conditions for which no drug treatment was previously available, or in place of less effective or less tolerable drugs. Newer drugs tend to be more expensive than older drugs and account for the majority of drugs on top-selling drug lists (Kreling, et al., 2000).

The Marketplace and Prescription Drugs

The United States market for prescription drugs generates unusually high profits for manufacturers. Manufacturers release 89% to 90% of their products to wholesalers and net an industry average return on equity of 29.4% - twice the median return on equity for all Fortune 500 industries. In 1998, the top 10 major pharmaceutical manufacturers spent 11.1% of sales on research and development, 24.3% on marketing, and 33.5% on general and administrative costs. In the same year, the top 10 generic pharmaceutical manufacturers devoted 5.9% of sales to research and development and 22% to marketing, general expenses and administrative expenses, with 15.8% going to profits. Theories offered for the profitability of pharmaceutical manufacturers include growth in third-party drug coverage, the introduction of successful new products, and aggressive technology transfer and marketing efforts (Berndt, 2001).

Measures of control over rising prescription drug expenditures include the ability to set pricing, limit profits, prohibit or restrict advertising, influencing consumer demand for pharmaceuticals, release more drugs to generic or over-the-counter status, reduce patent duration, and leverage purchasing power. Jurisdictional controls limit the ability of states to leverage purchasing power as a strategy to enforce economic discipline. Savings on prescription drug expenditures can be enhanced by volume purchasing, competing for rebates, increasing cost sharing by consumers, and combating fraud and abuse. (Sailors, 2001) Many of these strategies can be implemented by either contracting with a pharmacy benefit manager or by states acting as their own pharmacy benefit manager.

Pharmacy Benefit Managers

Pharmacy benefit managers (PBMs) design, implement, and administer outpatient drug benefit programs for employers, managed care organizations, and other third party payers. PBMs can provide administrative functions and/or drug utilization management. Administrative functions include: benefit structure and design; maintenance of retail pharmacy providers networks; claims processing and adjudication; and, record keeping and outcomes reporting. Drug utilization management functions include: formulary compliance; prior authorization; promotion of generic substitution where appropriate" drug utilization review (prospective and retrospective); step therapy; treatment guidelines; and, disease management programs. PBMs bring private sector best practices to bear in negotiating manufacturer rebates and lower retail pharmacy prices (Cook, Kornfield, & Gold, 2000). Fee-for-service (FFS) purchasing occurs when an agency pays a contracted pharmacy(s) for prescriptions dispensed to program members.

The Washington State Prescription Drug Project

In FY 1999, Washington State agencies spent approximately $520 million on prescription drugs (Joint House Health Care Committee, Nov 1999). Purchases made through the Department of Social and Health Services Medical Assistance Administration (MAA) and the Washington State Health Care Authority (HCA) accounted for 90% of state agency spending on prescription drugs. Furthermore, in 1999, several Washington State agencies experienced increases in prescription drug expenditures well above the national average of 15%. In 1999, the HCA Uniform Medical Plan (HCA-UMP) saw a 26% increase over 1998 expenditures, while the DSHS-MAA fee-for-service drug program had an increase of approximately 21%. Agencies with smaller prescription drug programs experienced similar increases as well.

In April 2001, Governor Gary Locke convened an inter-agency workgroup to begin work on the Prescription Drug Project (PDP). The PDP Workgroup is convened under the Health Care Authority's statutory authority to analyze state-purchased care programs in order to explore options for cost containment and service delivery alternatives, including state efforts to purchase drugs effectively (RCW 41.05.021(1) (b)(ii). The interagency workgroup includes representatives from the Health Care Authority, Department of Health, Department of Corrections, Department of Veterans Affairs, Department of Social and Health Services, and Labor and Industries, as well as the Office of the Attorney General, Department of General Administration, the State Board of Health, and the Office of the Insurance Commissioner.

The Prescription Drug Project (PDP) is supported by a conceptual framework based on value purchasing. The goal of the Prescription Drug Project (PDP) is to enhance the delivery of high-quality health care to Washington State residents by managing pharmacy benefits and

prescription drug expenditures through coordinated or consolidated prescription drug purchasing across state agencies within two years.

Phase I of the PDP includes a comprehensive study of current fee-for-service prescription drug programs and purchasing across state agencies and the formulation of recommendations to achieve the overall goal of the Prescription Drug Project. Phase I work focuses on issues related to current prescription drug programs and practices, legal and regulatory issues, stakeholders, and other prescription drug purchasing models. Specific Phase I objectives are:

- To describe, in detail, the agency's current fee-for-service prescription drug program(s) and practice(s)
- To explore the effect of existing or potential federal and state regulations, policies, programs or funding on the development and implementation of a coordinated or consolidated prescription drug purchasing program in the State of Washington
- To identify and anticipate the impact of coordinated or consolidated prescription drug purchasing strategies on stakeholders
- To explore programs from other states or entities that provide positive or negative models or examples for the development and implementation of a coordinated or consolidated prescription drug purchasing program in the State of Washington.

PDP Phase II entails the design and implementation of a consolidated prescription drug purchasing program across state agencies within two years.

Current Washington State Prescription Drug Programs

Six Washington State agencies currently purchase or provide health care benefits, including prescription drugs, to over 1.5 million Washington residents or qualified beneficiaries. These agencies are: the Washington State Health Care Authority (HCA), Department of Health (DOH), Department of Social and Health Services (DSHS), Labor and Industries (L&I), Department of Corrections (DOC), and Washington Department of Veterans Affairs (WDVA). Of the over 1.5 million individuals served in CY 2000, 902,812 (60%) were served through fee-for-service programs, while the remaining 40% were enrolled in managed care programs. (See Table 1).

Table 1
Individuals served by selected Washington State Agencies

Agency	FFS	%FFS	MCO	%MCO	Total
DSHS	583,884	77%	170,875	23%	754,759
HCA	87,793	17%	442,941	83%	530,734
L&I	205,979	100%	-	0%	205,979
DOC	14,696	100%	-	0%	14,696
L&I-CVC	7,389	100%	-	0%	7,389
DOH-APDP	2,570	100%	-	0%	2,570
WDVA	501	100%	-	0%	501
	902,812	60%	613,816	40%	1,516,628

Notes:

1. FFS – Fee-for-service; MCO – Managed Care Organization
2. DSHS managed-Medicaid services are provided through Healthy Options
3. HCA FFS program is Public Employees Benefits Board Uniform Medical Plan (PEBB-UMP)
4. HCA managed care programs are offered through either PEBB or Basic Health (BH) or Basic Health Plus (BHP-Plus)
5. DOC provides services in correctional facilities
6. WDVA provides services in residential facilities

Of those in fee-for-service programs, 64% were served through DSHS-Medical Assistance Administration (DSHS-MAA), 23% through L&I Industrial Insurance (L&I), and 10% through the HCA Uniform Medical Plan (HCA-UMP). In total, these three programs

accounted for 98% of members served in fee-for service. DOC, DOH-AIDS Prescription Drug Program (DOH-APDP), L&I Crime Victims Compensation (L&I-CVC) and WDVA comprised the remaining 3%. (See Figure 1.)

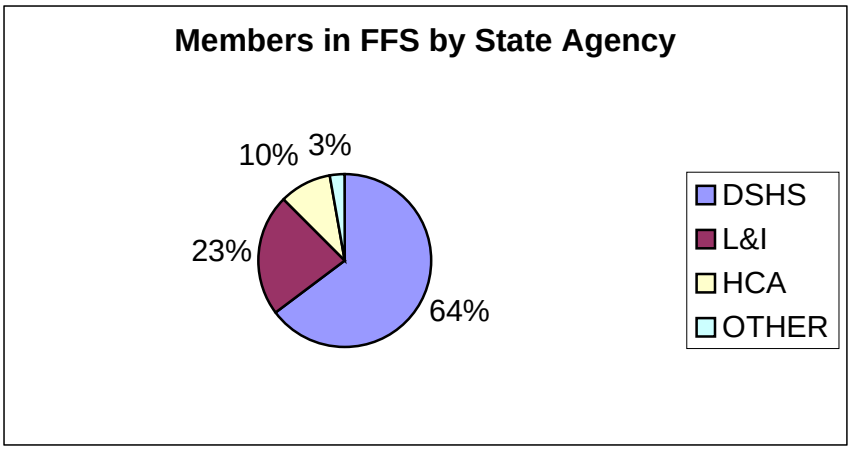

Figure 1. Members served in FFS by Selected WA State Agencies

In the combined CY 2000 fee-for-service population (902,812), an average of 55% of members used their prescription drug benefit in CY 2000. There was, however, a wide range of users by program. Only 4% of L&I-CVC and 26% of L&I Industrial Insurance beneficiaries used the program's benefits for prescription drugs. In the mid-range of utilization, 60% of members in DOH-APDP, 63% in DSHS-MAA and 70% in HCA-UMP filed claims for prescription drugs. DOC and WDVA utilization rates were reported at 100% for their populations. (DOC considers all drugs provided to inmates to be prescription drugs, since all medications require a prescription and must be dispensed by a pharmacist.) In CY 2000, a total of 11,067,596 prescriptions were filled for this population, yielding approximately 12 prescriptions per member or 22 per user.

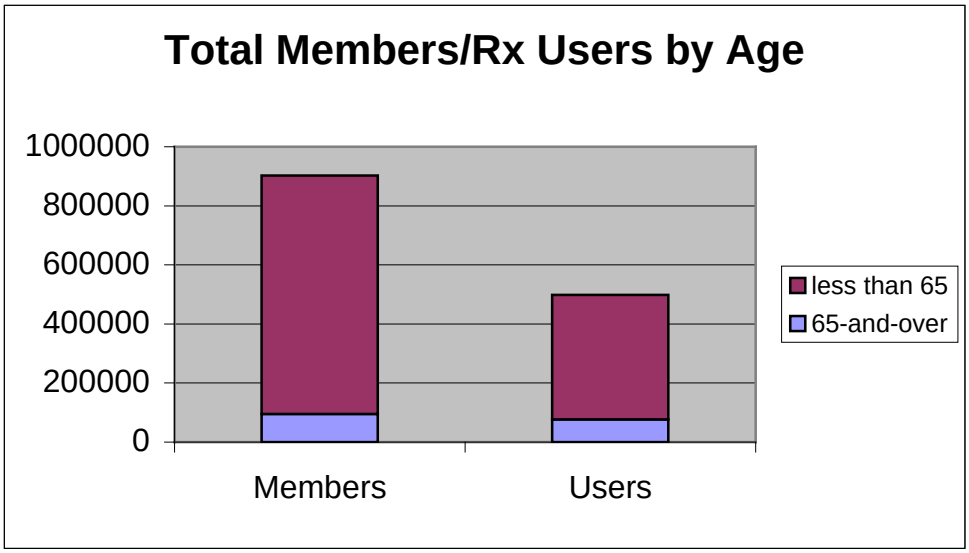

Figure 2. Total members/Rx users by age in selected WA State agencies

Members differed in prescription drug use by age group. Those age 65-and-over comprised 11% of the total population of members and accounted for 15% of total users. (See Figure 2.) Prescription drug use was higher, on average, among those 65-and-over (80%) compared to those less-than-65 years of age (52%). Across agencies, there is a significant range of Rx drug users by age, as illustrated in Table 2.

Table 2
Rx Users by Age Group in selected WA State agencies

	less than 65		65-and-over	
	members (#)	% Rx users	members (#)	% Rx users
DSHS-MAA	511,987	60%	71,897	82%
L&I	199,690	26%	6,289	18%
HCA-UMP*	71,227	65%	16,534	96%
DOC	14,530	100%	166	100%
L&I-CVC	7,273	4%	116	4%
DOH-APDP	2,560	60%	10	70%
WDVA	121	100%	380	100%
Total	807,388	55%	95,392	80%

* Total for UMP does not equal total in Table 1 because age group for 32 members was not reported.

Members also differed in prescription drug use by gender. Of agencies surveyed for the Prescription Drug Project, females comprised 50% of total members and 57% of total prescription drug users. In CY 2000, 63% of female members used their prescription drug benefit, while 47% of men did so. By age group, 60% of females in the less-than-65 age group used prescription drugs compared to 45% of males. Among those 65-and-over, utilization by females still exceeded that of males (85% vs 72% respectively).

In CY 2000, total health-related expenditures in fee-for-service programs exceeded $2.6 billion. Of this amount, prescription drug expenditures totaled $571,695,513 before rebates, averaging 22% of total combined health-related expenditures. Prescription drug expenditures as a percentage of total health costs *by agency* (before rebates) ranged from 2% for L&I-CVC to 74% for DOH-APDP. Net cost after rebates was $489,438,613. (See Table 3).

Agency prescription drug expenditures on a per-member-per-month and per-member-per-year basis are also shown in Table 3. There is wide variation in these standardized expenditures by agency. The variance is most likely due to the needs of

Table 3
FFS Rx Drug Expenditures (before rebates)
by Selected WA State Agencies

Agency	Tot Health Exp	Total Rx Exp	Rx % Tot	PMPY	PMPM
DSHS	$ 1,974,620,068	$ 497,012,159	25%	$ 851.22	$ 70.93
L&I	$ 380,000,000	$ 19,262,073	5%	$ 93.51	$ 7.79
HCA-UMP	$ 180,172,000	$ 41,838,618	23%	$ 476.56	$ 39.71
DOC	$ 55,050,630	$ 6,837,221	12%	$ 465.24	$ 38.77
WDVA	$ 14,719,527	$ 909,764	6%	$1,815.90	$151.32
DOH-APDP	$ 7,732,294	$ 5,718,746	74%	$2,225.19	$185.43
L&I-CVC	$ 6,900,000	$ 116,932	2%	$ 15.83	$ 1.32
Pre-rebate	$ 2,619,194,519	$ 571,695,513			
Post-rebate		$489,438,613			

special populations served by different agencies. For example, DOH-APDP primarily serves patients with HIV/AIDS whose treatment costs are high and for whom few generic drugs are

available. L&I Industrial Insurance, on the other hand, primarily serves injured workers whose drug treatment costs are relatively low due to the number of pain medications that have generic alternatives.

The top 100 drugs by total dollars spent are listed in Appendix B. This list is similar to the top drugs marketed and sold nationwide in CY 2000. Of the state's total drug spend *after rebates*, the top 10 drugs comprise 25%, the top 25 drugs make up 39%, and the top 100 drugs make up 65%. Expenditures by DSHS-MAA account for 86.9% of total expenditures and 86.1% of Top 100 drug expenditures, but only 64.7% of total members across state agencies. L&I had 22.8% of total members in this survey, 3.4% of total drug expenditures, and 4.1% of Top 100 Drug expenditures. HCA-UMP members comprised 9.7% of the project population but only 7.3% of total drug expenditures and 7.0% of Top 100 drug expenditures. The remaining agencies accounted for less than 3% of total drug expenditures and Top 100 drug expenditures. (See Table 4)

Table 4
Members, Rx Users and Drug Expenditures (Total and Top 100) by selected WA State agencies

Agency	% Members	% Rx users	% Total Exp	% Top 100 Exp
DSHS-MAA	64.7%	73.4%	86.9%	86.1%
L&I	22.8%	10.8%	3.4%	4.1%
HCA-UMP	9.7%	12.3%	7.3%	7.0%
DOC	1.6%	3.0%	1.2%	1.4%
L&I-CVC	0.8%	0.1%	0.2%	0.0%
DOH-APDP	0.3%	0.3%	1.0%	1.2%
WDVA	<0.1%	0.1%	0.0%	0.1%

Several of the top 100 drugs (e.g., Pepcid®, Prozac®, Prilosec®, and Glucophage®) will be going off patent in 2001 and 2002. The state will likely experience some cost savings. However, savings may be negligible as manufacturers strategically schedule and aggressively

market the launch of new products in order to replace drugs going off patent. Examples include the reformulation of Glucophage® into a once daily dose (Glucophage XR®) along with the placement of coupons in the newspaper for a free 30-day supply; the release of Nexium®, a stereoisomer of Prilosec®; the reformulation of Prozac® into a once-a-week dosage form; and, the approval of a new indication (premenstrual dysphoric disorder) for fluoxetine (generic name of Prozac®) marketed under the newly-patented product Saraphem®

Purchasing methods

Agencies purchase prescription medications either through bulk purchasing, fee-for-service or managed care plans. Bulk purchasing refers to the purchase of large volumes of medications directly from a manufacturer or indirectly through wholesalers. Prescription drugs are then dispensed through in-house pharmacies or other local entities. Agencies that bulk-purchase prescription medications include DOC, DOH Immunization Program (DOH-Imm), WDVA, DSHS Juvenile Rehabilitation Administration (DSHS-JRA), and Eastern and Western State Hospitals. These agencies may purchase prescription drugs through the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP), which is coordinated through the Department of General Administration (GA). Pricing under this contract is bid by the awarded manufacturer and invoiced through the prime vendor wholesaler (Cardinal Health, Auburn, WA). DOH distributes the immunizations to local public health jurisdictions, which then distribute the immunizations to public and private health care providers. WDVA is also eligible to purchase medications using the Federal Supply Schedule. With the exception of DOH-Imm, agencies that purchase prescription drugs in bulk have staff pharmacists and in-house pharmacies from which medications are stored and distributed.

Fee-for-service (FFS) purchasing occurs when an agency pays a contracted pharmacy(s) for prescriptions dispensed to program members. Washington State agencies that purchase prescription drugs using the FFS method are HCA, DOH AIDS Prescription Drug Program (DOH-APDP), L&I, DSHS Medical Assistance Administration (DSHS-MAA), certain DSHS-JRA facilities, and some DOC facilities. DOH-APDP, L&I, HCA-Uniform Medical Plan (HCA-UMP), and DSHS-MAA all provide prescription drugs through contracted retail pharmacy networks. These networks are developed and managed by each agency, either directly or through a pharmacy benefit manager. DOC and DSHS-JRA purchase prescription drugs using the Pharmaceutical Services Contract with Purdy Costless Pharmacy.

HCA and DSHS contract with several managed care organizations (MCOs) to provide health care services, including prescription drugs, to individuals eligible for health care benefits. Many MCOs contract with a pharmacy benefit manager to coordinate mail and retail dispensing programs, pharmacy networks, and data management. Some conduct part or all of these activities in-house. MCOs use a variety of utilization and formulary processes to control costs and trends. These methods include formulary development, utilization management, pre-authorization, prescriber education and pharmacy detailing. Washington State agencies that purchase prescription drugs through managed care organizations include the HCA (BH and PEBB) and DSHS-MAA programs.

Pharmacy Networks

The HCA-UMP, DOH-APDP, L&I, and DSHS-MAA programs dispense medications to enrollees through retail pharmacies. Each program's pharmacy network includes many retail pharmacies throughout the state to provide convenient access for plan members. Although there

are some differences in the size of the networks (with Medicaid having the highest number of pharmacy providers at 1,423), geographic access offered by the networks is quite similar. Each program uses an open network, meaning that any retail pharmacy willing to accept a program's payment rates may join its network. The L&I Crime Victims Compensation Program (L&I-CVC) uses a similar approach, but has a smaller list of contracted pharmacies (250). Differences in network size are likely the result of retail pharmacies making individual decisions about whether to accept a program's payment rates.

Agencies differ in how they manage their retail pharmacy networks:

- L&I manages its own contracts with retail pharmacies and administers its own point-of-sale system to provide electronic information and billing access for network pharmacies.
- DSHS-MAA manages its own network and contracts with an information services vendor for the point-of-sale electronic transaction component.
- HCA-UMP and DOH-APDP contract the management of their networks and the point-of-sale operations to pharmacy benefits management (PBM) companies.
- DOH-APDP's contractor is responsible for managing the program's coordination-of-benefits effort because most enrollees have other primary coverage.
- L&I-CVC uses a smaller network of contracted pharmacies that accept the program's rates.

Table 5
Agency management of retail pharmacy networks

Agency	Contract with PBM Or directly with pharmacy	Management of Electronic billing
L&I	Contract directly	In-house
DSHS-MAA	Contract directly	Contract with claims Processing company
DOH-APDP	PBM Network	Contract with PBM
HCA-UMP	PBM Network	Contract with PBM
L&I-CVC	Contract directly	(Manual claims)

- DOC, WDVA, DOH-Imm, and Eastern and Western State hospitals do not use retail pharmacy networks. They provide access to pharmaceuticals at specific sites (for example, hospital pharmacies, correctional institutions, or local health departments). (See Table 5.)

Reimbursement Methods

Within FFS purchasing, there are several variations in how agencies purchase medications. HCA-UMP, DSHS-MAA and DOH-APDP contract externally for prescription drug claims processing. L&I processes prescription drug claims using in-house staff. DOC and DSHS-JRA receive monthly invoices from Purdy Costless Pharmacy for medications dispensed to program members.

Although agencies have different methods for administering and managing prescription drug programs using the FFS method, they all pay contracted pharmacies a predetermined percentage of the drug's Average Wholesale Price (AWP) or the pharmacy's *usual and customary price,* whichever is lower. These discounted rates vary depending on the agency. Reimbursement rates for prescriptions dispensed by retail pharmacies range from 87% to 90% of AWP. HCA-UMP reimburses their mail order pharmacy between 50% and 79% of AWP. DOC and DSHS-JRA pay Wholesale Acquisition Cost (WAC) plus 10% for prescriptions purchased using the Pharmaceutical Services Contract. In addition to the discounted price, all agencies pay the pharmacy a dispensing fee for each prescription, ranging from approximately $2.00 to $5.00 per prescription.

Clinical and Member Services

In addition to purchasing prescription drugs and processing prescription drug claims, all agencies that administer prescription drug programs provide an array of clinical pharmacy

services and member service programs. These services include prospective and retrospective drug utilization review, disease management, and development and management of a prior authorization system. While each agency provides these services to program members, the methods by which they are provided vary. For example, HCA-UMP contracts with a pharmacy benefit manager to provide these functions to program members. L&I provides these services using in-house personnel, and DSHS-MAA and DOH-APDP use a combination of in-house personnel and a contracted claims processing manager. (MAA also maintains an advisory committee, the "Drug Utilization Education Council" (DUEC), to advise on drug utilization review issues and some other pharmacy-related issues.) WDVA and DOC have either in-house staff pharmacists who provide these services or receive these services as part of the Pharmaceutical Services Contract with Purdy Costless Pharmacy.

In addition, agencies that dispense drugs through retail pharmacies (HCA-UMP, DOH-APDP, DSHS-MAA, L&I, and L&I-CVC) offer customers and providers access to help during business hours and, in some cases, after hours as well. Agencies vary in whether these activities are conducted by state employees or through contracts and whether or not a pharmacist is available to answer questions. (See Table 6.)

Table 6
Customer Service Programs by Agency

	Who provides customer service?	Is a pharmacist available?	Are after-hours services available?
L&I	Agency	Yes	No
DSHS-MAA	Agency	Yes	No
DOH-APDP	Agency for enrollees; PBM for pharmacies	No	Yes, for pharmacies
HCA-UMP	PBM	Yes	Yes
L&I-CVC	Agency	Yes	No

Agencies that provide prescription drugs at specific facilities (DOC, WDVA, DOH-Imm) provide consulting pharmacy services on an in-house basis according to the needs of the facilities. For example, WDVA facilities each have one pharmacist and one pharmacy technician on staff. Large DOC facilities also have pharmacists and pharmacy technicians on staff, while smaller facilities receive support from larger facilities, as part of the Pharmaceutical Services Contract with Purdy Costless Pharmacy or through contracts they maintain with local retail outlets.

Formulary Use

Although the content of the prescription drug formulary varies among agencies, each agency, except DSHS-MAA, uses a formulary in their prescription drug program. (DSHS-MAA uses a list of covered drugs without prior authorization.) HCA-UMP has a voluntary formulary; L&I only covers drugs routinely used to treat industrial injuries and occupational diseases; DOH-APDP only covers medications specifically used to treat HIV infection; WDVA follows the Federal VA formulary; and, DOC uses their own formulary.

Federal rules require DSHS-MAA to cover all drugs whose manufacturer has signed a rebate agreement with the Centers for Medicare and Medicaid Services (CMS). However, DSHS-MAA has discretionary authority to list selected drugs as requiring "prior authorization" from MAA if certain criteria are met. Prior authorization requests are granted when the requested drug is medically necessary, as defined in WAC 388-500-0005.

Funding

DSHS-MAA and DOH-APDP receive matching federal funds. L&I-CVC receives federal funds for CVC benefits, although these funds are not specific to prescription drugs.

L&I's medical aid fund is funded by premiums paid by employers and workers. In addition to adult tetanus-diphtheria and pediatric diphtheria-tetanus vaccines purchased off DOH-negotiated contracts, DOH-Imm receives federal *Vaccines for Children* and *Title 317* funding and state funds to purchase immunizations.

Legal/regulatory issues

The PDP Workgroup considered legal and regulatory issues in developing this report and recommendations. Current federal and state statutes or regulations that define the structure or function of prescription drug programs, including the purchase of prescription drugs (directly or indirectly) by state agencies, are included in the following section.

Health Care Authority

State purchased health care RCW 41.05.011 defines state-purchased health care to include "medical and health care, pharmaceuticals, and medical equipment purchased with state or federal funds by the Department of Social and Health services, the Department of Health, the Basic Health Plan, the Washington State Health Care Authority, the Department of Labor and Industries, the Department of Corrections, the Department of Veterans Affairs, and local school districts." RCW 41.05.021(b) authorizes HCA to conduct analysis of state-purchased health care and to explore cost containment options and delivery alternatives, including coordinated state agency purchasing of drugs (references RCW 70.14.050).

RCW 70.14.050 focuses on development of a drug formulary, but subsection (2)(d) also authorizes agencies to limit the prices paid for drugs by central purchasing, volume contracting, or setting maximum prices to be paid. RCW 70.14.050 (2)(f) contains broader authority by authorizing "other necessary measures to control costs of drugs without reducing the quality of care." See WAC 182-08-020 (c). RCW 41.05.185(2)(a) provides that state purchased health care, except Basic Health, must provide diabetic pharmacy services coverage.

Public Employees Benefits Board (PEBB) Chapter 41.05 RCW directs the HCA to provide "health care benefit programs, funded to the fullest extent possible by the employer, that

provide comprehensive health care" for public employees and retirees. The benefit plans designed by PEBB are provided by HCA through a contract bidding process with insuring entities licensed under Title 48 or through a self-funding/self-insurance (the Uniform Medical Plan). PEBB benefits must be "substantially equivalent to the state employees' health benefits plan and eligibility criteria in effect on January 1, 1993," but does not prohibit increases in employee out-of-pocket costs. Health care benefits are specified in the health plan contracts and member materials.

Basic Health (BH) Under Chapter 70.47 RCW covered basic health care services include prescription drugs. (See also WAC 182-25-020). Maternity and well-child care are provided to subsidized enrollees through Medical Assistance. The design of enrollee cost sharing should not create a barrier to appropriate utilization of services. BH is to endeavor to provide enrollees access to two or more managed health care systems through a contracting process with managed health care systems. Within defined restrictions, BH is directed to provide alternative coverage, such as self-funded or self-insured insurance options, in areas where access to coverage by a contracted health plan is limited.

Community Health Services RCW 41.05.220 directs HCA to contract with community health clinics to provide funding for primary medical, dental, and migrant health care services. WAC 182-20-160 provides that applicants for funding must demonstrate that they provide primary health care services, including pharmaceutical services, as appropriate.

Department of Social and Health Services

Medical Assistance Program (Medicaid) Under Title XIX of the Social Security Act (1965), the Prescription Drug Program is optional. However, under state law (Chapter 74.09

RCW) the definition of medical care under “medical assistance” includes prescribed drugs. In 1995, MAA was instructed to seek federal waivers and state law changes to medical assistance programs in order to achieve greater coordination of health services in a cost-effective manner and expand access to care. In RCW 43.20A.860, DSHS is designated as the "single state agency" for administering the Medicaid program in Washington and, under 42 CFR 431.10, cannot delegate the administration or supervision of the state Medicaid plan to any other agency.

The Medicaid Drug Rebate Program is established in 42 U.S.C. 1396r-8(a)-(c). 42 U.S.C. 1396r-8(d) defines requirements for prior authorization and drug formularies. The manufacturer must have a rebate agreement in effect with CMS for the drug to be covered for outpatient use. A state may subject any covered drug to prior authorization under specific conditions. Only certain defined drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted by states. Exclusions must be based on clinically meaningful therapeutic comparisons with other drugs included in the formulary. Written explanations for excluding drugs must be made public.

42 CFR 447.331 – 334 requires that the state plan to provide a comprehensive description of the state’s payment methodology for prescription drugs. The federal regulation also provides limits on payment of drugs and requires the state to periodically demonstrate that its expenditures comply with limits on multiple source drugs, as well as all other drugs.

Under 42 CFR 447.10 – 20 providers must agree to accept the amounts paid by the Medicaid agency as payment in full in order to participate. The federal regulation also provides for timely claim submission and payment, and prohibits reassignment of provider claims.

Providers may not refuse to furnish covered services based on non-payment of a client's copayment liability or a third party's potential liability for the services.

42 CFR 447.53 – 55 allows for the establishment of a nominal standard or fixed co-payment for any service. These regulations define maximum cost sharing amounts, list exclusions from cost sharing requirements, prohibit multiple charges for a service, set out state plan requirements for cost sharing, and allow for a cumulative maximum to be imposed.

Department of Labor and Industries

Industrial Insurance Chapter 51.04 RCW requires that L&I ensure that injured workers receive proper and necessary medical care and/or prescription drugs in a prompt, efficient and economical manner within the recognized standard of care. See also WAC 296-20-01002. L&I has a fiduciary duty to spend state-fund monies wisely while ensuring consistent and efficient access to care for injured workers and uniformity in the provision of care and treatment. Injured workers are entitled to receive proper treatment from a physician chosen by the worker.

L&I is authorized to make medical coverage decisions which are general policy decisions on health care services and supplies rendered for the purpose of diagnosis, treatment or prognosis. These decisions define the inclusion or exclusion of health care services and supplies as a covered benefit related to an industrial injury or occupational disease and insure quality of care and prompt treatment (WAC 296-20-01002).

Chapter 296-20 WAC defines average wholesale price (AWP), the reimbursement formula currently used to reimburse pharmacists for the cost of the product plus a mark-up, and baseline price (BLP), the formula currently used to calculate the mean average for all National Drug Codes by product group. These regulations provide the requirements and process to

qualify as a provider for injured workers, and delineate certain types of treatment that require prior authorization (including certain long-term prescription medications). The regulations also establish the conditions for payment of prescription drugs (i.e. drugs deemed proper and necessary to treat the industrial injury or occupational disease), the types of prescription drugs for which L&I will pay, limitations on payment for prescription drugs, and authorization requirements and coverage for opioid prescription drugs. In general, L&I will consider coverage for all FDA-approved drugs for stated indications. L&I or self-insurer may pay for prescriptions for off-label indications when used within current medical standards and when prescribed in compliance with published contraindications, precautions and warnings.

Crime Victims Compensation Program (CVC) Under RCW 7.68.130 – prescription drug reimbursement is based on Industrial Insurance Medical Aid Rules. CVC is secondary to any public or private insurance benefits.

Department of Health

APDP Federal law (Ryan White CARE Act) authorizes federal spending for therapeutics to treat HIV disease or prevent serious deterioration of health arising from HIV, including treatment of opportunistic infections and up to 5% for outreach and evaluation activities. The federal law includes eligibility, covered services, and planning criteria. Evaluation and monitoring of access and quality of care for patients is required. Chapter 246-130 WAC establishes the HIV Early Intervention Steering Committee and a process for determining how medications are considered for the formulary. Additional federal guidance directs states to provide access to treatments recommended by the federal Public Health Service Treatment Guidelines and describes required cost containment measures, data reports, and quality

standards. Funds may be used to support health insurance premiums as a mechanism for persons with HIV to access pharmaceuticals. Federal rebate rules for Ryan White AIDS Drug Assistance Programs are described in the Federal Register at 63FR35239. Chapter 246-130 WAC also describes program eligibility, services, and other features of the HIV Early Intervention Program, which includes APDP and the associated medical, laboratory, dental, and insurance services. RCW 43.70.040 provides statutory authority for the rule.

Immunization program The Omnibus Budget Reconciliation Act (OBRA) created the Vaccines for Children (VFC) program (Section 1928 of the Social Security Act) on August 10, 1993. This program provides publicly purchased vaccines for eligible children at no charge to public and private providers. It automatically covers vaccines recommended by the national Advisory Committee on Immunization Practices (ACIP). States bulk purchase vaccine at lower prices while reducing state-to-state variations in contract prices. Prior to VFC, Section 317 grant funds were the major source of support for public vaccine purchase. In the past, 317 funds were used for pediatric immunization; however, use of these funds for adolescent and adult immunization has been permitted since 1994. 317 funds are intended to supplement state and local funds, not to replace existing state spending.

Department of Corrections

Federal and state laws governing the operation of a pharmacy or the licensing of a pharmacist apply to DOC operations, including rules under the Washington State Board of Pharmacy and the federal Drug Enforcement Administration.

Department of Veterans Affairs

Federal law 38 USC 1710 & 38 CFR 51.180 requires state veterans homes to provide pharmacy services for all residents. Title XIX of The Social Security Act and 42 CFR 483.60 require Medicaid-certified nursing facilities to provide routine and emergency medications to residents. The homes are required to provide medications directly or through outside agreement. RCW 72.36.045 states that homes are responsible for maintenance of veterans and that "such maintenance shall include, but not be limited to, . . . medical and dental care, physical and occupational therapy."

Department of General Administration

Chapter 43.19 RCW grants authority to GA to provide purchasing and contracting services for all state agencies and direction on how to conduct purchases. Chapter 39.34 RCW allows any public agency of the state to exercise its powers, privileges and authority in cooperation with any other public agency. GA uses its statutory authority to purchase prescription drugs for public agencies through two current contracts. Washington is a participant in the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP), specifically established in 1988 to consolidate the pharmaceutical requirements of multiple states and to take advantage of deeper discounts commonly attributed to large volume purchases. The State of Minnesota is the lead state and administrator of the contracts awarded. MMCAP has grown to 37 participating state members. Currently, there are approximately 6,355 pharmaceutical items available from 142 manufacturers distributed to pre-authorized locations. This contract provides those public agency facilities *with in-house pharmacies and staff pharmacists* access to prescription medications at discounted prices through a contracted vendor.

In addition, GA has a second contract that provides prescription medications to public facilities in Washington *without in-house pharmacies or staff pharmacists*. The contractor provides required services to all participating state agencies and local governments across the state. Prescriptions are forwarded to the contractor by agency staff and filled and delivered the same or next day to the requesting facility.

Office of the Insurance Commissioner

States have sole authority to regulate insurance for individuals, self-funded plans of state and local governments, and church organizations. The federal government has sole authority to regulate private-sector self-funded employee plans (ERISA) and union-operated plans (Taft-Hartley Trusts). Federal and state governments have joint authority to regulate private-sector employee insured plans; federal regulation has only recently begun for this group (through HIPAA, etc.).

Under Title 48 RCW, the OIC regulates insurers operating in Washington. Drug benefit disclosure is required of carriers in their plan filings with OIC and in enrollee information. There are 22 mandated benefits (requirements that health insurers cover specific health care services or reimburse a specific type of health care provider), but only one of these mandates directly involves drug benefits. Individual coverage (RCW 48.43.041) requires insurers to include a $2,000 drug benefit in non-catastrophic individual coverage. RCW 48.43.095 requires insurers to disclose to potential enrollees the plan's drug formulary, restrictions, and cost participation.

Under the federal Civil Rights Act of 1964 title VII, 42 USC 2000e et. Seq., the U.S. Equal Employment Opportunity Commission has jurisdiction over employers with 15-or-more

employees. Employers with 15-or-more employees must provide pregnancy services to female employees, which debatably includes contraception drugs. The Washington State Human Rights Commission has jurisdiction over employers with 8-or-more employees [Chapter 49.16 RCW]. The Office of the Insurance Commissioner has jurisdiction over insurers [Chapter 48.30 RCW].

The Basic Health Plan [Chapter 70.47 RCW], the Public Employee Benefits Plan [Chapter 41.05 RCW], and Medical Assistance [Chapter 74.09 RCW] all include drug benefits, but those programs, for the most part, are not regulated by OIC. However, Basic Health and PEBB, including the UMP, are required to comply with the Patient's Bill of Rights legislation 2SSB 6199 (C 5 L 00).

Agency Contracting Authority

State laws related to agency contracting authority include Chapter 43.19 RCW (purchase of goods and services), Chapter 39.29 RCW (personal services contracting), and Chapter 39.34 RCW (the Interlocal Cooperation Act). Contracts for client services are not required to comply with the competition requirements in Chapter 43.19 RCW and Chapter 39.29 RCW. Chapter 43.19 RCW provides that health care programs operated in university hospitals, state correctional institutions and veterans' institutions may participate in contracts for materials, supplies, and equipment entered into by nonprofit cooperative hospital group purchasing organizations. These facilities and the DSHS Voc-Rehab program are exempt from the requirements of formal sealed bidding for purchasing goods and services, if they meet the statutory conditions.

Federal or State Legislation or Proposals

The following federal or state legislation or proposals were considered by the Prescription Drug Project Workgroup when making their recommendations.

2001 Federal proposals

Immediate Helping Hand Initiative (George W. Bush Administration). This proposal would provide a prescription drug benefit for all Medicare beneficiaries so that all seniors have affordable access to prescription drug coverage, including sliding scale premiums for low-income seniors. At a minimum, catastrophic prescription drug coverage would be provided for all Medicare enrollees. The program would be 100% federally funded, with flexibility for states to enhance drug coverage with a four-year sunset. This initiative does not cover clients dually eligible for Medicare and Medicaid.

Breaux/Frist Legislation S. 357 and S. 358 These proposals would restructure the Medicare program and provide outpatient prescription drug coverage. S.357 would base enrollee premiums on a sliding scale.

Democratic proposal This proposal would create an optional drug benefit for Medicare with no deductible and would allow persons 55-65 years of age the option of purchasing Medicare coverage if they are without other coverage.

2001 Regional proposals (from Washington State)

SJM 8001 - petitions the governors of Oregon, Idaho, Alaska, and Montana, and the President to form a Northwest States purchasing cooperative.

HJM 4003 requests that Congress include a prescription drug benefit in the Medicare program.

2001 Washington State Proposals

For a complete list of proposals related to prescription drugs during the 2001 Washington State legislative session, the reader is referred to Appendix A.

Potential limitations to PDP implementation

Potential limitations to the implementation of workgroup recommendations were examined, including the need for federal waivers and the adoption of statutory/regulatory changes. Potential limitations include:

State Purchased Health Care It appears the authorizing language for exploring state-purchased health care options in RCW 41.05.021(b) and RCW 70.14.050 should be sufficient statutory authority for the recommendations developed by the workgroup. However, there are two issues to be examined:

1) RCW 70.14.050 references RCW 70.14.010 (repealed in 1988) which listed the state agencies authorized to implement cost controls in RCW 70.14.050. The repeal of RCW 70.14.010 has raised an issue about the effect on RCW 41.05.021 (1)(b)(iii) and RCW 70.14.050. The repeal of RCW 70.14.010 is contained in the legislation creating the Health Care Authority, which defines the state agencies included in "state purchased health care." This suggests that RCW 70.14.010 was repealed to eliminate an unnecessary redundancy.

2) Do the provisions in RCW 41.05.026 and RCW 70.47.150 provide the necessary protections from disclosure of proprietary information submitted to the state to implement the workgroup recommendations?

Public Employees Benefits Board Chapter 41.05 RCW appears to provide sufficient authority for HCA to implement workgroup recommendations through its contracts with health plans and operations of the HCA-UMP. PEBB approval may be required to implement certain workgroup recommendations and will need to be considered as a factor during the deliberative process. In addition, the requirement that PEBB benefits be substantially equivalent to the state employees' health benefits plan in 1993 may be a limiting factor to implementation of specific workgroup recommendations. Another limiting factor could be the willingness of managed care plans to participate and contract with PEBB. The impact of access to health plan options in every county was a factor in the development of recommendations.

Basic Health Chapter 70.46 RCW appears to provide sufficient authority for HCA to implement workgroup recommendations through its contracts with managed health care systems. Under Title 48 RCW, risk bearing entities are required to be licensed and HCA uses OIC criteria for measuring financial viability of its contracted health plans. A limiting factor to implementation of workgroup recommendations could be the willingness of health plans to participate and contract with BH. The impact of access to health plan options in every county was considered as a factor in the development of recommendations. The ability of BH to provide a self-funded, self-insured safety net as an alternative is very limited under Chapter 70.47 RCW.

Community Health Services RCW 41.05.220 – The relationship of this program to the provision of prescription drug services is indirect and workgroup recommendations will not likely include the program.

DSHS-MAA It is not clear what waiver(s), if any, would be necessary to implement a coordinated or consolidated prescription drug program, which would include Medicaid, in the State of Washington. It would depend upon how "consolidated or coordinated drug program" is interpreted.

As long as there were no improper delegation of DSHS' "single state agency" authority, Medicaid could participate in a uniform, multi-agency formulary using a prior authorization system to handle requests for non-formulary drugs. If the Medicaid program did not benefit at least as much under a consolidated drug program as it currently does under the Medicaid rebate program, the consolidated drug program could be vulnerable to challenge. If management and decision-making authority were to be consolidated under one department (other than DSHS), then several waivers might be needed to deal with issues surrounding the single state agency concept. If any of DSHS' discretion to administer the Medicaid drug program were delegated to some other entity without a waiver, that could be challenged by the federal government as improper delegation of the administration of the Medicaid program and, thereby, jeopardize federal funding of the state Medicaid prescription drug program. State legislation and/or new WACs may be needed if the state is looking at implementing a supplemental drug rebate requirement on drug manufacturers.

Industrial Insurance Participation in workgroup recommendations may necessitate statutory and regulatory changes, such as changes to the requirements that purchase of and payment for prescription drugs be consistent with the fee schedule rates established by L&I. This may require changes to RCW 51.04.030, WAC 296-20-015, WAC 296-20-020, WAC 296-20-03012 through WAC 296-20-03024. Participation in an aggregate drug purchasing program

should allow L&I to continue ensuring prompt access to proper and necessary prescription drug treatment for injured workers in the most economically efficient manner. It will also ensure that only qualified providers render prescription drug treatment to injured workers. The study should consider whether participation by L&I is necessary given its current and existing obligation to ensure economic and efficient purchasing of care and treatment. L&I-CVC regulatory changes would be the same as they are for the Industrial Insurance Program.

DOH-APDP As the federal grantee for Ryan White funds, DOH is the only entity eligible to apply for and receive rebates under this agreement. If DOH-APDP consolidated purchasing with other state agencies, DOH may still need to serve as the fiscal entity for APDP rebate invoices. This issue requires further research but would not likely be an obstacle to coordinated purchasing.

DOH-Imm Vaccines purchased with VFC or 317 grant funds must be purchased using the Centers for Disease Control federal contracts. There is no federal waiver process.

Department of Corrections DOC would still be required to obtain licensing for our pharmacists and pharmacies under any workgroup recommendations. Both federal and state laws would continue to apply. With these licenses, DOC would be able to participate in a consolidated program without the need for any waiver, exception or regulatory change.

Veterans Affairs WDVA is not aware of any waivers, exceptions or regulatory changes that would be required for the agency to participate in a coordinated or consolidated prescription drug program. WDVA's ability to continue to participate in a resource sharing agreement/contract with the United States Department of Veterans Affairs (USDVA) would be affected if participation were mandated. A concern is whether the benefits will exceed those that

the agency is currently able to access through agreement with USDVA. As a provider of services, WDVA is not aware of any federal or state requirements that impede the ability to develop or use a formulary.

Department of General Administration (GA) One of the main issues to be considered relates to the absence of authority under Chapter 43.19 RCW for GA to contract on behalf of private citizens. GA could work jointly with HCA and other agencies to develop a bid and/or contract under HCA's governing statute.

There are a variety of contracting strategies that should be explored by the workgroup in order to determine the best approach to meet the specific needs of the state. One approach would be to conduct a multi-state solicitation. The approach is generally to choose a lead state in which the procurement is done under that state's procurement statutes. Several states participate in development and award of the contract. GA's Office of State Procurement is a member of the Western States Contracting Alliance (WSCA).

The purpose of WSCA is to identify opportunities where multi-state procurements will benefit all participants (because of volume discounts, like requirements, similar distribution networks, etc.). WSCA already has in place a solid foundation of standard contract terms and conditions that have been preappoved by the Attorneys for each participating state. WSCA also has written procedures that have been agreed upon by each state on how to conduct multi-state ventures, including the roles and responsibilities of each participant.

An example of a successful WSCA contract is for infant formula rebates. GA and the Washington State DOH led an effort for 21 state and tribal organizations. The most recent bid resulted in 42% savings from the previous contract. The contract was awarded to Mead Johnson

in June 2001. Mead sends rebates directly to the WIC programs in each of the participating states. Over 215,000 infants will be served by the Washington State WIC program. Contract usage is projected to be upwards of $100 million in rebates for one year.

Stakeholder Assessment

The design, implementation and maintenance of any prescription drug program includes careful consideration of stakeholder interests. Potential stakeholders related to Washington State prescription drug programs include (but are not limited to): Washington residents and/or beneficiaries served by state agencies, Washington State agencies, physicians and other licensed prescribers, pharmacists, drug manufacturers, patient advocacy groups, pharmacy benefit managers and special interest groups.

If the State of Washington establishes a coordinated or consolidated prescription drug program, several positive outcomes may be realized. These include:

- Increased access to high quality, cost-effective medications
- Improved clinical management of prescription drugs
- Improved disease management programs
- Improved coordination of benefits for clients covered by more than one agency
- Enhanced customer service
- Increased uniformity of prescription drug programs across agencies
- Improved consistency of drug utilization protocols among agencies
- Integration of quality assurance processes across agencies
- Increased administrative and contracting efficiencies
- Decreased confusion among providers regarding preferred drugs
- Increased rebate collection leading to reduced prescription drug expenditures
- Improved mechanisms to combat fraud and abuse

While pursuing these positive outcomes, suggested PDP Phase II operational tasks include (but are not limited to) consideration of issues related to patient confidentiality, individual program requirements, and agency contracting requirements. In addition, legal, policy and statutory analysis will need to be completed.

Other Prescription Drug Programs or Purchasing Models

Rising prescription drug costs have captured the attention of public and private purchasers across the nation. Many states are exploring options to control rising prescription drug expenditures. Initiatives include the development of a statewide prescription drug formulary or the formation of multi-state purchasing coalitions. The goal of many initiatives or programs is to become a high volume prescription drug purchaser. Higher volume not only produces better unit pricing, it also provides the "critical mass" needed for effective implementation of some of the more sophisticated data management and utilization control strategies. A statewide preferred drug list is pivotal in shifting market share and in motivating drug companies to provide their best rebates for all the state agencies, including Medicaid.

Several states have implemented, or are exploring, multi-agency prescription drug purchasing and management strategies within their own state. In some states, this is viewed as a potential substitute for interstate arrangements, such as those that currently link several states' prison agencies. Some states, such as Maine, are experimenting with multi-state consolidated purchasing, a statewide formulary, and expanding the pool of state residents eligible for federal Medicaid rebate pricing all at once.

A common consideration in state consolidation strategies is whether to "make or buy" the complex data systems, provider and supplier contracting, analysis, decision making, negotiating and education functions needed to manage prescription drug use and costs. A handful of pharmacy benefit management companies (PBMs) have pioneered many of the tools now in vogue for prescription drug cost control. PBMs, such as Merck Medco, Express Scripts and

Consultec, now manage pharmacy benefits for almost half the US population, including many within our own state.

Several public purchasers (or groups of purchasers) serve as models for the design, implementation, maintenance and evaluation of a prescription drug program in the state of Washington. The progress of and lessons from (at least) these programs should be monitored during the development of a consolidated or coordinated prescription drug program in the state of Washington. Such programs include:

Florida Medicaid Pharmacy Program

Florida Governor Bush's budget for 2000/01 called for a $242 million Medicaid drug budget reduction. In order to achieve this reduction, the Florida Medicaid program expanded their current contract with a Pharmacy Benefits Manager, Consultec, to provide a Therapeutic Consultation Service and an Intensive Benefits Management Program for the Florida Fee-for-Service population (1.2 million lives). Initiatives of the program and the associated estimated budget reduction are listed in Table 7.

Table 7
Estimates reductions for 2000/01 budget from Florida Medicaid initiatives

Initiative	Est. reduction (millions)
Four-Brand Rx Limit/mo.	$70.0
Drug benefit management	$41.0
Voluntary preferred drug list	$25.0
Ingredient cost adjustment	$24.1
Pharmacy network controls	$22.5
Secure prescription pads	$18.0
FDA Drug Use Guidelines	$17.5
HMO Capitation Rate Adj.	$11.5
Drug Therapy Limits	$10.0
Generic Drug Rebates	$3.0

The Florida Medicaid program, administered by Consultec, is physician-centered and physician-driven. Consultec's clinical pharmacists talk directly to the Florida physicians and review the client's entire drug profile with the prescriber each time there is a request for a fifth brand name drug. Pharmacists suggest generic alternatives to the brand name request or suggest a less expensive (preferred) drug. Pharmacists also have an opportunity to discuss duplicate drug therapy with prescribers and delete unnecessary drugs.

In two months, Consultec hired 50 pharmacists, installed computer equipment and telephones, and set up a Consultation service. They went live in four counties in August 2000 and statewide in September 2000. Initials reports of savings in the Florida Drug Program have been extraordinary. Jerry Wells, Florida Medicaid Pharmacy Program Manager, reports savings averaging $6 million per week from the four-brand prescription limit alone since the start of the program in August 2000. (Personal communication.) The 2001 Medicaid Prescribed Drug Spending Control Program Report indicated that 51% of the reported savings were due to lower drug prices and 49% were the result of reduced utilization.

Florida's 2001-02 Governor's budget calls for savings in the drug budget of $281 million. The legislature has directed Florida Medicaid to implement the following:

- Restricted drug formulary
- Supplemental manufacturers' rebates
- Mandatory preferred drug list by October 2001

Consistent with this agenda, Florida has recently completed work to garner supplemental rebates from manufacturers and has instituted a program to tackle fraud and abuse issues related to the powerful painkiller, Oxycontin.

Northern New England Tri-State Initiative

Vermont, Maine and New Hampshire have formed a purchasing coalition in order to combine covered lives and enhance purchasing power. They have contracted with a PBM to achieve improved management of pharmacy administrative practices and better management of prescription drug utilization. Specifically, these states hope to achieve 20% savings in the first year through the following strategies:

- More aggressive drug utilization controls (DUR), including hard edits on duplicates, early refills, over- and under-utilization
- Enhanced and more aggressive prior authorization
- Better controls on fraud and abuse
- Expanded utilization management reporting, education and controls
- Enhanced use of generic drugs
- Improved management of the OBRA 90 rebate process
- Better controls on third-party liability
- Better enforcement of the 'lower-of' pricing requirements

In addition to the combined efforts of this coalition, each of these states (as well as many states in the nation) are working on multiple within-state initiatives or legislation to lower drug prices for the uninsured and the elderly, combat fraud and abuse, and challenge pharmaceutical manufacturer practices related to pricing, generic drugs and direct-to-consumer advertising.

Southern States Purchasing Coalition

Representatives from the state of Washington have participated in a pharmaceutical workgroup led by Tom Susman, Director of the West Virginia Public Employees Insurance

Agency. The workgroup is directing efforts toward forming a coalition and developing a Request for Proposal for the provision of a multi-state arrangement with a PBM. Although Washington State representatives continue to participate in this workgroup, a decision has been made not to participate in the RFP process, as Washington State is still early in considering the shape and needs of its own prescription drug program.

Georgia Department of Community Health

In Summer 1999, the Georgia Department of Community Health (DCH) was formed. It administers programs to ensure the health of state employees, school personnel and retirees; as well as the aged, low-income and disabled on Medicaid. The purpose of this entity is to insure nearly two million Georgians, maximize the state's health care buying power, plan for coverage of uninsured Georgians, and coordinate health planning for state agencies. Specific components include: Division of Medical Assistance, Division of Health Planning, Division of Public Employee Health Benefits, Office of Women's Health, Office of Minority Health, and Office of Rural Health Services, the Composite State Board of Medical Examiners, Georgia Board for Physician Workforce, and the State Medical Education Board.

In February 2000, DCH developed a PBM RFP and signed a contract with Express Scripts July 2000. A statewide Preferred Drug List was developed that applied to members or beneficiaries of both the State Health Benefit Plan and Medicaid/Peach Care. The DCH program has benefit designs, drug utilization review and other processes that serve as examples should Washington State develop a program with statewide preferred drug list, P&T Committee, DUR Board and other pharmacy management processes.

Oregon Health Plan Formulary

The Oregon legislature recently passed legislation (SB 819, HB 3300) authorizing a prescription drug formulary for fee-for-service plans within the Oregon Health Plan. Of particular interest is the careful stakeholder work that appears to have been done. Support for the Oregon Formulary was garnered and publicized from at least 18 key organizations, including AARP, the National Association of the Mentally Ill – Oregon Chapter, Oregon AFL-CIO, Oregon Law Center, Oregon Medical Association, and Oregon Nurses Association. In addition, an effort was made to educate consumers on the benefits of an Oregon Formulary, emphasizing that the Oregon Health Plan fee-for-service program is the only major insurer in the state that does not use a formulary.

Tracking changes

Several organizations offer web sites that contain updated information about states' efforts to control prescription drug expenditures. The National Conference of State Legislatures (NCSL) tracks state efforts that seek to expand access to affordable prescriptions through discount programs or outright subsidies. Since January 2001, almost 300 new bills have been introduced in state legislatures. As of June 1, 2001, the NCSL website contained information on prescription drug programs in 26 states, including 20 that provide subsidies, five that provide discounts and one that provides a tax credit. A summary of new legislative proposals to create similar programs is available on the NCSL website (http://www.ncsl.org). In addition, the National Governors Association (http://www.nga.org) provides summaries of selected state programs.

Summary

The Washington State Prescription Drug Project (PDP) is an interagency effort to enhance the delivery of high-quality health care to Washington State residents and program beneficiaries through appropriate management of pharmacy benefits and control of prescription drug expenditures. Currently, six agencies serve as major purchasers of prescription drugs in the state of Washington. These include the Department of Social and Health Services (DSHS), Labor and Industries (L&I), the Health Care Authority (HCA), the Department of Health (DOH), the Department of Corrections (DOC) and the Washington Department of Veterans Affairs (WDVA).

Of the over 1.5 million individuals served by these agencies, approximately 60% (902,812) are in fee-for-service (FFS) programs. DSHS-Medical Assistance Administration, L&I Industrial Insurance and HCA-Uniform Medical Plan members combined make up 97% of the FFS population. In CY 2000, total health-related expenditures in FFS programs exceeded $2.6 billion. Of this amount, prescription drug expenditures totaled over $571 million before rebates, averaging 22% of total health-related expenditures.

Examination of the Top 100 Drug by Total Amount Paid (after rebates) for CY 2000 reveals that the top 10 drugs comprise 25% of total expenditures, and the top 25 drugs make up 39% of total expenditures. DSHS-MAA expenditures account for 86% of the Top 100 Drug expenditures for the state.

Purchasing methods used by agencies include bulk purchasing, fee-for-service and managed care plans. Some agencies use retail pharmacy networks to dispense medications to

enrollees, while other (DOC, WDVA, DOH-Imm and Eastern and Western State Hospitals) provide access to medications at specific sites.

Purchasing and reimbursement methods, as well as clinical and member services, differ based on contractual arrangements by agency. With the exception of DSHS-MAA, all programs use a formulary tailored to the needs of the population served. Many programs have federal or state funding sources.

Federal and state statutes or regulations define the structure or function of each agency's prescription drug program(s). If a consolidated prescription drug program is implemented in the state of Washington, legal or regulatory issues will need to be addressed, including federal waivers and the adoption of statutory and/or regulatory changes. In addition, key stakeholder interests will need to be considered, including but not limited to the interests and agendas of Washington residents, members served by agency programs, retail pharmacists, pharmaceutical manufacturers, special interest groups, patient advocacy groups, and pharmacy benefit managers.

During the planning, implementation and evaluation of a Washington State consolidated prescription drug program, the experience of other states and entities should be monitored for both positive and negative lessons. Currently, programs of note include the Florida Medicaid Pharmacy Program, the Northern New England Tri-State Initiative (as well as the efforts of the individual states involved), the Southern States Purchasing Coalition, the Georgia Department of Community Health, and the Oregon Health Plan Authority.

After careful assessment, the PDP Workgroup recommends the development and adoption of a statewide preferred drug list, a statewide Pharmacy and Therapeutics Committee, and a statewide Drug Utilization Review Board. In addition, the Workgroup recommends a

feasibility study to determine whether the state should buy or build pharmacy benefits management services. For entities that purchase drugs directly, the Workgroup recommends that the feasibility of a consolidated rebate program be explored.

If the state of Washington proceeds with a consolidated prescription drug program, resources will need to be directed to operationalize the program, including but not limited to identification of a lead agency, delineation of project scope and direction, funding, staffing, consultants, legal and statutory analysis, cost benefit analysis, and stakeholder work. From the beginning of any program, identification and execution of a process and summative evaluation plan is essential.

Prescription Drug Project

Phase I: Recommendations

After careful discussion, the Prescription Drug Workgroup puts forth the following recommendations, to be accomplished either through third-party contract(s) or use of existing state resources or structures:

1. Establish a statewide Pharmacy and Therapeutics (P&T) Committee to develop, implement and maintain a Washington State Preferred Drug List. The P&T Committee shall, where appropriate, seek additional expertise to address issues concerning special populations.
2. Establish a statewide Drug Utilization Review Board to develop treatment guidelines and criteria for appropriate drug use.
3. Explore the feasibility of consolidating claims processing, claims adjudication, and other pharmacy management and information services.
4. For agencies and/or programs that directly purchase drugs, explore the feasibility of implementing and maintaining a consolidated rebate program.

Prescription Drug Project

Phase II: Next Steps

PDP Workgroup suggestions for tasks in Phase II of the Prescription Drug Project include:

1. Additional analyses for development and refinement of recommendations, including but not limited to:
    - Legal and policy analysis
    - Statutory authority
    - Managed care pharmacy contracts and their relation to Recommendations 1 -4
2. Consideration of Phase II Operational Issues
    - Project direction and scope
    - Identification of lead agency
    - Administration/Management/Staffing
    - Timeline
    - Resource inventory/assessment
    - Funding
    - Evaluation plan – process and outcomes
    - Needed consultations
    - Assessment of impact of 340b program changes
    - Cost-benefit analysis
    - HIPAA considerations

- Marketing
- Stakeholder management
- Exploration of partnerships with other public or private entities

Appendix A

2001 Legislative Session Prescription Drug Proposals

(Insert accompanying MS Word doc. file)

Appendix B

Washington State Top 100 Drugs

(by Total Amount Paid after rebates)

(insert accompanying MS Word doc. file)

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APPENDIX A

2001 LEGISLATIVE SESSION
PRESCRIPTION DRUG PROPOSALS

June 29, 2001

Bill/Sponsor	Title	What Does It Propose To Do?	Status	Bill Link	Fiscal Note Link
2SHB 1774 (Pennington)	Senior Pharmacy Assistance Program	• Requires HCA administrator establish a senior pharmacy assistance program that provides financial assistance to eligible individuals who purchase drugs. Eligible individuals are those whose incomes are above the standard of Medicaid categorically needy up to 300 percent of the Federal Poverty Level (FPL). The enrollees cannot be qualified for other local, state or federal prescription drug programs, and have not canceled their participation in a public or private prescription reimbursement plan within the last 6 months. • Seniors whose incomes are between Medicaid categorically needy and 125 percent FPL are required to pay a $10 copay. • Seniors in the 125-300 percent FPL income bands are required to pay a 20 percent coinsurance. • The annual benefit per eligible enrollee is limited to $1,500 per year. • Effective date of January 1, 2002, which coincides with HCA contract renewal.	House Rules R	2SHB 1774	2SHB 1774 FN
SSB 5030 (Thibadeau)	Creating the Washington Pharmacy Access Program	• Creates the Washington Pharmacy Access Program within the HCA. • The Washington Prescription Drug Insurance Plan program is similar to BH but for pharmacy benefits only. Eligibility includes seniors who are Medicare-eligible, and are not covered under a Medicare supplement plan. • Includes a grant program for education on the use of medications and application assistance for persons 65-and-over.	Senate Ways & Means	SSB 5030	SSB 5030 FN

Bill/Sponsor	Title	What Does It Propose To Do?	Status	Bill Link	Fiscal Note Link
SB 6197 (Thibadeau)	Creating the Washington Pharmacy Access Initiative	▪ Declares that the initiative includes the following components: (1) A subsidized prescription drug insurance plan for seniors and the disabled, designed and implemented pursuant to this act; (2) Prescription drug information and education grants awarded to local organizations pursuant to this act; (3) A uniform formulary of prescription drugs and a system for prescription drug utilization review for state-purchased health care programs as provided in this act. In consultation with appropriate state agencies, the administrator may determine the extent to which the formulary or prescription drug utilization review will apply to each state-purchased health care program; (4) A system of academic detailing and consumer counterdetailing that educates physicians and other prescribers and consumers on the therapeutic and cost-effective utilization of prescription drugs. ▪ Establishes the Washington prescription drug insurance plan within the Washington pharmacy access initiative. The plan shall be actuarially sound and designed to provide eligible persons with coverage for prescription drugs and pharmacy services. Enrollment in the plan is voluntary. ▪ Provides that, by January 1, 2002, and by January 1st of each year through 2005, the administrator shall submit to the governor and the legislature a progress report regarding the implementation and impact of the pharmacy access initiative, including, where appropriate, information regarding enrollment in and the financial status of each of its components. The report shall be prepared in consultation with the agencies and organizations participating in the development of the initiative under this act, and may present recommendations for modifications to the initiative, or for additional strategies that should be pursued to provide affordable access to and promote therapeutic and cost-effective utilization of prescription drugs by residents of the state of Washington.	Senate Health & Long-Term Care	SB 6197	

Bill/Sponsor	Title	What Does It Propose To Do?	Status	Bill Link	Fiscal Note Link
SB 6200 (Franklin)	Prescription Drug Price Reduction	▪ Declares an intent to make prescription drugs more affordable for qualified Washington residents, thereby increasing the overall health of Washington residents, promoting healthy communities, and protecting the public health and welfare of Washington residents. ▪ Creates the prescription drug advisory commission to review access to and pricing of prescription drugs for state residents, to advise the secretary on prescription drug pricing and to provide periodic reports to the secretary, the governor, and the legislature.	Senate Health & Long-Term Care	SB 6200	
SB 6201 (Franklin)	Prescription Drug Fair Pricing Act	Declares an intent to create a program whereby the state acts as a participant in the prescription drug marketplace, negotiating voluntary rebates from drug companies and using the funds to make prescription drugs more affordable to Washington residents. Such a program will improve public health and welfare, promote the economic strength of our society, and substantially benefit state health assistance programs, including the Medicaid program.	Senate Health & Long-Term Care	SB 6201	
HJM 4003 (Marine)	Prescription Drugs	Requests Congress to include a prescription drug benefit to the Medicare program giving senior citizens access to necessary and life-giving medication.	House Rules X	HJM 4003	
SHB 1652 (Cody)	Developing a Therapeutic & Cost-effective Drug Education & Utilization System	Effective July 1, 2001 the administrator of Health Care Authority (HCA) is to develop, with state and local agencies and private parties, a therapeutic and cost-effective prescription drug education and utilization system that includes: • a prescription drug uniform formulary and a system for utilization review for state purchased health care programs determined by the administrator and appropriate management of state agencies; • a program that educates physicians, other purchasers and consumers on therapeutic and cost-effective use of prescription drugs; • recommendations for continuing medical education for physicians and health care professionals who prescribe, dispense, or administer prescription drugs; • two pilot disease management programs for persons covered through state-purchased health care programs.	House App.	SHB 1652	SHB 1652 FN

Bill/Sponsor	Title	What Does It Propose To Do?	Status	Bill Link	Fiscal Note Link
SB 5026 (Franklin)	Creating the Aggregate Purchasing Prescription Drug Discount Program	• Effective date "no later than 7/1/02" • Requires the HCA to create a new prescription drug discount program. • After 7/2/02, no state program that provides prescription drugs may purchase them from a supplier that does not have an agreement with the state discount program.	Senate Health & Long Term Care	SB 5026	SB 5026 FN
SB 5027 (Franklin)	Providing for a Study of the Feasibility of Aggregating the Purchase & Distribution of Prescription Drugs	• Directs HCA and DSHS to contract with an independent entity to conduct a study to determine the feasibility of aggregating the purchase and distribution of prescription drugs for state, county and local government programs, and for uninsured or underinsured residents. • A report is due to the legislature and governor 18 months from the funding date. • Appropriates specific funds for the study.	Senate Health & Long Term Care	SB 5027	SB 5027 FN
HB 1703 (Conway)	Creating the Prescription Drug Fair Pricing Act	• Requires GA to establish a prescription drug price program. GA will negotiate rebates with drug manufacturers or labelers. All residents of the state are eligible to participate in the program. GA will establish discounted prices for drugs covered by a rebate agreement and will promote the use of efficacious and reduced-cost drugs for program participants. • Effective 07/01/0, retail pharmacies will offer prescription drugs at or below the average wholesale price minus 6%, plus a dispensing fee. After 01/01/02, retail pharmacies will offer prescription drugs at or below the price levels set in July 2001 minus the amount of any rebate paid by the state to the pharmacy. • A prescription drug price account is established in the state treasury. Receipts from revenue paid by manufacturers who pay rebates will be deposited into the account. Expenditures from the account will be used to reimburse pharmacies & offset the costs of the department administering the program.	House Health Care	HB 1703	HB 1703 FN
SJM 8001 (Franklin)	Prescription Drug Cooperative Program	• Petitions governors of Oregon, Idaho, Alaska, and Montana, and President to form a Northwest States purchasing cooperative.	Senate Rules 3	SJM 8001	
HB 1550 (Pflug)	Establishing a Drug Utilization Review Program	• Creates a drug utilization review board for MAA and authorizes MAA to contract with a pharmacy manager for all their programs.	House Health Care	HB 1550	

Bill/Sponsor	Title	What Does It Propose To Do?	Status	Bill Link	Fiscal Note Link
HB 1645 (Schual-Berke) See SB 6082	Establishing a Drug Utilization Review Program	• Directs DSHS MAA to administer its prescription drug prior authorization & drug utilization programs to ensure beneficiaries have access to medically necessary medicines, giving primary consideration to clinical efficacy & client care. • Cost-effectiveness may be considered where such consideration would not jeopardize beneficiary access to clinically efficacious prescription drugs.	House Health Care	HB 1645	HB 1645 FN
SB 6082 (Patterson) See HB 1645	Establishing a Drug Utilization Review Program	• Directs DSHS MAA to administer its prescription drug prior authorization & drug utilization programs in a manner that ensures that beneficiaries have access to medically necessary medicines, giving primary consideration to clinical efficacy & client care. • Cost-effectiveness may be considered where such consideration would not jeopardize beneficiary access to clinically efficacious prescription drugs.	Senate Health & Long Term Care	SB 6082	SB 6082 FN
HB 2022 (Alexander)	Prohibiting Therapeutic Substitution	• Declares that "therapeutic substitution" means the dispensing of a therapeutic alternative or preferred drug instead of the original drug product prescribed, in accordance with either established written therapeutic interchange guidelines or protocols from the prescriber for the pharmacist to follow or as a result of a patient-specific consultation between the pharmacist and the prescriber. • Provides that DSHS MAA shall not restrict access to prescription medication through therapeutic substitution or similar programs.	House Health Care	HB 2022	HB 2022 FN
HB 1720 (Edwards)	Seeking a Federal Medicaid Demonstration Waiver for Prescription Drug Assistance	• Requires DSHS to submit, and upon approval, to implement a section 1115 demonstration waiver request to establish a prescription drug assistance program.	House Health Care	HB 1720	
HB 1753 (Ballasiotes)	Medication Outreach Program	• Directs DSHS to establish a medication outreach program that shall: ▪ assist eligible persons (65 years of age +) enroll in the state medical assistance program under this chapter; ▪ assist residents of the state to obtain free or low cost prescription or nonprescription medications from private and public sources that offer this assistance. • Medication outreach program assistance should include telephone numbers for sources of assistance, instructional material for completing eligibility forms, and generally evaluating the possibility of an individual obtaining assistance.	House App.	HB 1753	HB 1753 FN

Bill/Sponsor	Title	What Does It Propose To Do?	Status	Bill Link	Fiscal Note Link
HB 1319 (Campbell)	Attempting to Ensure the Availability of Affordable Prescription Drugs	• Title Only. Declares an intent to pursue strategies that will ensure the availability of affordable prescription drugs to citizens covered or not covered by state health care programs.	House Health Care	HB 1319	
SSB 5462 (Costa)	Contraceptive Health Services	• Requires coverage for all prescription contraceptive drugs and devices approved by the FDA, even if using a closed formulary, and of all outpatient contraceptive services.	Senate Rules 2	SSB 5462	SSB 5462 FN
SB 5708 (Patterson)	Alcohol & Drug Use Insurance	• The law allowing individual disability insurance policies to deny payment for the treatment of injuries sustained as a consequence of the insured person being intoxicated or under the influence of a narcotic is repealed. • All health carriers are explicitly prohibited from denying coverage for the treatment of an injury solely because the injury was sustained as a consequence of the insured person being intoxicated or under the influence of alcohol.	Senate Rules 3	SB 5708	SB 5708 FN
SB 5960 (Parlette)	Exception to "Learned Intermediary Doctrine" for Prescription Products	• Intent is to create an exception to the learned intermediary doctrine for prescription products advertised directly to consumers. • The manufacturer of a prescription product that is advertised directly to consumers in this state, who would otherwise be liable for harm caused by the product, is not relieved of that liability solely because the manufacturer warned the practitioner who prescribed the product of its proper use and attendant dangers.	Senate Rules 2	SB 5960	
SHB 1301 (Cody) (ESSB 5566) (Thibadeau)	Requiring Uniform Prescription Drug Information Cards	• Requires health carriers that provide coverage for prescription drugs provided on an outpatient basis & issues a card or other technology for claims processing, or an administrator of a health benefit plan including, but not limited to, third-party administrators for self-insured plans, pharmacy benefits managers, and state administered plans, shall issue to its enrollees a pharmacy identification card or other technology containing all information required for proper claims adjudication. • Declares that this act applies to health benefit plans that are delivered, issued for delivery, or renewed on or after 07/01/03.	House Rules X	SHB 1301	SHB 1301 FN

Bill/Sponsor	Title	What Does It Propose To Do?	Status	Bill Link	Fiscal Note Link
ESSB 5566 (Thibadeau) (HB 1301) (Cody)	Prescription Drug Information Card	• A health carrier that provides coverage for prescription drugs provided on an outpatient basis and issues a card or other technology for claims processing, or an administrator of a health benefit plan including, but not limited to, third-party administrators for self-insured plans, pharmacy benefits managers, and state administered plans, shall issue to its enrollees a pharmacy identification card or other technology containing all information required for proper prescription drug claims adjudication. • Upon renewal of the health benefit plan, information on the pharmacy identification card or other technology shall be updated by the health carrier or other entity that issues the card. • Nothing in this section shall be construed to require any health carrier or administrator of a health benefit plan to issue a pharmacy identification card or other technology separate from another identification card issued to an enrollee under the health benefit plan if the identification card contains all of the information required. • This section applies to health benefit plans that are delivered, issued for delivery, or renewed on or after July 1, 2003. • For the purposes of this section, renewal of a health benefit policy, contract, or plan occurs on each anniversary of the date on which coverage was first effective on the person or persons covered by the health benefit plan. • The insurance commissioner may adopt rules to implement this act, taking into consideration any relevant standards developed by the national council for prescription drug programs and the requirements of the federal health insurance portability and accountability act of 1996.	C 106 L 01	ESSB 5566	ESSB 5566 FN

Appendix B

Washington State Top 100 Drugs
(by Total Amount Paid after rebates)

Drug Name	Therapeutic Class	Total Amount Paid
1. Zyprexa	Antipsychotic	$25,921,641.34
2. Prilosec	Ulcer Therapy	$15,552,686.80
3. Risperdal	Antipsychotic	$13,001,220.95
4. Neurontin	Anticonvulsant	$11,753,984.84
5. Prevacid	Ulcer Therapy	$11,571,524.41
6. Oxycontin	Narcotic Analgesic	$10,343,132.42
7. Prozac	Antidepressant	$9,809,598.52
8. Zoloft	Antidepressant	$8,914,573.14
9. Paxil	Antidepressant	$8,691,633.74
10. Depakote	Anticonvulsant	$8,183,127.04
	Top 10 Total	$123,743,123.20
11. Lipitor	Lipid/Cholesterol Lowering Agent	$7,321,377.06
12. Celebrex	NSAID/Cox-II Inhibitor	$6,184,934.44
13. Buspar	Anti-Anxiety	$5,475,294.00
14. Glucophage	Diabetes Therapy	$5,287,261.24
15. Clozaril	Antipsychotic	$4,630,602.40
16. Duragesic	Narcotic Analgesic	$4,446,883.50
17. Vioxx	NSAID/Cox-II Inhibitor	$4,303,271.57
18. Seroquel	Antipsychotic	$4,130,200.17
19. Norvasc	Antihypertensive	$3,954,706.79
20. Zocor	Lipid/Cholesterol Lowering Agent	$3,903,192.82
21. Wellbutrin SR	Antidepressant	$3,599,506.90
22. Effexor XR	Antidepressant	$3,333,265.02
23. Pepcid	Ulcer Therapy	$3,303,093.76
24. Premarin	Hormone Replacement	$3,034,448.72
25. Enbrel	Rheumatoid Arthritis	$3,021,268.24
	Top 25 Total	$189,672,429.83
26. Hydrocodone w/Acetominophen	Narcotic Analgesic	$3,013,669.64
27. Ultram	Non-Narcotic Analgesic	$2,979,359.49
28. Celexa	Antidepressant	$2,912,566.58
29. Flovent	Asthma/Allergy Therapy	$2,902,125.88
30. Lorazepam	Anxiolytic	$2,739,508.12

31. Claritin	Asthma/Allergy Therapy	$2,664,012.48
32. Remeron	Antidepressant	$2,595,317.35
33. Combivir	HIV/AIDS Therapy	$2,570,173.48
34. Augmentin	Antibiotic	$2,534,885.39
35. Viracept	HIV/AIDS Therapy	$2,511,649.91
36. Clozapine	Antipsychotic	$2,451,653.52
37. Zestril	Antihypertensive	$2,438,942.18
38. Imitrex	Migraine Headache Therapy	$2,348,491.05
39. Zerit	HIV/AIDS Therapy	$2,261,036.87
40. Ranitidine HCl	Ulcer Therapy	$2,164,155.11
41. Lamictal	Antifungal	$2,126,802.55
42. Pravachol	Lipid/Cholesterol Lowering Agent	$2,124,114.69
43. Clonazepam	Anticonvulsant	$2,100,071.75
44. Zithromax	Antibiotic	$2,052,942.89
45. Cipro	Antibiotic	$2,039,179.30
46. MS Contin	Narcotic Analgesic	$2,036,435.31
47. Epivir	HIV/AIDS Therapy	$2,033,422.06
48. One Touch Test Strips	Diabetes Therapy	$2,011,354.24
49. Avandia	Diabetes Therapy	$1,956,519.44
50. Topamax	Anticonvulsant	$1,929,100.06

Top 50 Total $249,169,919.17

51. Avonex Administration Pack	Multiple Sclerosis	$1,894,264.54
52. Serzone	Antidepressant	$1,857,912.28
53. Serevent	Asthma/Allergy Therapy	$1,827,008.85
54. Albuterol	Asthma/Allergy Therapy	$1,806,375.27
55. Ambien	Sedative/Hypnotic	$1,767,544.53
56. Plavix	Coagulation Therapy	$1,753,018.34
57. Rebetron	Hepatitis C	$1,734,472.60
58. Levaquin	Antibiotic	$1,725,431.27
59. Relafen	NSAID	$1,721,894.56
60. Zofran	Antiemetic	$1,681,057.54
61. Prinivil	Antihypertensive	$1,631,625.96
62. Procrit	Myeloid Stimulant	$1,564,115.44
63. Axid	Ulcer Therapy	$1,530,847.43
64. Zyrtec	Asthma/Allergy Therapy	$1,529,890.17
65. Fosamax	Osteoporosis Therapy	$1,504,487.93
66. Detrol	Urological	$1,490,339.64
67. Allegra	Asthma/Allergy Therapy	$1,481,702.49
68. Neoral	Immunosuppresant Therapy	$1,471,863.87
69. Carisoprodol	Musculoskeletal	$1,465,253.43

70.	Sustiva	HIV/AIDS Therapy	$1,416,335.40
71.	Aricept	Alzheimers	$1,388,282.44
72.	Diflucan	Antifungal	$1,385,849.93
73.	Actos	Diabetes Therapy	$1,359,406.63
74.	Azmacort	Asthma/Allergy Therapy	$1,340,799.66
75.	Singulair	Asthma/Allergy Therapy	$1,303,594.65

Top 75 Total $288,803,294.02

76.	Recombinate	Coagulation Therapy	$1,288,585.90
77.	Vasotec	Antihypertensive	$1,281,936.24
78.	Cozaar	Antihypertensive	$1,278,470.23
79.	Luvox	Antidepressant	$1,270,269.91
80.	Flonase	Asthma/Allergy Therapy	$1,250,041.04
81.	Dilantin	Anticonvulsant	$1,231,612.18
82.	Prempro	Hormone Replacement	$1,224,500.84
83.	Coumadin	Coagulation Therapy	$1,186,857.44
84.	Marinol	Antiemetic	$1,182,971.77
85.	Ipratropium Bromide	Asthma/Allergy Therapy	$1,175,037.42
86.	Atrovent	Asthma/Allergy Therapy	$1,174,170.91
87.	Cellcept	Immunosuppresant Therapy	$1,155,307.39
88.	Kogenate	Coagulation Therapy	$1,152,677.86
89.	Lotensin	Antihypertensive	$1,126,088.24
90.	Combivent	Asthma/Allergy Therapy	$1,114,510.24
91.	Trazodone HCl	Antidepressant	$1,110,280.05
92.	Humulin 70/30	Diabetes Therapy	$1,087,387.15
93.	Miacalcin	Osteoporosis Therapy	$1,087,082.81
94.	Humulin N	Diabetes Therapy	$1,086,628.89
95.	Neupogen	Myeloid Stimulant	$1,071,129.94
96.	Lovenox	Coagulation Therapy	$1,030,738.08
97.	Furosemide	Antihypertensive	$1,016,712.29
98.	Prograf	Myeloid Stimulant	$1,008,696.42
99.	Potassium Chloride	Electrolyte Replacement	$966,184.41
100.	Novolin 70/30	Diabetes Therapy	$921,740.31

Top 100 Total $317,282,911.98

APPENDIX D
NASHP REPORT

NASHP
NATIONAL ACADEMY FOR STATE HEALTH POLICY

States and the Rising Cost of Pharmaceuticals: A Call to Action

NASHP's Pharmacy Costs Work Group

Acknowledgments

Two papers were foundational to this report. Ellen Schneiter's "States and Prescription Drugs: An Overview of State Programs to Rein in Costs," provided a summary of current state actions and provided a baseline for the National Academy for State Health Policy's Work Group deliberations. Jane Horvath's "Sustainability of Prescription Drug Prices: Policy Options for States" provided important background about the pharmaceutical industry and introduced most of the concepts included here. That paper, and Horvath's guidance, were critical to this work.

NASHP staff had analytical help from Ameet Sarpatwari, J.D., Ph.D., Instructor in Medicine at Harvard Medical School and assistant director of the Program on Regulation, Therapeutics, and Law (PORTAL) in the Division of Pharmacoepidemiology & Pharmacoeconomics at Brigham and Women's Hospital.

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Background

States have a big stake in the rising costs of pharmaceuticals. They have broad regulatory responsibilities for consumer protection and they are significant purchasers of pharmaceuticals for Medicaid, corrections, public employees, and higher education constituents.

The Work Group found the industry's business model relies on price over volume to generate revenue. This skewed reliance creates:

- Record drug launch prices
- High annual price increases across all of a company's products
- Exorbitant price spikes for products with exclusive market positions – including drugs no longer protected by patents[1]

In 2013, the cost to insure 2.7 million public employees and their families was $31 billion, including employee contributions. Assuming public employer plans reflect those in the private sector, drug spending makes up 19 percent of health plan costs.[2]

Medicaid now covers 70 million beneficiaries, making it the largest insurer in the country, and it spent $27 billion in 2014 on outpatient drugs (state and federal share), including rebates and managed care plans. After years of slow growth, spending on drugs increased 24.6 percent in states that expanded Medicaid and 14.1 percent in non-expansion states. Drug coverage now represents 6 percent[3] of total Medicaid spending, and this does not include the cost of physician-administered drugs.[4]

Additionally, states face significant costs for prescription drugs used to treat inmates in state corrections institutions, accounting for nearly $8 billion in spending 2011. This figure did not include new, costly drugs such as new Hepatitis C medications.[5]

States have worked hard to contain the cost of prescription medicines by employing strategies, summarized in an earlier National Academy for State Health Policy (NASHP) paper,[6] such as negotiating supplemental rebates for Medicaid programs, implementing preferred drug lists (PDL) and utilizing pharmacy benefits managers and more.[7] Despite these efforts to maintain affordability, drug pricing and the unpredictability of price increases continues to vex state budgets.

Consumers are also feeling the pinch. Seventy percent of all Americans take at least one prescription medicine. In 2012, consumers paid out-of-pocket for about 18 percent of retail prescription drugs purchased.[8] As a result, state leaders are sensitive to public calls for government action to rein in drug prices. Seventy-eight percent of Americans favor limiting what companies can charge for high-cost drugs and more than two-thirds support re-importation of pharmaceutical drugs from Canada.[9]

The confluence of growing public support for action and the pressure of rising prices on state budgets that must be balanced has led state officials to seek new and sustainable strategies to constrain the high cost of pharmaceuticals. States have long been the laboratories of innovative health care reform in this country and were responsible for:

- Creating children's health coverage long before the Congress enacted the Children's Health Insurance Program (CHIP);
- Enacting insurance reforms before the federal Health Insurance Portability and Accounting Act (HIPAA) was enacted;

- Subsidizing health coverage and requiring insurers to meet standards of coverage and cost long before the Affordable Care Act (ACA) was established.

Now, states are tackling the issue of rising drug prices.

About the Work Group

NASHP convened a Pharmacy Costs Work Group of state leaders from governors' staffs, state legislatures, Medicaid, public employees health insurance programs, offices of attorneys general, state-based insurance exchanges, comptrollers' offices and corrections departments. Their job was to apply their unique perspectives and expertise to find new approaches to limit pharmaceutical costs. The Work Group recognized that rising and unpredictable costs were straining state budgets; but members were careful to balance that expense against the value that drugs provide while acknowledging the importance of the pharmaceutical industry to jobs and the economy. The Work Group examined the many levers state governments have as policymakers, regulators and purchasers of drugs. Participants recognized that without thoughtful policy reform, states could find themselves confronted with poor but necessary choices when balancing future budgets. Members acknowledged, for example, that drug coverage is an optional benefit under Medicaid and unless there is relief, states may be forced to review the sustainability of that benefit.

The Work Group believes the industry, to stay competitive, views high launch prices for new drugs as an opportunity to raise prices of older, therapeutically-competitive products. Competitors with drugs in the same class tend to raise prices by similar amounts as they mirror each other's pricing practices. Instead of competition holding down prices, competitors match each other's price increases.

State payers' efforts to negotiate discounts achieve only modest reductions in this rising tide of prices. Current state approaches do not make pharmaceuticals affordable, nor do they effectively incentivize the industry to change these current practices.

The Work Group understands that the basic pharmaceutical business model is built on three pillars:

- The drive to bring new products to market
- Promoting strong sales of those debut products
- Pricing products aggressively to maximize revenue throughout the product's lifecycle

These three driving forces underlying the pharmaceutical business model operate within an ever-changing business climate fueled by:

- The rising cost of bringing new therapeutic innovations to market;
- The need to accelerate scientific advances, which creates more branded competition than ever before;
- New barriers to successful market entry/market launch, such as prior authorization, litigation intended to block the introduction of biosimilars, high patient cost sharing and limited drug formularies;
- Unprecedented levels of generic competition in most therapeutic classes.

This constellation of new and old market dynamics has led to changes in pharmaceutical research and development (R&D). The industry is migrating to developing products for smaller patient populations, which means price becomes more important to revenue than volume. As a result, the industry now relies on high launch prices and annual price increases across their portfolios to generate revenue and returns for shareholders. States, as large drug purchasers, generally negotiate discounts against those high launch prices and against annual price increases, but they are powerless to change the trajectory of the industry pricing model.

State governments operate with no ability to deficit spend and face uncertain tax revenues year to year. States also tend to purchase health care in silos – each state agency or department may make different purchasing decisions and negotiate different deals. State governments must balance budgets and provide for the health, safety and general welfare of their citizens, but they also share an interest in sustaining the drug industry's incentive for innovation. This balancing act requires new approaches to drug pricing, spending and utilization.

Summary of Policy Options

As a result of its research and deliberations, the Work Group identified a range of policy options for states to consider -- from regulatory interventions to more market-oriented approaches -- to tackle rising drug prices. Some of the policy ideas require federal government support to implement, others are relatively novel. Some of the policy approaches require more discussion and development and our goal is to promote that public discussion. The market-oriented approaches are intended to change states' approaches to purchasing and the industry's approach to the market to achieve a middle ground where both states and the pharmaceutical industry can succeed.

These policy options include:

- Increase price transparency to create public visibility and accountability;
- Create a public utility model to oversee in-state drug prices;
- Bulk purchase and distribution of high-priced, broadly-indicated drugs that protect public health;
- Utilize state unfair trade and consumer protection laws to address high drug prices
- Seek the ability to re-import drugs from Canada on a state-by-state basis;
- Pursue Medicaid waivers and legislative changes to promote greater purchasing flexibility;
- Enable states to operate as pharmacy benefit managers to broaden their purchasing and negotiating powers;
- Pursue return on investment pricing and forward financing approaches to allow flexible financing based on long-term, avoided costs;
- Ensure state participation in Medicare Part D through Employer Group Waiver Plans;
- Protect consumers against misleading marketing;
- Use shareholder activism through state pension funds to influence pharmaceutical company actions.

The proposals in this paper require more dialogue, debate, development and experimentation. These policy proposals may not be appropriate for all states or agencies, nor for every pharmaceutical product. But states need to act and this paper presents a toolbox of options to consider. It may be appropriate to combine different policy options to maximize their benefits and effectiveness in order to control drug spending.

Strategy One: Increase Drug Price Transparency

Promoting greater transparency in the current opaque pricing and payment environment may be a helpful first-step to address rising prescription drug costs. While not a complete panacea, these efforts can give states critical information for more effective decision-making, and it can provide the data needed to implement other strategies.

In this spirit, a number of states[10] have proposed prescription drug price transparency laws that include one or more of the following mandated reporting strategies:

- Require manufacturers to provide cost data related to the development and marketing of a particular drug or group of drugs, such as high-priced drugs that cost $10,000 or more per treatment;
- Require manufacturers to publicly report and justify price increases for in-market drugs; and/or
- Require disclosure of price discounts provided by the manufacturer to healthcare entities in the state.

The strengths and weaknesses of these reporting requirements designed to increase drug price transparency are addressed below.

Drug Development Cost Reporting

Proponents of mandatory drug development cost reporting argue it would help states determine whether prices are fair, and enable them to negotiate better terms when they are not. While additional leverage may be possible, there are challenges inherent in requiring manufacturers to report R&D costs for a drug's development.[11] R&D budgets within a company are allocated across different therapeutic areas, and only 12 out of every 100 molecules that undergo testing make it to market.[12] Revenues from successful products are used not just to pay the cost of that one successful drug's development, but rather to support ongoing R&D efforts for all company's products. In short, drug pricing is based more on what the market will bear than on actual cost to a manufacturer.

It may be more useful for states to require pricing documentation, such as a manufacturer's analyses of what the market will bear given its current and anticipated product competition, for select high-priced drugs. Manufacturers will no doubt argue that this information is proprietary. However, launch prices are public, and how manufacturers arrive at these prices may be less proprietary than data on drug-specific spending for R&D or marketing.

Requiring Justification of Price Increases

Requiring justification for price increases could temper their frequency and degree. Vermont recently enacted a law that requires manufacturers of high-priced medications to justify their price increases to achieve this objective. This strategy might involve implementation of a price increase threshold above

which reporting would be required – necessary given the impracticality of reviewing all price increases – which could prompt manufacturers to keep their price increases below the review threshold. Without additional oversight measures, though, gaming would still be possible. To compensate for manufacturers' inability to increase prices throughout the lifecycle of a drug, manufacturers could simply avoid the rate increase review by inflating their drugs' launch prices. To avoid this, states could implement both price increase justification requirements with launch price determination reporting described above.

Public Disclosure of Price Discounts and Rebates

It is an open question whether public disclosure of price discounts and rebates would benefit states and consumers. Were the pharmaceutical market a zero-sum game, such disclosures could result in closer clustering around a drug's mean price, with some payers paying higher net drug prices than before and some lower. It is possible, though, that greater savings for some need not come at the expense of others. Indeed, were manufacturers able to extract additional revenue from a particular payer, market economics suggest that they would have already done so.

Confidential Disclosure of Price Discounts and Rebates to States

Regardless of the merits of public disclosure, knowledge about what contributes to surging prices, what profit is extracted by middlemen, and what incentives promote high-cost medication sales would help states develop and prioritize policy solutions to limit drug costs. This transparency could be achieved by imposing confidential reporting requirements on manufacturers, pharmacy benefits managers and 340B programs (a federal program that requires manufacturers to provide drugs to eligible healthcare organizations at reduced prices). States already have similar mechanisms in place for reporting sensitive information to insurance departments. Specifically, the following information could be mandated and used to inform states' cost-saving strategies.

- The net drug prices charged to state payers (e.g., Medicaid managed care plans) and their payers in the state;
- Drug-specific rebates offered to pharmacy benefits managers in the state;
- Drug-specific savings passed on to 340B programs in the state.

Strategy Two: Create a Public Utility Model to Oversee Drug Prices

States could regulate the pharmaceutical industry as a public utility. Examples of this regulatory approach include widely-implemented rate reviews and approval mechanisms for electricity and gas. Within healthcare, states already review health insurance premiums and can accept or reject proposed annual increases exceeding 10 percent.[13]

Under a public utility model, states could create a drug price review board to review, approve or adjust launch prices for all newly-approved drugs, or drugs with list prices above a certain dollar threshold. The board could also review price increases for brand or generic drugs that exceed a certain threshold (e.g., 10 percent for brand-name drugs and 20 percent for generics). As part of this review, the board could hold open hearings, review data submitted by manufacturers and collect other publicly-available information. It could also direct new research to assess the appropriateness of specific launch prices or price increases. Public utility commissions are typically funded in part by fees placed on the regulated industry.

States could structure their review boards in a number of ways. One model would be to create a standing committee with specified terms and advisors with expertise in different therapeutic categories, both of which would include patients, healthcare providers, pharmacists, clinical researchers and payers' medical officers. Several states already have cost review boards that provide the infrastructure needed to support pharmaceutical price review.

Legally, states have considerable discretion to exercise their police power to protect consumers of essential goods and services in markets that do not operate well or rely on a monopoly supplier. Prescription drugs are an essential good; they are as necessary to quality of life -- and life itself -- as water and sanitation. The prescription drug market does not operate well for most consumers, in large part due to federally-granted market exclusivities that enable manufacturers to charge monopolistic prices. [14]

Under a public utility framework, states would be responsible for setting reasonable rates for drug manufacturers. On this issue, states would have substantial flexibility. As the Supreme Court held in Federal Power Commission v. Natural Gas Pipeline Co. of America:

> *The Constitution does not bind ratemaking bodies to the service of any single formula or combination of formulas. Agencies to whom this legislative power has been delegated are free, within the ambit of their statutory authority, to make the pragmatic adjustments which may be called for by particular circumstances. Once a fair hearing has been given, proper findings made, and other statutory requirements satisfied, the courts cannot intervene in the absence of a clear showing that the limits of due process have been overstepped.*[15]

Of course, manufacturers could always elect to exit markets in which regulatory price setting is used, choosing not to supply drugs subject to price controls. While the possibility of such an outcome may be greater in smaller states with less purchasing power, it is currently threatened in the event that California passes Proposition 61 on November 8, 2016, which would require manufacturers to offer state payers the same prices as the U.S. Department of Veterans Affairs. The likelihood of a manufacturer opting to completely exit a state's marketplace, though, has not been tested.

Public utility price setting may also have implications for state Medicaid programs. If a board were to set the price of a drug less than 76.9 percent of its average manufacturer price, the federal Medicaid best-price provision could be triggered, which would require the drug's manufacturer to offer the same price to state Medicaid programs throughout the country. Similarly, were a manufacturer to refuse to supply a drug to a state or state payers at a board-set price, the state Medicaid program would likely have to continue providing the drug under a federal rebate agreement. Medicaid issues are addressed later in this paper.

Strategy Three: Bulk-Purchase Drugs That Protect Public Health

Two models exist for this proposal: the federal Vaccines for Children (VFC) program and another, more recent, initiative to make naloxone, a generic drug that reverses the effects of an opioid overdose, more widely available.

Vaccines for Children (VFC) Model: The VFC is a program, implemented in the 1990s, designed to improve vaccination of children who are:

- Enrolled in Medicaid
- Uninsured, or
- Under-insured by private plans that do not adequately cover childhood vaccines

Because vaccine costs limited public access to this vital preventive healthcare resource, the program was designed to constrain price increases. The legislation achieved this by limiting the annual price increases of vaccines in existence at the inception of the program, which the program covered.

Under the program, the U.S. Centers for Disease Control and Prevention (CDC) negotiates bulk purchase of vaccines directly from manufacturers. The vaccine products are shipped to states, which distribute them to participating healthcare providers who administer the vaccines and agree not to charge for the products. Central contracting allows drug manufacturers to anticipate production needs and avoid the labor and cost of distributing products to communities with the greatest need because the CDC and states track where the vaccines are most needed.

Naloxone Initiative: Opioid addiction is a public health crisis. Numerous states are working to make naloxone readily available to emergency responders and to family and friends of known opioid users so they can effectively respond to overdose situations. Manufacturers have capitalized on this increased demand by raising naloxone prices from 92 cents to more than $30 a dose over the last decade. A new auto-injector version[16] costs more than $2,000 a dose.

To blunt the impact of these price increases, some states have authorized bulk purchasing and distribution of naloxone. Under this model, legislation generally authorizes one state agency – often the state Attorney General's office – to negotiate the bulk purchase price of the drug. The drug is then made available to a variety of state and municipal purchasers, such as schools, jails, police departments and, in some instances, privately-insured groups. The purchase is generally funded from a trust, which in turn is funded by fees levied on the participating groups based on the number of drug units used during a prior period. Purchasers wishing to gain access to the preferential pricing are required to pay those fees into the trust; there is no mandate imposed on private sector participants. Manufacturers, in turn, gain ready access to a large patient population.

These two programs provide models for new approaches to fund and distribute drugs critical to public health.

Today, Hepatitis C is considered a major public health threat - curing the disease and halting its spread is essential. There are new medications available that, in some patients, cure this disease more than 90 percent of the time. However, the cost of the new drugs is staggering, threatening the budgets of state health programs and private insurers alike. For example, the wholesale cost of one of the drugs, is more than $1,000 per pill and it is usually taken daily for eight and 24 weeks. Similarly, the rapidly-escalating cost of the leading emergency response treatment for people experiencing anaphylaxis has become a pressing public health concern. The price increased 15 times since 2009, from $124 to $609. The manufacturer's recent introduction of an "authorized generic" version of the product has done little to alleviate cost concerns.

States and the federal government could adapt the VFC model for drugs that are critical to public health. States could negotiate favorable prices for high-priority drugs and also ensure their availability for their citizens. This includes Medicaid and CHIP enrollees, state employees and retirees and prison populations. States can also leverage their negotiating position and improve price, supply and accessibility of those same drugs for other groups. Just as the VFC program makes vaccine available and affordable to a large number of children outside of publicly-sponsored programs, a VFC-like program for other critical pharmaceuticals could expand access to other state populations and state-sponsored coverage programs.

It is not clear, however, whether the U.S. Department of Health and Human Services (DHHS) and CDC currently have the legal authority to create this type of program at the federal level for non-vaccine drugs. Congressional action may be needed. In contrast to the VFC program that makes free vaccines available to eligible children, a new, hybrid model could be structured with states and commercial payers covering the costs they currently bear without any federal assistance. In the absence of federal action, states acting individually or together, could create such a program.

The "naloxone initiative" could be adapted to pay for other critical drugs, including drugs used to treat life-threatening chronic conditions such as Hepatitis C or acute allergies. Enabling legislation would have to be amended or enacted to broaden a state's scope of authority beyond naloxone (in those states that adapted these statutes) to encompass other critically important drugs.

Strategy Four: Utilize Consumer Protection Laws

The concept of unfair trade practices or commercial conduct is not new and is generally outlawed by state and federal consumer protection laws. The goal is to prohibit unfair trade practices that materially mislead or deceive the average consumer. It is an activity that is variously defined as immoral, unfair, and/or which causes substantial harm to consumers.

Predatory Pricing

Pricing that affects the behavior of consumers or a patient population targeted by drug manufacturers could fall under the broad definition of unfair trade. Pricing that distorts patient behavior to the detriment of the patient – which forces them to forego treatment altogether or partially because of high drug price – can be interpreted to have materially distorted behavior and harmed consumers. Additionally, medical advocates have called pricing of certain critical drugs immoral and/or unethical. There are a number of ways to think about the application of these laws to pharmaceutical pricing.

In early 2016, the Massachusetts Attorney General's Office threatened to apply the Commonwealth's unfair trade practice laws against Gilead Sciences Inc. for its high-pricing pricing of its new Hepatitis C treatments, which included Harvoni. Between 2014 and early 2016, the Commonwealth's Medicaid program spent about $318 million on Hepatitis C drugs for about 2,800 people. Massachusetts argued that the pricing of Gilead's Hepatitis C treatments was unaffordable and allowed the disease to continue to spread, threatening public health. The two sides reached a settlement with Gilead agreeing to pay an unspecified amount through supplemental Medicaid rebates effective August 1, 2016, which will save Massachusetts a significant amount of money. Gilead's products were placed on the Medicaid preferred drug list as a result of the settlement, with the caveat that Medicaid patients could access other Hepatitis C drugs as well.[17]

It would appear that the Medicaid best-price provision was implicated in the Massachusetts outcome, given that the result was a *supplemental Medicaid* rebate agreement rather than a more general price reduction for all consumers in the Commonwealth. A Medicaid supplemental rebate is exempt from Medicaid best-price calculations. In contrast, a broader all-payer, all-consumer price discount agreement would not be exempt from Medicaid best-price.

Antitrust Enforcement of Pay-for-Delay Settlements

Strategies employed by brand-name drug manufacturers to extend market exclusivity help fuel high drug costs. "Pay-for-delay" settlements, in which generic manufacturers agree to postpone entering the market in return for compensation, have proven particularly successful. In 2010, the Federal Trade Commission estimated that such settlements cost the nation's healthcare system $3.5 billion annually from the delayed entry of safe, effective and low-cost generic drugs.[18] Three years later, the Supreme Court held that such settlements could violate state and federal antitrust laws,[19] a subset of unfair trade practices law prohibiting restraint of trade. The practical effect of the ruling has been to substantially reduce the number of cash-based, pay-for-delay settlements. Nevertheless, the number of pay-for-delay settlements involving alternate forms of payment, such as a promise by a brand-name manufacturer not to sell an "authorized" generic drug during the limited competition period enjoyed by the first successful generic challenger, remains high.[20] State Attorneys General could make a more concerted effort to bring suit against these non-cash-based, pay-for-delay settlements under state antitrust law.

Strategy Five: Re-import Affordable Drugs from Canada

Re-importation is not a new concept but new provisions regulating drug safety, growing public support and potential new roles for states make this proposal worthy of consideration. Current laws allow re-importation of drugs from Canada by wholesalers and pharmacies only after DHHS certifies that the program of re-importation is safe and likely to result in savings for the American public. To date, DHHS has never made such a finding in the U.S.

Under this option, states acting as licensed wholesalers or contracting with licensed wholesalers, would ask DHHS to confirm that the re-importation of drugs from Canada was safe. Rather than a national certification as is required under current law, states would be able to demonstrate to DHHS how they would ensure the safety, purity and pedigree of products to be imported to the state.

There is a new component to this policy option that did not exist the last time re-importation was publicly debated - enactment of the Drug Quality and Security Act (DQSA) of 2013. Title II of DQSA requires stakeholders to document a chain of custody all the way back to the manufacturing plant. While the track-and-trace operational details (the data field structure etc.) may be different between Canada and the U.S., the more important point is that the U.S. now has capacity to track the pedigree of drugs at the lot-level and will be able to track pedigree at the package level by 2023. The DQSA lays the groundwork for tracking and establishing the pedigree of pharmaceuticals. According to the legislation:

> *"The track-and-trace requirements of the DQSA are meant to improve drug security throughout the supply chain, including making it easier to track where a drug has been, to identify and remove counterfeit products, and to simplify drug recalls.*
>
> *All members of the supply chain—manufacturers, re-packagers, wholesale distributors, third-party logistics providers and dispensers, including retail pharmacies—will have to comply with the law as it's phased in over the next nine years."* [21]

While the idea of states as drug wholesalers and re-importers may be novel, the fundamentals of this approach are already in place and can be leveraged to allow interested states to begin to take on this new role in order to lower drug costs and improve the health and welfare of their residents.

Strategy Six: Change Medicaid to Promote Greater Purchasing Flexibility

Background

It is important to know several things about Medicaid drug coverage:

- Federal Medicaid law requires pharmaceutical companies to comply with the provision of per unit rebates to states, or else they are banned from sales to Medicaid and other federal programs.
- The law provides for a base rebate of 23.1 percent of an average manufacturer price (AMP) for each unit of drug dispensed, as well as a consumer price index (CPI) penalty add-on rebate when the price growth of the product exceeds the growth in the CPI in a quarterly reporting period.
- The AMP is calculated using sales to a limited group of payers and dispensers, and today the AMP closely tracks the price pharmacies pay for drugs, rather than factoring in other prices paid in the broader marketplace.
- State Medicaid programs benefit any time a manufacturer contracts with almost any other entity for a discount that exceeds 23.1 percent of AMP. State Medicaid programs automatically receive that new best-price for each unit dispensed to a Medicaid beneficiary.
- States also have the ability to negotiate additional manufacturer rebates and leverage their ability to create PDL, which serve a similar purpose to drug formularies in the private sector and Medicaid managed care, albeit with major restrictions imposed by federal law.
- In return for the federal rebate, state Medicaid programs are required to cover all drugs from manufacturers participating in the federal rebate program. However, states can use other techniques to promote drug choices, such as easing access to drugs on their PDL and restricting drugs not on their PDL. So, while states must cover all drugs that have a rebate, they have considerable latitude in limiting access to drugs with no supplemental rebate.
- Federal law does not require states to provide a Medicaid drug benefit, in fact prescription drug coverage for adults is optional. If states do provide this benefit - and all currently do - they must

provide coverage in amount, duration and scope to meet the general needs of the eligible population, and they must provide the same benefit to the entire eligible population. As essential as the drug benefit is, faced with double-digit growth in pharmaceutical spending, some states may have few options but to re-visit the sustainability of this optional drug coverage.

Some state officials believe federal law limits their ability to run a cost-efficient Medicaid drug benefit program because federal regulations prohibit or limit adoption of effective, private-sector formulary management techniques, which allow providers and pharmacists to work together to promote specific drug treatments. Some manufacturers believe that the best-price provision of the law limits their ability to creatively contract with commercial health plans or other state agencies.

It is not clear to what extent Medicaid law impedes performance-based, or value-based contracting. The Centers for Medicaid and Medicare Services (CMS) issued a brief guidance document[22] to states in July, 2016, that stipulates that commercial sector performance-based or value-based contracts can affect Medicaid best-price and that each potential arrangement is unique and therefore will require legal review. In thinking through the various non-Medicaid policy options in this paper, it does appear that the Medicaid law could be implicated in a number of approaches. This uncertainty warrants a separate, serious assessment.

To execute value-based pricing arrangement directly with Medicaid, CMS encourages use of the established supplemental rebate agreement, which is exempt from the Medicaid best-price rule.

It is clear that state Medicaid programs cannot completely forego covering therapeutic alternatives in favor of sole-source contracting for the best rebate. Medicaid programs can favor one product over another, but they must allow access to all drugs for which there is a federal rebate agreement in place. This makes it harder for state agencies to band together and operate like a pharmacy benefit manager (PBM) – which works to maintain or reduce drug costs while working to improve health outcomes - in order to gain market leverage.

Medicaid Policy Options

There are several potential policy options here. The concepts below are designed to start a conversation about how to minimize Medicaid's dampening effect on states' ability to negotiate with the pharmaceutical industry. These approaches could be mandated by law or facilitated through waivers.

- **Using a waiver process, allow states to opt out of the Medicaid rebate provisions of the drug benefit for all drugs while still maintaining a Medicaid prescription drug benefit that is eligible for federal matching funds**. Under this approach, state Medicaid programs would no longer get the mandatory minimum or best-price rebates. In exchange, a state's Medicaid program could more easily join sister state agencies and/or even other states to form a PBM to run a formulary as commercial payers do. A Medicaid program or consortium of states would have more flexibility to:
  - Respond to a State Drug Price Review Board determination or utilize performance-based contracting and pricing;
  - Exclude some drugs in classes where there are therapeutic alternatives;
  - Deploy reference pricing reimbursement;

  - Establish pharmacy networks that are willing to do more patient management, for example, or are willing to accept depot shipments.

- **Allow states to utilize the waiver process to opt out of Medicaid rebate provisions for a limited number of drug classes**. This approach could be appropriate for Medicaid programs that want to innovate in specific classes of drugs by employing:
  - New service delivery options
  - New copayment structures
  - A non-Medicaid purchasing pool or state PBM arrangement, or
  - Bulk purchasing of sole source products. An example would be allowing state Medicaid programs to participate in a VFC-style program for a particular class of drugs, such as Hepatitis C treatments purchased from the CDC or a prime vendor.

- **Allow states to waive requirements of the Medicaid drug rebate law while maintaining access to the minimum and best-price rebates**. Under this option, state Medicaid programs would continue to be guaranteed the minimum federal rebate and the best-price rebate but they would also be able to employ selective contracting, performance contracting and sole source contracting, etc., to enhance market leverage for better supplemental rebates.

- **Expand Medicaid rebate laws to a variety of state health financing and delivery programs, including state-operated exchange plans**. Under this policy option, non-Medicaid state programs and agencies would have access to some or all of the Medicaid price provisions, including the base rebate, the inflation rebate, best-price and/or line extension rebate. Unlike the other options in this section, this approach could limit the ability of commercial payers to negotiate performance-based contracts that implicate Medicaid best-price because the financial penalty to manufacturers of creating a best-price would be more financially significant than today, as other agencies bring more covered members to the Medicaid rebate program.

Effective, long-term treatment with medications profoundly affects a state's future delivery of:

- Mental health services
- State employees and retirees' medical care
- Long-term services and supports
- Social services
- Education
- Corrections, and
- Other programs that affect state spending and revenue

Strategy Seven: States Become Pharmacy Benefit Managers

States Could Take the Long View and Reassess Pharmaceuticals' Value to Society

Considerable opportunity to change the pricing dynamic between states and the pharmaceutical industry rests with states' ability to take a long-range view of spending and recalculate how they view the long-term value of pharmaceuticals to society.

States are employers, Medicaid administrators, correctional administrators, educators, mental health, public health and social service providers. States have economic and societal interests beyond immediate healthcare that include employee productivity, long-term services and supports, educational costs, management of correctional systems, and public and mental health services. States can view the economic and social value of pharmaceuticals over several years – a view that commercial payers may not be able to take. In thinking about the value of pharmaceuticals, states could conceivably assess the value of a product based on its long-term effect on spending across a broad range of state programs and services beyond immediate medical care or one program area.

By factoring in the economic impact of investments in pharmaceuticals across programs and spending areas over years, states could have a very different perspective than private commercial payers do. This unique, holistic perspective of pharmaceutical spending could provide opportunities for states to:

- Increase state market leverage relative to the pharmaceutical industry;
- Improve the sophistication of assessing the value of pharmaceuticals;
- Improve patient access to important new medicines; and
- Move the value and price of pharmaceuticals closer together.

This broad, long view provides an opportunity to negotiate with manufacturers for prices that reflect a state's return on investment (ROI). This ROI would measure and incorporate the cost avoidance produced by a drug across relevant state programs and cost centers. That ROI analysis could move states closer toward the industry position – that today's market does not appropriately recognize the real value of new pharmaceutical products. The ROI would be the basis governing price negotiation between a unified state purchaser (the state as PBM) and a manufacturer.

It is important to note that this view of pharmaceutical value does not mean that current industry pricing reflects that value. Instead, a long and broad view provides the basis for a real-world assessment of a product's value and provides the opportunity to establish a negotiated price that maximizes the value of the drug for states and for society.

Such an approach is a big stretch for states, but some of the opportunities to manage drug spending and improve patient access that could result from such thinking would be extremely beneficial for state governments and residents. Over the long-term, a movement toward ROI contracting would better align the interests of the pharmaceutical industry and large government purchasers as price would be linked to the amount of future costs avoided by the government purchaser and society.

What States Can Do Today – Purchasing Pools

States' efforts to date have largely focused not on price but rather on discounting strategies. Pooled purchasing by state Medicaid agencies has been a hallmark of that work. As of 2016, most states were involved in one or more of four Medicaid pharmaceutical pricing pools.[23] State membership in the pricing pools is not static, state Medicaid programs have entered and exited the different pools at varying times. These pools negotiate Medicaid supple-

State-purchasing pools allow states to negotiate prices and make purchases on behalf of one or more states or groups, including:

- Agencies that pay for pharmaceuticals
- Exchange-covered members in state-operated exchanges
- Uninsured individuals who are not eligible for other public or private drug coverage
- Public or privalthcare facilities that dispense or administer drugs
- Private sector employers
- Any combination of the above

mental rebates on top of the federal law base rebate of 23.1 percent of AMP for each unit of product dispensed.

Just two multi-state purchasing pools focus on state agencies and populations other than Medicaid – the Minnesota Multistate Contracting Alliance for Pharmacy and the Northwest Prescription Drug Consortium serving Washington and Oregon. The Minnesota alliance is a prime vendor program for states, cities and facilities and negotiates and purchases pharmaceuticals and other medical supplies. The Northwest Consortium was originally focused on making pharmaceuticals more affordable for the uninsured. It provides member groups with clinical pharmacy expertise and tailored formularies regardless of group size. All group members pay the same rates, all have 100 percent transparent contracts and all pharmacy discounts are passed through to groups with no spread kept by the contractor.

Consortium prices are better than commercial rates available to other large groups in Oregon and Washington because they are backed by a most favored nation-guarantee and an annual third-party market pricing check. All manufacturer rebates are passed through at 100 percent to member groups, including rebates on specialty drugs. Price discounts are guaranteed by a performance-based ceiling expenditure cap, and the contractor administrative expense is fixed. There are also a number of single-state drug purchasing/price negotiation initiatives that involve agencies and entities other than Medicaid. With a large number of covered members, state pool participants gain advantages such as:

- Helping the state and its covered members keep income that is otherwise extracted by commercial PBMs. Instead, the state purchasing pools can commit to cost-plus pricing (passing along all the negotiated savings but for the margin needed to cover administrative costs).
- And creating administrative efficiencies for participating agencies through central negotiation, pricing and even administration of the rebate operation.

However, these efforts have significant limitations. Purchasing pools do not change the trajectory of high launch prices and high annual price increases. Purchasing pools do not have much negotiation leverage. Pool members are typically not required to use the drugs negotiated by the pool and members have different formularies and different drug benefit structures. Manufacturers typically provide deeper discounts to entities that can incentivize members to purchase their products. A pool of nonaligned members with different benefit structures does not drive utilization. Another disincentive is that potential pool members may believe that they have stronger formulary controls that can garner better pricing and therefore do not join purchasing pools.

What States Could Do Tomorrow: Become Pharmacy Benefit Managers

State purchasing pools are important initiatives that represented ground-breaking policy when they were created. However, these purchasing initiatives are limited, as discussed above. While they keep pace with rising pharmaceutical prices, they are not structured to modify the trajectory of those prices. Instead, states can consider strengthening their negotiating leverage by operating more like commercial pharmacy benefit managers.

In order to strengthen market position and operate more like a commercial PBM, states could:

- Have pool participants use unified formularies for all covered members and dependents;
- Use different approaches for different types and therapeutic classes of pharmaceuticals;
- Require pharmaceutical manufacturers to price for ROI to the state within a specified time frame;

- Contract with pharmaceutical manufacturers to forward-fund utilization of a drug for an initial period of time until the state purchaser begins to gain a ROI across spending centers from the product (called ROI contracting).

Each of these options is explored in more detail below.

Purchasing pool participants unify around one formulary structure and management

The ability to negotiate with the pharmaceutical industry is strengthened when the payer has more covered members and exerts more control over drug promotion and utilization by them. Many state purchasing pools negotiate discounts on behalf of participant members that may or may not put the drug on a formulary, may or may not put the drug on the same tier and may or may not apply utilization management controls such as prior authorization and step therapy, which requires members to try a less-expensive drug first before moving up a "step" to a more expensive drug.

If purchasing pools can provide a manufacturer with a clear understanding of the structure and management of drugs for all members of the pool, the manufacturer can enter into more serious negotiations. Such uniformity provides the payer and manufacturer much more opportunity for innovative contracting around performance and ROI contracting.

However, it may be difficult to unify drug benefit design and coverage across programs and managed care contractors. In 2014, a handful of states (Florida, Kansas, Texas, and West Virginia) used a unified PDL for their Medicaid programs, holding managed care organizations to the same PDL as used for Medicaid fee-for-service. Others have considered this strategy as well. One of the considerations motivating the adoption of a single PDL was to enhance the program's negotiating position with manufacturers to gain a better price. It is not unreasonable to assume that a state's bargaining position would be enhanced if all public payers joined together and adhered to a single set of policies regarding a drug formulary and PDLs. As managed care has grown in Medicaid, states have held plans accountable for total cost of care and quality outcomes. Those plans, in turn, tend to use national pharmacy benefit managers to secure better drug prices, yet little is known about the effectiveness of those negotiations nor where risk is shared and savings accrue. But states routinely carve-in or carve-out the drug benefit from Medicaid managed care plans. Becoming a strong purchaser is potentially key to gaining leverage in the market. And a state, operating on behalf of its managed care contractors and other health vendors, could bring scale to innovative contracting that is difficult to achieve as a single-contractor.

It is not yet clear if states using this strategy for their Medicaid programs have, in fact, realized savings. Until 2011, New York's Medicaid drug benefit was carved out of Medicaid managed care and was subject to its Medicaid Preferred Drug Program (PDP). In 2011, the benefit was shifted back to the individual Medicaid managed care organizations and the PDP now only applies to the small fraction of enrollees in Medicaid fee-for-service programs.

A 2016 report prepared for the Texas Association of Health Plans[24] argues that substantial savings would accrue to the state if flexibility were given to the Medicaid managed care organizations, citing the plans' ability to negotiate net prices that are lower than the state's price with supplemental rebates

factored in. Favorable net prices are achievable by plans optimizing the mix of drugs (generics and brand-name drugs) in their formularies. The authors state that Texas would achieve $100 million in annual general fund savings if it rescinded the unified PDL requirement. There are no data readily available to either confirm or refute the conclusions in the report prepared for the Texas health plans.

Vary Management Approach by Type of Product and/or Therapeutic Class

States might also think about varying their purchasing strategies depending on the type of drug and product. Preventive pharmaceuticals may lend themselves more easily to performance-based contracting or ROI contracting. Pharmaceuticals that can demonstrate cost avoidance – such as reduced inpatient hospital days, less school absenteeism due to illness and utilization of fewer health-related services – could be treated differently in negotiations.

An example of this type of approach is pricing based on indication and outcomes. The drug manufacturer contracts with payers around the ability of the product to reduce inpatient hospital days for adherent patients. To the extent that the product meets performance goals, the payer pays more (rebates are reduced). If the product does not perform as expected and does not reduce inpatient days, then the price is lower and the manufacturer's rebate is higher.

Hypothetical Examples of ROI

The factors in any ROI estimation analysis will vary depending on the disease or condition, as well as particular state programs and spending patterns.

An ROI estimation analysis is not appropriate for all pharmaceutical products. However, an equitable ROI approach over a reasonable period of time is important to moving price and value closer together. The sophistication of the ROI estimation analysis will improve over time – including the ability to account for more intangible costs and savings such as patient or caregiver productivity.

A limiting factor to ROI pricing is the best-price provision of Medicaid law. Under the law, almost any price in the U.S. market that is better than a 23.1 percent discount off the Average Manufacturer Price in a calendar quarter becomes the national best price – the price at which the manufacturer must sell to all state Medicaid programs. ROI pricing could mean that a product price comes in with a discount greater than 23.1 percent. This is not a given, but it is not out of the question. Because of this, ROI pricing will have to involve a conversation with CMS.

However, with an eye toward Medicaid best-price, routine use of ROI analysis pricing may, over time, encourage lower industry launch prices and restrained price increases. Lower launch prices may be more aligned with ROI pricing, and perhaps not trigger the best-price provision or the effect of the triggering the provision may not be substantial.

Products with clear, measurable endpoints or clinical effects are more amenable to this performance-based contracting. Performance-based contracts are becoming more common in the U.S.

Strategy Eight: Pursue Return on Investment Pricing Strategies

As discussed above, a state has the option of taking a longer view of the role and effect of medical care on the health and welfare of its citizens. This longer view would take into consideration the impact of medical spending on education spending and outcomes, worker disability days and productivity, mental health service spending, long-term services and supports, and other expenditures.

ROI investment estimation analysis and pricing would put to the test the industry's assertion that pricing reflects the value of drugs over time by linking payment or price to a longer term ROI. Using this negotiating approach, the pharmaceutical industry would be forced to acknowledge the reality of budget impact and inability of governments to fund endless, unpredictable and growing amounts of new expensive treatments without reducing funding for other vital parts of state budgets, such as education, safe water, roads, environmental protection, and social services.

While the negotiating approach could be difficult and time-consuming at first, the cost-avoidance estimation tool approach has the potential over time to clarify how public payers can assess the value of a medical intervention and how the pharmaceutical industry brings products to market.
The negotiation between a state purchaser (a pooled purchaser or PBM ideally) and a manufacturer would establish a price that reflects the value of the product to the state as distinct from a price the manufacturer would set.

The first step in the price negotiation would be to estimate all the spending offsets/cost avoidance a state could expect across relevant state cost centers/programs that are estimated to result from coverage and use of the drug.

Based on that estimation analysis (which the manufacturer and state must agree on) the price would be set so that the expected state spending on the drug over a negotiated number of years would be based on the estimated/agreed-upon cumulative state costs avoided during that same period of time. For purposes of this discussion, that period of time would be 10 years.[25]

This approach would estimate the dollar amount of what the industry insists is generally true – that the price of pharmaceuticals reflect the value of the drug over time. Industry believes that price reflects the value to patients and society, and that value cannot be fairly assessed in the typically short payer economic timeframe. This ROI estimation negotiation would challenge the industry to negotiate a price that represents an estimated - but detailed - value to a state. It is a negotiation tool premised on bringing price and value together through estimating costs that will be avoided across an array of relevant state spending programs.

States do not approach healthcare spending this way today. Current state thinking about health spending is just as siloed as it is in the commercial sector. However, states have the ability and opportunity to think more broadly about healthcare spending and may need to do so in order to leverage opportunities for improved pharmaceutical spending, and to push the pharmaceutical industry to shift its pricing model as well.

The ROI estimation approach would be limited in early years. It would appear more practical to use ROI pricing for products that provide a relative amount of clarity about treatment impact in a population. States and manufacturers would negotiate the ROI formula and would have to agree to the validity of the formula.

States interested in negotiating with pharmaceutical companies using the ROI strategy outlined here could benefit from independent research to determine the value of drugs over time. One such resource is the Institute for Clinical and Economic Review (ICER), an independent, non-profit organization that evaluates new and innovative drugs and produces independent, scientifically rigorous reports to inform and support decision-makers.

In addition to helping answer questions about a drug's comparative clinical effectiveness, ICER's reports on new drugs, at or near the time of approval by the U.S. Food and Drug Administration (FDA), calculate value-based price benchmarks that align prices for new drugs with the long-term benefits for patients and the health system. Because all of ICER's work is public and vetted by independent public panels, states are free to use it to help identify drugs with prices out of line with the value they provide each state.

Once the ROI estimation analysis/formula is agreed upon, the price would be established. The price would be set to reflect the balance between estimated state spending for the drug and the estimated costs avoided resulting from utilization of the drug. Market dynamics and negotiating leverage would determine the final price of the drug, but the starting point for negotiations would be the projected long-term value of the drug to the state rather than a price that is independently and artificially set by the manufacturer.

In the "out" years, the ROI analysis and ROI price would be adjusted to account for changes in the market, including new therapeutic products in that drug category or class, expected utilization by the targeted patients and changes in other costs that are factors in the ROI formula. Each year represents a new and separate estimation, pricing and contract year.

For any particular product, it could be that ROI price contracting may not be necessary during out years as new, branded or generic therapeutic alternates enter the market and cause the price to drop substantially. As a result, market competition takes over and supplants ROI estimating and pricing. In this case, ROI estimation and pricing are simply bridging tools that guarantee that a drug's price and the cost to a state provide value in the absence of other therapeutic options.

To effectively negotiate beneficial contract terms under an ROI strategy, a state will have to utilize effective strategies commonly used in negotiations with pharmaceutical manufacturers today, including a product's ability to impact market share and market access. For example, the purchasing pool/state PBM may agree not to modify the FDA-approved and labeled indicated population - as states and other payers have attempted to do with Hepatitis C treatment criteria.

States may also consider entering into performance-based contracts in which reimbursement is based in part on the achievement of clinical outcomes related to savings estimates, similar to the pay-for-performance agreements now negotiated between some manufactures and large payers. A performance-based contract based on the direct measurement of an ROI target may not be feasible in the short-term. The ROI is theoretical and not intended to represent an absolute; instead, it is an estimate and a negotiation tool. Over time, the ROI formulas, analyses and data sources may evolve to such a point as to be able to verify the ROI and create contract provisions around it. Alternatively, contracts that measure clinical outcomes may stand as a proxy for meeting estimated savings targets, and thereby allow states to enter into risk-based contracts that may be attractive to both parties.

Over time, the sophistication of the ROI estimating formulas will improve. However, the basis of the approach and the result of the negotiation is a contractual agreement around an estimated, formula-based state ROI and the resulting price.

Forward Financing Using ROI Pricing

ROI pricing could be coupled with manufacturer financing of utilization over a period of time. The period of time would be negotiated, but states may be interested in financing through to the point at which their estimated costs avoided are equal to costs of product utilization. This would be a new way for states to think about drug purchasing.

In an ROI estimation/forward financing strategy, risk is removed, product price is negotiated up front, and the manufacturer provides product in the state with reimbursement/payment delayed until some negotiated future point.

Forward financing requires manufacturers to finance the utilization of their product (through direct delivery of product without immediate payment) under the terms of an ROI contract until the year in which estimated state costs to purchase the product equal the costs avoided over that time period. Essentially, a manufacturer provides the product for a calendar year. The utilization is tracked for 2016, and the ROI estimation analysis shows that at the negotiated price, the cost of utilization in 2016 is estimated to be balanced by costs avoided by the year 2026.

For any forward financing year, a manufacturer could supply product for some or all of the state purchasing pool/PBM through direct delivery using specialty pharmacy distribution or depot distribution like the AIDS Drug Assistance Program (ADAP) or VFC. States would repay the manufacturer for product at the agreed upon, theoretical, point in time at which the economic benefits to the state (costs avoided) balance the costs of covering the product in the original contract year.

In return for forward financing, manufacturers would gain either market share, market access or seek to benefit from upside risk. For example, states could be obligated, under terms of the contract, to provide ready access to the product for the indicated patient population. Take Hepatitis C treatments for example, all members of the state's purchasing pool/PBM would be obligated to cover the products in accord with FDA-approved indications. In the Hepatitis C example, members of the state purchasing pool could not limit coverage to people who are sicker than the FDA-approved use, or to people who are clean of any addiction for a number of years. It is appropriate that people who are covered by the purchasing pool should benefit to the fullest extent from the new medicines. Other considerations include formulary management or performance-based contracts in which the manufacturer receives a higher price if clinical outcomes are met. Manufacturers could benefit if they increase market share or market access beyond what would otherwise be achieved through negotiations that did not include a forward-financing provision. Any additional costs of forward financing to the state must be weighed against the benefits, namely reduced volatility in pharmaceutical costs as payments are delayed until the benefits of the product begin to accrue to the state.

To implement forward financing, states and manufacturers would get the product to the purchasing pool/PBM network pharmacies. There is precedent for this type of depot approach or direct delivery of product in the VFC and ADAP programs. In a depot or other product delivery system, the pharmacist is paid the usual dispensing fee by the state program and the patient pays cost-sharing at the point of service (doctor's office or pharmacy counter). Claims are filed so that utilization is tracked. Patient cost-sharing is remitted to the manufacturer on some regular schedule, and this cost-sharing would offset the amount due by the state to the manufacturer at the start of the repayment period. How distribution and pharmacy product reimbursement is handled will depend on the state, the manufacturer and the

product. However, specialized pharmaceutical purchase and delivery systems are common in today's market – much more so than when VFC was first established.

The state repayment schedule would be patient cohort-based, consistent with annual ROI contracting. As an example, if the basis of a contract today is a 10-year ROI price - with economic benefits accruing by 2026 for product purchased in 2016 - then the state repays the manufacturer in 2026 for utilization from 2016, minus the patient cost sharing that was remitted to the manufacturer in 2016.
Like the ROI financing discussed above, it would be necessary to renegotiate the ROI analysis, time horizon and thus the price each year for utilization in that new contract year because many of the factors in the ROI estimation analysis will have changed.

Forward financing using ROI pricing benefits states by matching price to value and delaying unanticipated budget impacts associated with the launch of new pharmaceutical products until the benefits of such products, in terms of future cost avoidance, begin to accrue. At the time when payments to the manufacturer start, states would have started to see budgetary effects resulting from the health and societal benefit of the treatment. Again, this proposal assumes that state agencies work together as one PBM.

There are a number of administrative, political and budgeting issues to be worked out in this model. This paper provides the starting point for the work that needs to be done. The important point is that it is a model that allows states to provide ready access to new important pharmaceuticals and has the potential to reduce industry reliance on high launch prices and annual price increases. ROI pricing with forward funding is a market-based approach that leverages the strengths and interests of each party and it can help states manage drug price volatility.

Strategy Nine: Ensure State Participation in Medicare Part D through Employer Group Waiver Plans

States as employers can leverage the Medicare Part D prescription drug benefit subsidy for their state retirees by creating an Employer Group Waiver Plan (EGWP). This Medicare Part D prescription drug plan is offered to retirees who have been promised prescription drug coverage as a retirement benefit. This option became more widely used after federal law was changed to eliminate a 20 percent subsidy of employer-sponsored retiree drug benefits. The purpose of this original subsidy was to encourage employers to continue to provide retiree drug benefits rather than dropping retiree prescription drug coverage altogether and placing a greater financial burden on Medicare.

However, since the subsidy was eliminated in 2013, employers have accessed the EGWP program, which allows them to continue to shoulder some financial responsibility for their retiree drug benefits while shifting more of the burden to Medicare.

It is not known how many states have converted to EGWP status for their government retirees, but there was a trend in this direction in 2013.

Strategy Ten: Protect Consumers Against Misleading Marketing

To help blunt consumer criticism of rising prescription drug prices, manufacturers have established coupon (or discount) programs. Coupons from these programs can often be accessed on the Internet, downloaded and printed for use at pharmacies. In some instances, they are distributed at doctors' offices or mailed to consumers' homes. Regardless of mode of delivery and administration, coupons reduce out-of-pocket, but not third-party payer costs. As a result, they can effectively steer patients toward high-priced drugs despite the availability of clinically-comparable, lower-cost alternatives. This action places upward pressure on insurance premiums, which are ultimately borne by the same consumers enjoying these short-term savings.

The use of coupon programs has increased significantly over the past few years. A 2014 report by the DHHS Office of Inspector General noted that there were 86 programs in mid-2009 and by the end of 2012 there were 525.[26] This 612 percent rise coincides with a period when many blockbuster drugs were coming off-patent.

Many coupon or discount programs have important restrictions.[27] First, coupons are often time-limited, expiring after a certain date or after a few months of use. This leaves patients facing high out-of-pocket costs. To avoid these costs, patients may switch medications—a difficult ask—or deviate from their prescribed treatment regimen.

Coupon or discount programs may also be available to only certain patients, like those with a particular diagnosis. Such restrictions may come as a surprise to patients when they present their coupon card to pharmacists, who must confirm eligibility at the point-of-sale. If patients are ineligible, pharmacists must explain the issue, effectively pushing the discussion of price away from doctors' offices.[28]

Many insurers and plan sponsors utilize copays and coinsurance in prescription drug benefit design to encourage the use of lower-cost, generic medicines when available and appropriate. While discount or coupon programs can facilitate access, they also countermand those incentives. Some payers have accordingly instituted policies prohibiting coupon use. The federal government, for example, has long deemed coupon use within federally-sponsored programs as an illegal kickback. Several states also prohibit coupon programs, but these outright bans have all been removed with Massachusetts the last state to do so in 2012.[29]

Several options are available to address coupon programs. States can impose transparency requirements on program administrators – who may be third-party organizations with unclear or suspect financial arrangements with manufacturers. Shedding light on those relationships might help payers and policymakers better understand the motivations underlying the programs, while raising awareness of their potential negative impact.

States could also pass legislation or promulgate regulations requiring manufacturers to more clearly highlight the use terms of their coupons. This could mean providing more prominent and accessible eligibility, expiration dates and impact information (e.g., poor likelihood of long-term adherence) on coupons and with advertisement -- similar to health warnings on cigarettes. The aim of such a policy would be to bolster consumer awareness, resulting in more informed buying decisions.

Such disclosure could also be driven by more indirect approaches. Consumer protection laws in all 50 states offer potential recourse for people harmed by deceptive trade practices. However, the strength of these laws -- from which insurers but not manufacturers are generally immune—vary considerably.[30] Some states, for example, have adopted a broad definition of deceptive. In these states, a designated state agency could file suit against manufacturers that failed to clearly disclose eligibility and/or expiry information if patients unwittingly relied upon a reasonable assumption that they would remain able to use their coupon indefinitely. Equitable relief could be sought that would help clarify ambiguity for future patients.

Finally, states could (re)instate bans on the use of coupons for state-sponsored programs, including state employee/retiree health programs. The justification for this exclusion could rest on the inflationary impact of coupon use on premium costs.

Strategy Eleven: Use Shareholder Activism to Hold Pharmaceutical Companies Accountable

Public pension funds hold $3.8 trillion in assets, with most invested in securities[31]. Pension funds have been under scrutiny for unfunded liabilities and states have been working to find general fund dollars to meet their pension obligations. In a very real way, increasing costs to state governments for the pharmaceuticals they purchase for their employees, retirees, corrections and Medicaid beneficiaries compete for scarce revenues at a time when pensions need to be fully-funded.

Conversely, pharmaceuticals tend to be profitable businesses and can be good investments promising healthy returns for pension funds. One strategy investors have used to influence corporate behavior is socially-responsible investing. Advocates seek to divest from companies whose businesses they deem contrary to the public good, such as tobacco. But pension managers are bound to achieve the best return on their investments and, given the size and scope of their investments in pharmaceuticals and their current rate of return, it could be challenging for pension investors to find a mix of other investments that achieve balance in a portfolio that delivers the same competitive returns.

Pensions, along with mutual funds, are the biggest investors in the market and the size of public pension investments invites consideration of a different strategy – shareholder activism – to gain concessions on price from the nation's pharmaceutical industry. Publicly-traded companies must provide voting rights to shareholders in order to hold corporate managers accountable. Through proxy voting, shareholders can vote on the election of directors of corporate boards, advise on executive pay and weigh in on corporate buy-outs and mergers.

Shareholders can also submit resolutions for consideration by corporate boards as long as they hold a certain amount of stock for a fixed period of time. Sthreeuch shareholder proposals may require time to get traction, but any proposal that receives 3 percent of shareholder support in its first submission can be re-introduced again, but each year the proposal must receive increasing shareholder support. In 2011, the shareholder group As You Sow introduced a shareholder proposal to the McDonald's Corporation asking the company to use more environmentally-friendly beverage containers. Twenty-nine percent of shareholders supported the proposal and McDonald's took action.[32] CalPERS, the nation's largest public pension fund with assets of $229 billion, has been active in pursuing corporate reforms and since 1992 has published an annual Focus List of companies with poor financial and corporate governance designed to highlight and bring change to particular companies.[33]

Public pension managers as shareholders, acting collectively or through organizations like the Council for Institutional Investors, could introduce ballot proposals requiring certain pharmaceutical companies to reduce launch prices or engage in ROI pricing with state governments, for example. The challenge would be balancing the demand for lower prices with the need to assure shareholder value is not compromised. And, for the several states in which pension investment and health benefits are administered by a single agency, strict firewalls would be essential to assure the integrity of both.

Next Steps

The Work Group, which released this report at NASHP's Annual Health Policy Conference in October 2016, invites interested states to develop these and other proposals. While these ideas require additional development, including conversations with purchasers and industry leaders, states must act as laboratories of innovation, continuing to press for reforms while exploring new policies. NASHP will convene a meeting with the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Work Group in November to discuss the options presented here.

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About the National Academy for State Health Policy:
The National Academy for State Health Policy (NASHP) is an independent academy of state health policymakers working together to identify emerging issues, develop policy solutions, and improve state health policy and practice. As a non-profit, nonpartisan organization dedicated to helping states achieve excellence in health policy and practice, NASHP provides a forum on critical health issues across branches and agencies of state government. NASHP resources are available at: www.nashp.org.

APPENDIX E
SMART-D REPORT

State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)

Summary Report

September 2016

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Preface

This report analyzes the options available to state Medicaid agencies to purchase and pay for high-cost specialty drugs under current federal law. Drug prices are set by manufacturers, and Medicaid price and coverage regulation is most clearly within the domain of federal policy and legislation, so this report cannot offer a quick solution to high drug launch prices. Rather, in this first phase of SMART-D, the Center for Evidence-based Policy has sought to identify tools and techniques that states can use under current law to enable patient access to needed drugs while being an effective steward of scarce public dollars.

Implementing alternate purchasing and payment models for high-cost drugs is not an effort to be taken lightly; it requires time, planning, data, and sustained oversight. This level of effort may, at first, seem off-putting. But state Medicaid programs are already pursuing value-based purchasing strategies more broadly as they struggle with escalating drug costs. Moreover, SMART-D's pipeline forecast has identified more than 110 new high-cost drugs awaiting approval by the U.S. Food and Drug Administration (FDA) in the next 18 months. States cannot wait for some undetermined federal upending of the pharmaceutical market status quo; now is the time for state Medicaid programs to pilot alternative purchasing and payment models that will enable them to better respond as new high-cost drugs are approved.

Executive Summary

Prescription drug costs are the single fastest growing component of U.S. health care spending (Larner, 2015). Spending by Medicaid on prescription drugs increased 14% in overall costs and 3.6% in expense per enrollee (MACPAC, 2015a), with the total expenditures increasing from $37.1 billion to $42.3 billion between 2013 and 2014. A major factor in this surge has been the introduction of several high-cost specialty drugs that treat serious conditions such as cancer, hepatitis C, blood disorders, and HIV. These innovative drugs are being introduced at an accelerating pace and present exciting opportunities to improve the health and lengthen the lifespan of patients. At the same time, the high prices of the new therapies pose a challenge for all health care payers' budgets, especially state Medicaid programs that must ensure access to a broad range of health services for low-income individuals and families within state budget parameters and federal requirements.

Many Medicaid enrollees have complex and expensive health needs. These factors contribute to a per capita cost for Medicaid beneficiaries that is more than $2,000 above the per capita cost in the private insurance market (CMS, 2015d). Patients, providers, and policymakers expect state Medicaid programs to provide ready access to new therapies—a demand that in several states has been enforced by actual or threatened class-action lawsuits (Ollove, 2016). Yet these state programs must operate within finite budgets subject to legislative approval and state constitutional limits, often including a requirement that the state's budget be balanced. Compared to private payers, states have additional challenges. Unlike commercial insurance companies, state Medicaid programs have very limited latitude to increase budgets by shifting costs to Medicaid enrollees through premium obligations or patient cost-sharing. Both are extremely restricted under federal law. Moreover, the Medicaid Drug Rebate Program (MDRP) requires states to provide coverage for all drugs produced by drug manufacturers with federal rebate agreements, with very limited exceptions.

For these reasons, high-cost specialty drugs have put state Medicaid budgets into crisis. For example, in 2016, Missouri had to seek a midyear supplemental appropriation of $150 million to address escalating drug costs within its Medicaid program. In 2014, Florida's Agency for Health Care Administration needed to provide an additional "kick-payment" to Medicaid managed-care plans for covering hepatitis C drug costs. Faced with increasing drug costs, state Medicaid officials are seeking novel ways to manage their prescription drug purchases. Yet, drug purchasing stakeholders—states, managed care organizations (MCOs), pharmacy benefits managers, drug manufacturers, federal policymakers, and others—are operating in a charged political environment. Scrutiny of drug costs and patient access make it difficult for these stakeholders to collaborate, take risks, and find new solutions. State officials are under intense pressure to balance budgets, improve health, achieve broad patient access to treatment, avoid lawsuits, and deliver on the expectations of the state's executive and legislative branches.

The State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D) initiative seeks to clarify this complicated state drug purchasing landscape and identify and test new drug payment options for states to consider. These alternative payment model (APM) options are designed to provide improved access to evidence-based therapies for Medicaid enrollees, while improving state officials' ability to predict and manage prescription drug costs in a manner that connects price, payment, value, and health outcomes. Any models identified through SMART-D are voluntary collaborations between a drug manufacturer, prescribing stakeholders, and a Medicaid program. They build upon the substantial contracting experiences that drug manufacturers have in international and U.S. commercial markets. Through the SMART-D initiative, the Center seeks to enable states to achieve four aims: provide access to effective drug therapy for Medicaid enrollees, develop payment strategies for innovative drugs, enhance patient health outcomes, and improve state fiscal status.

Scope and Objectives of the SMART-D Project

The SMART-D initiative is envisioned as having three-phases. Phases I and II include the following key objectives:

- **Map the landscape of Medicaid drug purchasing**. Drug purchasing by Medicaid programs is extraordinarily complicated. State program officials must navigate federal statutes and regulations, state budget frameworks, complex market incentives, and nontransparent rebates and pricing. SMART-D's Phase I research explores these complexities in a way that will help states more easily develop alternate purchasing models.

- **Identify payment options for states**. Drawing upon models used in international and U.S. commercial markets, this project identifies a series of alternative payment options and legal pathways for state Medicaid programs to use when paying for high-cost drugs. Phase I of SMART-D identifies the best practices. Phase II will develop concrete proposals for state Medicaid programs.

- **Increase patient access and outcomes**. State Medicaid directors want to reach more people within their existing budgets and connect patients with drug therapies that improve health outcomes and minimize side effects and toxicity. SMART-D will support state officials in their efforts to use budgets in a way that maximizes these benefits to patients. This goal guides the entire SMART-D initiative but will specifically drive the development of APMs in Phase II.

- **Identify specific opportunities to collaborate with drug manufacturers.** SMART-D supports engagement with drug manufacturers for the joint development of voluntary, financial, or health outcome-based alternative payment arrangements with Medicaid programs. Opportunities exist to enable broad patient access to critical drug therapies while operating in the context of state budget constraints.

- **Provide implementation technical assistance and support to states**. As state officials develop models with drug manufacturers, the Center will support their efforts with technical and other assistance in Phases II and III. When viable models are developed that produce improvements in patient outcomes, the health of populations, and/or the per capita cost of

care, the Center will disseminate information about these best practices among participating states.

Findings of SMART-D Phase I Research

This summary report includes the results of SMART-D's Phase I research, which consists of four components: a review of current Medicaid prescription drug coverage and purchasing practices, a financial analysis of Medicaid drug spending, identification of alternate payment models used in international and U.S. commercial markets, and an analysis of key federal and state laws relevant to Medicaid drug purchasing. The research encapsulates complex issues, addresses the current status of state Medicaid program high-cost drug coverage and purchasing, and identifies new opportunities to integrate value into purchasing.

Medicaid Best Practices to Manage Specialty Drugs

State Medicaid directors are actively managing prescription drugs, with an added focus on high-cost specialty drugs, to reach the most patients despite limited budgets. Management tools include Medicaid drug payment and pricing strategies (340B and actual acquisition cost), utilization management (prior authorization, preferred drug lists, and care management), and managed care coverage of prescription drugs (carving-in the pharmacy benefit and MCO care management). To date, prescription drugs have mostly been excluded from broader value-based payment model discussions and delivery system transformation initiatives developed for other Medicaid-covered health care services. Yet, there is growing interest among Medicaid policymakers to deploy drug pricing and payment models that reflect the underlying clinical value a drug provides and move drug purchasing into the realm of value-based purchasing.

Economic and Pipeline Analysis

The SMART-D analysis found that 64 high-cost specialty drugs accounted for 32.6% of Medicaid drug reimbursement spending and 3.1% of overall Medicaid spending in 2015. These 64 drugs all had reimbursements of more than $600 per prescription and an annual Medicaid expenditure of $72 million or more per year. There are at least 110 additional drugs in the pipeline in the next two years that are likely to meet this same criteria and have a similar budget impact. These trends reinforce state officials' interest in strategic alignment of drug reimbursement with overall payment reform efforts and, specifically, the possibility of implementing APMs for high-cost specialty drugs.

Alternative Payment Models

Alternative payment models (APMs) are used by private and public-sector payers to manage drug utilization and costs in the United States and Europe. APMs are widely used in Europe and their use appears to be increasing in the U.S. commercial market. An APM is a contract between a payer

and drug manufacturer that ties payment for a drug or drugs to an agreed-upon measure; it is generally either financial or health outcome-based.

Financial-based APMs, designed at either the patient or population level, rely on financial caps or discounts to provide predictability and limit the risk of uncontrolled spending. In health outcome-based APMs, payments for drugs are tied to predetermined clinical outcomes or measurements, or conditional coverage is provided while data regarding a drug's effectiveness is being collected and assessed. Financial-based APMs, which focus on lowering costs and expanding patient access, have proven to be easier to administer. APMs based on health outcomes require additional planning and data collection, but have the potential to increase the quality, value, and efficacy of treatments.

Legal Analysis

Although the federal Medicaid Drug Rebate Program constrains state Medicaid purchasing flexibility in return for guaranteed statutory rebates, states still have latitude to pursue APMs. The SMART-D legal analysis has identified seven potential legal pathways that states can employ to implement financial and outcome-based payment arrangements with drug manufacturers and other health care providers.

In summary, APMs could be one of many levers that a state needs to create changes in patient outcomes or prescription drug spending. States should be cautioned about anticipating net savings with their first APM implementation; the immediate state-level outcomes are likely to be better patient access and budget predictability. Initial APM implementation will require an investment of time and resources to design, implement, and monitor, but if APMs are viewed in terms of the Triple Aim, states could see important advancements including improvements in patient outcomes and the health of populations, with reductions in the per capita cost of health care over time.

Next Steps for the SMART-D Initiative

The above section summarizes research conducted during Phase I of the SMART-D initiative. Phase II will involve planning and producing a detailed tool through which states can assess their level of interest in and readiness to develop and implement APMs. For Phase II, the Center has identified four areas to focus its work with states on:

- Determine the strategic fit, scope, and potential design of APMs within state Medicaid programs and identify stakeholders that must be engaged in the planning process.
- Assess technological readiness to identify, manage, and track health, drug, or cost outcomes related to APMs, while ensuring appropriate patient confidentiality.
- Establish or build upon a professional relationship between the state and one or more drug manufacturers to facilitate good-faith discussions about APM opportunities.
- Identify legal pathways that pair with the targeted APM and state Medicaid program design.

During the final phase of the project, Phase III, the Center anticipates supporting a small number of implementing states and drug manufacturers by: 1) providing technical assistance, 2) convening meetings to share implementation experiences and address challenges, 3) evaluating pilot projects, and 4) developing a consistent framework to capture results. When viable models are developed and produce improvements in patient outcomes, the health of populations, and/or the per capita cost of care, the Center will disseminate information about these best practices among participating states.

Section I: How Medicaid Pays for Drugs

Overview of the Medicaid Drug Rebate Program

Under the Medicaid program, states have the option of providing coverage for outpatient drugs as part of state plans (in practice, all states provide such coverage). In 1990, Congress responded to reports that Medicaid was overpaying for prescription drugs by enacting the Medicaid Drug Rebate Program (MDRP). Enactment of the MDRP, codified as section 1927 of the Social Security Act,[1] ensures that states receive a discount on a drug's average manufacturer price and never pay more than a brand name drug's best price (Best Price) in the U.S. pharmaceutical market. Under the MDRP, for states to receive federal Medicaid matching funds for expenditures on a covered outpatient drug, the manufacturer of the drug must have entered into a rebate agreement with the Secretary of the Department of Health and Human Services. In exchange for entering into a federal rebate agreement, manufacturers are guaranteed Medicaid and Medicare coverage of their drugs, subject to reasonable limits (SSA § 1927(a)). The MDRP directs state Medicaid programs to collect statutorily prescribed rebates from manufacturers on covered outpatient drugs; a portion of the rebates is shared with the federal government.

The rebate amount under the MDRP is the greater of either: (1) a statutory discount off the drug's average manufacturer price, or (2) the difference between that price and Best Price. Average manufacturer price is "the average price paid to the manufacturer for a 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" (42 C.F.R. § 447.504(a)). Best Price is generally the lowest price at which a given drug is sold to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity (SSA § 1927(c)(1)(C)(i)). Average manufacturer price and Best Price are reported by the drug manufacturer to the federal Centers for Medicare and Medicaid Services (CMS); these data are confidential and can only be disclosed in limited situations (SSA § 1927(b)(3)(D)).

The statutory discount on an average manufacturer price, called the rebate percentage, varies with the type of drug. The rebate percentage is currently set at 23.1% for single-source or innovator drugs (i.e., brand name drugs), 17.1% for innovator blood-clotting factor drugs and drugs approved by the FDA only for pediatric care, and 13% for non-innovator or multisource (i.e., generic) drugs (SSA § 1927(c)(1)(B), (c)(3)(B)). Congress increased the statutory discount percentages as part of the Affordable Care Act. The rebates attributable to this increase belong entirely to the federal government (SSA § 1927(b)(1)(C)). Whether the rebate is provided as a percentage discount or as a difference between average manufacturer price and Best Price, manufacturers owe additional rebates if the average manufacturer price increases faster than the consumer price index (SSA § 1927(c)(2)). Rebates are calculated based on a drug's national drug

[1] 42 U.S.C. § 1396r-8.

code (NDC), an 11-digit number that identifies the drug's manufacturer, product type, and package size.

Although states are entitled to receive rebates on the prescription drugs they cover under the MDRP, it is difficult for them to exclude any FDA-approved drug from Medicaid coverage. States are required to reimburse all drugs from any manufacturer that has signed a rebate agreement, unless a state committee of pharmacists and physicians determines that a drug "does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome… over other drugs in the formulary."[2] Regardless, states are empowered to establish preferred drug lists and use prior authorization as a way to negotiate rebates that supplement the statutory rebates required under the MDRP. Manufacturers are often willing to pay supplemental rebates for placement of their drugs on the state's preferred drug list, which in turn protects them from prior authorization requirements and the related administrative burdens that tend to discourage providers from using non-preferred drugs. Prior authorization programs have broader applications. They can be used to ensure evidence-based prescribing and to support patient adherence programs. For this reason, even drugs on a state's preferred drug list can be subject to prior authorization.

Recently, CMS issued a rule updating and modifying the agency's prior Medicaid managed care regulations.[3] The rule explicitly requires that MCOs with contracts that include prescription drug coverage must provide coverage of covered outpatient drugs that meets the coverage standards imposed by section 1927.[4] Thus, all of the MDRP requirements applicable to covered outpatient drugs subject to fee-for-service reimbursement are equally applicable to covered outpatient drugs subject to managed care contracting.

Dynamics Created by the MDRP

For many in health care, the workings of drug purchasing and the MDRP in particular are difficult to decipher. The SMART-D Phase I research has yielded some insights about the incentives and market behaviors fostered by the MDRP. These insights could be useful to state Medicaid leaders and other policymakers as they craft alternative and value-based payment approaches.

- **Medicaid Best Price provisions do not always apply to Medicaid itself**. Drug manufacturers participating in the MDRP are required to give CMS and Medicaid access to the Best Price offered elsewhere. But, within certain bounds, Medicaid programs have latitude to negotiate voluntary agreements with drug manufacturers that do not create a new Medicaid Best Price threshold (CMS, 2016b). For example, supplemental rebates negotiated by or for the state are excluded from Best Price determinations. See *Legal Brief: State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)* for a more detailed discussion.

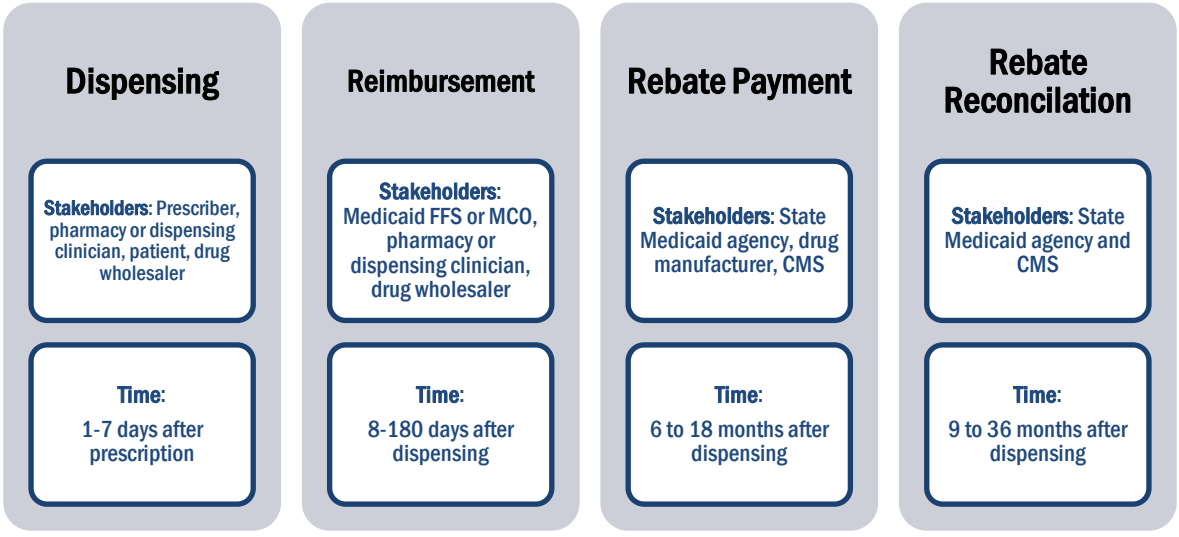
[2] SSA § 1927(d)(4)(C).
[3] Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. 27,498 (May 6, 2016).
[4] 42 C.F.R. § 438.3(s) (effective July 5, 2016).

- **The consumer price index penalty provision has an impact on price and purchasing behavior.** The consumer price index penalty provision in the MDRP is intended to protect Medicaid programs from price increases above the index. This provision, however, creates an incentive for drug manufacturers to set a high price upon entering the market because they cannot achieve price increases from Medicaid that are larger than the index after a drug enters the program. The consumer price index penalty can apply when a generic equivalent is first introduced, and in certain situations the penalty can reduce the price of the brand name drug to Medicaid so that it is less expensive than a new generic equivalent.

- **Federal rebates and state supplemental rebates are interdependent.** The Affordable Care Act increased the federal statutory rebate amount, with the increase allocated only to the federal government and not shared with states. This federal-only share interacts with state supplemental rebate agreements when supplemental agreements are negotiated to include a price floor. In essence, the states may lose a portion of their supplemental rebate to the federal government (OIG, 2014). Moreover, states bear the administrative burden and cost of billing drug manufacturers for the federal rebates, resolving any disputes regarding these rebates and then reconciling these amounts with CMS. In addition, states must share their supplemental rebates with the federal government based upon the federal Medicaid matching fund percentage set for each state.

- **Drug purchasing, reimbursement, rebates, and reconciliation are separate processes.** Three years or longer can elapse between dispensing a drug and reconciling rebates. There are four distinct stages to this process—dispensing, reimbursement, rebate payment, and reconciliation of rebates—each with a distinct set of stakeholders. Medicaid programs do not purchase drugs per se, rather they reimburse for drugs and then undertake rebate collection and reconciliation. This extended time horizon makes it difficult to calculate the financial impact of rebates because reconciliation occurs long after the patient receives the drug in question.

Figure 1: Time Horizon for Drug Dispensing to Medicaid Rebate Reconciliation

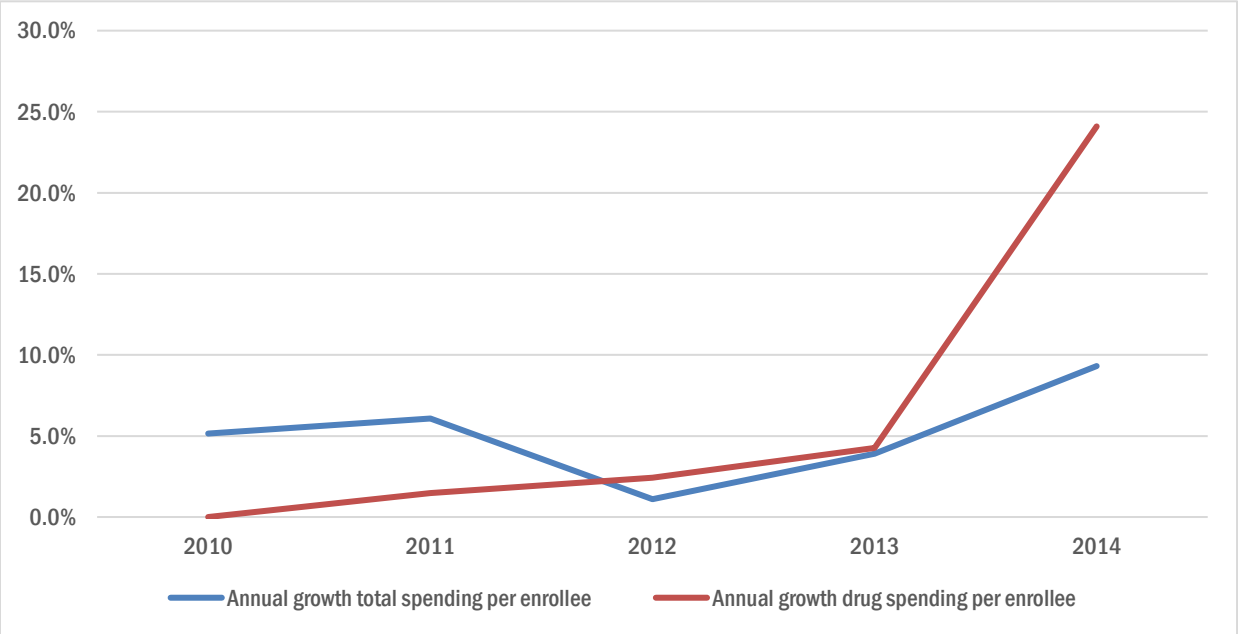


Section II: Medicaid Drug Spending and Cost Analysis

Overview of Medicaid Prescription Drug Spending

Between 2013 and 2014, the U.S. as a whole experienced a 12.2% increase in outpatient prescription drug costs—the largest increase in more than a decade. In this same yearlong period, spending by Medicaid on prescription drugs increased even more rapidly—14% in overall costs and 3.6% in expense per enrollee, with the total expenditures jumping from $37.1 billion to $42.3 billion (MACPAC, 2015a). CMS identified several drivers for the sudden growth in spending, including "increased spending for new medications (particularly for specialty drugs such as hepatitis C), a smaller impact from patent expirations, and brand-name drug price increases" (CMS, 2015d).

Figure 2. Percentage Change in Medicaid Spending per Enrollee



Source: MACPAC, 2015a

State Medicaid budgets have been drastically affected by the introduction of a small number of expensive specialty drugs. In a recent 50-state budget survey, a majority of states identified specialty and other high-cost drugs as a major factor in increasing financial outlays (NCBI, 2015). These high-cost therapies include hepatitis C antivirals, oncology drugs, cystic fibrosis agents, hemophilia factor drugs, and cholesterol medications (Smith et al., 2015).

Increases in Medicaid prescription drug expenses are also caused by spikes in prices and acquisition costs for certain kinds of generic drugs (Smith et al., 2015). Although there has been tremendous price escalation for some generic drugs, thus far the issue appears to be limited to

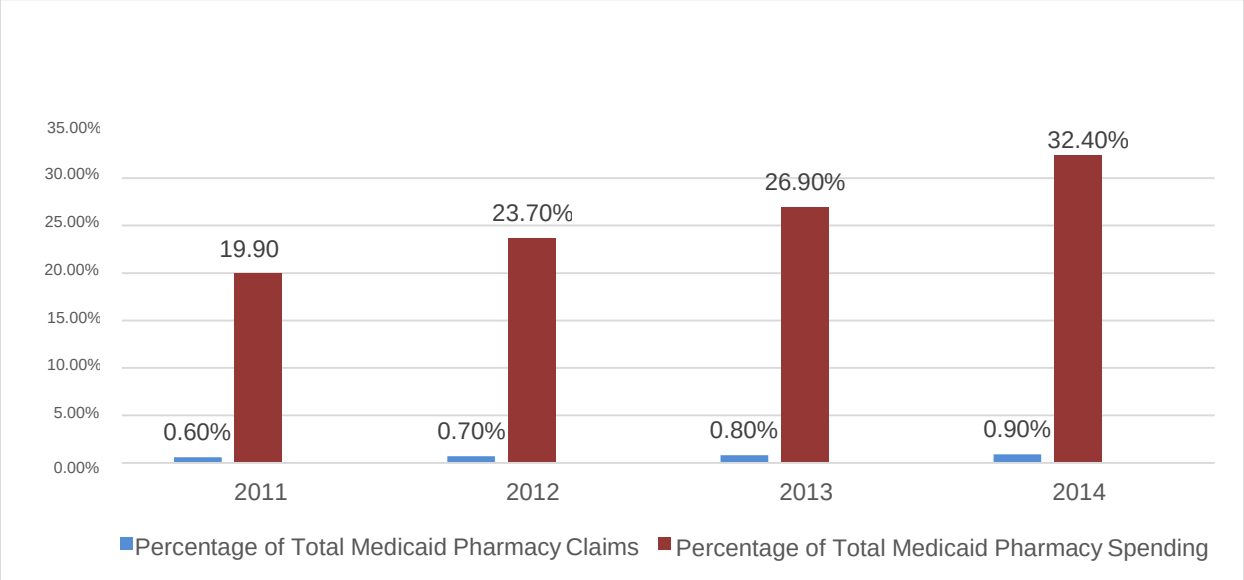
certain small market segments. A recent Department of Health and Human Services report (DHHS, 2016) attributes the rising costs in generic drugs to low competition in the market stemming from high barriers to market entry, mergers and acquisitions of pharmaceutical companies, or drug producers having exited the market. Yet, the costs of generic drugs remain small compared to brand-name drugs. In the Medicaid program, generic drugs accounted for 81% of prescriptions, but only 26% of expenditures (DHHS, 2016).

State Medicaid programs can pay directly for prescription drugs for some of their enrollees through fee-for-service delivery systems, but the programs increasingly rely on capitated arrangements with MCOs. Of the almost 64.8 million people covered by Medicaid in 2014, 43 million were enrolled in some kind of managed care, up 24% from 2013 (CMS, 2014). In a Medicaid state budget survey in October 2015, 35 states indicated that they "carve-in" prescription drugs to some degree in their contracted managed-care arrangements (Smith, et. al., 2015). According to the Medicaid and CHIP Payment and Access Commission (MACPAC), almost 60% of Medicaid prescription drug costs ($14 billion) are covered through Medicaid managed-care plans.

Impact of High-Cost Specialty Drugs on State Medicaid Costs

High-cost specialty drugs are typically used to treat complex, often rare diseases. Many of these medicines require ongoing assessments of the therapeutic response and patient adherence, complex patient or provider training, specialized handling by pharmacy or individualized distribution networks, and continuous monitoring of side effects.

Figure 3. Medicaid Prescription Drugs over $1,000 per Claim



Adapted from MACPAC, 2016

State Medicaid programs have spent billions of additional dollars on high-cost specialty drugs. A recent report on prescription drug spending indicates that high-cost specialty drugs accounted for

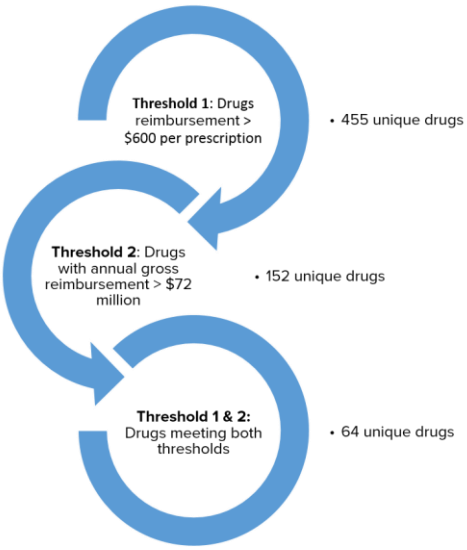
0.9% of claims but resulted in 32% of total spending (before rebates) in 2014 (See Figure 3: *Medicaid Prescription Drugs over $1,000 per Claim*). Between 2011 and 2014, prescription drug expenditures by Medicaid grew by 12.2%, with prescription drugs accounting for $42.3 billion in total spending in 2014 before rebates (CMS Drug Utilization Dataset, 2015).

SMART-D Analysis of "High-Cost" Specialty Drugs

Although there is anecdotal information about specific drugs driving up costs, this effect has not been isolated to a list of drugs or to Medicaid programs in particular. To that end, the SMART-D team developed a definition for "high-cost" drugs and undertook an analysis of these drugs. For the purposes of this study, high-cost, specialty drugs are defined as having the following characteristics:

- Reimbursement of more than $600 per prescription; and
- Total Medicaid reimbursements of $72 million per year.

After aggregating the CMS Medicaid State Drug Utilization Data across packaging, dosages, and labelers, the study team found 455 drugs for which average total reimbursements exceeded $600 per prescription and 152 drugs for which Medicaid reimbursement, gross of rebates, exceeded $72 million in the most recent four quarters for which data were available. There were 64 drugs that met both criteria. See the Appendix for a list of the 64 drugs, their average total reimbursement per prescription, and their cost to Medicaid in fiscal year 2015.



In fiscal year 2015, these 64 drugs accounted for 9.3 million prescriptions or 1.5% of Medicaid prescriptions nationally. However, this group of drugs comprised a much larger share of prescription drug spending: 32.6% of Medicaid drug reimbursement dollars or $16.9 billion in Medicaid drug reimbursements (before rebates). This spending was for covered outpatient drugs and those that physicians administer. To contextualize this, consider that the Medicaid program spent an estimated $538.4 billion for all services in 2015 (Kaiser, 2015b). **The estimated $16.9 billion spent on these 64 high-cost drugs accounts for 3.1% of total national Medicaid spending for all services.**

This analysis demonstrates that a small number of high-cost specialty drugs are driving Medicaid drug spending and having an impact on states' Medicaid budgets. In the near future, there are at least 110 additional drugs in the pipeline that are likely to be high-cost and could have large effects on state Medicaid budgets. See the *SMART-D Economic Analysis* for details on the economic analysis and pipeline forecast.

Section III: Current Medicaid Environment and Drug Management Strategies

Importance of State Medicaid Program Configuration

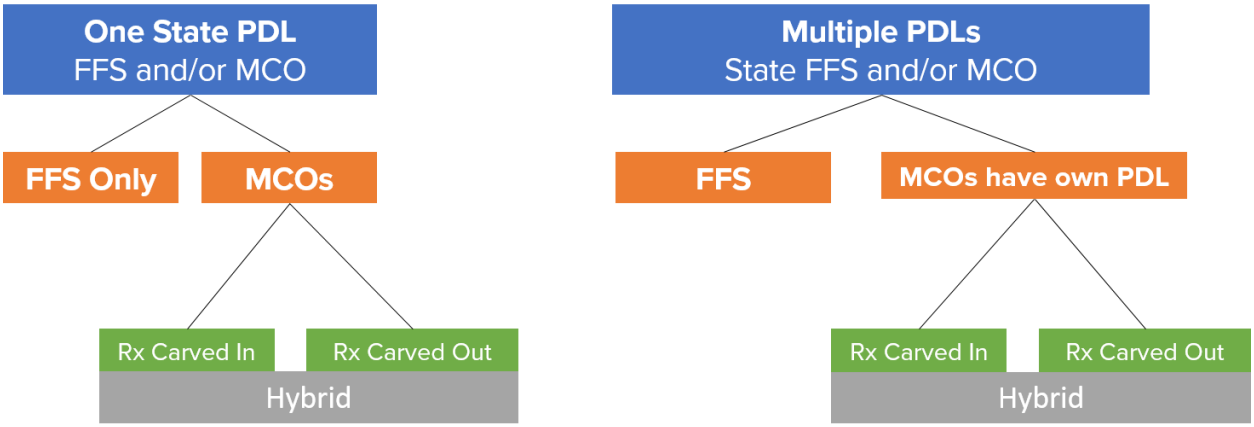
State Medicaid programs have different approaches to prescription drug coverage and payment, making it difficult for drug manufacturers and policymakers to identify a single intervention that is applicable to all states. This variability in approach is not limited to prescription drug purchasing. During stakeholder interviews conducted by SMART-D team members, drug manufacturers described state Medicaid program design as confusing and said that APM-centric classifications would help drug manufacturers approach individual states with more specific models.

Medicaid programs have many design elements that vary by state, but three elements are particularly important when considering alternative drug payment models:

1. *Preferred drug list*. Does the state have one Medicaid preferred drug list or multiple lists?
2. *Fee-for-service and managed care*. Does the state provide Medicaid benefits only through a fee-for-service program? Or does the state use fee-for-service and managed care?
3. *Pharmacy benefit configuration*. For states with Medicaid managed care, is the pharmacy benefit included (carved-in), excluded (carved-out), or a hybrid?

Figure 4, *State Categories for Alternative Drug Payment Models*, depicts how these elements occur across states. In SMART-D's Phase II planning process, the Center will work with state officials and drug manufacturers to design APMs that fit with these varying practices.

Figure 4: State Categories for Alternative Drug Payment Models



PDL = preferred drug list; FFS = fee for service; MCO = managed care organization; RX = drug coverage; Hybrid = combination of carve-in and carve out

Other Program Attributes Affecting Drug Purchasing

State Medicaid programs have drug purchasing programs and pricing tools that must be figured into the development of alternative and value-based models, which include the 340B Drug Program, membership in prescription drug purchasing pools, management of clinician-administered drugs, and actual acquisition cost pricing.

340B Drug Program

The 340B Drug Program provides reduced-price prescription medications to certain health care facilities (referred to as "covered entities") participating in the program. Drug manufacturers must offer discounts to 340B entities as a condition of Medicaid coverage of the drugs. Drugs included in the 340B program generally include outpatient prescription drugs and drugs administered by physicians in an outpatient setting (HRSA, n.d.).

State Medicaid programs could try to maximize drug savings through 340B prices, however, the program can be burdensome to administer. Most states' program administrators expect 340B entities to bill the state at their actual acquisition cost for 340B drugs, which is generally lower than Medicaid drug prices. But because 340B prices are proprietary, states' program administrators must rely on post-payment reviews to determine payment accuracy. In addition, it can be challenging for state officials to determine whether to submit claims from 340B providers for federal rebates or to exclude them to avoid duplicate discounts. Some states have created programs to take advantage of drug pricing offered through 340B and offer "whole person care" approaches, such as centers of excellence used to establish hemophilia treatment centers. In these states, Medicaid beneficiaries with hemophilia are required to receive care through these providers.

Purchasing Pools

States can negotiate supplemental rebates as a single state, through multistate purchasing pools, or both individually and through a purchasing pool, depending upon the drug(s) being purchased. As state Medicaid program directors seek to implement APMs, these purchasing pools are a key stakeholder. According to a CMS survey from December 2015, almost all states (47) participate in some type of supplemental rebate agreement (CMS, 2015b); 31 states have single-state supplemental rebate agreements with an effective date ranging from the 1980s through 2015. More than half of states (28) participate in multistate supplemental rebate agreements with effective dates ranging from 2004 through 2015; 12 of those states participate in both single-state and multistate supplemental agreements.

Clinician-administered Drugs

Clinician-administered medications often fall outside of states' (and other payers') traditional pharmacy management systems and are reimbursed through the payer's medical, rather than pharmacy, benefit. Because of the significant number of high-cost specialty drugs that are clinician-administered, states have undertaken efforts to more closely manage these drugs. These efforts include management and payment of clinician-administered medications through state pharmacy systems, as well as state efforts to expand pharmacy management of clinician-administered medications that continue to be billed and reimbursed as a medical benefit (Pinson, 2016). Nationally, across payer types, it is estimated that clinician-administered medications reimbursed through the medical benefit amount to 28% of overall drug spending, although many estimates of prescription drug spending omit these figures (ASPE, 2016a). An even greater proportion of specialty drug spending (55%) is estimated to be reimbursed through the medical benefit. Forecasts for the drug approval pipeline show significant activity for clinician-administered drugs, meaning that growth in this area is likely to continue.

Actual Acquisition Cost

In February 2016, CMS released a final rule requiring states to shift to actual acquisition cost reimbursement for drugs provided through outpatient pharmacies that are reimbursed on a fee-for-service basis. This rule covers only outpatient drugs, not physician-administered drugs. This shift to actual acquisition cost is intended to establish Medicaid pharmacy payments that more accurately reflect the amount that pharmacies pay for drugs. With the new federal rule, many states are now in the process of evaluating and determining plans to comply with these actual acquisition cost requirements by April 2017 (CMS, 2015a and 2016d).

Medicaid MCOs and the Pharmacy Benefit

Since 2011, many states with Medicaid managed care programs have shifted the pharmacy benefit into managed care. This shift has been driven by the new opportunity, authorized by the Affordable Care Act, for states to claim federal drug rebates on managed care pharmacy claims. Some states that had previously retained pharmacy as a fee-for-service benefit have begun to carve pharmacy into their managed care contracts. In addition, states have further increased pharmacy spending through managed care plans by expanding populations covered through

managed care (Pinson, 2016). Between 2011 and 2014, managed care drug spending grew from 14% to 47% of total gross Medicaid drug spending (MACPAC, 2016).

Increased responsibility for pharmacy expenditures has also generated greater scrutiny for MCOs in the areas of MDRP compliance, preferred drug lists, and care management. In recently issued Medicaid managed care regulations, CMS recognized the variability in how MCOs have implemented the pharmacy benefit for covered outpatient drugs, and therefore clarified that the requirements of the MDRP apply equally to both Medicaid fee-for-service and MCO prescription drug purchasing (42 C.F.R. § 438.3(s)). Historically, states have allowed some variability of preferred drug lists between their fee-for-service programs and MCOs. Some states might continue to allow this variability in preferred drug lists, while others might tighten alignment between the managed care and fee-for-service components of their programs (or among their contracted MCO's). In addition, state Medicaid programs are starting to hold MCOs accountable for care management to support adherence to drug regimens, particularly for high-cost drugs (Pinson, 2016).

Medicaid administrators have maximized the use of existing drug utilization management tools in their fee-for-service programs, particularly the use of prior authorization and preferred drug lists. To further align efforts to support patients with complex care needs, through health homes or primary care case management, state officials are exploring the use of drug case-management programs and centers of excellence to improve patient outcomes when using complex and high-cost drug regimens (Pinson, 2016). These tools are well-known to states, commercial payers, drug manufacturers, providers, and pharmacies and are described in more detail in the *Medicaid and Specialty Drugs: Current Policy Options* report (Pinson, 2016).

As Medicaid directors have maximized the use of current management tools, their interest in alternative drug payment models is increasing. In individual interviews, state Medicaid leaders expressed interest in adopting alternative payment models. Reasons for this interest include garnering better value for tax dollars spent, improving health outcomes and quality of care for patients, reducing waste, achieving better cost predictability, and meeting state budget requirements.

State Medicaid Political Environment

Drug purchasing stakeholders—states, MCOs, pharmacy benefit managers, drug manufacturers, federal policymakers, and others—are operating in a politically charged environment. Scrutiny of drug costs and patient access make it difficult for stakeholders to collaborate, take risks, and find new solutions. State officials are under intense pressure to balance their budgets, achieve broad patient access to treatment, avoid lawsuits, and deliver on the expectations of the state's executive and legislative branches. Alternate drug purchasing and payment models will not address all of these concerns. But APMs can be one of the tools states use to create fiscal predictability for high-cost drugs and to support patient access.

As the Center for Evidence-based Policy, state Medicaid programs, drug manufacturers, and other stakeholders navigate the process of developing APMs for Medicaid drug purchasing, it is critical to bear in mind the following sensitive dynamics:

- *Medicare has proposed changes for clinician-administered drugs*. A draft proposal from Medicare to test new models for reimbursing clinician-administered drugs within the Part B program has received both criticism and support (CMS, 2016c). The controversy associated with this Medicare proposal could make drug manufacturers, providers, pharmacies, and others more sensitive about changes to drug purchasing within state Medicaid programs.

- *Congress is making inquiries about rising drug costs*. The National Association of Medicaid Directors (NAMD) released a letter in March 2016 to the U.S. Senate Finance Committee underscoring Medicaid agency concerns with the limits of Medicaid's existing policy levers to negotiate drug prices and the need to move toward valued-based payment models (NAMD, 2016). The Senate Finance Committee has been actively investigating pricing for hepatitis C drugs, and 14 members of the Committee have opposed the Medicare Part B test for clinician-administered drugs (U.S. Senate, 2016).

- *High-cost drugs have strained state Medicaid budgets*. The new drugs, such as hepatitis C drug therapies, have created midyear or mid-biennium Medicaid spending deficits for several states. In response to financial concerns from Medicaid managed-care plans, California, Florida, and Pennsylvania are among states that needed supplemental funds to support state and MCO expenditures for these drugs. These supplemental budget appropriations attract legislators' attention—and are an unsustainable method of managing drug costs.

- *State legislatures are scrutinizing drug cost and access*. A search of the National Council of State Legislatures prescription drug state database for calendar year 2016 found 183 bills in 40 states related to pharmaceutical pricing and payment and 81 bills in 30 states related to Medicaid drug use and cost (NCSL, 2016a). State Medicaid program directors know that state legislators are worried about drug costs and are under pressure from patient groups, MCOs, pharmacies, providers, drug manufacturers, and others.

- *Lawsuits against state Medicaid programs*. Numerous states are contending with class action lawsuits, or threats of such lawsuits, to expand patient access to hepatitis C drugs (Ollove, 2016). These lawsuits make state officials risk averse, whether the state has been sued or not, because the lawsuits allege violation of federal Medicaid statutory provisions that are applicable to all states. State Medicaid programs could end up in an adversarial position to patients and drug manufacturers, and efforts to collaborate could be hampered while lawsuits are active. Patients expect access to drugs they believe may improve and better manage their condition, but state Medicaid programs—and state governments as a whole—might not have the funds to meet this demand or the tools to ensure that the drugs deliver the results patients expect.

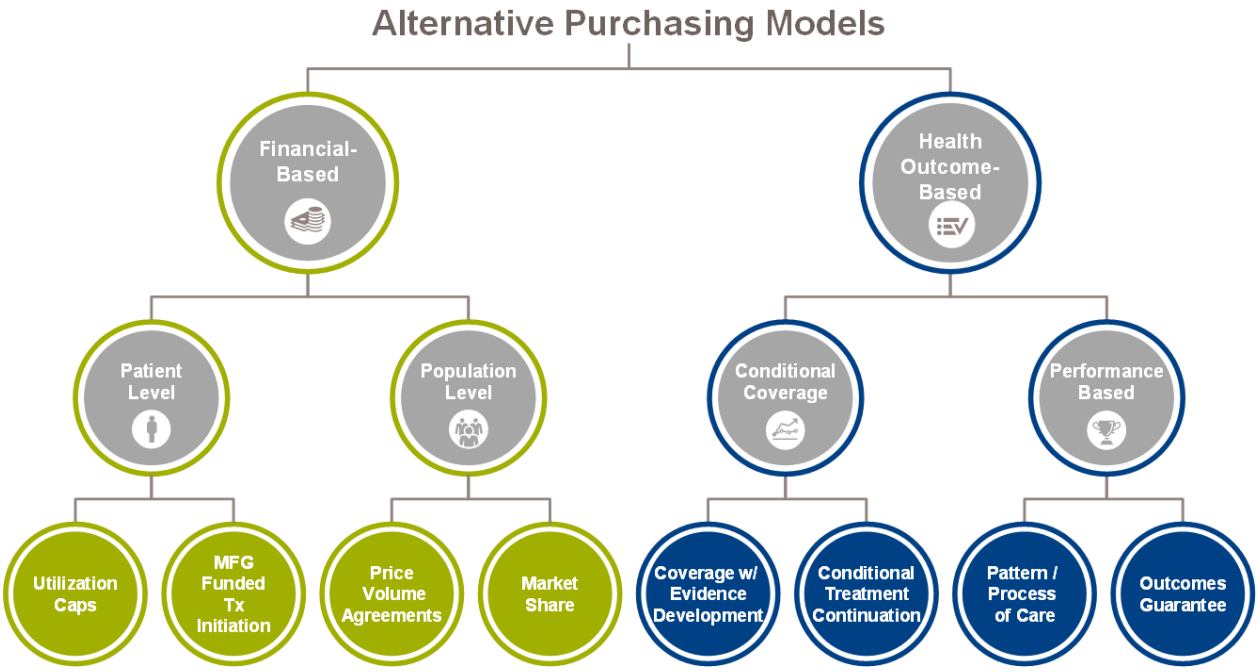
Section IV: Alternative Payment Models Used in U.S. Commercial and International Markets

To address the issues outlined above, state officials are exploring the potential of alternative payment models. An APM is a contract between a payer and drug manufacturer that ties payment for a drug or drugs to an agreed-upon measure. Currently, in Medicaid drug purchasing, the manufacturer sets a price for the drug wholesaler, pharmacy, or provider, and Medicaid reimbursement is based upon that price, with a subsequent, time-delayed reconciliation for rebates. An APM changes the price-setting dynamic and creates shared risk between the manufacturer and payer for an agreed-upon outcome measure.

APMs are generally financial- or health outcome-based. (See Figure 5: *Alternative Payment Models Taxonomy*.) Financial-based APMs, designed at either the patient or population level, rely on financial caps or discounts to provide predictability and limit the risk of uncontrolled spending. In health outcome-based APMs, payments for drugs are tied to predetermined clinical outcomes or measurements, or conditional coverage of the drug is offered while data regarding its clinical effectiveness is being collected. Financial-based APMs, which focus on lowering costs and expanding patient access, have proven to be easier to administer. APMs related to health outcomes require additional planning and data collection, but have the potential to increase the quality, value, and efficiency of treatments.

This summary report provides a short overview of APMs. An in-depth analysis of European and U.S. commercial market APMs, including examples and lessons learned, is provided in the *Alternate Payment Model Brief: State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)*.

Figure 5: Alternative Purchasing Models Taxonomy



Adapted from Garrison, 2014; INSEAD, 2014

APMs are less common in the United States than in many other parts of the world because purchasing power is distributed among a large number of entities rather than being centralized, as it is in most other developed countries. The extent to which APMs are used in the U.S. is not well-known because most programs involve confidential contracts between pharmaceutical manufacturers and MCOs or their pharmacy benefit managers. However, there are indications that the use of APMs might be growing.

APMs have been used in numerous European Union (EU) countries for many years and in some, such as Italy, they have become relatively commonplace. APMs in the EU have developed into a valuable tool for financial management, patient access, quality improvement, and successful negotiations with drug manufacturers. The types of APMs utilized in the EU vary across markets; currently, the majority of APMs in effect are financial-based. In Italy, outcomes-based agreements are more frequent. In some EU markets, the purpose of an APM is to take a drug that is deemed not cost-effective and make it cost-effective by reducing the price of the drug (e.g., a simple price-volume discount). In other markets where cost-effectiveness is not the primary criterion, outcomes-based APMs are used to limit coverage to specific indications while coverage evidence is gathered. See Table 1 for a summary of European APMs.

Table 1: Types and Percentage of Total APMs in Europe

Type	% of APMs	Description
Price-Volume	39.2%	The price of a drug is tied to the volume of utilization. Thresholds may exist where the price would gradually decrease (e.g., $100 per patient for the first 10,000 patients; above that, $80 per patient).
Data Collection	29.2%	Additional data collection is required for coverage so that either (a) a more thorough analysis of a health intervention can be conducted at a later time or (b) claimed cost savings can be validated in the real world.
Limited Access	13%	Access to a drug is more restrictive than the regulatory label. The covered group might include special populations perceived to receive the highest value from a treatment. Or certain health centers or specialists may be tasked with acting as "gatekeepers" of prudent use.
Conditional Coverage	5.6%	Coverage is provided under pre-specified conditions such as running additional clinical trials or publication of outcomes studies.
Results-based	5.4%	The price corresponds to an economic, clinical, or humanistic outcome, for example, if the price was only paid for patients who achieved the agreed-upon outcome.
Simple discounts	4.6%	A typically nontransparent price is provided to bring the affordability, cost-effectiveness, or value to an acceptable level. Generally used in markets that utilize cost-effectiveness-based coverage decisions, such as in the UK.
Price or dose cap	2.2%	The price may be capped per patient or dose. For instance, the payer would pay the same, singular, standard price for all patients, including those who remain on treatment for extremely long durations or require significantly higher doses.
Price match	0.8%	The price of a health technology is tied to a comparator benchmark for any given setting. Typically done when products are widely available but there is a large variation in price depending on the technology used.

(Fessario, 2013)

APM options that are available in other countries, where one entity negotiates for all citizens, are likely not directly transferable to the U.S., in either the private or public sectors, although these options have elements to borrow and experiences to learn from. In addition, state Medicaid programs have less leverage over manufacturers than private U.S. payers because of the requirements of the MDRP. They also encounter significant regulatory and technical challenges in the implementation of APMs. However, SMART-D interviews with a range of Medicaid officials showed a distinct interest in these programs, especially those related to health outcomes. Please see the SMART-D *Alternate Payment Model Brief* for an in-depth analysis of European and U.S. commercial market APMs, including examples and lessons learned. During Phase II of the project, concrete APM proposals will be developed for consideration by state Medicaid programs.

Section V: Legal Analysis and Pathways

To enable states and other interested stakeholders to move forward with APMs, SMART-D analysts conducted a detailed legal analysis of the MDRP and other federal and state laws relevant to Medicaid drug coverage and payment. SMART-D analysts identified seven legal pathways for developing APMs that appear to offer significant value-based opportunities for states: supplemental rebate arrangements, MCO contracting, MCO/340B covered entity partnerships, hospital-dispensed covered outpatient drugs, physician-administered drugs that fall outside the definition of a "covered outpatient drug," Section 1937 alternative benefit plans, and Section 1115 waivers.

This summary report provides an overview of these seven pathways. Any state or stakeholder considering moving forward with APMs should review the entire SMART-D legal analysis: *Legal Brief: State Medicaid Alternative Reimbursement and Purchasing Test for High-cost Drugs (SMART-D)*. This detailed report provides an overview of the MDRP and analyzes federal and state laws, including those associated with the MDRP, that affect a state Medicaid agency's opportunity to establish an APM. It also provides a detailed discussion of the seven pathways and their strengths and weaknesses.

Seven Pathways

The approach taken in each of the legal pathways described below varies significantly. Pathway One builds upon supplemental rebates, a tool currently used by almost all Medicaid programs to gain additional rebate revenue from drug manufacturers. Pathway Two offers opportunities to implement payment pathways through managed care contracting. In states that include prescription drug benefits in managed care contracts, the ability to implement prescription drug APM opportunities under Pathway One or Pathway Two depends heavily on the ability of state officials and their MCO and pharmacy benefit manager partners to bring manufacturers to the negotiating table, unless state officials choose to carve one or more therapeutic drug classes out of their managed care contracts in order to negotiate directly with manufacturers. The remaining five pathways take a different approach. They are structured to allow states to negotiate value-based arrangements outside of the MDRP, either in whole or in part. Pathways Three and Four are based on explicit statutory exceptions to the MDRP. The MDRP statute only applies to "covered outpatient drugs," so Pathway Five focuses on opportunities related to prescription drugs that fall outside the statute's definition of a "covered outpatient drug."[5] Pathway Six relies on the Secretary of Health and Human Service's authority to approve differing benefit packages for certain groups of Medicaid enrollees. Pathway Seven relies upon the Secretary's authority to waive MDRP requirements or to interpret them more narrowly when in conflict with other Medicaid provisions.

[5] SSA § 1927(a), (k)(2)-(3).

The seven pathways are not necessarily mutually exclusive. Some are more appropriate for a narrow class of drugs and others can be used more broadly. For example, Pathways One and Seven could be applied to virtually any group of drugs covered by a state plan, whereas Pathways Two and Three are limited to MCO-covered drugs, and Pathway Five applies only to physician-administered drugs. In designing a specific prescription drug APM, state officials could choose to combine two or more of the pathways detailed below or limit the APM to only one of the pathways.

Pathway One: Supplemental Rebate Arrangements

States, either individually or through multistate purchasing groups, are expressly authorized under the MDRP to enter into supplemental rebate agreements with manufacturers. Under these negotiated agreements, manufacturers pay rebates that supplement the statutory rebates they are obligated to pay as part of their MDRP participation. Apart from being subject to CMS approval, supplemental rebate arrangements are largely unregulated, allowing states and manufacturers to negotiate terms and conditions designed to implement health outcome-based and financial-based APMs. Pathway One capitalizes on this opportunity by using the tools underlying supplemental rebate arrangements (including prior authorization, preferred drug lists, generic and therapeutic substitution, among others) to launch APM's. CMS expressly encourages use of value-based arrangements as part of supplemental rebate agreements between Medicaid and drug manufacturers in a July 2016 program notice (CMS, 2016b).

Since enactment of the Affordable Care Act, states have been entitled to receive MDRP statutory rebates on covered outpatient drugs paid by Medicaid MCOs, not only those reimbursed on a fee-for-service basis. Extension of the MDRP to drugs purchased through MCOs, most of which are reimbursed by pharmacy benefit managers on behalf of MCOs, means that states now have an opportunity to negotiate supplemental rebates on such drugs.

Pathway Two: MCO Contracting

Pathway Two is designed to take advantage of the greater flexibility and experience that Medicaid MCOs offer in negotiating alternative payment or value-based arrangements with manufacturers and providers. Because actual acquisition cost reimbursement under the covered outpatient drug rule does not apply to drugs purchased through MCOs, they have more leeway than states in reimbursing covered outpatient drugs so that pharmacies are rewarded for engaging in outcome-based best practices. Such authority allows MCOs to establish alternative payment models for retail drugs that states are precluded from pursuing in the fee-for-service setting. Pathway Two is also structured to capitalize on the significant experience that pharmacy benefit managers have in negotiating with manufacturers on behalf of private non-Medicaid payers, to the extent that an MCO has subcontracted with a pharmacy benefit manager. Under Pathway Two, states would delegate to the pharmacy benefit managers the task of negotiating the states' supplemental rebates in lieu of the pharmacy benefit managers' own rebates, and these arrangements could mirror the structure of financial- or health outcome-based APM's that a pharmacy benefit manager might negotiate for a commercial health plan. This approach would require delicate

negotiations in contracting with MCOs because the terms of an MCO-based supplemental rebate program would have to be incorporated into the MCO's subcontract with the pharmacy benefit manager.

In considering the viability of an APM based on Pathway Two, a state must consider at the outset how to structure the pharmacy benefit managers' supplemental rebate arrangement in a manner that does not adversely affect a manufacturer's Best Price. Pharmacy benefit manager rebates are historically included in a manufacturer's Best Price calculations, so it would be understandable if most manufacturers hesitated to entertain a pharmacy benefit manager supplemental rebate proposal for fear of setting a new Best Price. In this case, though, the rebates would be passed through to the Medicaid program, either directly to the state Medicaid agency or indirectly through the MCO. The rebates would therefore qualify for the explicit Best Price exemption applicable to pharmacy benefit manager rebates that are not designed to adjust prices at the retail or provider level.

Pathway Three: MCO/340B Covered Entity Partnerships

Section 1927(j) of the Social Security Act establishes two explicit MDRP exemptions for covered outpatient drugs that, in the absence of the exemptions, would be subject to the full range of MDRP requirements. The first exemption, found in 1927(j)(1) (hereafter the (j)(1) Exemption), was created to protect drug manufacturers from providing both a discount and an MDRP rebate on a drug purchased through the federal 340B drug discount program. It states that manufacturers are not required to pay an MDRP rebate on drugs purchased through the 340B program and paid for by an MCO.[6] The (j)(1) Exemption covers the entire MDRP statute, not only the rebate requirements.[7] The second exemption was established under Section 1927(j)(2) (hereafter the (j)(2) Exemption) and serves as the basis of Pathway Four, which is discussed in the next section.

The (j)(1) Exemption only applies to drugs purchased through the federal 340B drug discount program, and therefore the scope of Pathway Three is limited to this cohort of 340B activity. The 340B program allows certain types of safety net providers, called "covered entities," to purchase covered outpatient drugs at substantially discounted prices. Often these providers pay less than the amount that state Medicaid agencies pay, even after the MDRP rebate is factored in. 340B covered entities include federally qualified health centers, disproportionate-share hospitals (which serve a high proportion of Medicaid and uninsured patients), children's hospitals, clinics funded by the Ryan White HIV/AIDS Program, and hemophilia treatment centers, among other safety net providers. Some of these providers treat large and diverse Medicaid populations, some focus on specific conditions, and some do both.

Importantly, besides protecting manufacturers from the duplicate discount risk associated with 340B drugs paid for by MCOs, the (j)(1) Exemption removes such drugs entirely from regulation under the MDRP. The (j)(1) Exemption therefore creates an opportunity for state Medicaid

[6] SSA § 1927(j)(1).
[7] *Id.*

agencies to experiment with alternative payment models outside of the MDRP's constraints. The (j)(1) Exemption is triggered when two events coincide: (1) a covered entity purchases a drug through the 340B program, and (2) the drug is "dispensed" by a Medicaid MCO.[8] CMS has interpreted the word "dispensed" to mean "paid for."[9] If the exemption is triggered, the drugs in question "are not subject to the requirements" of the MDRP statute.[10]

Perhaps the most significant advantage of Pathway Three is that the drugs in question are already purchased at discounted prices that approximate, and in many cases are less than, the prices the state pays after receiving the MDRP rebate. In that sense, the pathway is less dependent on replacing the MDRP rebate revenue. States can therefore focus their negotiations with manufacturers on patient outcome and quality of care measures and worry less about the size of their rebates. This pathway should also reduce the state's administrative costs in seeking the rebate and managing manufacturer rebate disputes.[11]

Pathway Three offers several additional advantages. As a result of the (j)(1) Exemption, MCO 340B drugs are not regulated under the MDRP. State Medicaid program directors are therefore liberated from the MDRP requirements preventing them from setting different prescription limits, varying rebate amounts based on indication, linking payment to a drug's clinical performance, or establishing closed formularies. States and manufacturers have broad latitude to negotiate creative and mutually beneficial agreements. There is an explicit Best Price exemption for 340B drugs, so the risk of establishing a new Best Price should not interfere with negotiations.[12] The pathway also allows for innovative pharmacy payment models because the drugs would not be subject to actual acquisition cost reimbursement standards. Lastly, CMS approval would not be required unless the state chooses to couple the pathway with broader reforms requiring a state plan amendment or waiver.

Pathway Four: Hospital-Dispensed Covered Outpatient Drugs

In the same way that Pathway Three is built around the (j)(1) Exemption, Pathway Four is based on the second MDRP exemption, the (j)(2) Exemption. The exemption applies to hospitals that dispense covered outpatient drugs using formulary systems and bill Medicaid at no more than the hospital's purchasing cost for the drug.[13] The statute specifies that the state's Medicaid plan "shall provide" that a hospital billing such drugs "shall not be subject to the requirements of this section."[14] Although the statute could be read to exempt hospitals from the MDRP rather than the drugs billed by hospitals, CMS has interpreted the (j)(2) Exemption to mean that the drugs

[8] SSA § 1927(j)(1).
[9] *See* Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability, 81 Fed. Reg. at 27,546.
[10] SSA § 1927(j)(1).
[11] Note that some administrative burden would remain to remove the 340B claims from the other rebate claims. Also, the availability of the model would be both payer-dependent (only when an MCO is the payer) and drug-dependent (only when 340B drugs are used).
[12] Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. at 5,256.
[13] SSA § 1927(j)(2).
[14] *Id.*

themselves are not subject to the rebate requirement.[15] Virtually every hospital buys drugs using a formulary. As long as hospitals bill the drugs at no more than their purchasing costs—a requirement states could add to their state plans—such drugs would appear to fall within the (j)(2) Exemption.

The scope of the (j)(2) Exemption is not entirely clear, and CMS has only interpreted it in response to litigation.[16] On the one hand, the (j)(2) Exemption is a clean slate, and CMS is not restricted by how it has viewed the provision previously. On the other hand, the public has no way of knowing whether CMS might be willing to allow states to employ the exemption.

Subject to clarification with CMS, Pathway Four has the potential to offer many of the advantages of Pathway Three described above, but only for drugs obtained through a hospital formulary. Because the manufacturer rebate arrangements would not be governed under the MDRP, rebates could be indication-specific and adjustable. Value-based provider payment innovation would also be possible for hospital physician-administered drugs. Importantly, most of the hospitals serving large numbers of Medicaid beneficiaries are likely to be enrolled in the 340B Program. By only having to pay hospital purchasing costs, states could reduce their drug expenditures to levels comparable to or below their current expenditures under the MDRP, which in turn would allow them to pursue health outcome-based arrangements with drug manufacturers that do not involve paying large rebates.

Pathway Five: Physician-Administered Drugs That Fall Outside the Definition of "Covered Outpatient Drug"

The MDRP, and the restrictions it imposes on drug coverage, only apply to "covered outpatient drugs." The definition of covered outpatient drugs is broad, encompassing all prescription drugs, biologics (other than vaccines), and insulin.[17] The definition, however, is narrowed by a "limiting definition," which excludes physician- and clinician-administered drugs. This limiting definition provides a potential opportunity for Medicaid agencies to experiment with APM arrangements, free of the constraints of the MDRP.

The scope of Pathway Five is narrower than that of the other six pathways because it only applies to drugs that are not separately billed and reimbursed within a state's Medicaid program. Virtually every drug dispensed in the retail setting is separately billed and paid for by Medicaid, so Pathway Five would be limited to drugs administered by a physician or a professional operating under a physician's supervision such as a nurse. States have a strong incentive to consider these physician-administered drugs as covered outpatient drugs because they would then become eligible for rebates under the MDRP. For this reason, Pathway Five might be

[15] *See* CMS, MDRP Release No. 153 (Oct. 16, 2009), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-153.pdf; *see also* Safety Net Hospitals for Pharm. Access (now known as 340B Health), *CMS Clarifies NDC Reporting Requirements* (Nov. 3, 2009), http://www.340bhealth.org/files/ndc_packet.pdf.

[16] Safety Net Hospitals for Pharm. Access (now known as 340B Health), *CMS Clarifies NDC Reporting Requirements* (Nov. 3, 2009), http://www.340bhealth.org/files/ndc_packet.pdf.

[17] SSA § 1927(k)(2).

appealing for only a small group of physician-administered drugs, although that category of drugs may be growing. A state would have to be willing to surrender its MDRP statutory and supplemental rebates in exchange for the right to negotiate an APM arrangement outside the limitations of the MDRP. State Medicaid officials would have to feel confident that, by applying a closed formulary or using promising payment strategies not permitted under the MDRP, they could negotiate rebates comparable to those available through the MDRP and/or establish health outcome-based arrangements that are sufficiently attractive to justify lower rebate amounts.

As far as the SMART-D team knows, Pathway Five is untested, probably because it runs counter to the prevailing practice (among states and CMS) of trying to qualify as many drugs as possible as covered outpatient drugs in order to apply clinical prior authorization criteria and maximize rebate revenue under the MDRP. The approach proposed in Pathway Five works if the drugs in question can be paid for as part of a broader set of services. The most suitable drugs might be those for which the value of the forfeited MDRP rebates is outweighed by the potential benefits of improving patient outcomes, avoiding waste, reducing the use of costly health services such as hospitalizations, or achieving other value-based goals. This pathway could therefore be used in conjunction with provider payment models centered on specific disease states or episodes of care involving the administration of drugs that generally have low rebate value but high patient-outcome potential. Provider payments could be structured to create an incentive for value-based patient care because they would not be subject to actual acquisition cost limitations.

Pathway Six: Section 1937 Alternative Benefit Plans

Enacted under the Deficit Reduction Act of 2005, and amended in 2010 by the Affordable Care Act, section 1937 of the Social Security Act provides states with the flexibility to develop Medicaid benchmark or benchmark equivalent coverage, now referred to by CMS as "alternative benefit plans" (ABPs).[18] States are required to provide Medicaid expansion populations with a benefit package in accordance with ABP standards,[19] and in addition, may develop ABPs for targeted populations or geographic regions of a state.[20]

[18] SSA § 1937(a); CMS, State Medicaid Director Letter 12-003 (Nov. 20, 2012), https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD-12-003.pdf; CMS, *Alternative Benefit Plan Coverage*, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/alternative-benefit-plans.html (last visited June 20, 2016). The following coverages are considered to be benchmark coverage: (1) The standard Blue Cross/Blue Shield preferred provider option service benefit plan offered under the Federal Employee Health Benefits program; (2) a coverage plan that is offered and generally available to the state's employees; (3) a health insurance coverage plan that is offered by an health maintenance organization (HMO), and "has the largest insured commercial, non-Medicaid enrollment of covered lives of such coverage plans offered by such a [HMO] in the State involved"; and (4) a "Secretary-approved" plan. SSA § 1937(b)(1); 42 C.F.R. § 440.330.

[19] SSA § 1902(k)(1).

[20] CMS, State Medicaid Director Letter 12-003 (Nov. 20, 2012), https://www.medicaid.gov/Federal-Policy-Guidance/downloads/SMD-12-003.pdf; CMS, *Alternative Benefit Plan Coverage*, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/alternative-benefit-plans.html (last visited June 20, 2016).

Alternative benefit plans must cover essential health benefits (EHBs) as defined by 10 categories of health care services, including prescription drugs.[21] For prescription drugs, Medicaid ABP/EHB standards are defined in reference to EHB standards for health insurance exchange plans requiring coverage of the greater of (1) one drug in every United States Pharmacopeia category and class; or (2) the "same number of prescription drugs in each category and class as the EHB-benchmark plan."[22] In addition, to the "extent states pay for covered outpatient drugs under their [ABP's] prescription drug coverage, states must comply with the requirements under section 1927 of the [Social Security] Act."[23] In the comment and response preamble to the final Medicaid EHB rule, there is a lengthy discussion of the application of section 1927 of the Social Security Act to Medicaid ABPs and EHB coverage standards for prescription drugs.[24] Initially, in the proposed Medicaid EHB rule, CMS suggested a blanket application of Medicaid section 1927 outpatient drug requirements to Medicaid ABPs.[25] In the final rule, however, CMS retracted this position, explaining that it was "over-inclusive," and clarified that "section 1927 requirements do not apply to ABPs to the extent that they conflict with the flexibility under section 1937 of the Act for states to define the amount, duration, and scope of the benefit for covered outpatient drugs."[26]

Therefore, unlike traditional Medicaid, Medicaid ABPs are not required to cover all drugs from manufacturers that have signed a federal rebate agreement. The flexibility for ABPs allowed under section 1937 trumps section 1927 requirements, and ABPs can design a formulary in

[21] SSA § 1937(b)(5). The 10 categories of health care services are:

> (1) Ambulatory patient services;
> (2) Emergency services;
> (3) Hospitalization;
> (4) Maternity and newborn care;
> (5) Mental health and substance use disorders, including behavioral health treatment;
> (6) Prescription drugs;
> (7) Rehabilitative and habilitative services and devices, except that such coverage shall be in accordance with § 440.347(d);
> (8) Laboratory services;
> (9) Preventive and wellness services and chronic disease management; and
> (10) Pediatric services, including oral and vision care, in accordance with section 1905(r) of the Act.

42 C.F.R. § 440.347; Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1302(b), 124 Stat. 119, 163-65 (2010). The state must also adhere to other applicability and coverage requirements. SSA § 1937(a)(2)(B), (4), (6), (7); 42 C.F.R. §§ 440.315, 440.320, 440.335, 440.345, 440.350, 440.360, 440.365, 440.390, 440.395.

[22] 42 C.F.R. § 440.347(a); 45 C.F.R. § 156.122(a)(1).

[23] 42 C.F.R. § 440.345(f).

[24] Medicaid and Children's Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment, 78 Fed. Reg. 42,160, 42,219-24 (Jul. 15, 2013).

[25] Medicaid, Children's Health Insurance Programs, and Exchanges: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes for Medicaid and Exchange Eligibility Appeals and Other Provisions Related to Eligibility and Enrollment for Exchanges, Medicaid and CHIP, and Medicaid Premiums and Cost Sharing, 78 Fed. Reg. 4,594, 4,631 (Jan. 22, 2013).

[26] Medicaid and Children's Health Insurance Programs: Essential Health Benefits in Alternative Benefit Plans, Eligibility Notices, Fair Hearing and Appeal Processes, and Premiums and Cost Sharing; Exchanges: Eligibility and Enrollment, 78 Fed. Reg. at 42,219.

compliance with the EHB standards noted above for health exchange plans. After a drug has been put on the formulary for an alternative benefit plan, then the plan and the drugs covered must comply with the MDRP as laid out within section 1927.

Pathway Seven: Section 1115 Waivers

Section 1115 of the Social Security Act grants the Secretary of the Department of Health and Human Services the authority to approve experimental, pilot, or demonstration projects likely to assist in promoting the objectives of the Medicaid and children's health insurance programs.[27] Under section 1115 authority, the Secretary can waive federal Medicaid requirements set forth in section 1902 of the Social Security Act governing the state plan.[28] This authority also allows the Secretary to provide federal financial participation for costs of the demonstration project that would not otherwise be included as matchable expenditures under section 1903 of the Social Security Act.[29]

Pathway Seven seeks to take advantage of the opportunities authorized under section 1115 of the Social Security Act to implement various APM initiatives. The most significant advantage of Pathway Seven is that the states are afforded considerable flexibility in designing an APM that furthers value-based goals and the objectives of the Medicaid program. Notably, section 1115 authorizes the Secretary to waive section 1902(a)(54) of the Social Security Act, which specifies that any state providing medical assistance for covered outpatient prescription drugs through its Medicaid program must comply with the applicable requirements of section 1927 of the Social Security Act.[30] The reference to section 1927 in section 1902 provides the authority for the Department of Health and Human Services to waive provisions of the MDRP in Medicaid demonstration projects.

To date, Department of Health and Human Services waivers of section 1927 through section 1115 demonstration waivers have been limited. A March 2016 search of state section 1115 demonstration waivers identified only six states—Arizona, Arkansas, Iowa, Michigan, New Hampshire, and Tennessee—whose waivers extended to a provision within section 1927. An advantage of Pathway Seven is that it could complement other pathways presented in this report, providing authority to implement an innovative arrangement that wouldn't otherwise be permissible. However, this Pathway does have one considerable disadvantage: the state must first apply for and obtain CMS approval of the section 1115 waiver. The state must ensure that its demonstration application contains all of the required elements,[31] including a requirement that

[27] SSA § 1115.
[28] SSA § 1115(a)(1).
[29] SSA § 1115(a)(2)(A).
[30] SSA § 1902(a)(54).
[31] *Id.* § 431.412; CMS, State Medicaid Director Letter 12-001 (Apr. 27, 2012), https://www.medicaid.gov/federal-policy-guidance/downloads/sho-12-001.pdf.

the proposed demonstration be budget-neutral, such that "during the course of the project Federal Medicaid expenditures will not be more than Federal spending without the waiver."[32]

[32] CMS, *Section 1115 Demonstrations*, https://www.medicaid.gov/medicaid-chip-program-information/by-topics/waivers/1115/section-1115-demonstrations.html (last visited June 19, 2016).

Section VI: Barriers and Practical Constraints

In addition to the MDRP, there are some practical constraints that state Medicaid agencies might encounter when developing or implementing alternative prescription drug purchasing and payment programs. These constraints relate to state officials' ability to solicit stakeholder engagement and cooperation, navigate regulatory approvals, and deploy the data and analytics infrastructure necessary to assess APM-related outcome measures.

Stakeholder Engagement and Cooperation

To successfully implement APMs, state Medicaid agencies need to work with stakeholders to gain their buy-in, as with other delivery system or payment reform initiatives. This buy-in helps create a sufficient volume of Medicaid enrollees for any APM, which is important to generating drug manufacturer interest. States may need to negotiate with the prescribers, providers, pharmacies, hospitals, pharmacy benefit managers, and MCOs to adjust their operations. They might also venture into fields in which stakeholders already have complicated arrangements among themselves, such as those between an MCO and its contracted pharmacy benefit manager. Organizations representing Medicaid enrollees will need to be consulted as well.

Managed care organizations (MCOs) are a key stakeholder. Many state Medicaid programs contract with MCOs to manage the pharmacy benefit for their enrollees. Some states have strict pharmacy coverage and management policies that must be followed; others provide MCOs with more flexibility to manage pharmacy benefits. As MCOs take more responsibility for managing the pharmacy benefit, their input to any potential APM becomes a larger consideration. For example, an agreement between a state Medicaid program and a manufacturer that provides a drug preferred access status could potentially clash with the utilization management efforts of MCOs (e.g., the MCO's preferred drug list), creating challenges for the state and the MCOs in managing the pharmacy benefit.

States that participate in multistate purchasing pools must also consider whether engaging in an APM with a manufacturer would conflict with or support the efforts of the purchasing pool program. The SMART-D legal analysis has found pathways that would work both within and outside of existing supplemental rebate constructs. A consistently cited concern of state Medicaid agency staff members was whether an APM would be able to accommodate the supplemental rebates negotiated through the purchasing pools; that is, would states have to choose between receiving the supplemental rebate and engaging in an APM? In the latter case, many state Medicaid representatives expressed reluctance to forgo supplemental rebate revenue because programs rely upon that revenue and APM fiscal results are less certain.

Health care providers are another stakeholder group that must be engaged with APM development. Medicaid program staff members interviewed by SMART-D were understandably concerned about successfully engaging providers, especially if APMs require physicians to submit clinical data. In a health outcome-based agreement, in which rebates or payments from the

manufacturer might be tied to a predefined clinical outcome, physician involvement is most likely a necessity. Physicians might not be willing to collect and send data regarding patient outcomes unless an incentive were provided. States can use existing prior authorization tools and the Healthcare Effectiveness Data and Information Set (HEDIS) quality measures, but both approaches have some limitations well-known to state officials.

Regulatory Approvals

As publicly funded government entities, state Medicaid programs are constrained by certain legal statutes and regulations at both the federal and state level. An in-depth analysis of these legal constraints, including potential legal pathways to implement APMs, is provided in the *Medicaid Policy Options to Manage High-Cost Specialty Drugs* issue brief. Two issues should be emphasized: CMS approvals and state-specific statutes and regulations.

The Medicaid program is jointly administered by states and the federal government, so federal support is important when pursuing new models. Depending on the value-based or alternate payment approach, implementation will likely require varying levels of federal oversight and/or approval. Many APM strategies will need approval from CMS through the submission of a Medicaid state plan amendment or waiver. Prior authorization programs, purchasing pools, payment changes, and manufacturer-risk sharing arrangements generally need approval from CMS through a state plan amendment. Regardless of formal approval, the political reality is that states will need a high degree of confidence that CMS will not reject an APM strategy or render their pursuit of APMs moot.

State statutes and regulations will need to be considered when implementing an APM. If a state has an “any willing pharmacy” or “dispense as written” law that prevents certain alternative payment arrangements, new legislation could be necessary to dismantle implementation barriers.

Lack of Clinical Data and Other Information

Medicaid program administrators might be constrained by the lack of clinical effectiveness and outcomes data available to implement and track APMs and their outcomes. Medicaid agency interviewees had mixed opinions on whether health outcome-based APMs were feasible given their current data and analytics capabilities. In contrast to EU countries with centralized registries, state Medicaid programs are potentially less able to track and analyze patient outcomes, making administration of health outcome-based APMs challenging. In addition to possible deficiencies in data collection, other issues include disconnects between various data systems, limited data analysis capabilities, and potential legal hurdles to storing and sharing data.

Some state Medicaid agencies contend with Medicaid management information systems that were implemented more than 30 years ago. These systems may not be able to record, codify, and report needed data for an APM. Moreover, these systems sometimes have limited ability to integrate data from external data sources such as electronic health records, laboratory information systems, and health information exchanges. Important health outcome data is often collected by external

systems, so administrators could encounter significant delays in gathering and aggregating the data and in conducting analyses.

There is a possibility that capabilities for collecting and tracking patient data can be improved through upgraded IT infrastructure, but the ability to analyze, store, and share data within the confines of regulatory requirements remains a concern. Some state Medicaid representatives interviewed have the necessary analytics teams in place, whereas others rely on third-party vendors. Still others anticipate encountering issues in securing the appropriate resources for rigorous data analysis.

Section VII: Concluding Remarks and Next Steps

APMs are an intriguing tool, but they are only one of many levers that a state needs to create changes in patient outcomes or prescription drug spending. APMs can support and reinforce a state's strategic direction toward value-based payment. However, states will need to ensure necessary capacity to implement APMs, negotiate agreements, track outcomes, and identify high-yield opportunities. When thoughtfully deployed, APMs can help states align incentives between their medical and pharmacy benefits. APMs can catalyze change within an existing framework by including drugs in total cost of care models, capitation arrangements, and care management models.

Realistically, states may not save money with their first APM implementation. An initial APM will require an investment of time and resources to design, implement, and monitor; the immediate state level outcomes are likely to be improved patient access and budget predictability. But if APMs are viewed in terms of the Triple Aim—improving the experience of care, improving the health of populations, and reducing per capita costs of health care—states could see important potential benefits, including improvements to patient outcomes and the health of populations, along with reductions in per capita costs of health care over time (Berwick, 2008). APMs can also provide a measure of control over prescription drug spending. States can engage in voluntary agreements with drug manufacturers that fit their state's goals, their Medicaid program configuration, and specific patient populations. Financial-based APMs will give state budgets a level of predictability that they currently lack.

This report summarizes the findings of research conducted under Phase I. Phase II of the SMART-D Initiative will seek to develop an APM implementation plan for participating states that includes the following:

- *Development of alternative purchasing models.* Drawing on international and commercial APMs and following the legal pathways identified in Phase I, the Center will work with states to develop a strategic approach and an APM implementation plan for their state. Some APMs will likely be narrow in focus, looking at one drug or drug class and a simple health outcome measurement approach. Some might be bundled into larger value-based reform efforts.

- *Readiness assessment tool*. APM implementation will require states to develop new capabilities or extend existing capacities. To enable states to evaluate their readiness for this work, the Center will develop an assessment tool, which could include the categories of data gathering and outcome tracking, stakeholder relations, state political environment, state budget situation, current value-based work, number of PDLs, MCO contractual arrangements, and Medicaid agency staffing.

- *Legal and policy tools*. APM implementation within a given state will require specific policy analysis and legal support. The Center anticipates that state Medicaid officials may need assistance to assess which legal pathways best accommodate the APM strategies they would like to pursue, develop model contract language and confidentiality agreements, prepare a Medicaid state plan or waiver amendment for submission to CMS, engage in ongoing communication with CMS, and analyze state-specific statutes and regulations.

- *Outreach to and engagement with drug manufacturers*. Successful, voluntary models require that drug manufacturers feel enfranchised in the model's development and see a value proposition for their companies and their drugs. Outreach is necessary to other stakeholders as well, including health care providers, MCOs, pharmacy benefit managers, and state legislators.

APMs hold strong promise as a tool to support Medicaid value-based reform efforts, but not every state will be able to undertake such a project. The Center will work with State Medicaid Officials to help them identify APMs, assess readiness, and develop the legal and policy structures for implementation. These Phase II efforts will result in identification of several states that are ready to implement APM pilots with drug manufacturer partners in Phase III.

Appendix

High-cost specialty drugs are typically used to treat complex, often rare diseases. Many of these medicines require ongoing assessments of the therapeutic response and patient adherence, complex patient or provider training, specialized handling by pharmacy or individualized distribution networks, and continuous monitoring of side effects. For the purposes of this study, high-cost, specialty drugs are defined as those that have reimbursement of more than $600 per prescription and total Medicaid reimbursements of $72 million per year. The 64 drugs listed below meet this two-part definition.

	Brand Name(s)	FY 2015 Total Reimbursement per Prescription[33]	FY 2015 Gross Cost to Medicaid	New Since 2012?
1	Abilify	900	2,746,712,000	NO
2	Harvoni	28,300	1,540,228,000	YES
3	Humira	3,500	693,300,000	NO
4	Truvada	1,400	667,395,000	NO
5	Sovaldi	24,400	643,446,000	YES
6	Atripla	2,200	596,965,000	NO
7	Latuda	800	555,665,000	NO
8	Omnitrope, Genotropin, Humatrope, Zomacton, Serostim, Saizen, Norditropin	3,500	485,258,000	NO
9	Invega	1,500	472,003,000	NO
10	Stribild	2,600	413,342,000	NO
11	Enbrel	3,000	396,948,000	NO
12	Prezista	1,200	336,474,000	NO
13	Complera	2,200	293,270,000	NO
14	Copaxone, Glatopa	5,300	276,151,000	NO
15	Advate	19,100	270,617,000	NO
16	Neulasta	3,600	248,221,000	NO
17	Reyataz	1,300	240,591,000	NO

[33] Prescriptions are most commonly written for 30 days. In some circumstances, prescriptions can be 15, 60, or 90 days. The dataset used for this analysis does not provide data regarding days per prescription.

	Brand Name(s)	FY 2015 Total Reimbursement per Prescription[33]	FY 2015 Gross Cost to Medicaid	New Since 2012?
18	Synagis	2,300	240,280,000	NO
19	Invega	1,000	221,648,000	NO
20	Novoseven	81,500	219,484,000	NO
21	Isentress	1,200	219,434,000	NO
22	Pulmozyme	3,300	202,733,000	NO
23	Tecfidera	5,300	199,262,000	YES
24	Vimpat	700	184,365,000	NO
25	Viread	900	183,553,000	NO
26	Gleevec	9,100	173,214,000	NO
27	Tivicay	1,400	166,653,000	YES
28	Remicade	3,500	150,666,000	NO
29	Herceptin	3,100	150,052,000	NO
30	Avastin	1,300	148,259,000	NO
31	Jadenu, Exjade	6,400	147,722,000	NO
32	Gammaplex, Flebogamma Dif, Vivaglobin, Gammagard, Bivigam, Privigen, Carimune, Gammagard S/D, Hizentra	3,100	146,327,000	NO
33	Kogenate Fs, Novoeight, Kovaltry, Nuwiq, Xyntha	21,500	142,953,000	NO
34	Creon, Ultresa, Viokace, Pertzye, Zenpep, Pancreaze	1,000	140,508,000	NO
35	H.P. Acthar	43,700	138,727,000	NO
36	Epzicom	1,200	137,677,000	NO
37	Onfi	900	135,133,000	NO
38	Revlimid	9,800	131,926,000	NO
39	Avonex,Rebif, Rebif Rebidose	5,200	131,275,000	NO
40	Triumeq	2,400	127,545,000	YES
41	Xolair	2,500	121,190,000	NO
42	Xifaxan	1,400	119,251,000	NO

	Brand Name(s)	FY 2015 Total Reimbursement per Prescription[33]	FY 2015 Gross Cost to Medicaid	New Since 2012?
43	Sabril	9,400	114,468,000	NO
44	Remodulin, Tyvaso, Orenitram	12,200	114,006,000	NO
45	Viekira Pak	25,400	111,334,000	YES
46	Zortress, Afinitor	7,900	104,599,000	NO
47	Rituxan	4,700	98,123,000	NO
48	Makena	2,700	97,899,000	NO
49	Eligard, Lupron Depot	1,800	94,554,000	NO
50	Implanon, Nexplanon	700	90,423,000	NO
51	Sprycel	8,800	89,670,000	NO
52	Gilenya	5,400	89,594,000	NO
53	Banzel	1,400	83,923,000	NO
54	Humate-P, Alphanate	21,800	83,737,000	NO
55	Feiba	50,100	83,540,000	NO
56	Cinryze, Berinert	32,300	80,357,000	NO
57	Xeloda	2,300	77,078,000	NO
58	Renvela	1,100	76,998,000	NO
59	Letairis	7,200	75,603,000	NO
60	Neupogen	1,300	75,602,000	NO
61	Stelara	11,700	75,180,000	NO
62	Olysio	19,900	73,568,000	YES
63	Saphris	600	72,472,000	NO
64	Renagel	1,300	72,398,000	NO

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	APPENDIX F	
SUMMIT 1 – AUDIENCE QUESTION: What is the most important lesson you will take away from this Summit? Why?	**SUMMIT 1 – AUDIENCE QUESTION: What potential next steps for Washington State do these take-aways point to? Why?**	**SUMMIT 1 – AUDIENCE QUESTION: What additional topics should HCA investigate around prescription drug pricing?**
Revisit --- in -- containment is more immediately possible - PA, rebates while expand additional value based opportunities as well as initiatives around deeper issues such as end of life cost of care	Work in starting regulations to withhold ----- for re-patented generic drugs. Monitor consolidations in the generic space ca--- M&A activity that increases morbidity concentration and process.	Increases in drug costs due to inflation (i.e. insulins) what are best alternatives to counter inflating pricing. FDA approved requirements-regarding the release of generic alternatives - stringent requirement delay release of generic alternative.
That we do not have influence over price of drugs and that value-based purchasing still doesn't address the underlying issue of constant price increases.	That potential actions just address a piece of the issue and value based purchasing requires resources.	How to translate penalty of price increase above CPI across sectors. How drug pricing is set by manufacturers. How/why do we see increases in old generic drugs?
How widespread the drug cost problem is - not only specialty drops, but increasing cost for old generics. You can add to that perverse incentives for prescribers (e.g.: for oncology drugs)	Conduct more value-based purchasing for everything, not just drugs	Prescribers financial COI (e.g.: oncology drugs)
There is interest and enthusiasm for change	Participate in pilots Reports to facilitate discussion (i.e.: expected us realized expenditures and outcomes	Value based pricing
PBMs are a barrier to innovative modes to enhance value	Reducing variability in prescribing is feasible - focus on incentives Post launch dry price increases may require a legislative solution	Price transparency - How to convey value for money concepts to consumers
Monopsony : Rx purchasing consortium But need rigorous comparison of prices in consortium with prices outside	how to get MDRP prices/rebates for consortium	Value-based purchasing - indication based pricing.
I learned a lot of information on current trends and research being conducted to address the issue of	Creating concrete implementation strategies that could potentially pilot these trends to look at their real world	What role can the pharmaceutical industry or manufacturers play to address this issue? What are their

increasing prescription drug prices.	applicability state-wide or nation-wide	thoughts on outcome-based risk-sharing agreements?
The rebate portion of this market seems to be hugely complex and may mark many of the issues. As prices continue to rise, the rebate becomes null but still people seem to claim savings	Expanded procurement contracts to drive down price that would be available for state and non-state covered lives.	Building partnerships to address the issues.
There are multiple tactics for addressing medication affordability but no one size fits all approach. This may necessitate a rethinking of the drug pricing model in the US.	Develop some type of value-based approach for payment (because this is one way to work within the current framework) Consider the patient perspective (because they are the reasons we provide care)	Questions for Pharma: Are there plans to make pricing in the US more comparable to those in other developed countries? Is there a potential to provide uniform patient assistance programs? (not all restricted to individual manufacturers)
That multiple health systems are stuck nibbling away at the price of drugs problem. We all shy away from being able to truly deny coverage for a drug. That has limited cost effectiveness. The Premera value tiering begins to address this issue	Consider adopting the value tiering with non-coverage after a certain QALY limit. So as to drive down drug prices manufacturers will have to respond with lower prices and better outcomes data. FDA approval is insufficient evidence.	Public education about drug value in later stage cancer may be valuable. Better quality of life at lower cost with Palliative care. Public engagement has helped with the generic price gauging issues.
Great work is being done, at the same time, we dance around FED programs restrictions (i.e.: Medicaid Best Price) as excuse for not "going there"	We need to lobby the FED Change	Can't really change without the above
We are just at the beginning	Invent safe Texas Model / Invent other Medicaid approach.	Best practices for bringing down drug spend / Get Pharma's perspective
Tools to address root cause of high US drug costs are limited at best.	Baseline best practices (e.g.: NAMD recommendations.) Should be explored-different purchasers have diff limitations and strengths that could be leveraged if working on common goals.	transparency & information organized into dis ---- decisions for public discussion & participation (e.g.: Oregon evidence based list) Piecemeal focus misses where $ move and who benefits
If the NW Drug Consortium is a good idea for 2 states, wouldn't it be an even better idea for 3? (Or 50?) A national drug consortium? Or regional?	Many creative models discussed today. Focus on expanding one or more	What about state legislation enabling TX contracting similar to the provincial pricing policies in Canada? May run afoul of federal regulations but might be worth pushing the envelope for state funded prescription costs.

Realizing we are all facing the same issues? Possible partial solutions to these issues. Also limited control over these issues.	Need to work with government and industry to establish roles. Paying for what works especially oncology and specialty drugs.	1- Ethics of Pharma pricing & tools to impact this. 2- Ability to negotiate in all settings.
Pooling resources and thinking out of the box will help us achieve better outcomes and make changes to better manage drug spend and transition to release purchasing.	Continue to leverage expertise from around the state and partnering states to strategize. We all have a common goal of triple aim, and can benefit from collaboration	
Outcomes-based risk-sharing Because I had little awareness of this very promising option in helping control drug costs. It links actual outcomes with coverage/reimbursement, providing incentives to help ensure that treatments covered are leading to positive outcomes. Also intrigued by value=based formulary but skeptical about applicability in Medicaid population.	Further exploration of the topics discussed; also ask more questions that get to the heart of the issue. Topics disc. Today are mostly small steps and very helpful. But most are already being employed to varying degrees. What do pharm manufacturers suggest? Hold meeting w/ them for more complete picture (Thanks for announcing such a meeting)	How can introduction/implementation of outcomes-based risk-sharing be facilitated or incentivized? How can a value-based formulary be applicable (if at all) in a Medicaid population?
No silver bullet. Must employ a variety of strategies to insure the best care at the best cost.	Single formulary for all states funded Health Care.	Price increases in Generic Drugs
Treatment protocol/variations to control Rx End of Life cost - (30 days or 90 days) Cost trend for specialty drugs	More $ needed for coverage Member & payer impacts	Single formulary for Medicaid? National conversation - legislation? Discount - how it works? Pharma - how & partner to solve this issue as a society?
This summit reemphasized the complexity of the pricing. Each of the individual stakeholders has strategies such as payers using tiering to impact utilization but those are countered by Patient Assistant Programs. Another great example was the negative expenditure for Insulin for Medicaid but it was paid for by large price increase in other programs.	Work with groups that include all stakeholders - Delivery, Pharma, Payers and legislative. Legislative needs to understand that creating band aids for symptoms with a broke system only worsens problems (i.e. CAPS on copays only drives premiums and masks the price inflation by pharma.	Need to focus on creating a competitive market in drug classes that provide opportunity. Pharma issue it direct to consumer advertising. What value to health status and society.
There are multiple problems and multiple potential solutions. It sounds as if our spend is the MODAs we would assure all the folks receiving specialty drugs are appropriate and benefit from	What interest if any does Pharma have in being part of the solution and collaborating? Continue to be more aggressive about provider variations.	What happens in Canada? How do we move Federal fixes/supports forward?

them.		
1- There are many forces moving in the same direction. The summit helped me put all the various work efforts into a framework. 2- Time to act is now (over next 1-3 years)	Smart-D initiative has a lot of potential to develop alternative payment models that can be put into place & the State of WA has real purchasing power that it can leverage. (i.e. Value-based bundled payments, 340B)	Bundled payments that include drugs for medical based series such as rheumatology, oncology. Retail pharmacy networks to drive up quality or improved discounts. Technology that would give providers information at the point of care about member/patient benefits & preferred drugs.
Very concerning what comes next - more specialty -brand/brand combos & cancer drugs. How are we going to deal with this - Public has NO idea	What can we do to combat multimillion ads in this regard? What can legislature do?	What innovative programs does Pharma suggest to incent value based designs that benefit patients? Why are prices going up so much? Must stop and be fair.
There are several strategies states can use to mitigate using costs of prescription drugs but the root of the problem is that capitalism doesn't work in the field of health care / drug manufacturing.	1- State agencies should review all the strategies currently being used to determine if current strategies can be improved or additional strategies can be added to mitigate costs. 2- We should work with our federal partners to address the root of the problem.	HCA should further explore and possibly pilot a value-based formulary in the PBB population. HCA might also consider piloting a shared decision aid with cost effective data.
How can I get better contracting and pricing for medication for Molina? Why? Utilization is nearly flat, but cost is up are double digit with no end in sight.	I can only hope they represent a more collaborative effect to work with the Health plans for the betterment of health if the people of WA State.	How can HCA & all the MCOs work collaboratively for better cost containment of specialty drug costs?
The VA is able to secure their funding by being a direct purchaser. The reimbursement discussions are outside of my area of understanding so purchasing is generally my focus.	Could WA consider utilizing the Vas idea to secure better pricing? Better pricing will reduce budgetary requirements at both a state and federal level.	Is there a way to balance the drug company profits against the budgetary needs of the government funded programs?
Complexity of the issues Finding alignment of interests across relevant entities - shared risks and opportunities.	Engage the Apple Health MCOs in discussions to determine whether they're willing to work with HCA on, for example, APMs. If not, consider carving out the drug class to allow design by HCA. Hopefully, use the SMART-D project's products to inform your work.	In any ACO like models under PEBB, are prescription drug costs included? If so, engage those ACOs and Regence as TPA in APM discussions. Among DSRIP projects, assuming waiver is granted; can they build in drug purchasing strategies? When SMART-D legal pathways are available, think about applicability beyond high-cost

		drug classes.
No silver bullet. Strategies are complicated and involve many parties Scale of Rx VBP will be difficult	Manage expectations Acknowledge Rx trend is here to stay Engage contracted payers to better understand their specific strategies Evaluate effectiveness of more centralized decisions---WRT Rx Purchasing	Multi-payer arrangements around Rx VBP Long-term price guarantees Role of MCOs in PDL supplemental rebate negotiations Getting to "real" Rx costs - specifically the process of netting out Medicaid rebates
Most state agencies are facing the same issues with increasing costs.	Legislation is needed to help support the DOC in their formulary and process improvement efforts. Possibilities of modeling DOC DSH programs after models such as Florida.	Continues price increases in the generic drug market due to consolidation of manufacturers. Promoting programs such as the third party reimbursement program to move clients from Medicaid only to private insurance. Drive efforts to explore additional benefits that may be available (Medicare, OPM/Federal, VA etc.)
this has all become far too complicated and the big winner is Pharma		Finding ways to tell drug companies we don't pay for drugs if they don't provide significant results. ..
Very complex topics. Business as usual is not sustainable for the future. The most leverage is held by Pharma.	Pursue alternative formulary structures such as value based formularies.	Strategies to employ that result in cost saving at the patient level.
Fascinated by Top drug spends in different populations. I can't believe we are using that much Therazine at Western and wonder why our state employees have Thyroid problems!	I would like to see drug utilization in some of our private psych hospitals.	Whether the state should be looking at getting rebates for our managed care patients.
We can nip at the price issues through care management but few effective tools.	Implement VBP and incentives, but doubt it will have much effect on price. Need strategy to increase competition	

Sign in operating healthcare & Rx in an environment that is not a market, getting solutions that link payment to value is extremely difficult. There are silver BB's, but few silver bullets.	There are 2 - 1) Coordinate programs, policies and utilizations among agencies. 2) Look to legislation activity to get mfg. to table without mfg. engagement, meaningful solutions are challenging.	340B detail - More detailed discussion about medical Rx and ways to battle money there. (thru risk sharing) How to move discussion beyond rebates since drug inflation is a significant driver of cost. Can we discuss with pharmacy to guarantee price by indexing to CPI?
Infinite layers of complexity breeds opportunity for rethinking this problem. Incentivizing prescribers and pharmacists to utilize training to improve therapy regimens and minimize other avoidable health care costs.	Pricing is only one portion of this problem. Appropriate use and positive patient outcomes is vital. The most expensive medication is on that was used incorrectly or not at all. Medication use support for patients in key.	At the end of the day, there is a commodity for purchase. There are multiple layers of complexity in contracting & distribution channels with rebates, leverage and accountability. Transparency is key. Missing parties: PBMs, wholesalers, and as mentioned Pharma.
Better understanding of structure of current state purchasing arrangements. Ideas about options for cost control in current environment (there are some possibilities in "broken market") Good to hear out of the box thinkers. Hearing perspectives of different payers/purchasers	Explore alternative payment methods in various agencies, especially Medicaid & PEBB. Continue to share methods being tried and results seen among state agencies.	(Public) Data sharing on provider utilization patterns (such as variation in utilization in cancer care)
The problem is complex but some of the simple examples such as manufacturers raising generic prices double digits need more publicity. This is not just a case of the manufacturers needing to cover their R&D for new drugs.	We have a lot of work to do - let's get some details from other states about what is working - if anything.	Collaborate with pharma but ask them for examples of VBP/cost effectiveness that might work here in WA.
There exist key opportunities to improve access for specialty drugs and attempt to limit cost. There is large reason for interpretation and research for more conclusive research.	We need to increase transparency from Pharma companies to perform improved cost benefit analysis and improve research for more directional outcomes	Prescribing methods that reduce cost Concepts of end of life in pharmaceutical costs. Concept of drug wasting/over prescribing Pharma: Do you care about affordability/ humanity or simply self-profit
Many great lessons about the variety of innovative approaches being developed/piloted. I found the value-based formulary and outcome based risk sharing approaches especially	Consider piloting some of the above innovative approaches. Investigate MCO rebate issues (though this will be complex given the existing rebates).	A lot of these are incremental steps, which are critical but also may be inadequate to address a problem that is increasing at an exponential rate. I think that

interesting.	Think about ways to leverage statewide purchasing volume.	engagement with legislative approach (including at the federal level) to drug pricing is important in addition to the topics discussed here.
The list of NAMD policy suggestions provides the best set of policy initiatives proposed today because they address affordability and that is the core issue. Indeed the policy initiative could be the basis for spread from the public to private sector benefitting all of us. How do we get these considered by the Feds and by Congress? Could the group today "sign-on" to support a demand for consideration by the Feds & Congress?)	Send our Medicaid leadership to the other Washington along with leadership from other states to demand a Congressional hearing.	Of the remaining topics, PBRSA schemes could provide the greatest push but there is a big need for transparency, otherwise learnings will be slow and inconsistent. The SMART-D project needs support and expansion as well. The economic analysis by Dr. Ramsey offers great promise for a variety of reasons - a deeper dive into clinic costs is needed. Dr. Young's research is fascinating: how to insert Medicaid beneficiaries with no co-pay or co-insurance?
Value based payments are real. We've been talking about them a lot in Oregon - nice to see concrete examples	Help support development of it. Participation in an APM model, perhaps with Oregon	Data sharing / HIE platforms
Alternative payments models with risk sharing or that are outcome based are where the current research around price lowering is forced.	How are we pursuing these methodologies in the public purchased healthcare arena in Washington? I know that there's a focus in ACO contracts and that overall with the Healthier WA but specifically with drugs. How are we driving risk sharing with the MCOs?	I'm curious about how other states are pursuing secondary rebates - the degree to with they are successful. How nimble is our formulary with respect to the drug pricing market. If a brand drug becomes cheaper than the generic, once the rebate is factored in, do we have a mechanism to change the generic first directive?
Medicaid is behind and needs to leap ---------- pharmacy in a mere sophisticated/ agile manner	Need an organized strategy for specialty and some of these strategies discussed today cannot be managed by HCA Need to develop value-based revenue programs for MCOs to compete to deliver better outcomes Would encourage HCA to consult with its stakeholders before putting any policy forth.	Utilization controls for mental health Needed pay for performance management for prescribers Need a system for management of polypharmacy Consider pharmacy home programs to up outcomes Consider closely managing the legislature to remove spread pricing the way Texas has - this allows MCOs to manage w/o having to negotiate PBM margin.

Perspective and needs of the various stakeholders including non-clinical & non-healthcare individuals	Identify the 2-3 topics that were most interesting the group to take a deeper dive into.	Innovative pilot programs such as the oncology care model that might tie several of these topics together.
Every strategy presented today had something in common. The rationale for every strategy was either based on increasing scale and or decreasing variability to varying degree.	Conclusion: States provide mice experimental sandboxes but transformation must come from the federal level to create effective scale. We must find a way to manage medication spend on medical & Rx benefit in a unified way. (channel management)(can state encounter data be useful here)	How to align the care delivery system with value based concepts for pay? Ask PBMs what is the most effective opportunity they see to help reduce drug costs?
There is a lot of swirl and there are a lot of opportunities. Dig deep and you may find gold	No one size fits all Organizations have different priorities and cost is always important as a common theme nevertheless & as is affordability. Not sure what could be next for WA. Cost is likely continuing to rise - We can maximize appropriate use & optimize value based on outcomes	Teasing out Medical benefits drug spend Contracting Dos & Don'ts Legislation updates and Best practices across the nation Projection methodology on drug spent Question to Pharma: How / what methodology was used to determine the price?

APPENDIX G

Washington State Prescription Drug and Purchasing Summit Part 1 - Attendees **2016**

Blythe Adamson, MPH	UW
Elizabeth Bentley, PharmD	Kaiser
Jane Beyer, JD	OHSU
Amy Blondin,	HCA
Rachel Burke	HCA
Josh Carlson, PhD, MPH	UW
Pia Ching, PharmD, MBA	CCC
Rep. Eileen Cody	LEG
Tom Colleran, RPh	GHC
Victor Collymore, MD, FACP	CHP
John Coster, PhD, RPh	CMS
Bob Crittendon, MD, MPH	GOV
Tanya Dansky, MD	AGP
Michelle Davis	DOH
Missy Dolan	OR
Petra Eichelsdoerfer, RPh, MS, ND	UHC
Iman Eletreby, PharmD	AGP
Bill Ely, ASA, MAAA	Kaiser
Leta Evaskus	HCA
Mary Fliss	HCA
Charissa Fotinos, MD, MSc	HCA

APPENDIX G (cont'd)

Washington State Prescription Drug and Purchasing Summit Part 1 - Attendees **2016**

Gary Franklin, MD, MPH	LNI
Steven Hammond, MD	DOC
Ray Hanley	HCA
William Hayes, PharmD	DOC
Alicia Hermann	LEG
Leah Hole-Marshall, JD	LNI
Thuy Hua-Ly	HCA
Nathan Johnson	HCA
Sean Jones, MD	Kaiser
Robert Judge	Moda
Kristina Kristofferson, CPhT	DSHS
Dan Lessler, MD, MHA	HCA
MaryAnne Lindeblad, BSN, MPH	HCA
Kathy Lofy, MD	DOH
Jaymie Mai, PharmD	LNI
Louis McDermott	HCA
Jason McGill	OFM
Neil Mills, MD, MBA	Moda
Louis Nguyen, RPh, MBA	GHC
Mich'l P. Needham	LEG
Senator Linda Parlette	LEG

APPENDIX G (cont'd)

Washington State Prescription Drug and Purchasing Summit Part 1 - Attendees **2016**

Ryan Pistoresi, PharmD, MS	HCA
Patti Raymond	HCA
Scott Ramsey, MD, PhD	Fred Hutch
Yusif Rashid	CHP
Jim Rickards, MD, MBA	OR
Jeff Rochon	WSPA
Rep. Joe Schmick	LEG
Kristin Sisourath	Moda
Bruce Smith, MD	REG
Donna Sullivan, PharmD, MS	HCA
Dorothy Teeter, MHA	HCA
Katy Tomisser, PharmD, BCPP	DSHS
Mark Underwood, PharmD, BCPP	DSHS
Lauren Vela	PBGH
Melet Whinston, MD	UHC
Robyn Williams	OFM
Bruce Wilson, MD	GHC
Kai Yeung, PharmD, PhD	UW
Casey Zimmer, RN	HCA

APPENDIX G (cont'd)

Washington State Prescription Drug and Purchasing Summit Part 2 - Attendees **2016**

David Barhoum, M.S.	GT
Bill Beckman	API
Barry Benson	MSD
Jane Beyer, JD	OHSU
Michelle Bice	GSI
Chris Blake	LEG
Amy Blondin	HCA
Amy Brackenbury	OAP
Nathan Breuer	CVS
Kathryn Brown, Pharm D, MHA	Premera
Wilson Bruce, M.D.	GH
Rachel Burke	HCA
Reuven Carlyle	WA State Senate
Piao Ching, Pharm D, MBA	CC
Cordell Christopher Jr.	TMC
Dwight Cobb	Quintiles
Victor Collymore, M.D., FACP	CHP
James Colyer, MBA	AZP
Christopher Conner, Pharm D, PhD	BMS
Cheyanne Cook	BI
Tanya Dansky, M.D.	AMG
William Davis	API
Chris DeSimone	AG

Jason Dohm, Pharm D	Express Scripts
Missy Dolan	OR
Cynthia Dold	UW
David Dugdale	UW
Petra Eichelsdoerfer, RPh, MS, ND	UHC
Leta Evaskus	HCA
Mary Fliss	HCA
Sydney Forrester	LEG
Jessica Fortescue	JF Consult
Charissa Fotinos, M.D., MSC	HCA
Rick Frees	VP
John Goddard	GSK
Jeff Gombosky	PRMA
Frances Gough, M.D.	Molina
Steven Hall	BIP
Ray Hanley	HCA
William Hayes, Pharm D, CCHP	DOC
Alicia Herrmann	LEG
Kate Hoffman	LEG
Lori Howarth	Bayer
Thuy Hua-Ly	HCA
Elizabeth Jaeckels	HCA
Robert Judge	Moda

Judy Hull	HCA
Dan Kent, M.D.	UHC
Camille Kerr	Amgen
Ryan Ketterling	TMC
Katie Kolan, JD	WSMA
Ryan Kuehn	CVS
Erik Landaas, MPH	UW
Stephanie Lattig	Novo Nordisk, Inc
Kimberly Laubmeier, PhD	SPI
Dan Lessler, M.D., MHA	HCA
MaryAnne Lindeblad, BSN, MPH	HCA
Amanda Locke Pharm D, BCACP	Virginia Mason
Dan Locke	UW
Catrina Lucero	LEG
Jaymie Mai, Pharm D	LNI
Tyler Mamiya	CHP
Dee Mann Aust, MSW	Overlake Hospital
Leslie Mann, MBA	CG
Jeremy Martinez, CPA, MBA	CC
Mai Masri	AMGEN
Gregory McCunn	BSM
Lou McDermott	HCA
Newell McElwee, Pharm D, MSPH	Merck

APPENDIX G (cont'd)

Washington State Prescription Drug and Purchasing Summit Part 2 - Attendees **2016**

Brian Mischel	Express Script
Kate Mundell, MBA, PMP	MCHS
Mich'l Needham	LEG
Valerie Ng, Pharm D/ MSIA	US Script
Louis Nguyen RPh, BCACP, MBA	GH
Ryan Pistoresi, Pharm D, M.S.	HCA
David Putelo	ViiV HC
Yusuf Rashid	CHP
Gayle Reinhart	D2 Consult
Susan Robinson, M.D.	CC
Carly Rodriguez	Moda
Sara Rutherford, MPH, RHIA	PSHVN
Phillip Santa Maria, MBA	API
Mindy Schimpf	UCB
Joseph Schreck	ALG
Ann Schwemm	UW
Craig Sexton	GSK
Tina Shriner	Abbvie
Scott Sigmon	Public Affairs
Alexa Silver	LEG
Mika Sinanan	UW
Kristin Sisourath	Moda
Bruce Smith, M.D.	BlueShield

APPENDIX G (cont'd)

Washington State Prescription Drug and Purchasing Summit Part 2 - Attendees **2016**

Shabir Somani	UW
Claudia St. Clair	Molina
Donna Sullivan, Pharm D, M.S.	HCA
Sean Sullivan, BSPharm, Msc, PhD	UW
David Testerman, RPh, MBA	AMG
Lisa Thatcher	GSK
Ashley Van Allen, Pharm D, BCACP	MCHS
Raisa Volodarsky	Premera
Danielle Walters	Sanofi
Charles Weeden	CVS
Melet Whinston, M.D.	UHC
Shea Wilson, R.Ph.	Molina
Stephanie Yamamoto, Pharm D, BCPS	Major Markets
Laura Zaichkin	HCA
Sydney Zvara	AWHP

APPENDIX H

Washington State Prescription Drug Price and Purchasing Summit 2016
Part 1 - Biographies

Jane Beyer, JD
Program Officer, Milbank Memorial Fund/CEbP

Jane Beyer is currently a Program Officer with the Milbank Memorial Fund and the OHSU Center for Evidence-based Policy. In that role, she supports state legislators and executive branch agencies in their efforts to develop and implement evidence-informed health and social services policy to improve health outcomes for the people they serve. Previously, Jane served as Assistant Secretary for the Behavioral Health and Service Integration Administration in the Washington State Department of Social and Health Services from September 2012 – August 2015.

Jane served as senior counsel to the Washington State House of Representatives Democratic Caucus from 1988 through 1994, and again from January 1999 to 2012. In that position, she handled a broad range of health care, human services and criminal justice issues, with a focus on Medicaid and access to health care. From 1995 through 1998, Jane served as the Washington State Medicaid director. She began her work in health law as a legal aid attorney in Tacoma, Washington.

Josh Carlson, MD, PhD
Assistant Professor, Department of Pharmacy, Pharmaceutical Outcomes Research and Policy, University of Washington

Dr. Josh Carlson graduated with his PhD from the Institute for Public Health Genetics in the School of Public Health and Community Medicine at the University of Washington in 2007 and received his Master of Public Health from the same department in 2004. Carlson is an assistant professor in the Pharmaceutical Outcomes Research and Policy Program and an affiliate faculty member at the Fred Hutchinson Cancer Research Center. Dr. Carlson conducted his postdoctoral training in pharmacoeconomics with the University of Washington from 2007-2009.

Dr. Carlson's current research interests and work to date has primarily focused on the intersection of three areas: 1) genomics and emerging technologies in the field of personalized medicine, 2) uncertainty both in our decision-making processes and as the concept applies to the application of medical technologies in "real world" settings (i.e. outside of clinical trials) including comparative effectiveness research, and 3) economic and policy options to address these uncertainties as we seek to improve our healthcare system and the health of our population.

Yohan Cho,

Yohan is a Consultant at GfK specializing in drug pricing, payer research, competitive landscape assessments, and market access strategies.

Yohan has led numerous engagements involving strategic insight for commercial development of small molecule and biologic products across a number of therapeutic areas including oncology, hematology, and infectious diseases. Yohan is a member of the Oncology Center of Excellence at GfK, leading numerous projects for several high profile oncology therapies. As an internal oncology expert, Yohan has had led and contributed to a multitude of thought leadership initiatives in pricing, value assessments, and innovative agreements, including poster presentations at major conferences such as ASCO and significant contributions to publications.

Through his experience at GfK, Yohan has become familiar with the market access implications in numerous markets globally including the US, EU5, Japan, Canada, Australia, and emerging markets.

Yohan graduated with a Bachelors of Arts in Biology from the College of the Holy Cross in Worcester, MA.

John Coster, PhD, RPh
Director of Pharmacy Center for Medicaid & CHIP Services, Centers for Medicare & Medicaid Services

John M. Coster is Director of the Division of Pharmacy at the Center for Medicaid and CHIP Services, which is a component of the Centers for Medicare and Medicaid Services. He is responsible for policy and operational issues relating to the Medicaid pharmacy and prescription drug rebate program. He holds a MPS and PhD in health policy from the University of Maryland Graduate School and a BS in Pharmacy from St Johns University. Prior to joining CMS, he served in various senior government affairs positions in safety net hospital and pharmacy professional associations.

APPENDIX H (cont'd)

Washington State Prescription Drug Price and Purchasing Summit **2016**
Part 1 - Biographies

Bill Ely, ASA, MAA
Vice President, Actuarial Services, Kaiser

William (Bill) Ely has 35 years of experience in the insurance industry, both in consulting and corporate roles. Bill currently is Vice President, Actuarial Services for Kaiser Permanente (KP). Bill's responsibilities include overseeing actuarial functions for the Northwest and Hawaii regions of KP as well as actuarial functions for Individual and Small Group lines of business, nationally.

Prior to joining KP, Bill held a wide variety of positions in the industry including Chief Actuary for a 600,000 member Blues plan, senior consultant for an international actuarial firm and, for over ten years, CEO/Founder of a health care consulting company.

Bill has held an elected position in a section of the Society of Actuaries professional organization, currently serves on the Board of Directors of Oregon's Temporary Reinsurance Program, and has been involved in many internal and external working groups related to implementation of the Affordable Care Act and Coordinated Care Organizations.

Bill has lived in Portland, OR for almost five years with his wife Michele, 3 dogs and 1 cat. He has two adult sons that reside in the Kansas City area.

Ray Hanley
Director Prescription Drug Program, Washington Health Care Authority

Ray Hanley is currently Director of the Prescription Drug Program at HCA. Over the last 40 years he has applied his knowledge of the organization and finance of health care to further better thinking in both the public and private sectors while employed by the Brookings Institution Economic Studies Program, WA State OFM Forecasting, UW School of Medicine, US DHHS ASPE, Third Wave Research (now MEDSEEK) and HCIA (now Truven Health Analytics).

Robert Judge,
Director of Pharmacy Services, Moda Health

Robert Judge is the Director, Pharmaceutical Services at Moda Health. In this capacity, Robert is responsible for managing Moda's pharmacy services teams for the company's fully insured, ASO and MCO clients, as well as governmental entities and individuals enrolled in the Northwest Prescription Drug Consortium, a collaboration between the States of Washington and Oregon to provide affordable medications to residents in both states.

Scott D. Ramsey, MD, PhD
Full Member, Cancer Prevention Research Program, Fred Hutchinson Cancer Research Center
Director, Hutchinson Institute for Cancer Outcomes Research (HICOR)

Dr. Ramsey is a general internist and health economist. He is a Full Member in the Cancer Prevention Program, Public Health Sciences Division at the Fred Hutchinson Cancer Research Center, where he directs Hutchinson Institute for Cancer Outcomes Research, a multidisciplinary team devoted to clinical and economic evaluations of new and existing cancer prevention, screening and treatment technologies. In addition, Dr. Ramsey is a Professor in the School of Medicine, School of Pharmacy, and the Institute for Public Health Genetics at the University of Washington.

Trained in Medicine and economics, Dr. Ramsey's research focuses on economic evaluations in cancer. He has published widely on patterns of care, costs, and cost-effectiveness of treatments for lung, colorectal, and prostate cancer. His research portfolio and interests include: large scale SEER-Medicare/Cancer Registry data linkages, patient reported outcomes, economic modeling of health care interventions, cost-effectiveness analysis, quality of life assessment, patterns of care, health care utilization, economic burden of disease for patients and society, pragmatic trial design, early technology assessment, and stakeholder engagement.

Kai Yeung, PharmD, PhD
Post-Doctoral Fellow, Pharmaceutical Outcomes Research and Policy Program (PORPP), UW

Kai Yeung earned his PhD from the Pharmaceutical Outcomes Research and Policy Program at the University of Washington, in December 2016. His dissertation was entitled, "Does Cost-Effectiveness Analysis Have a Role in US Managed Care Drug Formularies? An Empirical Study of Utilization, Costs, Outcomes and Elasticity in a Value-Based Formulary." Related to this work, Kai has coauthored a paper published in the Journal for Managed Care and Specialty Pharmacy, presented at ISPOR as a student podium presentation, and awarded dissertation funding from the NIH National Center for Advancing Translational Sciences, and the Agency for Healthcare Research and Quality. Prior to the University of Washington, Kai was at the University of Southern California where he completed his PharmD at USC. Kai has cultivated a keen interest in the expanded use of evidence and analytics in decision making having worked for: Kaiser's Drug Information Services, AHRQ, Tufts University's CEA Registry and NICE, UK.

Jane Beyer, JD
Program Officer, Milbank Memorial Fund/CEbP

Jane Beyer is currently a Program Officer with the Milbank Memorial Fund and the OHSU Center for Evidence-based Policy. In that role, she supports state legislators and executive branch agencies in their efforts to develop and implement evidence-informed health and social services policy to improve health outcomes for the people they serve. Previously, Jane served as Assistant Secretary for the Behavioral Health and Service Integration Administration in the Washington State Department of Social and Health Services from September 2012 – August 2015.

Jane served as senior counsel to the Washington State House of Representatives Democratic Caucus from 1988 through 1994, and again from January 1999 to 2012. In that position, she handled a broad range of health care, human services and criminal justice issues, with a focus on Medicaid and access to health care. From 1995 through 1998, Jane served as the Washington State Medicaid director. She began her work in health law as a legal aid attorney in Tacoma, Washington.

Kathryn R Brown, PharmD MHA
Director of Pharmacy, Premera Blue Cross

Kathryn Brown is the Director of Pharmacy at Premera Blue Cross and is accountable for pharmacy strategies, programs and initiatives to ensure market competitiveness in medication management. She leads a team that supports products, programs and services to manage drug costs, quality and access including formulary management, UM, clinical pharmacy programs, legal, regulatory and legislative affairs pertaining to pharmacy.

Kathryn has over 20 years' experience leading health plan and delivery system health care operations. Prior to coming to Premera, Kathryn was Executive Director of Pharmacy for an integrated system, Director of Home Infusion and Pediatrics for a local home care company and a clinical pharmacist for oncology service, hospice/palliative care and general hospital practice. She maintains Affiliate Clinical Professor at University of Washington and is on the Board for the UW

School of Pharmacy. She also serves on a Board for the Seattle YWCA and Health Innovators Northwest.

Kathryn received her BPharm from Washington State University and her Pharm D and MHA from University of Washington. She did a Pharmacy Residency at Group Health Cooperative in Seattle, Washington.

Jason Dohm, PharmD
Vice President, Clinical Account Management, Commercial Division, Express Scripts

As vice president of Clinical Account Management, Mr. Dohm is responsible for the following:

- Development and testing of Express Scripts clinical offerings
- Recruiting and developing best-in-class clinical account executives
- Ensuring clinical staff meet and exceed client total healthcare needs
- Providing clinical consultation to identify strategies and tactics to meet client needs
- Serving as strategic leader representing client interests within Express Scripts' senior leadership

Mr. Dohm first joined Express Scripts in 1996 as a clinical specialist. Mr. Dohm earned a PharmD from the University of Minnesota.

Robert Judge
Director of Pharmacy Services, Moda Health

Robert Judge is the Director, Pharmaceutical Services at Moda Health. In this capacity, Robert is responsible for managing Moda's pharmacy services teams for the company's fully insured, ASO and MCO clients, as well as governmental entities and individuals enrolled in the Northwest Prescription Drug Consortium, a collaboration between the States of Washington and Oregon to provide affordable medications to residents in both states.

Newell McElwee, PharmD, MSPH

Associate Vice President, Center for Observational and Real- World Evidence (CORE), Merck Research Laboratories

Newell McElwee's team at CORE focuses on ensuring payer / HTA agency informed research plans, conducting collaborative research with academic institutions and health plans, developing strategic partnerships with international research institutions, and conducting research in medication adherence and health policy. Newell has worked in health economics and outcomes research in the pharmaceutical industry for over 20 years and prior to joining Merck was Vice President in Outcomes Research at Pfizer. Prior to joining the pharmaceutical industry, he was in academia and worked in the poison control center arena for over 10 years. Newell has numerous publications in medication adherence, health policy, and outcomes research. He currently serves on several boards and committees including the Academy of Managed Care Pharmacy Format Executive Committee, the Academy of Managed Care Pharmacy Board of Directors, the Agency for Healthcare Quality and Research Centers for Centers for Education and Research on Therapeutics Steering Committee, the Institute for Clinical and Economic Review Advisory Board, the Corporate Advisory Board at the University of Washington School of Pharmacy, and the Institute of Medicine Roundtable on the Promotion of Health Equity and Elimination of Health Disparities. He has served on the ISPOR Board of Directors (2011-2013) and the Agency for Healthcare Research and Quality National Advisory Committee (2012-2014). Newell received his PharmD degree from Mercer University, his MSPH (epidemiology) at the University of Utah and completed a clinical pharmacy residency at Osteopathic Medical Center of Texas and a McNeil Clinical Pharmacology and Toxicology Fellowship at the University of Utah.

Louis Lap H. Nguyen RPh, BCACP, MBA

Manager, Pharmacy Health Plan ad Delivery System Business Operation, Group Health

Louis Nguyen is trained as a pharmacist with many years of experience spanning over all facets of pharmacy (managed care, hospital, clinics and retails). "I live and breathe the struggle between practicing evidence base medicine and containing rising drug cost". In his current role as a key business operator for the health plan and the pharmacies, he takes part in the push and pull negotiations amongst stakeholders along the drug therapy value stream.

Louis is responsible for over one-half billion dollars of drug prices and rebates as his primary role. He serves as an internal consultant for other business strategies that include drug cost reduction,

repatriation, and channel management. He works closely with executive leaders to refine Group Health's position in the market place.

On the clinical side, Louis's pharmacy career has led him to speak at the American College of Cardiology regional chapter. He is also a merit reviewer on research applications for the Patient Centered Outcome Research Institute (PCORI).

Louis earned a Master in Business Administration in 2006. Board certified in Ambulatory Care in 2016. Experienced with international finance and modeling on Revenue and Cost analysis.

Sean D. Sullivan, BSPharm, MSc, PhD
Professor and Dean, University of Washington School of Pharmacy

Sean Sullivan holds a joint appointment as Professor of Health Services in the School of Public Health. He holds adjunct appointments in the School of Medicine, the Public Health Sciences Division at the Fred Hutchinson Cancer Research Center, and at Group Health Research Institute.

Dr. Sullivan completed training in pharmacy at Oregon State University in 1983, obtained a master's degree at the University of Texas in 1986 and a PhD in health economics and policy at the University of California-Berkeley in 1991.

Dr. Sullivan has authored more than 400 journal articles, book chapters, task force reports and organizational and governmental publications. In many of these, he has assessed the evidence and applications of medical technology in relation to coverage and reimbursement decisions. His research interests include technology assessment, medical decision-making and economic evaluation of medical technology. He is past president of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) and past chair of the Academy of Managed Care Pharmacy (AMCP) executive committee of the *Format for Formulary Submissions* – the United States evidence-based guidelines for formulary decision-making.

Dr. Sullivan served as a member of the Medicare Evidence Development and Coverage Advisory Committee, a member of the Regence Blue Shield and Premera Blue Cross P/T Committee and chair, Premera Blue Cross Value Assessment Committee. He is also on the editorial boards of *Value in Health, PharmacoEconomics,* and *Journal of Medical Economics*. He was awarded the 2014 Stephen G. Avey

Lifetime Achievement Award from the *Academy of Managed Care Pharmacy* and the 2015 *APhA Academy of Pharmaceutical Research Sciences (APRS)* Research Achievement Award.

Laura Kate Zaichkin
Deputy Chief Policy Officer, Washington State Health Care Authority

Laura Zaichkin leads the Office of Health Innovation and Reform, HCA's health policy and innovation engine. This program is primarily focused on the development and implementation of the state's five-year plan for health system transformation, called Healthier Washington. Prior to joining HCA in 2013, Laura was with the National Quality Forum in Washington, DC. There she convened a public-private partnership of national health care entities to help shape and catalyze action around the National Quality Strategy. Laura has a master's degree in public health policy from The George Washington University.