



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 Schneider'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.

We thank Susan Stuard and Jane Beyer with the Center for Evidence-Based Policy at Oregon Health Science University and Milbank Memorial Fund for their collaboration.

Thanks also to Work Group members for the time they are devoting to this undertaking and to Kaiser Permanente and The Laura and John Arnold Foundation for their generous support for this project.

Work Group Members

Susan Barrett

Executive Director
Green Mountain Care Board, Vermont

Burl Beasley

Clinical Pharmacist
Oklahoma Health Care Authority, Oklahoma

Robert Crittenden

Senior Policy Advisor to the Governor
State of Washington

James DeBenedetti

Director, Plan Management Division
Covered California, California

Rebekah Gee

Secretary, Dept. of Health and Hospitals
State of Louisiana

Richard Gottfried

Chair, Committee on Health
New York State Assembly, New York

Emily Hancock

Clinical Pharmacist
Department of Social and Family Services, Indiana

Nathan Johnson

Chief Policy Officer
Washington State Health Authority, Washington

Wendy Kelley

Director
Arkansas Department of Corrections, Arkansas

Heather Korbolic

Executive Director
Silver State Insurance Exchange, Nevada

Kevin Lembo

Comptroller
State of Connecticut

Eileen Mallow

Deputy Director
Wisconsin Department of Employee Trust Funds

Janet Mills

Attorney General
State of Maine

John McCarthy

Medicaid Director
State of Ohio

Rebecca Pasternik-Ikard

Chief Executive Officer
Oklahoma Health Care Authority, Oklahoma

David Seltz

Executive Director
Massachusetts Health Policy Commission, Massachusetts

Norman Thurston

State Representative, 64th District
Utah State Legislature, Utah

Staff

Trish Riley

Executive Director
National Academy for State Health Policy

Ellen Schneider

Deputy Director
National Academy for State Health Policy

Corinne Alberts

Research Analyst
National Academy for State Health Policy

Ameet Sarpatwari

Consultant
Brigham and Women's Hospital/Harvard Medical School

Jane Horvath

Consultant (through 8/2016)
National Academy for State Health Policy

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 patents¹

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 percent³ 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 states¹⁰ 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 version¹⁶ 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 document²² 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 private healthcare 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 Plans²⁴ 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.

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.

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.

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 securities³¹. 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.

Endnotes

1. For ease of reading, we use the term "pharmaceutical" or "Pharmaceutical industry" to encompass the depth and breadth of the industry producing brand name pharmaceuticals, generic pharmaceuticals, biologics/pharmaceuticals, vaccines, orphan drugs and specialty drugs
2. Schneider, Ellen. "States and prescription Drugs: An Overview of State Programs to Rein in Costs." National Academy for State Health Policy. Published April 2016. Accessed October 4, 2016 <http://nashp.org/wp-content/uploads/2016/04/Drug-Brief1.pdf>
3. Medicaid covers a wider array of benefits than commercial coverage (e.g.: long term care; supportive services) which affects the percent spent on pharmaceuticals as a percent of total spend.
4. Young, Katherine, Robin Rudowitz, Rachel Garfield, and MaryBeth Musumeci. "Medicaid's Most Costly Outpatient Drugs." The Henry J. Kaiser Family Foundation. Published July 15, 2016; MACPAC, Report to Congress on Medicaid and CHIP, June , 2016.,p.15
5. "State Prison Health Care Spending" Pew Charitable Trusts and the John D and Catharine T MacArthur Foundation. July 2014 Accessed at: <http://www.pewtrusts.org/~media/assets/2014/07/stateprisonhealthcarespendingreport.pdf>
6. Schneider, Ellen. "States and prescription Drugs: An Overview of State Programs to Rein in Costs." National Academy for State Health Policy. Published April 2016. Accessed October 4, 2016 <http://nashp.org/wp-content/uploads/2016/04/Drug-Brief1.pdf>
7. Schneider, Ellen. "States and prescription Drugs: An Overview of State Programs to Rein in Costs." National Academy for State Health Policy. Published April 2016. Accessed October 4, 2016 <http://nashp.org/wp-content/uploads/2016/04/Drug-Brief1.pdf>
8. Daniel, Hilary. "Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians." Health and Public Policy Committee of the American College of Physicians. Ann Intern Med. 2016;165:50-52. doi:10.7326/M15-276
9. Rau, Jordan. "Poll Finds Majority Want Restraint in Drug Prices." Kaiser Health News. September 29, 2016. Accessed October 2016.
10. "State Legislative Action on Pharmaceutical Prices" National Academy for State Health Policy / September 2016. Accessed October 2016 at "<http://nashp.org/state-legislative-action-on-pharmaceutical-prices/>"
11. For ease of reading, we use the terms "pharmaceutical" and "pharmaceutical industry" to encompass the depth and breadth of the industry producing brand name pharmaceuticals, generic pharmaceuticals, biologics/pharmaceuticals, vaccines, orphan drugs and specialty drugs.
12. Saraptwari A, Avorn J, Kesselheim AS. State Initiatives to Control Medication Costs – Can Transparency Help? (2016) New England Journal of Medicine. 374:2301-2304. DOI: 10.1056/NEJMp1605100
13. Pharmaceutical Research & Development: The Process Behind New Medicines." PhRMA May 2015. Accessed October 2016 at http://www.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf

14. Kesselheim Aaron, Avorn J, Sarpatwari A. "The high cost of prescription drugs in the United States: origins and prospects for reform." *Journal of American Medicine*. doi:10.1001/jama.2016.11237. Released August 2016. Accessed October 2016 at <http://jama.jamanetwork.com/article.aspx?articleid=2545691>
15. 315 U.S. 575 (1942).
16. Mylan to Launch First Generic to EpiPen® Auto-Injector at a List Price of \$300 per Two-Pack Carton, a More than 50% Discount to the Brand Product. Mylan. Accessed online October 11, 2016 at <http://newsroommylan.com/2-16-08-29-Mylan-to-Launch-First-Generic-to-EpiPen-Auto-Injector-at-a-List-Price-of-300-per-Two-Pack-Carton-a-More-than-50-Discount-to-the-Brand-Product>.
17. Media coverage at the time also indicated that Medicaid was continuing to coverage Hep C treatments from other manufacturers, which gets to the issue of how Medicaid may undercut normal market negotiating leverage.
18. FTC. Pay-for-delay: how drug company pay-offs cost consumers billions. Published January 2010. Accessed September 22, 2016.
19. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).
20. Carrier M. After Actavis: seven ways forward. *Rutgers Law Rev.* 2015;67(3):543-55.
21. "Track and Trace: Understanding the Requirements of the Drug Supply Chain Security Act." *Elements Magazine*. Published 2015. Accessed October 2016 at <https://www.pbahealth.com/track-and-trace-understanding-the-requirements-of-the-drug-supply-chain-security-act/>
22. Centers for Medicare and Medicaid Services. "Medicaid Drug Rebate Program Notice." Published July 14, 2016. Accessed October 2016 at <https://www.medicicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-176.pdf>
23. "Pharmaceutical Bulk Purchasing: Multi-state and Inter-agency Plans." National Conference of State Legislatures. Accessed online October 11, 2016: www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx.
24. Menges Joel, Amira Mouna, and Nick Pantaleo. "Assessment of Medicaid MCO Preferred Drug List Management Impacts." Released February 2016. Accessed September 30, 2016. https://www.themengesgroup.com/upload_file/report_on_texas_pdl_February_2016.pdf
25. Ten years provides the potential for a pharmaceutical product to demonstrate its value to patients, payers and society. Five years – which is used by the Institute of Clinical and Economic Review (ICER) – may be too short a period of time to assess value and set a price based on that value assessment. Five years may limit incentives for innovation in areas such as vaccines against AIDS or treatments for small group patient populations. However, the period of time for a value/return on investment assessment would be negotiable.
26. Department of Health and Human Services, Office of Inspector General. "Manufacturer safeguards may not prevent copayment coupons use for Part D drugs." Released September 2014. Accessed October 4, 2016 at <https://oig.hhs.gov/oei/reports/oei-05-12-00540.pdf>.
27. Ross J and Aaron S Kesselheim. "Prescription-drug coupons – no such thing as a free lunch." *New England Journal of Medicine*. DOI:10.1056/NEJMp1301993. Published August 2013. Accessed October 2016
28. Personal communication with J. Mulligan, Kaiser Permanente. September 14, 2016.
29. Lazar K. "New Mass. Law drug coupons for prescription drugs." *Boston Globe*. Published July 29, 2012. Accessed October 4, 2016 at <https://www.bostonglobe.com/lifestyle/health-wellness/2012/07/29/new-massachusetts-law-allows-discount-coupons-for-prescription-drugs/YXJdBcxhMMn0XqZfPKi56M/story.html>.
30. Carter C. Consumer protection in the states: A 50-State Report on Unfair and Deceptive Acts and Practice Statutes. National Consumer Law Center. Released February 2009. Accessed October 4, 2016 at https://www.nclc.org/images/pdf/car_sales/UDAP_Report_Feb09.pdf.
31. Vidal, Phillip. "Annual Survey of public pensions: State and locally-Administered Defined Benefit Data Summary Brief: 2015." US Census Bureau, DC. Released June 2016. Accessed October 2016 at <https://www.census.gov/content/dam/Census/library/publications/2016/econ/g15-aspp-sl.pdf>
32. "McDonald's and Dunkin'-No More Styrofoam." As You Sow Winter Newsletter. Accessed October, 2016 at <http://www.asyousow.org/2013-q4-winter/mcdonalds-and-dunkin-no-more-styrofoam/>
33. Barber, Brad. "Monitoring the Monitor: Evaluating CalPERS' Activism." University of California, Davis. Released November 2006. Accessed October 2016 at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=890321

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.