



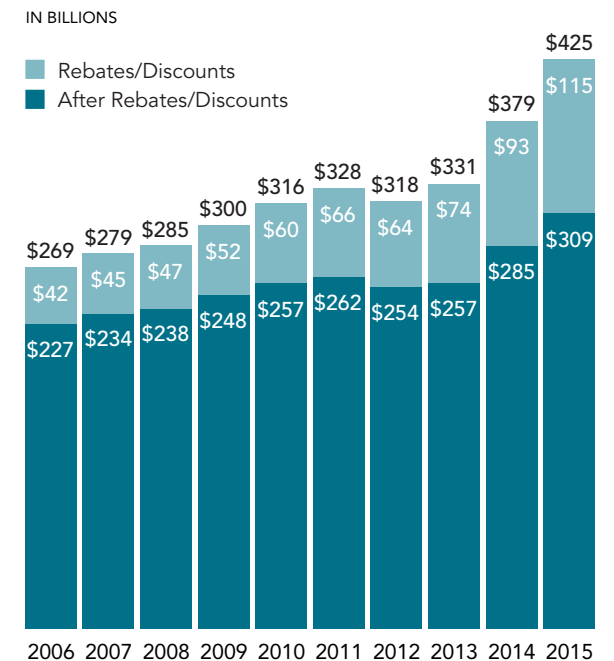
# When the Price Is Not Right: State Options on Prescription Drug Pricing

In 2013, more than 3 million patients with hepatitis C in the US heard the good news about Gilead Sciences' development of an effective new drug, Sovaldi. The bad news: it was \$84,000 for the three-month course of treatment. Since the Sovaldi price tag came to public attention, the media have been shining a continuous spotlight on skyrocketing drug prices. And while health care policy leaders have wrestled with drug pricing policy reform over the years, recent examples of sudden price escalations — such as the 62-year-old drug Daraprim going from \$13.50 a pill to \$750, and the antibiotic doxycycline going from \$10 for a 50-count bottle to \$250 — have reignited concerns about preserving affordability while assuring support for drug innovation.

In 2015, the total US expenditure on prescription medicines was \$425 billion, a 12.2% increase over 2014 total expenditure or an 8.5% increase when adjusted for net expenditure (which includes pharmaceutical manufacturer rebates and discounts) (See Figure 1).<sup>1,2</sup>

Balancing affordability and new drug development is challenging for two reasons: (1) the complexity of federal price and rebate policies and regulations,

Figure 1. US Spending on Medicines, 2006-2015



Notes: Figure shows total public and private spending on prescription medicines by retail pharmacies, hospitals, and other institutional pharmacies at invoice prices. Segments may not add to totals due to rounding.

Source: Reprinted with permission from IMS Institute, 2016.

and (2) the powerful standing that pharmaceutical manufacturers have in the health care arena. In response to California's interest in pursuing reasonable and effective strategies for high-value medical care, this issue brief presents information about the cost of prescription drugs, details the landscape of rebates and barriers (primarily around outpatient prescription drugs), describes the various strategies being pursued at the national and state levels, notes California's own efforts, and speculates on possible outcomes.

### Focus on Outpatient Pharmacy Benefit

Prescription drugs are covered under an insurance medical benefit (where the drug is administered by a health care provider) or under a pharmacy benefit, also referred to as the outpatient pharmacy benefit. The authors simplify this complex issue by focusing on the outpatient pharmacy benefit, which comprises approximately 70% of total drug expenditures and is subject to some laws and regulations different from those for drugs under the medical benefit.

**US pharmaceutical prices are among the highest worldwide, and escalating costs have been a concern for many years, presenting challenges for federal, state, and private purchasers.**

## The Problem of Prescription Drug Costs

US pharmaceutical prices are among the highest worldwide, and escalating costs have been a concern for many years, presenting challenges for federal, state, and private purchasers.<sup>3</sup> Outpatient prescription drugs reportedly account for 10% of total health expenditures in the United States, and the rate of pharmaceutical spending is increasing rapidly.<sup>4</sup> Spending on just 10 medications alone is estimated to cost the federal government (Medicare, Medicaid, and health exchange subsidies) nearly \$50 billion over a decade, and these drugs represent a small subset of the more than 5,400 medications in the drug pipeline.<sup>5</sup> Thus, it is likely pharmaceutical spending will continue to consume a larger share of health care expenditures.

Of particular concern are specialty drugs, structurally complex medications that often require special handling or delivery mechanisms, and/or are very costly. Although these drugs account for only 1% of prescriptions, they represent nearly one out of every three dollars spent on prescription drugs.<sup>6</sup> Experts report that specialty medications priced in excess of \$10,000 per course of treatment are increasingly commonplace, with more than 900 drugs now in this category.<sup>7</sup> Their prices have been increasing, too; in 2012, all but one new cancer drug was priced at or above \$100,000 per year, and by 2014, all but one was priced at or above \$150,000.<sup>8</sup>

Generic drug prices are also climbing. Typically priced up to 80% less than their brand-name equivalents, generics comprise 8 of 10 prescriptions dispensed in the US.<sup>9</sup> In 2012, generic drugs were

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estimated to have saved the US health care system (i.e., Medicare, Medicaid plans, commercial third-party payers, and patients paying for drugs out of pocket) nearly \$217 billion, up from \$188 billion in 2011.<sup>10</sup> However, between 2013 and 2014, generics in more than 220 drug categories saw increased prices of at least 100%, and in 17 categories prices increased by more than 1,000%.<sup>11</sup>

Drug costs are the product of two components: price and use. The expanded use of prescription drugs — from 3.9 billion prescriptions dispensed in 2009 to 4.3 billion in 2014 — has contributed to escalating drug budgets.<sup>12</sup> To manage demand, purchasers have implemented utilization strategies such as prior authorization and formularies featuring selective copayment tiers. However, these demand-focused strategies may have a limited impact on total costs. While finding responsible ways to influence use is important, this issue brief focuses on what is being done to influence the purchase price of prescription drugs.

## The Landscape: Rebates and Barriers

Understanding current laws and regulations that impede cost controls is necessary to identifying tenable solutions for drug purchasers. The following section summarizes key parameters established by pharmaceutical manufacturers and federal programs.

### Pharmaceutical Manufacturers

**Confidential arrangements confound the comparison of net prices, which limits purchasers' ability to calibrate the value of drugs.** Purchasers (often represented by pharmacy benefits management companies, called PBMs) negotiate deals with pharmaceutical companies; commonly, the more covered lives represented by a purchaser, the better the deal. Purchasers, however, must sign contracts containing nondisclosure agreements regarding prices, discounts, and rebates.<sup>13</sup> These “gag” clauses preclude purchasers from publicly sharing the net purchase price of medications.

**Manufacturers receive multiyear monopolies in the form of patents.** In an effort to stimulate drug development, a number of protections are offered to manufacturers. Pharmaceutical manufacturers may seek patents (through the US Patent and Trademark Office) at any point during the drug development process for a wide range of elements associated with the composition and delivery of a drug.<sup>14</sup> On average, patents provide a manufacturer with a 7- to 12-year monopoly after the drug is approved by the FDA and released to market.<sup>15</sup> Average profit margins for manufacturers with patent-protected drugs are reported to be 18.4%, compared with

5.6% for manufacturers of non-patent-protected generic drugs.<sup>16</sup> Pharmaceutical manufacturers may also obtain patent extensions ranging from three to seven years for simple reformulations or changes in dosage and delivery method of existing drugs, which extends a manufacturer's monopoly.<sup>17,18</sup>

### Food and Drug Administration (FDA)

**The FDA can extend the monopolies of pharmaceutical manufacturers by awarding exclusivity periods.** These exclusive marketing rights (for new drug formulations) are awarded directly by the FDA at the time of approval for a new drug and prohibit the submission or approval of a generic counterpart throughout the life of the award. Most novel drugs receive five years of “new chemical exclusivity”; however, the duration of market exclusivity ranges from 180 days to seven years, depending on the type or intended use of the drug, and may run concurrently or consecutively with patents.<sup>19</sup> Although intended to provide a balance between rewarding innovation and maintaining a competitive generic market, exclusivity has encouraged manufacturers to engage in several “life cycle management” strategies designed to slow the entry of generics into the market. These practices include repurposing a drug for pediatric use, which grants an additional six months of exclusivity, or seeking novel uses of an already established drug for a three-year extension beyond the initial award.<sup>20</sup>

Additionally, manufacturers may obtain marketing exclusivity through the Orphan Drug Act of 1983, which was intended to stimulate development of drugs for rare diseases (those affecting fewer than 200,000 people in the US). In 2014, 17 of the 41

new drug approvals were for rare diseases, each costing an average of \$137,000 per year per patient — almost seven times greater than the average cost of a non-orphan drug.<sup>21-23</sup> A consequence has been the production of high-cost drugs with an expected return on investment of 1.89 times greater than non-orphan drugs, and an industry focusing on a smaller subset of the population.<sup>24</sup> In one study, three of four top-selling orphan drugs were used more commonly for non-orphan indications, illustrating situations where expensive products have become widely used for non-FDA-approved indications without adequate evidence.<sup>25</sup>

### Centers for Medicare and Medicaid Services (CMS)

**Manufacturers do not have a strong incentive to negotiate lower prices with private purchasers because they know that discounts will have to be passed on to Medicaid.** The Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) created the Medicaid Drug Rebate Program to ensure that Medicaid receives a net price lower than the “Best Price” paid to manufacturers by any private-sector purchaser for a particular drug.<sup>26</sup> This “Best Price” amount is used to calculate the federal Medicaid basic rebate (shared between the federal and state Medicaid program) required of manufacturers. In exchange for rebates, state Medicaid programs must generally cover a participating manufacturer's drugs.<sup>27</sup> In addition to the federal basic rebate, states may also receive supplemental rebates for drugs placed on their Medicaid preferred drug list. Private purchasers are precluded from negotiating a price that is lower than the Medicaid Best Price, which includes all rebates, discounts, or other adjustments

that directly or indirectly adjust prices for non-Medicaid entities.<sup>28</sup>

**The government is prohibited from directly negotiating drug prices for Medicare Part D.** The 2003 Medicare Prescription Drug, Improvement, and Modernization Act prohibits the Secretary of Health and Human Services from interfering with negotiations between drug manufacturers, pharmacies, and Part D plan sponsors (for both fee-for-service and managed care beneficiaries), even in cases of market failure or other circumstances when plan sponsors are unable to negotiate significant price reductions. It also limits the secretary's ability to establish a Medicare formulary or to exclude excessively expensive drugs from Medicare coverage. However, similar to that of private purchasers, Part D plan sponsors retain the ability to negotiate prices and establish formularies that offer at least two drugs in every class of drugs to ensure patient choice.

**CMS has added a requirement that Part D plans cover all drugs in certain protected classes.** These classes include antiretrovirals, antidepressants, antipsychotics, anticonvulsants, antineoplastics, and immunosuppressant drugs to prevent organ rejection. Even though these Part D plans can negotiate directly with manufacturers, such rules impair their ability to obtain price concessions for certain drug classes. However, these provisions may change pending final approval of the federal FY 2017 budget (see discussion in National Strategies section).

## Department of Veterans Affairs (VA)

**The VA is permitted by law to negotiate prices lower than the Medicaid Best Price.** The VA uses several strategies to obtain low drug prices. First, it negotiates drug prices for the Federal Supply Schedule (FSS) using as a baseline the prices paid by the manufacturer's "most favored" commercial purchaser (the lowest price obtained by a commercial entity); these prices may not increase faster than inflation. All direct federal purchasers can obtain prescription drugs at the FSS prices.<sup>29</sup>

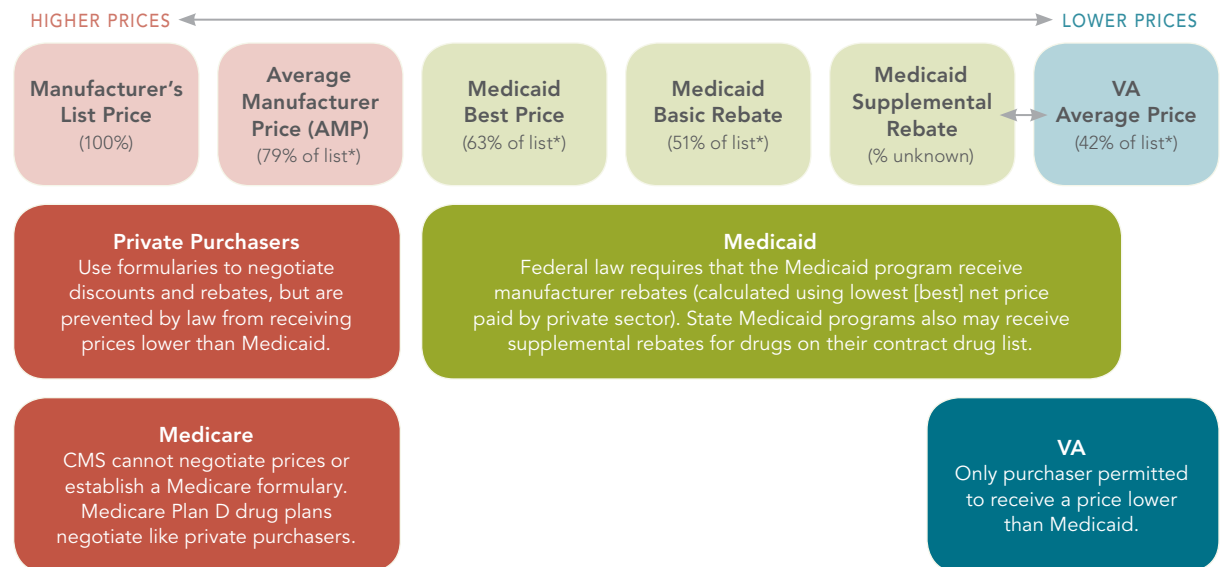
Second, the VA is one of the "Big Four" (along with the Department of Defense, the Public Health Service, and the Coast Guard) that benefit from a separate program that caps the price of branded

drugs (federal ceiling cap) at 76% of the FSS prices. There is a strong incentive for manufacturers to participate in the Big Four program; those that do not participate are prohibited from selling to Medicaid and other federal agencies.<sup>30</sup>

Finally, the VA's national preferred formulary provides significant leverage for negotiating further price discounts. Although the FSS and Big Four drug price data are publicly available, the prices negotiated for VA formulary drugs remain confidential. These advantages for the VA do not directly pose price negotiation barriers to private purchasers.

Figure 2 illustrates the overall purchasing power among major groups of purchasers as defined by

**Figure 2. Estimated Value of Discount/Rebate Programs for Different Purchasers**



\*Estimates based on *Prices for Brand-Name Drugs Under Selected Federal Programs*, Congressional Budget Office, June 2005. The degree of overlap in prices paid (if any) between the VA and Medicaid agencies with supplemental rebates is unknown.

current law and practice. The list price is the baseline from which purchasers begin their negotiation. Private purchasers and plans providing Medicare coverage, by law, will always pay higher prices than Medicaid or the Veterans Administration because of the price floor established by the aforementioned Medicaid Best Price. (Wholesaler/distributors are excluded from this illustration because, although they purchase the majority of prescription drugs from manufacturers, they are only intermediary purchasers.<sup>31</sup>)

### Consequences of Government Benefits and Restrictions

The favorable pricing programs for the VA and Medicaid essentially set the floor for the lowest prices that other purchasers may try to negotiate. Confounding this issue is the nondisclosure of net drug prices; purchasers have no method to calibrate the comparative value of the drugs they are purchasing since contracts remain confidential. Consequently, purchasers are prevented from comparison shopping net prices. In fact, this lack of transparency was highlighted in a \$785 million settlement between the US government and Pfizer in 2016, after that company failed to give Medicaid programs the same discount given to private purchasers for a heartburn medication.<sup>32</sup>

As noted previously, PBMs are able to leverage their large group purchasing power to achieve price discounts and rebates for the private sector and some public-sector purchasers (e.g., Medicaid managed care organizations). Some stakeholders note, however, that PBMs may not be motivated to negotiate the fullest discount possible since they also receive

rebate payments from drug manufacturers based on total sales. It is safe to assume that not all of the rebate savings are passed along to employers, health plans, or, ultimately, consumers.

Despite these constraints, stakeholders at the state and national levels are proposing various ways to reduce — radically or incrementally — barriers to achieving affordable prescription drug budgets.

## National Strategies to Control Drug Costs

While there are many state legislatures, coalitions, and individual stakeholders leading public and private efforts to lower drug prices, those working in this arena agree that the most effective strategies require modifications in federal laws or regulation. These modifications are being pursued by those in both the public and private sectors.

### Public-Sector Approaches

Federal government leaders are proposing a variety of reforms. The FY 2017 White House budget would include strategies to increase competition among pharmaceutical manufacturers to help the public and private sectors control escalating drug budgets. In addition to a transparency requirement for manufacturers to publicly disclose information about research and development costs, discounts, and other data, the proposed budget would also allow the US Secretary of Health and Human Services to negotiate prices for biologics and other high-cost prescriptions on behalf of Medicare, and would require Medicare to receive rebates comparable to Medicaid.

It would also prohibit “pay-for-delay” agreements between generic and branded pharmaceutical companies, reduce from 12 to 7 years the exclusivity granted for innovator biologics, and prohibit additional periods of exclusivity for branded biologics due to minor changes in product formulations.<sup>33</sup> Additionally, the budget would increase the power of states by establishing a voluntary tool to negotiate lower drug prices through the creation of a Federal-State Medicaid negotiating pool for high-cost drugs. Together, increased competition and transparency would save the federal government \$21 billion over 10 years.<sup>34</sup> The budget proposes a wide variety of far-reaching reforms; however, congressional approval of these strategies is unlikely.

The US Senate is considering S.2615, the *Increasing Competition in Pharmaceuticals Act*. This would promote competition in the off-patent drug marketplace by instituting a priority-review pathway at the FDA to disrupt off-patent drug monopolies. It would also establish a voucher system to encourage generic drug makers to take more interest in low-margin, off-patent products.<sup>35</sup> Independent of this legislation, the FDA recently announced a new priority-review pathway to expedite any generic drug that would compete with an off-patent drug that is only made by one company. It is expected that the accelerated review process would reduce the review period from years to months, effectively limiting the time the company has a monopoly, and thus, lower the prices for those drugs where generics were more rapidly introduced to the market.<sup>36</sup>

## Private-Sector Approaches

The Campaign for Sustainable Rx Pricing, a project of the National Coalition on Health Care, is an initiative that promotes a national dialogue on bipartisan, market-based solutions.<sup>37</sup> Seeking a balance between innovation and affordability, the campaign released its *Proposals for Change* in April 2016, focusing on three domains: (1) transparency, (2) competition, and (3) value.<sup>38</sup> Within each domain are four or more specific strategies. For example, to address competition, one strategy is to provide the FDA with the resources needed to reduce the backlog of generic drug applications, where the average approval time may be three or more years. The focus on value is to assure there is a relationship between a drug's cost and its effectiveness. One value strategy is to require manufacturers to conduct comparative effectiveness research of new products relative to existing ones. The campaign notes that these strategies require action at the federal level, and its 80+ partners are working closely with government and elected officials to move them forward.<sup>39</sup> The campaign recognizes that this is a long-term effort and invites manufacturers to engage with them.

Other private-sector efforts emphasize educating policymakers and the public. An initiative by America's Health Insurance Plans focuses on educating health plans, the public, and policymakers about the effect specialty drugs have on insurance premiums and total health care costs.<sup>40</sup>

## States' Strategies to Control Drug Costs

Despite the sober acknowledgment of intransigent federal laws, purchasers and advocates are doggedly proposing new state laws that may open the door, however slightly, to an environment conducive to lowering drug costs. Appendix A is a summary of state proposals in 2015-2016, which include a variety of approaches:

- ▶ Mandating drug price transparency
- ▶ Aligning drug prices with those of the VA
- ▶ Purchasing drugs through international sources (reimportation)
- ▶ Educating the public and providers about drug costs
- ▶ Banning direct-to-consumer advertising
- ▶ Prohibiting pharmaceutical manufacturer gifting to providers

As of May, Vermont is the first state to pass legislation, a drug cost transparency bill, now awaiting the governor's signature.<sup>41</sup> Some states' bills are still pending; others have failed due to industry lobbying, concerns about conflicts with federal law, and costs to states to implement the legislation.

States can also pursue direct legal action against drug manufacturers. In one successful example, the Massachusetts Attorney General brought suit against pharmaceutical manufacturers for inflating and fraudulently reporting Medicaid drug prices, and in 2011, successfully recovered more than \$47 million from 13 drug manufacturers.<sup>42</sup>

## Improving Transparency of Drug Costs

Of the strategies proposed, price transparency is by far the most common of the states' approaches and is a logical place to start. The concept of transparency is dominating health care discourse today, with the quality and costs of health care providers and services being measured and publicized, and the public being urged to use available data to help inform individual decisions. Yet to date, transparency regarding prescription drug prices is greatly lagging behind other realms of health care, frustrating patients, providers, payers, and policymakers.<sup>43</sup>

Many transparency bills share a common theme: They seek to require pharmaceutical companies to disclose how much they spend on research, manufacturing, and marketing. Supporters of the drug price transparency approach assert that educating policymakers and consumers on the disparity between a drug's production cost and its selling price will encourage public scrutiny of prices that seem unjustified, and pressure (or even shame) manufacturers into moderating their prices.

## Experimenting with Value-Based Design

A few private purchasers are experimenting with innovative value-based formularies. US insurance carrier Humana recently partnered with Novartis Pharmaceuticals in an outcomes-based payment model for its multiple sclerosis drug Gilenya.<sup>44</sup> Novartis also entered into pay-for-performance agreements with Cigna and Aetna regarding Entresto, a new heart failure drug said to be more effective than less-expensive angiotensin-converting

enzyme (ACE) inhibitors.<sup>45</sup> Entresto patients will be monitored to see if the drug can replicate results achieved during clinical trials (e.g., reductions in hospitalizations). Novartis had agreed to a base price and a modest rebate, which would fluctuate based on hospitalizations and savings to the insurance plan. However, due to the large volume of data that must be collected and analyzed, outcomes-based pricing deals can be difficult to administer.<sup>46,47</sup>

Another example is from Premera Blue Cross in Washington. It developed a value-based formulary in which a cost-effectiveness ratio is assigned to each tier, and drugs that fall into each tier's ratio threshold are included in that tier with a flat copayment. The higher tiers have progressively higher copays, reflecting lower value compared with other drugs.<sup>48</sup> This strategy could influence drug costs if manufacturers lower their prices to improve the cost-effectiveness of their drugs.

## California's Efforts

California has also been active in attempts to impact the drug pricing environment. The California Association of Health Plans is sponsoring the Runaway Rx campaign, which educates stakeholders and policymakers about the need for affordable prescription drug prices in California.<sup>49</sup> The state is engaged in several approaches targeted to the public and private sectors.

### Medi-Cal

The Medi-Cal program administered by the California Department of Health Care Services (DHCS) reports maximizing the federal and state supplemental

rebates with drug manufacturers, which results in a lower net cost of drugs provided under the program.<sup>50</sup> In FY 2014-2015, California collected \$2.6 billion in federal drug rebates, and \$159 million in state supplemental rebates.<sup>51</sup> These rebates are then shared with the federal government based on specific formulas. California especially benefits from the state supplemental rebate program as the size of the Medi-Cal population makes it an appealing market for manufacturers.

While DHCS reports the total savings from drug rebates, it cannot make public the individual rebates provided by manufacturers per federal and state law. And while DHCS must make available nearly all FDA-approved drugs to Medi-Cal beneficiaries, its contract drug list helps direct providers to use more cost-effective alternatives (where supplemental rebates may be procured) by allowing them to forgo submission of Treatment Authorization Requests (TARs).

### Proposed Laws

California legislators and advocacy groups have turned to bills and initiatives to address this issue. During 2015-2016, several bills have been introduced in the state legislature; one initiative qualified for the November 2016 ballot.

- ▶ **AB 2436** (R. Hernandez) — Among several provisions, the *Health Care Coverage Disclosures of Drug Pricing* bill would require health care plans notify an enrollee, when purchasing a prescription drug, about the net cost of the prescription drug to the plan, and the cost of the prescription drug in US dollars in Canada, Germany, and Mexico.<sup>52</sup>

- ▶ **AB 2711** (Chiu) — This bill would reinstate mandated reporting to the state about the number and description of state contracts entered into with manufacturers and suppliers of drugs, including any discounts, rebates, or refunds obtained.<sup>53</sup>

- ▶ **SB 1010** (E. Hernandez) — Among other requirements, this bill would mandate that branded and generic drug manufacturers provide a 60-day notice to state purchasers and insurance carriers about price increases greater than 10% for generic drugs costing \$100 per 30-day supply, and for branded drugs costing more than \$10,000 per year or per treatment.<sup>54</sup> Manufacturers would provide documentation justifying the increase, as well as total public funding received for development and marketing, the expected marketing budget, and a schedule of past price increases for the drug.

- ▶ **AB 463** (Chiu) — The *Pharmaceutical Cost Transparency Act of 2016* (which died in committee in January 2016) would have required pharmaceutical companies to report annually the cost of the most expensive drugs to enable policymakers, government agencies, and others to understand the cost.<sup>55</sup>

- ▶ **Ballot initiative** — The *California Drug Price Relief Act*, an initiative slated for the November 2016 ballot, would prohibit California state administrative agencies or entities (i.e., DHCS [excluding Medi-Cal managed care], Department of Corrections and Rehabilitation, CalPERS, etc.) from paying

more than the lowest prices paid by the VA, with the goal of reducing the state's drug costs to that of the much-lower federally mandated range.<sup>56</sup>

These bills focus primarily on price transparency strategies, while the ballot initiative goes further by establishing a price ceiling (defined as the lowest net cost as negotiated through the VA) for other California state purchasers. Some experts are concerned that this action may motivate manufacturers to try to recoup their profit losses by increasing prices or reducing rebates to private-sector purchasers or Medicare Part D plans.

## Covered California

As the country's largest state-based health care marketplace, Covered California currently serves 1.57 million people. While not involved in negotiating drug prices, it has written into the contracts with its qualified health plans disclosure language about health plans' actions concerning drug assessments and pricing. This language is intended to help them understand health plan strategies. Effective 2017, health plans must describe:

- ▶ The extent to which they consider value in pharmaceutical decisions. This might be through the use of independent drug assessment reports on comparative effectiveness to design benefits, to negotiate prices, to develop pricing for consumers, and/or to determine formulary placement and tiering.
- ▶ The extent to which formularies are based on total cost of care rather than on drug cost alone.

- ▶ How off-label use of pharmaceuticals is monitored and the efforts undertaken to assure that off-label prescription use is evidence-based.
- ▶ How they provide decision support for prescribers and consumers related to the clinical efficacy and cost impact of treatments and their alternatives.

This information sets a baseline for future consideration of efforts to bring consistency, quality, and affordability to Covered California patients.

## California Technology Assessment Forum (CTAF)

Established by Blue Shield of California Foundation more than 30 years ago, CTAF is now under the auspices of the nonprofit Institute for Clinical and Economic Review (ICER).<sup>57</sup> CTAF has always facilitated a nonpartisan, evidence-based process for comparing the effectiveness and safety of new interventions with existing products. Since its affiliation with ICER three years ago, CTAF uses the ICER Evidence Rating Matrix for rating Comparative Clinical Effectiveness, a multistep assessment for calculating the net health benefit for patients of new or existing drugs or other medical interventions. Following an assessment of effectiveness, the ICER process then applies a method for assessing cost-effectiveness as well as an evaluation of the impact on state or national budgets. However, not all characteristics of "value" can be quantified; the review panel that considers the data also takes into account features of the intervention that are more subjective. The CTAF panel typically reviews and evaluates the

intervention in a one-day meeting that is open to the public. Besides CTAF, ICER also leads similar programs in New England and the Midwest.

ICER recently received a five-year grant to expand its work on prescription drugs and to include in all its reports a calculated "value-based price benchmark" that reflects a fair price for the degree of improvement in patient outcomes provided by a new drug. ICER's analyses have found that some drugs, such as new proprotein convertase subtilisin-kexin type 9 (PCSK9) inhibitors for treating high cholesterol, would require more than a 50% discount off the list price for their cost to be aligned with the benefit they bring to patients. Other drugs, such as the aforementioned Entresto, have been found to be reasonably priced. These suggested prices are now being used by growing numbers of payers, including Express Scripts, OptumRx, Blue Shield of California, and others, in their negotiations with drug manufacturers.<sup>58</sup>

The comprehensiveness, credibility, and transparency of the ICER process are lauded by many working in the drug pricing arena.<sup>59-61</sup> While the CTAF panel results — or those of other ICER sites — do not carry the authority to set formulary or pricing limits, they are an important step forward for California purchasers and patients.



## Conclusions

Based on the current environment and consistent messages gleaned from the literature and interviews with key informants (see Appendix B), the authors came to the following conclusions.

**Federal rules will be slow to change.** Modifying key federal rules is critical to altering the landscape in which purchasers and manufacturers operate, but the change will be slow and incremental. The greatest obstacles to achieving lower drug prices in general include:

- ▶ The requirement that no private-sector entity can obtain a lower purchase price than the Medicaid best price
- ▶ The lack of public disclosure of the individual net drug prices paid by major payers like the VA and Medicaid
- ▶ The requirement that Medicaid and Medicare Part D include all FDA-approved drugs in their formularies (without the leverage to say “we will not cover that drug,” negotiating lower prices is difficult)
- ▶ The prohibition on CMS from considering cost or cost-effectiveness in coverage of prescription drugs

**The power imbalance is a challenge.** The pharmaceutical industry has resources to lobby that far surpass the resources of most other stakeholders. In addition, there is considerable debate about the true costs of pharmaceutical research and development; it is overwhelming for policymakers and the public to fully grasp the claims and counterclaims of

the costs of bringing a drug to market. Several informants mentioned the importance of both of these as factors in the historical lack of success in changing rules around price negotiation.

Although surveys have shown that the public supports enabling the government to negotiate Medicare drug prices, the public also has strong convictions about the importance of medical innovation and is likely to continue to be swayed by pharmaceutical messages.<sup>62,63</sup> The Campaign for Sustainable Rx Pricing acknowledges that the goal of managing drug prices is to reach a reasonable compromise that accommodates fair profit margins without squelching innovation. Yet, anticipating a slippery slope, manufacturers may not yield willingly to compromises.

**The tide will turn.** The health care sector today has placed great emphasis on value. As policy leaders, providers, and patients become more accustomed to viewing health care through the lens of “benefit relative to cost,” the pressure on the pharmaceutical industry to adhere to that paradigm will increase. Vermont’s recent success with transparency legislation is likely to encourage other states to persist in these efforts. Most groups working on this issue believe it is the constant education about the problem that will eventually bring needed changes. Moreover, new models for assessing drug value — such as the one developed by ICER — will likely gain credence as exposure to and experience with these processes grow.

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## Limitations and Acknowledgments

The elements that comprise US drug pricing are extraordinarily complex, multifaceted, and rife with conflict. In this paper, the authors sought to provide a balance of essential facts and readability.

To assist in preparing this paper, the authors spoke with a number of content experts (see Appendix B), who were enormously helpful in clarifying important details and helping to unravel some of the nuances embedded in drug pricing policies. The authors are grateful for their generosity of time and expertise. The details and conclusions presented in this paper, however, reflect the perspectives of the authors and not necessarily those of these key informants or their organizations.

## About the Foundation

The California Health Care Foundation is dedicated to advancing meaningful, measurable improvements in the way the health care delivery system provides care to the people of California, particularly those with low incomes and those whose needs are not well served by the status quo. We work to ensure that people have access to the care they need, when they need it, at a price they can afford.

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## Appendix A. Summary of Solutions Proposed by States to Manage Prescription Drug Prices

### STATES WITH PROPOSED LEGISLATION (2015-16)

#### Price transparency mandates

Legislation generally focuses on specialty/high-cost drugs (\$10K/episode) and may include such wording as:

- ▶ Requires public or private disclosure to the state for pharmaceutical manufacturers' "actual" costs for R&D, clinical and regulatory, manufacturing/distribution, federal/state/other contributions to R&D, and purchase costs (patents, licensing, etc.)
- ▶ Requires state to set maximum allowable cost if drug is found to be excessively priced
- ▶ Requires independent audit of manufacturer-submitted data
- ▶ Requires insurance carriers to notify enrollees about the net cost of the prescription drug to the insurer (after applying any discounts, rebates, or other reductions in cost to the insurer) and the cost of the prescription drug in the United States and foreign countries (e.g., Canada, Germany, and Mexico)
- ▶ Establishes a state all-payer claims database, including prescription drug cost data

CA, CO, MA, MI, MN, NC, NJ, NY,  
PA, RI, TN, VA, VT, WA

#### Pricing studies (transparency, value purchasing)

- ▶ Requires legislative committee to study drug pricing and recommend actions to mitigate rising drug prices/maximize drug pricing discounts; based on report results, designates state agency to audit drug-purchasing practices
- ▶ Establishes a task force to study value-based pricing of prescription drugs

CT, GA, IN, NM

#### Exempt insurers from drug coverage requirement

- ▶ Exempts insurers (public and private) from having to cover drugs costing >\$5K if manufacturer does not file a report on costs/price with state Department of Insurance — silent on public availability of report

PA

#### Public/provider education

- ▶ Requires or allows "academic" counterdetailing of providers
- ▶ Requires state to publicly list drug products and corresponding biopharmaceutical studies
- ▶ Requires educational or marketing materials for providers to include price information

CT, LA, MA, NY

#### Drug reimportation/international purchases

- ▶ Permits residents to purchase prescription drugs at lower cost from other countries (as permitted under the Federal Food, Drug, and Cosmetic Act)

MA, ME;  
NY would outlaw

#### Anti-gifting to providers

- ▶ Prohibits pharmaceutical manufacturers from providing economic incentives to providers to prescribe certain drugs or to discourage bioequivalent generic substitution
- ▶ Requires published list of gifts to providers from manufacturers
- ▶ Publishes fact sheet for consumers about publicly accessible federal database of payments/gifts to providers by medical product manufacturers

AR, MA, MD, ME, NY, PR

## Appendix A. Summary of Solutions Proposed by States to Manage Prescription Drug Prices, *continued*

	STATES WITH PROPOSED LEGISLATION (2015-16)
<p><b>Bans on direct-to-consumer (DTC) advertising</b></p> <ul style="list-style-type: none"> <li>▶ Eliminates tax deduction of expenses incurred for DTC pharmaceutical marketing; requires manufacturers to report (confidentially) drugs' market value, nature, purpose, and recipient to state, with fines for failure to report</li> <li>▶ Prohibits plans from paying for drugs manufactured by companies that conduct DTC advertising to state residents</li> <li>▶ Requires cost-benefit analysis of pharmaceutical advertising to state citizens</li> </ul>	MA, MN, NY, WV
<p><b>Medicare prescription drug price</b></p> <ul style="list-style-type: none"> <li>▶ Urges federal legislative and executive branches to require federal government to negotiate Medicare prescription drug prices</li> </ul>	NJ
<p><b>Cost controls</b></p> <ul style="list-style-type: none"> <li>▶ Caps consumer costs</li> <li>▶ Targeted cap on select prescription drugs (72) passed in Puerto Rico to control costs, especially for generic versions</li> </ul>	PR, WA
<p><b>Anti-price gouging</b></p> <ul style="list-style-type: none"> <li>▶ Permits executive order to prevent manufacturers from "unreasonably excessive" drug pricing related to market shortages, with \$10K penalty for each day in violation</li> </ul>	RI
<p><b>Parity with Veterans Administration price</b></p> <ul style="list-style-type: none"> <li>▶ Establishes a price ceiling by prohibiting certain state entities from paying more than the lowest price paid by the VA for the same drug</li> <li>▶ Requires monthly drug-to-drug cost comparison between state agencies and the VA for at least the top 25 specialty and traditional drugs that are the most expensive/most commonly prescribed</li> </ul>	CA and OH ballot initiatives, WA

Source: *Prescription Drug State Database: 2015-2016 State Legislation on Prescription Drugs*, National Conference of State Legislatures, accessed March 1, 2016, [www.ncsl.org](http://www.ncsl.org).

## Appendix B. Key Informants

Charles Bacchi, president and CEO  
California Association of Health Plans

Anthony Barrueta, JD, senior vice president of government relations  
Kaiser Foundation Health Plan

Robert Galvin, MD, CEO, Equity Healthcare; operating partner, Blackstone; professor adjunct  
Departments of Medicine and School of Management, Yale University

Harry Hendrix, Jr., chief, Pharmacy Benefits Division  
California Department of Health Care Services

William Kramer, MBA, executive director, National Health Policy  
Pacific Business Group on Health

Lance Lang, MD, chief medical officer  
Covered California

Steven D. Pearson, MD, president  
Institute for Clinical and Economic Review

Lindsay Petersen, MS, Plan Management Division  
Covered California

Lynn Quincy, MA, director, Healthcare Value Hub  
Consumers Union

Brian Rosman, JD, government relations and policy director  
Health Care For All (Massachusetts)

John Rother, JD, president and CEO  
National Coalition on Health Care

Michael Wofford, PharmD, chief, Pharmacy Policy Branch, Medi-Cal Pharmacy Benefits Division  
California Department of Health Care Services

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