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Rising Health Care Costs: Drivers, Challenges and Solutions

Addressing High Care Cost Drivers A Critical Role for Insurance Regulators

By Joel White, President
and Paul Hewitt, Senior Consulting Economist
Council for Affordable Health Coverage

Regional Cost Variation and the Collaborative Path to Affordability

By Ellen Gagnon, Executive Director
Healthcare Affordability, Network for Regional Healthcare Improvement

Prescription Drug Cost Drivers

By Susan Pantely, Principal and Consulting Actuary
Milliman
and Co-Chairperson
Prescription Drug Work Group, American Academy of Actuaries

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This National Association of Insurance Commissioners (NAIC) Center for Insurance Policy and Research (CIPR) study presents independent research the purpose of which is to inform and disseminate ideas to regulators, consumers, academics and financial services professionals. CIPR studies are available at no cost on the CIPR website: www.naic.org/cipr_special_reports.htm.

This study would not have been possible without the valuable contributions by members of the CIPR and the notable authors from the academic community and industry distinguished for their expertise in health care. All the contributors are listed on page ii.

Disclaimer: This study represents the opinions of the author(s) and is the product of professional research. It is not intended to represent the position or opinions of the NAIC or its members, nor is it the official position of any NAIC staff members. Any errors are the responsibility of the author(s).

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Authors

Joel White, President, Council for Affordable Health Coverage

Joel.White@cahc.net

Paul Hewitt, Senior Consulting Economist, Council for Affordable Health Coverage

Paul.Hewitt@cahc.net

Ellen Gagnon, Executive Director, Healthcare Affordability, Network for Regional Healthcare Improvement

EGagnon@nrhi.org

Susan Pantely, Principal and Consulting Actuary, Milliman

Susan.Pantely@milliman.com

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Rising Health Care Costs: Drivers, Challenges and Solutions

Foreword

This CIPR study brings together thought leaders, researchers and practitioners in the health care field to provide a wide spectrum of viewpoints on the rising cost of care. The study, by intention, is a compilation of individually authored papers designed to address various drivers of health care costs. The contributing authors also present recent government actions and advance possible solutions for state insurance regulators and other stakeholders to consider.

Following the release of the [executive summary and the first paper “Food is Medicine: Why Healthier Eating Should Be a Priority for Health Care Providers, Insurers and Government,”](#) in December 2018, this is the second installment of the study. It includes three papers, “Addressing High Health Care Cost Drivers—A Critical Role for Insurance Regulators,” “Regional Cost Variation and the Collaborative Path to Affordability,” and “Prescription Drug Cost Drivers.”

Consistent with the primary purpose of this study, these papers examine the underlying factors driving health care costs. The first paper focuses primarily on unit prices and changing market dynamics and presents policy options and insurance regulatory actions available to effect change. The second paper analyzes prices and care delivery patterns across states and examines the drivers of regional cost variations. The third paper investigates the role of pharmacy benefit managers (PBMs) in prescription drug price increases and presents potential actions to address the high cost of prescription drugs.

The intent of these papers is to inform policymakers and further the conversation on effective health care cost solutions.

Upcoming Releases

The remainder of the papers in this study will be released in the fall of 2019. They will discuss the growing acceptance of value-based reimbursement, the issue of waste and administrative costs, and the role of data analytics in health care. The full study will be available to download on the CIPR website at cipr.naic.org.

Addressing High Health Care Cost Drivers—A Critical Role for State Insurance Regulators

By Joel White, President, Council for Affordable Health Coverage and Paul Hewitt, Senior Consulting Economist, Council for Affordable Health Coverage¹

Overview

Despite decades of federal and state tinkering with health policy, affordability at the household level is a growing consumer worry, often trumping concerns about jobs, crime and safety, housing, college, and other pressing issues.² On a per capita basis, inflation adjusted health care spending has increased about sixfold since 1970.³ The Centers for Medicare & Medicaid Services (CMS) projects national health expenditures (NHEs) to continue growing at 5.5% annually over the next eight years. If this holds true, health care spending will eclipse the average estimated gross domestic product (GDP) growth rate by 1 percentage point.⁴ Commercial coverage costs have more than doubled as a percentage of household incomes since 2000. This potentially poses issues for the insureds, as well as governments and private employers, who sponsor commercial coverage for over 175 million workers and dependents.

In its 2018 NHE projections tables, CMS reported that employer health spending per enrollee grew by an average of just 2.8% per year during 2011–2015. Over the same four-year period, industry surveys found that employer spending per enrollee grew by an average of 4.7% per year,⁵ while family premium increases (exclusive of cost sharing) averaged 3.9%.⁶ This discrepancy suggests that CMS may be understating the extent of NHE growth. Yet, even under the CMS methodology, NHE is projected to grow faster as a percentage of GDP during 2018–2027 (1.6% of GDP) than it did during 2008–2017 (1.4%)⁷—a period that saw annual spending for the typical working family of four increase by \$11,335.⁸

When commercial costs rise faster than wages, the likely effect is to disproportionately curb non-health consumption, especially for lower wage earners. In commercial health plans, benefits are paid out of risk pools—cash reserves funded by payments from all enrollees—on behalf of those

¹ This paper reflects the views of the authors, not necessarily their affiliated organizations.

² Frank Newport, “Top Issues for Voters: Healthcare, Economy, Immigration,” *Gallup*. Nov. 2, 2018.

³ Rabah Kamal and Cynthia Cox, “How has U.S. spending on healthcare changed over time?” *Kaiser Family Foundation*. Accessed online March 22, 2019.

⁴ CMS, “NHE Projections 2017–2026 – Tables,” Table 1. Accessed online Feb. 26, 2019.

⁵ 2017 Willis Towers Watson Best Practices in Health Care Employer Survey, Jan. 21, 2018. “High-performance insights—best practices in health care,” Figure 2.

⁶ Kaiser Family Foundation, Oct. 3, 2018. “2018 Employer Health Benefits Survey,” Figure 1.10.

⁷ CMS, “NHE Historical and Projections 1960–2027.” Accessed online Feb. 26, 2019.

⁸ Girod, C.S., S.K. Hart, and S.A. Wetz, May 16, 2017. *2017 Milliman Medical Index*, Milliman. (Online.) For previous year estimates, see Milliman Insight archives online.

with medical needs. Contributions to the risk pool are proportional, such that premiums for any given level of coverage are the same for all participants, regardless of income. The proportionally unequal burden on lower income households has intensified income stagnation and disparity in the 21st century.

A 2018 Council for Affordable Health Coverage (CAHC) study found that during 2000–2015, at the fifth earnings decile, real hourly compensation (in 2015 dollars) rose by \$3.69, while premiums—deducted from paychecks before taxes—rose by \$4.46, reducing take-home pay in absolute terms.⁹ Only the majority of workers in the seventh decile and above saw their paychecks grow in real terms. Yet, premiums tell only part of the story. A 2018 study by the Commonwealth Fund found that average deductibles had increased 107% during 2008–2017.¹⁰ Out-of-pocket costs, including those for specialty-tier prescription drugs, have also grown rapidly in recent years.

These regressive outcomes have fueled political demands for income-based subsidies. The federal Affordable Care Act (ACA), which provides means-tested subsidies to individuals earning up to 400% of the Federal Poverty Level (FPL) when they purchase commercial insurance on qualified health exchanges, offers a cautionary tale about the corrosive effect of rising commercial costs.

Since 2014, the benchmark cost of exchange coverage has risen 75%.¹¹ During 2010–2018, premiums for employer-sponsored single coverage increased by \$1,847, while the average deductible rose by \$656.¹² If commercial prices continue growing faster than our ability to pay—whether measured as wages, tax revenues or GDP—they will overwhelm not only the effect of existing subsidies but the government’s ability to provide them.

In this paper, the authors maintain that state insurance commissioners are mandated to investigate and address the structural forces driving the cost of health care. This mandate is consistent with the NAIC mission to “[p]rotect the public interest” and “[f]acilitate the fair and equitable treatment of insurance consumers.”¹³ As such, this paper provides insights on:

- The evidence explaining health care cost drivers.
- Direct actions state insurance regulators can take to address high costs.
- Actions state insurance regulators should support as part of multi-stakeholder efforts in their state.

⁹ Schieber, S.J., and S.A. Nyce, Sept. 4, 2018. “Health Care USA: A Cancer on the American Dream,” CAHC Foundation.

¹⁰ Collins, S.R., and D.C. Radley, December 2018. “The Cost of Employer Insurance Is a Growing Burden for Middle-Income Families,” The Commonwealth Fund.

¹¹ Kaiser Family Foundation, State Health Facts, “Marketplace Average Benchmark Premiums.” Also see: “NHE Projections 2017–2026 – Tables,” Table 17.

¹² Kaiser Family Foundation., Oct. 3, 2018. “2018 Employer Health Benefits Survey.”

¹³ NAIC website. Accessed online March 22, 2019.

Notably, the authors focus on the drivers of spending for those enrolled in the private health insurance system, rather than strategies of which their main effect is to shift costs, such as risk pooling, reinsurance, and taxpayer funded subsidies.

Drivers of High Health Care Spending

Unit Cost Pricing

There is widespread evidence that, in recent years, unit price growth has been the leading driver of rising health care costs. Trends in utilization and disease prevalence have played comparatively modest roles in most markets.^{14, 15} More detail on regional cost variation can be found in the CIPR paper “Regional Cost Variation and the Collaborative Path to Affordability.” To be sure, insurance markets have also become less competitive, with fewer plans on offer, particularly in the individual market. However, the rise in prices has been far more consequential.¹⁶

The divergent trend lines in Figure 1 illustrate how, since 2010, medical inflation at the point of care has been the main driver of household health spending. PricewaterhouseCooper’s (PwC) Health Research Institute (HRI) publishes an annual projection of medical cost growth in the employer insurance market. Its latest report indicated that prices continue to increase despite utilization reduction efforts.

PwC estimates that the Medical Cost Trend—a composite of commercial provider prices—has grown four times faster than wages and five times faster than income since 2010 (see Figure 1).¹⁷ The Medical Cost Trend is expected to grow another 6% in 2019—about 2% faster than wages.¹⁸ Clearly, price containing strategies will be needed to drive the medical cost trend down.

¹⁴ Papanicolas, I., L.R. Woskie, and A.K. Jha, March 13, 2018. “Health Care Spending in the United States and Other High-Income Countries,” *Journal of the American Medical Association (JAMA)*. Accessed at <https://jamanetwork.com/journals/jama/article-abstract/2674671?resultClick=1>.

¹⁵ See for example: “Why Are Hospital Prices Different? An Examination of New York Hospital Reimbursement,” Cooper et al. 2015, Gaynor et al. 2014, Melnick et al. 2011, White et al. 2013.

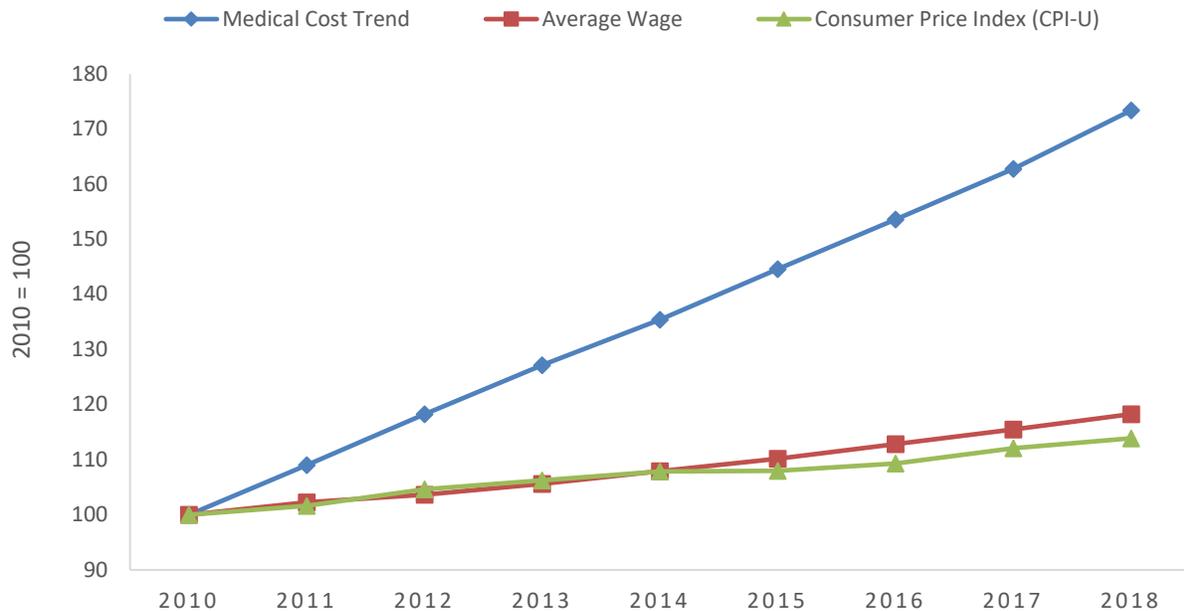
¹⁶ Jeannie Fuglesten Biniek and John Hargraves, February 2019. “2017 Health Care Cost and Utilization Report,” *Health Care Cost Institute (HCCI)*. See also: “2016 Health Care Cost and Utilization Report.”

¹⁷ CAHC calculations based on PwC, Census, and Bureau of Labor Statistics (BLS) data.

¹⁸ HRI, June 2018. “Medical cost trend: Behind the numbers 2019,” PwC.

Figure 1: Medical Cost Trend is Increasing Faster than Wages and Inflation (2010–2018)

Source: PwC, Census, BLS, CAHC Calculations



While utilization was an important driver of commercial costs in the early 2000s—rising by more than 21% during 1999-2003¹⁹—recent trends point to a reversal. Figure 2 shows the extent to which pricing power has offset the economies from falling utilization. During 2012–2016, commercial inpatient spending per person grew 24.3%, even as utilization fell 12.9%. In other words, had prices not gone up, per-patient hospital costs in 2016 would have been 42.7% less.²⁰ Similarly, outpatient spending grew 17.7%, while utilization fell 0.5%.²¹

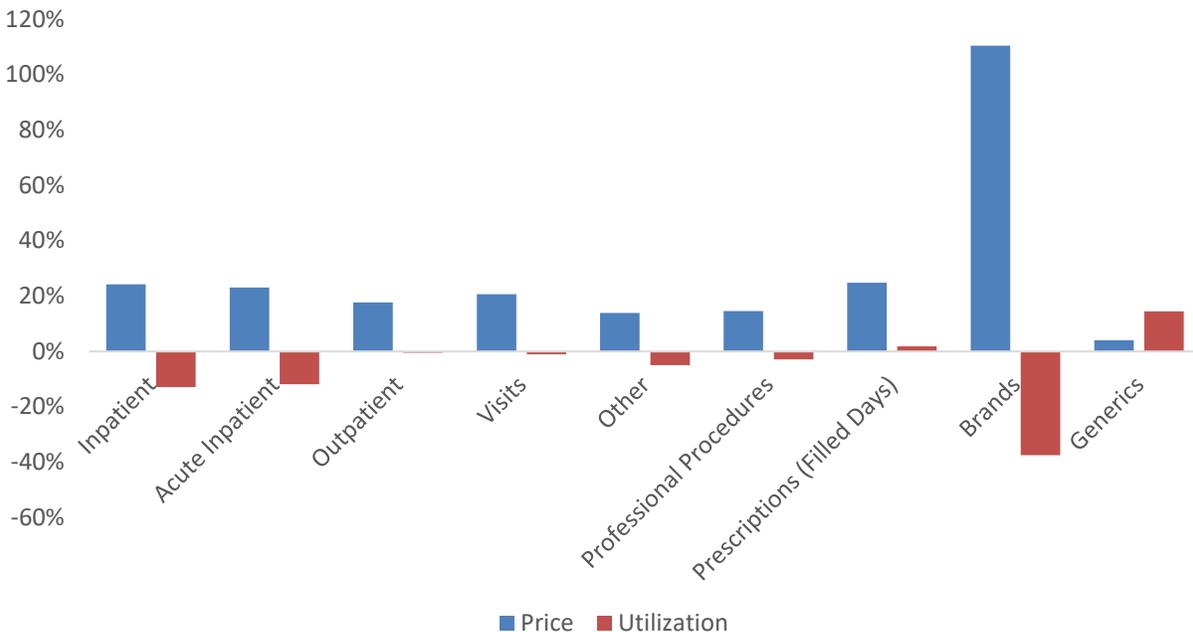
¹⁹ Strunk, B.C., and P.B. Ginsburg, June 9, 2014. “Tracking Health Care Costs: Trends Turn Downward in 2003,” *Health Affairs* Web Exclusive, Exhibit 3.

²⁰ Had prices stayed the same, per-patient spending would have fallen 12.9%, in line with utilization. This means that, without price effects, hospital spending per patient in 2016 would have been 87.1% of spending in 2012. In fact, per-patient spending in 2016 was 124.3% of spending in 2012. To calculate the unit price increase needed to get this result, divide the actual increase over 2012 (124.3%) by the counter-factual reduction (87.1%).

²¹ Biniak, J.F., and J. Hargraves, February 2019. “2017 Health Care Cost and Utilization Report,” *HCCI*. See also: Peterson-Kaiser Health System Tracker. Accessed online March 22, 2019; and Joseph Dieleman, et al., Nov. 17, 2017. “How have Health Prices Grown in the U.S. Over Time?,” *JAMA*.

Figure 2: Changes in Private, Commercial Health Spending, by Category (2012–2016)

Source: HCCI, Health Care Cost and Utilization Report, 2016



Most health care sectors are seeing costs grow at roughly the same rates. Specifically, as shown in Figure 3, hospital and professional services consume nearly 59 cents of every health dollar—and thus exert the most influence on medical cost inflation. Prescription drugs rank a distant third.²²

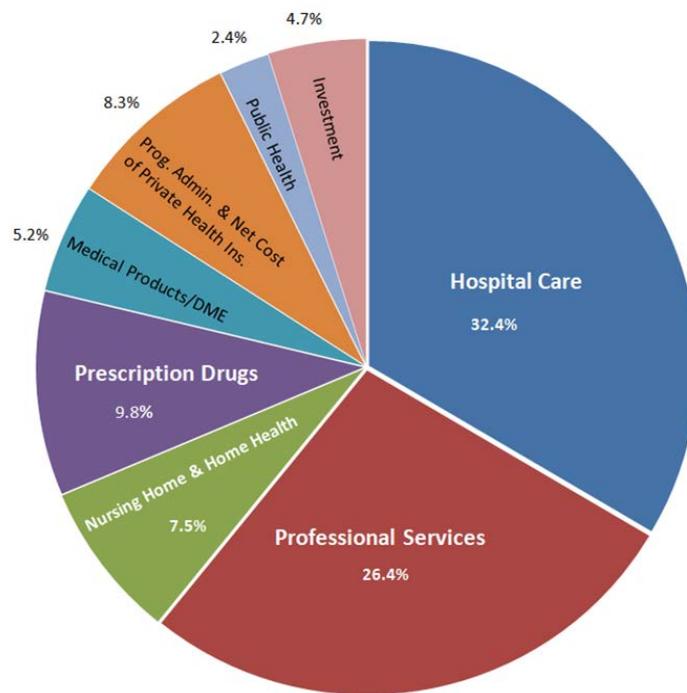
The factors driving up prices in the drug sector are different than those in health services. Notably, drugs are the main source of technical improvement in health delivery. Pharmaceutical manufacturers account for more than 16% of total U.S. spending on research and development versus 0.4% for health services.²³ The availability of expensive therapies for a range of hard-to-treat illnesses, such as Hepatitis C, gives these new medicines a high degree of visibility in the debate over costs. Yet, as the patents expire, high prices invariably give way to a robustly competitive generic drug sector. During 2012–2016, the price of generics, which account for 89% of prescriptions, rose just 4%—less than half the rate of wage growth. More detailed discussion of the pharmaceutical prices will follow in a subsequent paper in this series.

²² Figure 3 understates total spending on pharmaceuticals as a separate category, as it only captures spending in the retail sector. When spending on drugs administered in the hospital or physician office is included (typically paid under the medical benefit), total drug spending rises to 14% of total healthcare spending.

²³ National Science Foundation (NSF), “TABLE 33. Companies with domestic R&D paid for and performed by the company in health or medical, defense, and agricultural application areas, by industry and company size: 2013.”

Figure 3: Composition of Health Care Spending, 2017²⁴

Source: CMS



A broad body of research has documented the impact of anti-competitive market consolidation on pricing. By consolidating, providers gain greater pricing power, allowing them to increase commercial rates. This has led insurance markets to become less competitive, with fewer plans on offer. This trend is particularly prevalent in the individual market. However, the rise in prices has been far more consequential.²⁵

Incentivized by health plan designs, consumers are using less care, while paying more for it. This trend cannot continue indefinitely, nor is it wholly positive. Consumers are as likely to curb necessary care as unnecessary care. This has adverse implications for long-term health outcomes and costs.²⁶

Pricing power in the health care sector is driven largely by market concentration—the result of a two-decade long spree of mergers and acquisitions that has saddled many local communities few choices among providers. The Federal Trade Commission (FTC) measures the competitiveness of

²⁴ CMS, NHE Projections 2018–2027,” Table 1.

²⁵ See for example: “Why Are Hospital Prices Different? An Examination of New York Hospital Reimbursement,” Cooper et al. 2015, Gaynor et al. 2014, Melnick et al. 2011, White et al. 2013.

²⁶ Brot-Goldberg, Z.C., A. Chandra, B.R. Handel, and J.T. Kolstad, November 2015. “What Does a Deductible Do? The Impact of Cost-Sharing on Health Care Prices, Quantities, and Spending Dynamics,” *National Bureau of Economic Research (NBER) Working Paper No. 21632*.

local hospital markets using the Herfindahl-Hirschman Index (HHI).²⁷ Under antitrust guidelines, markets with HHIs of 1,500–2,500 are considered moderately concentrated, while those with HHIs of 2,500 or greater are considered highly concentrated, thus meriting antitrust scrutiny.²⁸

In 1990, the typical resident of a Metropolitan Statistical area (MSA) lived in a hospital market with an HHI of 1,576.²⁹ By 2016, 90% of MSAs had an HHI above 2,500.³⁰ About 10% of MSAs were monopoly markets, with an HHI of 10,000.³¹ PwC estimates that, in 2019, 93% of metropolitan markets will be highly concentrated—leaving many communities unable to benefit from price competition.³² In addition, almost all rural areas have hospital monopolies. Increasing hospital closures in rural areas limit both choice and access to health care due to the growing distance between hospitals. Beyond the potential health consequences for the rural area residents, hospital closures can contribute to increasing health care costs and adversely affect the local economy.^{33,34}

Adding to hospitals' pricing power has been the trend toward vertical consolidation, whereby hospitals acquire, or form business alliances with, physician practices and ambulatory surgical and testing centers. The percentage of physicians employed by or affiliated with hospitals stood at 43% in 2000. By 2016, that share had risen to 67%.³⁵

This brings up the question of why hospitals seek pricing power. More than 80% are nonprofit or state-run, and thus lack the incentives that motivate for-profit institutions. One clue may lie in changes to the physician workforce. During 2005–2015 the number of physician specialists grew 48%—nine times faster than the number of generalists. Specialists earn about 78% more than

²⁷ The HHI is the sum of squared market shares. For example, a market consisting of four firms (which can be unaffiliated hospitals or a multihospital chain) with market shares of 30%, 30%, 20%, and 20% has an HHI of 2,600 ($30^2 + 30^2 + 20^2 + 20^2 = 2600$). In Figure 5, 2,500 = .25000. All orange and green areas are highly concentrated.

²⁸ The U.S. Department of Justice (DOJ) and the FTC, Horizontal Merger Guidelines (Aug. 19, 2010): 18–19. Under the 1992 Guidelines (p. 15), the agencies defined “moderately concentrated” as having an HHI of 1,000–1,800 and “highly concentrated” as above 1,800.

²⁹ Vogt, W.B., and R. Town, February 2006. “How Has Hospital Consolidation Affected the Price and Quality of Hospital Care?” Research Synthesis Report No. 9, *Robert Wood Johnson Foundation*, 9–10.

³⁰ Fulton, B.D., September 2017. “Health Care Market Concentration Trends in the United States: Evidence And Policy Responses,” *Health Affairs*, 36(9). Accessed at www.healthaffairs.org/doi/10.1377/hlthaff.2017.0556.

³¹ Capps, C., and D. Dranove, June 2011. “Market Concentration of Hospitals,” *Bates and White Economic Consulting*, 2.

³² Stiver, I., Nov. 20, 2018. “One inflator of medical cost trend in 2019: Provider megamergers,” PwC HRI.

³³ Fulton, B.D., September 2017. “Health Care Market Concentration Trends in the United States: Evidence and Policy Responses.” *Health Affairs*, 36(9). Accessed at www.healthaffairs.org/doi/10.1377/hlthaff.2017.0556.

³⁴ Frakt, A., Oct. 29, 2018. “A Sense of Alarm as Rural Hospitals Keep Closing.” *The New York Times*. Accessed at www.nytimes.com/2018/10/29/upshot/a-sense-of-alarm-as-rural-hospitals-keep-closing.html

³⁵ Accenture, 2015. “The (Independent) Doctor Will NOT See You Now.”

generalists (\$420,000 versus \$235,000).³⁶ In part, this is because they prescribe more complex care, which in turn requires more facilities and support staff.³⁷

Since 2000, total employment in the health services sector has grown 3.5 times faster than total U.S. non-farm employment.³⁸ Health services are especially labor intensive with compensation accounting for 77% to 83% of value-added.³⁹ Hence, payrolls are obviously driving health cost growth. While consolidation relieves hospitals of the need to compete for patients, it enhances their ability to provide earnings opportunities for specialists.

Opaque Health Markets

Recent research has found that consumers with deductibles greater than \$2,501 (much less than the average second lowest cost silver plan deductible) were more likely to shop for coverage or switch doctors than consumers with a lower or no deductible. Then again, consumers have less information on the price and quality of health care providers than they do on products such as televisions and smart phones. Most providers do not make their prices public, and if they do, the prices typically reflect charges—list prices—that often exceed actual amounts collected by several multiples. In addition, prices within local markets can vary by as much as 700%. For example, MRIs are largely a commodity, but their price varies greatly.

Unnecessary Utilization

Although working households are consuming fewer services (see Figure 2), experts believe that the prescription of unnecessary care remains a serious problem. As much as 60% of care is thought to be supply-sensitive, meaning its provision is motivated as much by the availability of resources as medical need. For example, patients are prescribed longer hospital stays when hospitals have empty beds. Another 24% of care is preference-sensitive.⁴⁰ For example, spinal fusion often produces results no better than low-tech physical therapy. Given an informed choice, most patients will opt for the less invasive, less costly alternative. Yet many choose such treatment for lack of better advice.

³⁶ Health Value Group, “2017 Physician Compensation Report.”

³⁷ Barbey, C., N. Sahni, R. Kocher, and M.E. Chernew, July 28, 2017. “Physician Workforce Trends and the Implications For Spending Growth,” *Health Affairs*. Figure 3 comes from this article.

³⁸ BLS, Table B-1. Employees on non-farm payrolls by industry sector and selected industry detail. Data Retrieval.

³⁹ The U.S. Bureau of Economic Analysis (BEA), GDP by Industry, Components of Value Added by Industry as a Percentage of Value Added, May 23, 2017. Data Retrieval. By other estimates, compensation, professional fees, and other labor-intensive services account for 71.9% of hospital costs. See also: 2016 American Heart Association (AHA) Trendbook, Chart 6.10.

⁴⁰ Wennberg, J.E., 2010. “Tracking Medicine: A Researcher’s Quest to Understand Health Care,” pp. 54–117. *Oxford University Press*.

The Institute of Medicine (IOM) estimated that in 2009 unnecessary care comprised 30% of health spending.⁴¹ A later study found that as much as 41% of private health spending was unnecessary.⁴² By definition, eliminating these costs would not harm patient care, and it might even improve outcomes.

Waste takes many forms:

- Overuse (imaging), and misuse of services (prescribing antibiotics for viral infections).
- Services that have little therapeutic value, such as an MRI for lower back pain that has been present for a short duration.
- Duplicative services due to poor care coordination.
- Care associated with medical errors—a surprisingly common occurrence.

Former CMS Acting Administrator Donald Berwick, puts the economic toll even higher: as much as 49% of care may be wasted when the false economies of neglect are factored in.⁴³ Millions of Americans elect not to purchase coverage in order to save money on premiums—or to forego needed drug therapies when copayments are high. Some neglect may result from health plan incentives designed to curb the frivolous use of medicine. Researchers have found that high out-of-pocket costs are as likely to deter necessary care as unnecessary care.⁴⁴ For example, neglecting insulin treatments for diabetes can lead to debilitating, and much costlier, complications, including heart failure and strokes.

Taxes and Regulation

Health insurance redistributes premium dollars from the healthy to the sick and between other groups as well. Inefficient regulatory policies can transfer income from taxpayers and consumers to providers. Much of the industry's wastefulness is rooted in a tangle of federal and state rules—from the ACA's insurance rules, to the federal Emergency Medical Treatment and Labor Act (EMTALA), to licensure, to privacy—that promote cost shifting, hardwire labor practices, compartmentalize care, and drive up costs.

These rules, in effect, turn insurers, employers and many hospitals into tax-collectors for a regulatory welfare state that redistributes trillions of consumer dollars with little accountability for efficiency or effectiveness. Many of today's rules were adopted as part of the ACA, to

⁴¹ May 31, 2018. "Wasted Health Spending: Who's Picking Up The Tab?," *Health Affairs*.

⁴² Altarum Healthcare Value Hub. Accessed online Feb. 5, 2019.

⁴³ Berwick, D., and A. Hackbarth, April 11, 2012. "Eliminating Waste in US Health Care," *JAMA*. 307(14): 1531–6.

⁴⁴ Brot-Goldberg, Z.C., A. Chandra, B.R. Handel, and J.T. Kolstad, November 2015. "What Does a Deductible Do? The Impact of Cost-Sharing on Health Care Prices, Quantities, and Spending Dynamics," *NBER Working Paper No. 21632*.

implement a regulatory agenda designed, among other things, to protect some consumers at the expense of others.

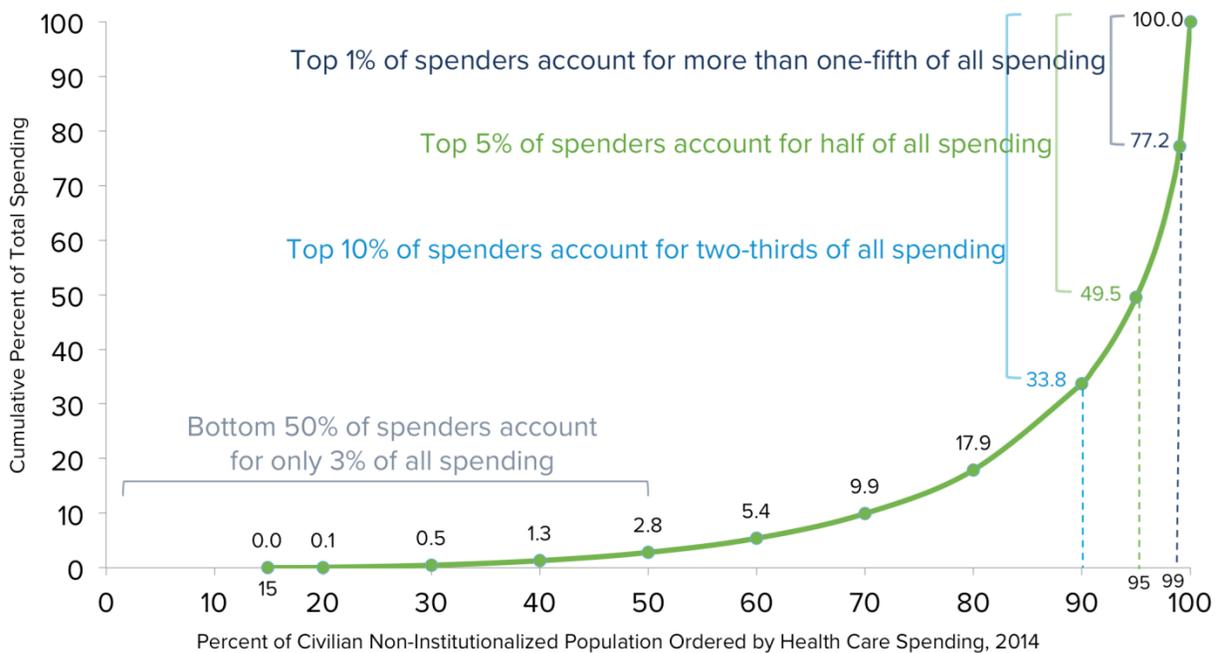
One result was a deterioration of the exchange risk pool that increased premiums from 44% to 68% and may have priced some consumers out of the market.⁴⁵ Taxes imposed by the ACA also directly raise the cost of coverage for consumers, such as the health insurance tax, device and drug taxes, and the so-called Cadillac tax.

The Role of Disease Prevalence

As shown in Figure 4, health care spending is highly concentrated among a relatively small share of the population, most of whom have debilitating chronic conditions. Only 16% of health spending goes toward patients with one or fewer chronic diseases.⁴⁶

Figure 4: Concentration of Health Spending in the U.S.

Source: National Institute for Health Care Management (NIHCM) Foundation



Yet, a 2017 study decomposing spending growth during 2000–2012 into changes in price and prevalence—the number of treated cases—found that prevalence was not the principal driver of

⁴⁵ See: http://en.wikipedia.org/wiki/U.S._patients'_bill_of_rights. Two of the three lead sponsors, John Edwards and John McCain, were presidential aspirants at the time. See also: <http://dailysignal.com/2017/03/23/to-lower-premiums-congress-must-roll-back-obamacare-regulations/>

⁴⁶ Anderson, G., 2010. "Chronic Care: Making the Case for Ongoing Care," Robert Wood Johnson Found.

Addressing High Health Care Cost Drivers

health costs. Cost per case was more important.⁴⁷ Within this general finding, there was considerable variation, depending on the period being examined and the specific disease.

For example, during 2005–2014, the growth in cost per case slowed, but it was accompanied by a slight increase in treated prevalence. For this period, treated prevalence and cost per case each contributed about equally to the growth in real per capita spending. Cost and price are clearly interlinked. An increase in demand can lead to scarcity, which can drive up medical salaries. Additionally, an increase in the number of physician specialists can lead to supply-sensitive over-prescription of treatments.

Population Growth/Aging of the Population

Although population size and age were associated with increased national spending for most health conditions and types of care, demographic change typically has not been a leading cost driver. One reason is that the prices Medicare pays for many common procedures are lower than those in the commercial sector,⁴⁸ nor are population dynamics a promising area for actionable policy. As state insurance regulators analyze spending data for their local markets, they should look at per capita, age-standardized data. National spending data indicate increases in service price and intensity for all types of care, and health conditions had the strongest associations with total spending growth.⁴⁹

Local Health Care Spending Drivers Vary

As it will be analyzed in more detail in the following paper “Regional Cost Variation and the Collaborative Path to Affordability,” it has been shown that there is considerable variation both across and within markets in commercial prices paid, price variation, the extent of unnecessary utilization, and population health status.⁵⁰ To better understand the relative role of health spending drivers in their local commercial markets, state insurance regulators will need customized, local-market analyses.

State insurance regulators should adjust spending data to remove the impact of population growth and aging, and then decompose their local spending into disease prevalence, price and utilization components. If this data is further segmented by disease category and health care

⁴⁷ Cox, C., A. Dunn, L. Rittmueller, and B. Whitmire, March 29, 2016. “A new way of measuring health costs sheds light on recent health spending trends,” Peterson-Kaiser Health System Tracker. Accessed online March 22, 2019.

⁴⁸ Maeda, J.L., and L. Nelson, April 2017. “An Analysis of Private-Sector Prices for Hospital Admissions,” *Congressional Budget Office Working Paper 2017-02*. See Table 1.

⁴⁹ Dieleman, J.L., E. Squires, A.L. Bui, et al., 2017. “Factors Associated with Increases in US Health Care Spending, 1996–2013,” *JAMA*. 318(17):1668-1678

⁵⁰ Claxon, G., M. Rae, L. Levitt, and C. Cox, May 8, 2018. “How have healthcare prices grown in the U.S. over time?” Kaiser Family Foundation. Accessed online Feb. 5, 2019.

segment, along with input costs, state insurance regulators will have highly actionable data for addressing healthcare spending.

Strategies to Address Underlying Medical Costs

There are no silver bullets for reining in health care costs. However, there are several direct steps state insurance regulators can take to reduce spending and, by extension, insurance premiums and cost sharing. They can use rate review to incentivize aggressive negotiations between health plans, service providers and product manufacturers.

Another option is to encourage health plans to use evidence-based payment approaches and benefit designs. Upstream investments designed to reduce serious and expensive health problems can also be supported. Another option would be to give payers more leverage in markets where provider consolidation has resulted in uncompetitive oligopoly or monopoly. Reforms targeting prices are likely to have the greatest impact in sectors with the highest spending, namely in hospital and physician markets. Even so, efficiencies can be found in all sectors.

Rate Review

The rate review process can provide an opportunity for state insurance regulators to examine coverage pricing and underlying assumptions. The review process could also evaluate the presence of interventions to address high underlying costs and wasteful spending. While state laws vary, state insurance regulators are generally charged with ensuring that rates are “reasonable and not excessive, inadequate or unfairly discriminatory.”

In carrying out this duty, many state insurance regulators focus on the expenses, which are directly under a health plan’s control. This includes items such as administration expense and expected enrollee mix. It is less common to focus on the price of medical services and products.

However, state insurance regulators could increase transparency by educating others on the medical costs driving premium and cost sharing rate increases. Such public disclosure and transparency can broaden the consensus about how best to rein in medical inflation.

Specifically, state insurance regulators should disclose to the public the key drivers of cost increases, using plan filings as a basis of consumer information and including what portion of premium goes toward services, drugs and devices, administrative expenses, mandates, and taxes. Unit prices, of course, are an important metric.

Hospitals and other providers can augment this data with relevant information regarding their input costs. For example, nationally, since 2000, the number of caregivers per capita in the health services sector has increased 27%, even as public health indicators have stagnated or declined.

This suggests that the growth in health care provider market power not only spawns higher prices, but inefficiency as well. Understanding which markets, or even hospitals, are more efficient can avoid the unintended effects of one-size-fits-all policy.

Some states bring additional factors into the Rate Review process:

Washington State: Has the authority to review provider contracts, which is critical for learning how monopoly power might be affecting rates in local markets.

- **Other states work closely with their All Payer Claims Databases (APCD).**⁵¹ Several states rely on this approach to improve their analysis of proposed rates. The Maryland Insurance Administration uses its state’s APCD, the Maryland Medical Care Database, to check payer submissions and run deeper analyses. Oregon’s Department of Consumer and Business Services uses its APCD (All Payer All Claims Database—APAC) data in its review of premiums for individual and small group health plans. Massachusetts’ Center for Health Information and Analysis has directly sourced several insurance reports from its APCD (supporting “administrative simplification”). This has enabled Massachusetts and its Division of Insurance to reduce the statewide payer-reporting burden.

State insurance regulators can take additional steps in their plan approval process to encourage greater consumer value, including:

- **Encouraging value-based insurance designs.** Methods to better address high-cost conditions, such as diabetes and mental health, should be targeted. One simple method is for state insurance regulators to encourage plan designs that target and improve care for patients with high-cost conditions.⁵² Because the health exchange population has been shown to have greater medical needs than the general population, specialized plans can help insurers keep enrollees with higher cost conditions healthier, which can lower costs and premiums in a unified risk pool. However, current non-discrimination rules may make it difficult for plans to offer such coverage. Standard benefit designs should allow for the clinically nuanced cost-sharing associated with these models.
- **Encouraging creativity in network design.** Networks have grown increasingly narrow to contain costs. This is particularly true in areas where there is an imbalance in market share between insurers and providers. Rural areas are particularly affected because they contain fewer providers. This makes it more difficult to both meet network adequacy standards and to negotiate competitive rates. The result is higher premiums and fewer options for everyone, but particularly

⁵¹ APCDs are centralized state data repositories for health insurance membership and claims records.

⁵² July 2016. “Value-Based Insurance Design: Potential Strategy for Lower Costs, Increased Quality,” Healthcare Value Hub.

for rural consumers. State and federal insurance regulators have recently addressed this by holding insurers to quantitative network design standards (such as time and distance). *HealthCare.gov* has even begun rating plans based on network breadth alone. State insurance regulators should consider approaches focused on informing consumers about network quality and breadth.

- **Rewarding healthy behaviors and health literacy.** Providing rewards to people for engaging in healthy behaviors, meeting health goals, participating in preventive activities, promoting health literacy, and adhering to treatment regimens (particularly for those at risk of or who currently have a chronic condition) can improve outcomes and lower health costs. This should be encouraged. Employers have been increasing their investment in these programs for years, with 70% of employers offering wellness benefits in 2015. While allowed in the group market, it is against the law, in most instances, for insurers to provide wellness incentives, such as rebates, for individuals who pay for their own health insurance in the individual market. This policy could be reversed, and the states could set up programs to encourage healthy behavior and adherence to care plans and medications. Individual market insurers should have the ability to reward enrollees for engaging in healthy behavior and managing their conditions with help from the plan and its network providers.
- **Considering flexible benefit designs.** The statutory definition of the essential health benefits (EHB) is narrow, but regulations have significantly increased mandates and restricted benefit design by, among other methods, including all state benefit requirements imposed prior to the enactment of the ACA in the EHB. These restrictions have limited the types of plans available to consumers and increased costs. A narrower interpretation of the EHB requirements would lower costs. Additionally, these types of plans are not available to consumers in states that prohibit variation from rigid standardized benefit designs. Finally, the U.S. Department of Health and Human Services (HHS) expanded the use of short-term health plans as an additional option for consumers. The states should consider strategies that use single risk pool design to encourage younger, healthier individuals to obtain coverage. One strategy may be to use 1332 Waiver Authority as one way to expand coverage.

State Insurance Regulators as Members of the Larger Stakeholder Community

State insurance regulators can take several indirect actions in addition to their direct actions through the rate review process. They play a vital role as informed truth-tellers in their community by providing evidence on health care cost drivers and solutions. Doing so can shine a spotlight on health care affordability issues. This promotes action in concert with other decision makers, such as state legislatures and governors, to lower costs.

Support Needed Data Infrastructure in the State

It will be very difficult for any stakeholder to address health care affordability problems in the absence of local data on cost drivers and outcomes. State insurance regulators should use data on price and utilization, and an adequate infrastructure to help all payers target their initiatives to maximally affect cost.⁵³ More detail and specific state examples are found in the following CIPR paper “Regional Cost Variation and the Collaborative Path to Affordability.”

Empower Consumers and Promote Transparency

Some states have decided to run their own insurance exchanges as an alternative to *HealthCare.gov*, while others offer consumer transparency tools to assist in choosing wisely across health care providers. To manage increasingly burdensome medical costs, families need comparison-shopping tools designed to highlight the differences in cost and coverage among competing insurance plans, including drug formularies. Such tools can play a critical role in helping consumers to choose plans that maximize out-of-pocket cost savings. Consumers are more likely to purchase plans with unsustainable cost-sharing structures when they are unaware of the expected total out-of-pocket expenses.

A review of public tools has found serious defects and significant lag behind private sector innovation. For example, about half of the exchanges, including *Healthcare.gov*, organize the presentation of plans by premium price. Research has shown that such default plan sorting can prompt consumers to make suboptimal product choices, resulting in overspending. For example, a consumer might choose a lower premium plan with a higher deductible, even if it means spending more out-of-pocket for diabetic supplies and medicines. To the extent that consumers are unaware of the expected total out-of-pocket expenses, they are more likely to purchase plans with unsustainable cost-sharing structures.

The states should seek to empower consumers by allowing them to shop for and enroll in coverage via privately facilitated exchanges.

Likewise, consumers need better tools to make informed decisions about their health care providers and access to affordable prescriptions. Health insurers are in the best position to make this information available for those with private coverage. The states may consider establishing baseline requirements for consumer disclosure as part of both shopping and ongoing decision support.

⁵³ Altarum Healthcare Value Hub, “An Advocate’s Guide to State-Level Healthcare Value Data.” Accessed February 5, 2019.

Address Market Concentration

As it has been noted, the last several years have seen rapid consolidation in local health services markets. PwC estimates that 93% of MSAs will be highly concentrated this year,⁵⁴ up from 90% in 2016. This trend was facilitated by court rulings based on now-disproven behavioral theories. The relaxation of antitrust guidelines in 1992, 1994, 1996 and 2011 also promoted consolidation.

As in other industries, a central motive for consolidation is pricing power. Private patient charges are determined through annual negotiations between insurers and myriad providers in thousands of local markets. Insurers' ability to hold down prices depends on their ability to exclude high-cost providers. Concentration gives high-cost providers the ability to exclude low-paying insurers.

Hospitals are achieving pricing power by acquiring physician groups. This allows them to consolidate provider systems and create their own health plans. The result has been a steady shift away from physician services toward outpatient hospital costs. For example, analysis of rate filings for 2017 show that costs for hospital outpatient services contributed most to premium increases. This was followed by taxes and costs for hospital inpatient services. These trends illustrate how consolidation further deteriorates competition between major payers and providers in markets.

Other areas where state insurance regulators can work with state leaders and other stakeholders include:

- Banning uncompetitive practices, such as anti-tiering, anti-steering, most-favored-nation, and other contract clauses contributing to cost escalation.
- Instituting an all payer rate setting mechanism⁵⁵ or institute reference pricing for services tied to the average allowed charges state-wide. Medicare already allows private insurers to pay CMS-administered rates under the fast-growing Medicare Advantage program. Creating a similar upper payment limit for all private health plans would be straightforward and affect all local markets nearly equally. Such limits could be phased in over several years rather than implemented all at once.
- Examining Provider Licensing and Scope of Practice Rules. For example, telemedicine services for appropriate provider types, such as behavioral health, should count in

⁵⁴ Stiver, I., Nov. 20, 2018. "One inflator of medical cost trend in 2019: Provider megamergers," PwC HRI.

⁵⁵ Altarum Healthcare Value Hub, August 2017. "Hospital Rate Setting: Promising, but Challenging to Replicate," Research Brief No. 1. Accessed at <https://www.healthcarevaluehub.org/advocate-resources/publications/hospital-rate-setting-promising-challenging-replicate/>.

meeting network adequacy requirements. Such a policy could improve patient access, promote provider competition, and lower prices while lowering costs.⁵⁶

- Setting upper payment limits in areas where competition is non-existent. Medicare already allows private insurers to pay CMS-administered rates under the fast-growing Medicare Advantage program. Medicare prices are transparent and adjusted to reflect geographic and other trends. A similar upper payment limit for state employee plans and all private health plans would be straightforward and affect all local markets equally. Such limits (set at a percentage above Medicare rates) could be phased in over several years, rather than implemented all at once. Montana has already implemented such a system for their state employee plan. This has saved taxpayers in Montana \$17 million in 2016 and 2017. Taxpayers are projected to save \$15 million in 2018.⁵⁷

Conclusion

While there are no politically easy ways to curb medical inflation, the alternative is even less palatable. Policymakers should aim to shift their focus from the margins of health care reform to directly addressing cost growth factors. Failure means costs will likely continue to rise much faster than wages. The result will be less affordable coverage for working Americans with associated non-favorable economic and political consequences.

⁵⁶ Altarum Healthcare Value Hub, November 2017. "Telemedicine: Decreasing Barriers and Increasing Access to Healthcare," Research Brief No. 22.

⁵⁷ Allen, M., Oct. 22, 2018. "In Montana, a Tough Negotiator Proved Employers Don't Have to Pay So Much for Health Care," *ProPublica*.

Regional Cost Variation and the Collaborative Path to Affordability

By Ellen Gagnon, Executive Director, Healthcare Affordability, Network for Regional Healthcare Improvement

Introduction

Attempts to rein in rising health care costs and the underlying causes are at the forefront of public policy discussions, media coverage and even kitchen table conversations. According to the 2018 [Milliman Medical Index](#), the annual cost of health care for a typical American family—two parents and two children covered by an employer-sponsored preferred provider organization— is \$28,166, a record level. This likely unsustainable trend is causing emotional distress and financial harm to individuals, communities, states and our country.

Credible, digestible information that quantifies and compares overall health care costs at the depth and granularity necessary for providers, policymakers, payers, purchasers and patients to act is essential. The Network for Regional Healthcare Improvement (NRHI) examines what drives health care costs at the regional level and why costs for the same services or procedures tend to be different across the U.S. Through its multi-region initiative, NRHI measures and reports on differences in the total cost of care (TCOC) within and across regions.

Nationally, NRHI and its members have agreed that there is an urgent need to improve health, eliminate waste and reduce cost to achieve more affordable health care. The challenge, however, has been moving from conceptual consensus to securing the commitments necessary to achieve change. Now, with reliable, actionable data in hand and strong multi-stakeholder partnerships established, the shift is occurring.

NRHI is a national nonprofit organization representing more than 30 regional health improvement collaboratives (RHICs) and state agency partners working to achieve better, more affordable health care. RHICs serve as a local neutral convener, present actionable data, define priorities for improvement, and develop and facilitate aligned strategies for action. RHICs can also serve as a data aggregator or leverage data gathered via state-run all-payer claims databases (APCDs).

For many stakeholders convened by NRHI and its members, it is clear the way Americans receive health care today is broken. As a result, they pay too much and are comparatively less healthy than residents of other developed nations.⁵⁸ Furthermore, most stakeholders recognize that

⁵⁸ Schneider, E.C., D.O. Sarnak, D. Squires, A. Shah, and M.M. Doty, 2017. "Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Health Care," *The Commonwealth Fund*, July 14, 2017, accessed at www.commonwealthfund.org/publications/fund-reports/2017/jul/mirror-mirror-2017-international-

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health care providers, payers, employers and consumers have helped create the unsustainable problems facing health care today and that they need to work together to solve them. Few would question the fact health care is too expensive. This often leads to necessary care being avoided or unnecessary care being received, placing undue stress on patients.⁵⁹

Multi-stakeholder approaches bringing together providers, insurers, employers, unions, consumer and patient groups, and government agencies are critical to improving value. No one entity has sufficient data or power to do it alone. Achieving real reductions in total spending and improvements in health outcomes requires meaningful collaboration, a regulatory environment supportive of robust transparency and healthy market pressure. RHICs bring these perspectives together, mobilizing community resources to develop and implement solutions that no one sector or market participant could achieve individually.

Leveraging Total Cost of Care Reporting for Change

A barrier to achieving affordability has been the lack of a credible approach for quantifying overall health care cost, utilization and price that could simultaneously empower national understanding, inspire state and regional policy change, and promote care delivery transformation. There are accepted methods to measure some elements of cost and utilization. However, they lack the breadth, depth and granularity necessary to be actionable to providers, policymakers, payers, purchasers and patients.

Working collaboratively and with the support of the Robert Wood Johnson Foundation, NRHI and its members began to produce high-quality, comparative data on health care spending. Beginning in 2013, NRHI intensified its focus on making health care more affordable through an initiative now known as *Getting to Affordability*. Supporting six of its members in measuring and reporting on differences in total cost of care and the impact of price and resource use have been a core part of this work. NRHI recently released its third round of national total cost of care benchmarks.⁶⁰

The third release of the *Getting to Affordability* TCOC confirmed once again that although price is the driver of both higher and lower health care costs in some regions, utilization makes the difference in others. Figure 1 shows the regional deviation from the average health care cost of comparable populations.

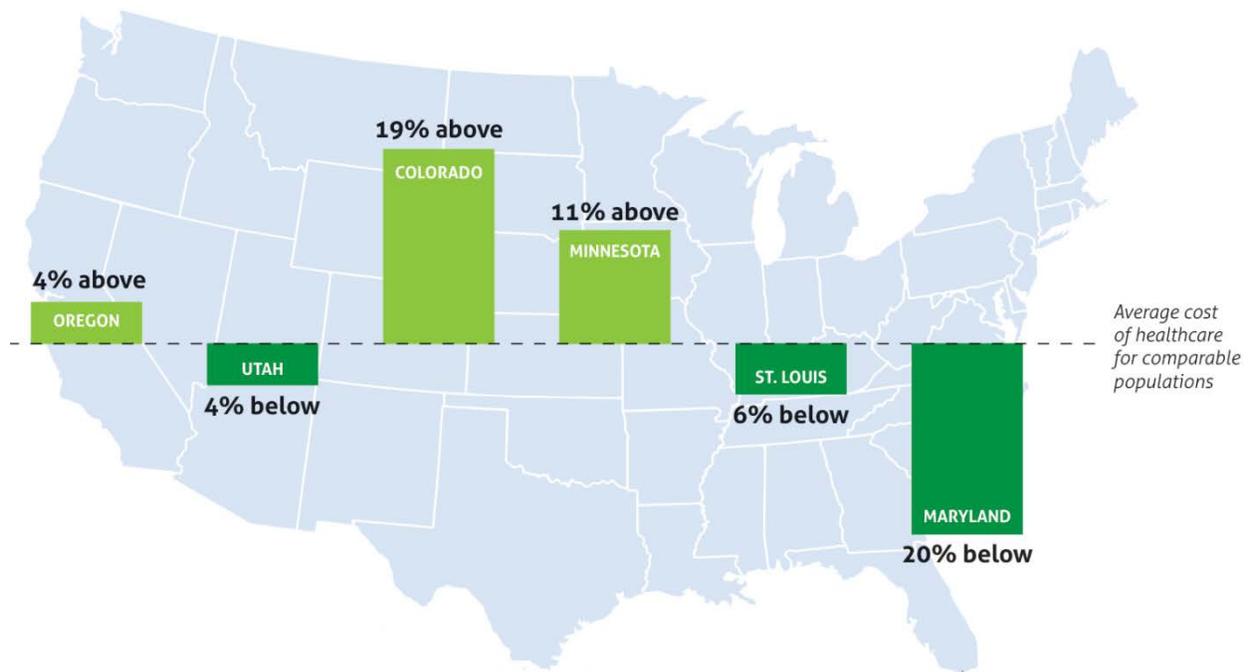
[comparison-reflects-flaws-and.](#)

⁵⁹ Berwick, D.M., and A.D. Hackbarth, 2012. "Eliminating Waste in US Health Care," *JAMA*, 1513–1516.

⁶⁰ www.nrhi.org/uploads/rwj_tcoc_phaseiii_benchmark_2018_r7.pdf.

Figure 1: Variation in Underlying Drivers of Health Care Costs Across Regions

Source: NRHI



The NRHI TCOC work has three inputs: 1) reliable, standardized measures of cost, price and resource use that could be applied across different populations such as states, regions, provider practices, health plan memberships and employer workforces; 2) high-quality data sets with transparent cost information including the amount paid for services; and 3) a detailed and well-documented process to ensure consistency in data processing and analysis and, in turn, results.

Over three years, RHCs and state partners participating in TCOC measurement have collaborated to produce three reports comparing their performance against one another and developed state, regional and local results to inform policy and practice. Consistency across the three measurement periods suggests the project's extensive efforts to standardize data collection, measurement and analysis processes have produced reliable, comparable results across the regions. (See Table 1 and Table 2.)

**Table 1: Year to Year Comparison of Total Cost of Care Compared to Average
(Only Participants in All Three Years, 2014–2016)**

Source: NRHI

Measure	Maryland	Minnesota	Oregon	Utah
Total Cost				
2014	-16%	11%	7%	0%
2015	-12%	11%	4%	0%
2016	-17%	14%	7%	-1%
Rank*				
2014	1	4	3	2
2015	1	4	3	2
2016	1	4	3	2

Rank Order: 1=Lowest; 4=Highest

**Table 2: Year to Year Comparison of Total Cost of Care Compared to Average
(All Participants for all Three Years, 2014–2016)**

Source: NRHI

Measure	Colorado	Maryland	Minnesota	Oregon	St. Louis, MO	Utah
Total Cost						
2014	-	-14%	14%	10%	-10%	2%
2015	17%	-16%	7%	0%	-	-4%
2016	19%	-20%	11%	4%	-6%	-4%
Rank*						
2014	-	1	5	4	2	3
2015	5	1	4	3	-	2
2016	6	1	5	4	2	3

Rank Order: 1=Lowest; 6=Highest

The work has been featured in major publications and highlighted at national conferences, providing meaningful contributions to the national dialogue on affordability. It is estimated that for each year of the benchmark, health care cost information on more than 5 million patients attributed to approximately 20,000 individual physicians has been calculated and shared. NRHI members are providing comparative cost data to state legislatures and state agency leaders, physician practices, health plans, leading national employers, and, in some regions, consumers. The information is used to inform strategy, shape policy and support interventions.

Gathering and Analyzing Data

RHICs' ability to access, understand and use claims data for the purposes of cost measurement and their experience bringing together diverse stakeholders to act on the results made them an ideal home for the first national project to develop a total cost of care benchmark across the participating regions.

Before the project began, it was clear previous attempts to reduce costs often had a balloon effect. Market pressure squeezed the balloon to save in one part of the system, such as emergency department use or imaging, but the balloon expanded elsewhere, resulting in the same high health care costs. Deflating the balloon would require an understanding of what is behind the total cost of care and monitoring to ensure overall costs are reduced. Through *Getting to Affordability's* multi-region analysis of total cost of care and its drivers, NRHI found striking variation between regions.

The regions base their analysis on data collected via the claims databases they steward. To produce comparable results, extensive standardization is critical. This work uses the TCOC and Total Care Relative Resource Value (TCRRV) measures developed by HealthPartners, which were first endorsed by the National Quality Forum (NQF) in 2012 and again in October 2017. NRHI members work closely with each other and a technical advisor to standardize the application of these measures, including the risk adjustment methodology, and analyze the reasonableness of results.

To better ascertain whether observed cost differentials are a result of higher/lower than average utilization, prices or a combination thereof, three different indices were developed. The primary Total Cost Index (TCI) and its two components, the Resource Use Index (RUI) and the Price Index (PI), make it possible to make meaningful cost comparisons across regions and better understand where to look for the underlying causes of these differentials. The percentages in Table 3 indicate the contribution to total cost each of the components made. A positive percentage indicates utilization or price is driving cost higher compared to the benchmark, and a negative percentage indicates utilization or price is driving cost lower compared to the benchmark. In some cases, the RUI and the Price Index are working in opposite directions. In those cases, the component that contributes most determines if the cost is above or below average. The TCI compares total per member per month spending, and the RUI focuses on differences in intensity of utilization. The RUI and the PI allow separate analysis of the intensity of utilization and price. Both the TCI and RUI are adjusted for differences in the populations' underlying health status using the Johns Hopkins Adjusted Clinical Groups (ACG) System.

The risk scores in Table 3 were determined by conducting a sensitivity analysis on the risk scores and then indexing the results. This analysis considered variation in claim detail across data

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contributors. After consulting with subject-matter experts (SMEs) about the potential effect of variation in claim detail, maximum potential variation was applied to affected risk scores. Some regions experienced higher variation in risk score due to the variation in claim level detail. The risk scores were indexed so that their unweighted average was equal to one. This was done by dividing each region's risk score by the overall unweighted risk score. (See Table 3.)

Table 3: Risk Adjusted Total Cost, Resource Use and Price Compared to Average (2016)

Source: NRHI

Measure	Colorado	Maryland	Minnesota	Oregon	St. Louis, MO	Utah
Risk Score	-7%	15%	-1%	-2%	4%	-9%
TCI	19%	-20%	11%	4%	-6%	-4%
RUI	5%	-7%	7%	-10%	10%	-5%
PI	13%	-14%	4%	16%	-15%	1%

Of course, none of this work would be possible without high-quality claims data. The work also requires either supportive regulatory environments or highly engaged health plans and self-insured employers that allow this data to be used in ways that illuminate opportunities to drive improvements in cost, quality and utilization. APCDs are typically created by a state mandate.

They systematically collect health care claims data, such as medical, pharmacy, eligibility and provider data, from a variety of payer sources. Three of the six RHICs participating in this project use data provided voluntarily by health plans. In Minnesota, each payer applies the HealthPartners methodology to its own data. Then, Minnesota Community Measurement (MNCM) aggregates all the plans' data and analyzes. MNCM sends the data to NRHI for the national benchmark.

With three national total cost of care benchmark reports complete, the following trends have begun to emerge:

- In each of the three benchmarks, Maryland was the lowest cost of the regions. In the most recent year, the TCI varied from 20% below the benchmark for Maryland, to 19% above the benchmark for Colorado, the highest cost region. As shown in Table 1 and Table 2, similar differences for these same states were observed in previous reporting periods. Further, the ordering of the four RHICs participating in all three of the total cost of care benchmark periods has remained consistent.
- Prices and care delivery and utilization patterns vary across states and within states across markets. Those variations drive differences in cost. (See Figure 2.)

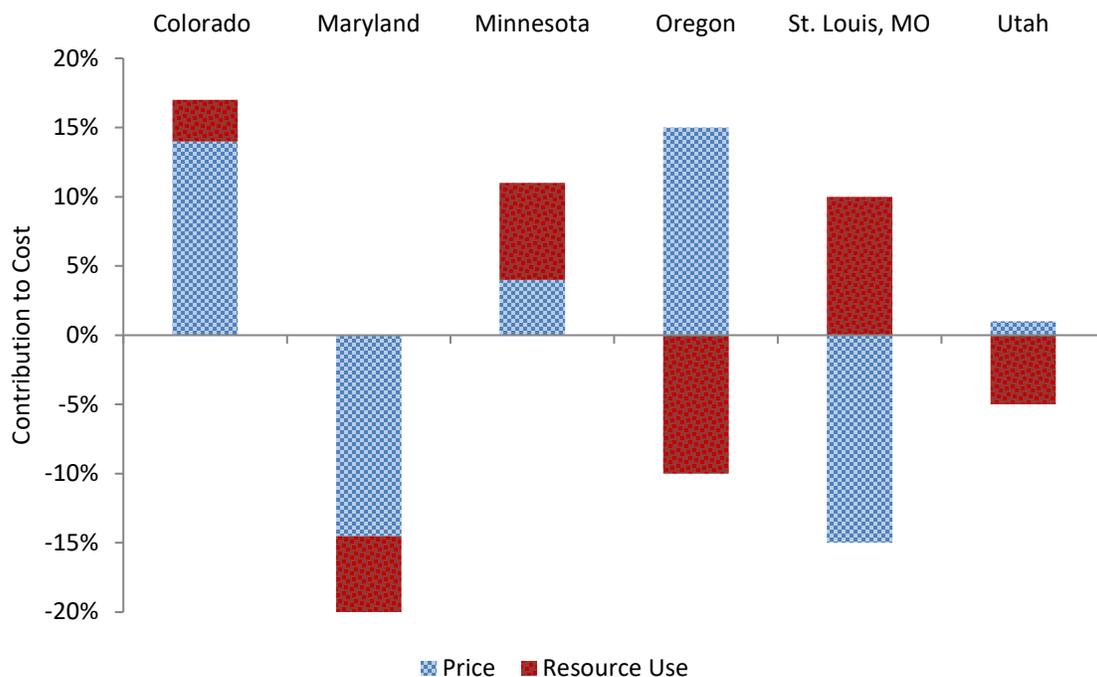
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- Showing differences in price, cost and resource use gives stakeholders a framework to consider the roles of policies, demographics and market factors in steering health care costs. (See Table 3 and Figure 2.)
- Consistency in year-over-year total cost of care results, despite some differences in the underlying populations, reflects the regional norms in care delivery and pricing.
- Most regions tend to have the same higher price and/or higher utilization service lines year-over-year (YOY) .

Pharmacy pricing showed the least variability, which is largely a result of the influence of a few large pharmacy benefit managers (PBMs) and pharmaceutical manufacturers' national pricing policies. It is also important to note that many of the new and expensive specialty medicines are being administered and represented in the medical expense, so they may not be reflected in the pharmacy service line results.

Figure 2: Untangling the Cost Drivers

Source: NRHI



Local Intelligence Deepens Understanding of the Data

NRHI members' standardized process, granular data and strong connections to stakeholders allow them to dig into the "why" and reveal how variations in care delivery and local prices contribute to the significant cost differences. The process also highlights differences in underlying

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populations and how risk adjustment affects the numbers. This local intelligence applied to data increases the utility of the information and enables stakeholders to take steps to address the specific issues facing their states and regions.

In four of the six regions, some service lines reported higher prices or resource use than the benchmark, and other service lines reported lower prices or resource use than the benchmark. Colorado reported a higher price than the benchmark for all service lines, and Oregon reported lower resource use than the benchmark for all service lines. (See Table 4.)

In all three sets of results, Oregon prices, outside of pharmacy costs, have consistently been higher than the benchmark, while resource use has been lower. In contrast, in St. Louis, MO, prices have consistently been shown to be lower than other regions. However, resource use in St. Louis has consistently been higher. (See Table 4.)

The HealthPartners TCOC measure set offers many dimensions of comparisons. It can be used to analyze price, utilization or their sum, total cost, across regions, provider groups, and other populations. Prices and care delivery patterns vary across states and within states across markets. Those variations drive differences in cost. Showing differences in price, cost and resource use gives stakeholders a framework to consider the roles of policies, demographics and market factors in steering health care costs.

The Oregon and St. Louis divergence described above was most dramatic in outpatient care, where St. Louis' use of outpatient care was 53% more than Oregon, but its prices were 54% less. Similarly, for inpatient care, prices were 48% less in St. Louis than Oregon, but resource use was 29% more. All the results are provided on a risk-adjusted basis. The lower prices in St. Louis reflect the region's lower cost of living. (See Table 4.)

Across states, inpatient care had the greatest variation in price in all three of the benchmark periods. Colorado's hospital prices were 31% higher than the average, compared to 23% below average in St. Louis, in the most recent period. During the most recent period, the same differential was reported for outpatient care, as well across the two regions. (See Table 4.)

Outpatient care also showed the greatest differences in resource use, with Maryland coming in 26% below average and St. Louis coming in 29% above average. Professional services had the least variation in resource use across the regions. (See Table 4.)

Table 4: Total Cost of Care by Service Category (2016)

Source: NRHI

Measure	Colorado	Maryland	Minnesota	Oregon	St. Louis, MO	Utah
Total Cost						
Overall	19%	-20%	11%	4%	-6%	-4%
Inpatient	21%	-27%	12%	5%	-13%	8%
Outpatient	34%	-34%	3%	0%	1%	5%
Professional	2%	-16%	30%	18%	-22%	-9%
Pharmacy	28%	-3%	%	%	%	%
Resource Use						
Overall	5%	-7%	7%	-10%	10%	-5%
Inpatient	-8%	-10%	9%	-16%	13%	13%
Outpatient	17%	-26%	6%	-24%	29%	3%
Professional	-4%	2%	17%	-3%	-5%	-8%
Pharmacy	22%	-4%	-16%	-7%	21%	-17%
Price						
Overall	13%	-14%	4%	16%	-15%	1%
Inpatient	31%	-19%	3%	25%	-23%	-4%
Outpatient	15%	-11%	-3%	32%	-22%	3%
Professional	7%	-18%	11%	22%	-17%	-1%
Pharmacy	5%	1%	7%	-10%	-5%	4%

Informing Health Care Cost Policy

HealthInsight Oregon, one of the original RHICs participating in the project, has been sharing the information with policymakers, providers and payers for several years. Legislators have convened several workgroups addressing various components related to cost. HealthInsight Oregon is frequently called in to present the total cost of care data to help inform policy. Legislators tell HealthInsight Oregon that they see this data as an important source of information as they consider how to create a higher-value health care system for the state.

Data from the project has been persuasive to the Colorado legislature. The Center for Improving Value in Health Care (CIVHC), the RHIC that participates in the NRHI project on behalf of Colorado, looked at regional variation across the state and triangulated the data against other publicly available sources. CIVHC consistently found the state's high use of outpatient services and the high prices of those services have the greatest impact on its total cost. To highlight its findings, CIVHC developed and distributed a white paper to the Colorado legislature and other stakeholders so policymakers, providers and purchasers could better understand how the cost of care in Colorado compares to other states and consider policy changes to have an impact those costs.

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CIVHC found the data shut down anecdotal conversations and shifted the conversation to focusing on solving the problems rather than debating if they existed.

With its unrestricted funding sources, CIVHC worked with legislators to help inform the development of several bills aimed at increasing health care transparency in the state. A key piece of legislation passed. It requires every freestanding outpatient facility—freestanding emergency departments, urgent care centers, imaging centers and others—to bill using its own unique national provider identifier. This change will give CIVHC the ability to identify these various facilities in its dataset rather than have the care provided by those facilities look as though it were provided by a hospital or another facility. The additional data will allow CIVHC to conduct valuable analyses on the care, and the cost of care, that these facilities deliver.

For more than 35 years, Maryland has operated the nation's only all-payer hospital rate regulation program. In 2014, this program was expanded. Under the new model, the state agreed to limit all-payer per capita hospital growth, including inpatient and outpatient care, to 3.58%. In addition, Maryland agreed to limit annual Medicare per capita hospital cost growth to a rate lower than the national annual per capita growth rate per year for 2015–2018. This year, the program was expanded to physicians and nursing homes and extended until 2023. State agency leaders have said the results from this project may suggest the model is having a positive impact for the commercially insured.

States and other health care purchasers also see the importance of the data in developing local comparisons of medical groups and practice sites. Five of the six regions share detailed total cost of care data with providers. Increasing interest in population health management and value-based contracting have generated increasing interest in the reports over the years. At Midwest Health Initiative (MHI) in St. Louis, employers were invited to join representatives of the region's leading provider groups for a joint discussion. At the event, MHI shared how each of the groups performed on the total cost of care, utilization and quality measures compared to each other and a regional benchmark. HealthInsight Utah also is working with an employer workgroup to think about the cost information that would be most meaningful to employers and other purchasers and how it should be reported.

Early Adopters Set Foundation for National Spread

In addition to the six sites currently contributing to the benchmark, another dozen sites have participated in the project in other ways, including exploring various barriers to reporting on cost, such as data availability and stakeholder readiness. Each entered the project in a different place, with varying access to data and interest from stakeholders. Each has moved along its own continuum at a pace fast enough to sustain momentum and slow enough to maintain trust. All have benefited from being part of a larger effort and its collective knowledge. These regions can learn from the sites that have gone before them, offer their stakeholders tangible examples of success and offer their own contributions to the collective knowledge base. For many of these sites, the result is the ability to break down technical barriers to reporting. For others, the focus is on engaging stakeholders to assess or broaden support for total cost of care reporting. Across

Washington Health Alliance's Call to Actions

- Overuse must become central to discussions of health care value
- Clinical leader must take up efforts to incorporate reduction of overuse into local practice culture
- Shared decision-making must become the bedrock of provider-patient communications
- We need to transition from paying for volume to paying for value to align incentives
- Value-based provider contracts must include measures of overuse

a wide array of market structures, political environments and data infrastructures, RHICs have worked with their regional partners to find solutions to make progress in achieving cost transparency.

Identifying Waste, Reducing Harm

Eliminating waste—a combination of unnecessary care, low-value care, harmful complications, missed diagnoses, medical error and even administrative costs—is a focus of many RHICs. In its report, *First, Do No Harm: Calculating Health Care Waste in Washington State*,⁶¹ Washington Health Alliance (Alliance) found an estimated \$282

million was spent on low value services across the 47 measures included in the Health Waste Calculator, a tool developed by the actuarial consulting firm Milliman. The Alliance analysis included care delivered to 2.4 million commercially insured lives from July 2015 to June 2016. To define unnecessary services, the Health Waste Calculator leverages nationally-standardized quality measures; recommendations from the U.S. Preventive Services Task Force; and recommendations from Choosing Wisely, an initiative of the ABIM Foundation that seeks to

⁶¹ Washington Health Alliance, 2018. "First, Do No Harm: Calculating Health Care Waste in Washington State," Washington Health Alliance.

Washington State's Choosing Wisely Mission

Promote conversations between clinicians and patients to help patients choose care that is:

1. Supported by evidence
2. Not duplicative of other tests or procedures already received
3. Free from harm
4. Truly necessary

advance a national dialogue on avoiding unnecessary medical tests, treatments and procedures. **Error! Hyperlink reference not valid.**

“First Do No Harm” was endorsed by the Washington State Choosing Wisely Task Force, a group of 21 clinician leaders working to ensure safe, high-value care

for patients in Washington state by significantly reducing health care overuse and waste. It is co-sponsored by the Alliance, the Washington State Medical Association (WSMA) and the Washington State Hospital Association (WSHA).

Eleven of the 47 measures in the tool accounted for 93% of the low-value services and 89% of the estimated spend. A total of 578,503 individuals received at least one of these 11 low-value services, or about one-quarter of the approximately 2.4 million individuals included in this analysis. And the problem of waste was not limited to expensive services. Too frequent cervical cancer screenings, baseline laboratory studies, EKGs and chest X-rays before low-risk surgeries, and unnecessary imaging for eye disease were among the services its stakeholders are focused on reducing. Other potentially avoidable services included PSA screening, population-based screening for OH-Vitamin D deficiency, imaging for uncomplicated low back pain in the first six weeks, and imaging for uncomplicated headache.

Working across its stakeholders, with strong leadership from its employer members, the Alliance issued a call to action describing the sometimes difficult, yet transformative, road that would need to be traveled to remove waste from the system.

Five years ago, the ABIM Foundation launched the Choosing Wisely⁶² campaign to raise awareness about unnecessary care and encourage changes in practice. Six NRHI members led efforts to disseminate the principles of Choosing Wisely in their communities through grants provided by the Robert Wood Johnson Foundation (RWJF). Now, building on the best practices and lessons learned, NRHI and the ABIM Foundation are working together, with support from the HealthDoers Network, to package resources most helpful to other RHCs looking to engage community stakeholders in the spread of Choosing Wisely principles. Across all these efforts, there is a consistent theme: If preventable complications, unnecessary treatments, inefficiencies and errors are reduced, then we can reinvest in services that add value.

⁶² Levinson, W., K. Born, and D. Wolfson, 2018. “Choosing Wisely Campaigns: A Work In Progress,” *JAMA*, 1975–1976.

In Pittsburgh, the Pittsburgh Regional Health Initiative (PRHI) also has a focus on reducing unnecessary services and paying for value. Frustrated and saddened that mothers giving birth in the U.S. are nearly three times more likely to die than in any other developed country,⁶³ PHRI is focusing on perinatal care. PRHI is developing a maternity bundle aimed at minimizing risks for mother and baby and promoting strong attachment immediately after birth. The RHIC has a long history of working collaboratively across stakeholders to support providers in improving quality, safety and affordability. For this project, providers began by identifying ways to improve care for patients and eliminate avoidable costs. Then, payers began a process to design bundled payments for maternity care services that provide adequate payment for high-quality care and incentivize providers to take accountability for quality and efficiency.

Innovative Collaborations to Improve Health

NRHI members recognize the impact on the health of populations on health care affordability. Healthier people create more productive communities, use fewer resources and are less likely to live in poverty. They also recognize that the stress of high health care costs causes serious concern to many individuals and families, particularly those already facing serious health conditions. With this mind, several RHICs are focusing their affordability efforts on ways to improve health outcomes.

Better Health Partnership Methods for Success

- Publicly report comparative quality measure performance
- Identify protocols from high-performing outliers
- Disseminate through learning
- Coach on workflow redesign, care coordination and tailored communication across different sub-populations (e.g., the meaningful use of electronic health records (EHRs) quality improvement projects)

Better Health Partnership (Partnership), the RHIC serving Cleveland, OH, and its surrounding communities, combined clinical data with data on social determinants of health, such as insurance type, race/ethnicity, language preference, education and household income. The goals were to increase care coordination for complex patients and improve primary care. To align with the collaborative nature of its culture, the

Partnership focused on a “positive deviance” approach. It identified best practices for care of patients with diabetes, heart failure and hypertension, and then shared them publicly to accelerate adoption. Results published in 2018 in *Health Affairs* found dramatic improvements in rates of hospitalizations for ambulatory-sensitive conditions compared to other counties after

⁶³ Alkema, L., D. Chou, D. Hogan, S. Zhang, A.B. Moller, and A. Gemmill, 2016. “Global, Regional, and National Levels and Trends in Maternal Mortality Between 1990 and 2015, With Scenario-Based Projections to 2030: a Systematic Analysis by the UN Maternal Mortality Estimation Inter-Agency Group,” *The Lancet*, 462–474.

Regional Cost Variation

the establishment of the partnership. The research estimated that 5,746 hospitalizations for ambulatory care-sensitive conditions were averted in 2009–2014, leading to cost savings of nearly \$40 million.⁶⁴

Also, in Ohio, the Healthcare Collaborative of Greater Columbus (HCGC) is focused on increased care coordination. Local stakeholders determined that leveraging health information exchange data to increase whole person health was a priority. HCGC responded and worked with partners to develop a cloud-based, shared referral tool to use among local health care providers, social service agencies and other stakeholders. The tool gave patient-centered medical homes (PCMHs) a place to store valuable information on patients so it could be easily and securely accessed by the patient’s providers, as well as support referrals and coordination of services across community agencies, hospitals, EDs and specialists. Clinical and community partners receive information as they need it, and then the PCMH can track the status of the referral and the care received outside of the primary care setting.

In New Jersey, the multi-sector partners participating in the New Jersey Health Care Quality Institute (NJHCQI) were moved to action after reading the results of a poll that found 60% of New Jersey adults had no written documents expressing their wishes for care at the end of their lives. The poll results were particularly concerning considering NJHCQI’s review of Dartmouth Atlas⁶⁵ data found New Jersey patients near the end of life are treated with more aggressive medical care than in almost any other state in the country. According to the United Health Foundation’s Senior Report 2018, New Jersey ranked 47th in hospital deaths for seniors at the end-of-life, at 25.6%. The top 10 performing states in the nation are between 14% and 17%.

NJHCQI developed The End-of-Life Care Strategic Plan⁶⁶ for New Jersey, which shares tactical solutions to improve end-of-life care for New Jersey adults. It outlines how doctors, nurses, health systems, state leaders and community members can act to improve care. The plan calls for improvements in technology, patient and family education, payment reform, and changes in culture.

⁶⁴ Tannenbaum, J., R.D. Cebul, and D. Einstadter, 2018. “Association of a Regional Health Improvement Collaborative with Ambulatory Care-Sensitive Hospitalizations,” *Health Affairs*, 1377.

⁶⁵ America's Health Rankings, 2018. “Senior Report 2018: A Call to Action for Individuals and Their Communities,” United Health Foundation.

⁶⁶ The New Jersey Health Care Quality Institute, 2018. “End-of-Life Care Strategic Plan for New Jersey,” New Jersey Health Care Quality Institute.

Aligned Goals, Collective Success

Within each RHIC, the stakeholders who receive, provide and pay for health care are coming together around the same table, viewing trusted data and reaching a shared understanding of the best path to improve health, reduce prices and remove waste in their communities.

The result is the development of aligned goals, the deployment of consensus-driven strategies and a feeling of collective success that spurs interest in future collaborations. These projects would not be possible without the necessary regulatory support to allow data sharing and cross-sector collaboration. In return, the insights gained from the data and collaborations provide policymakers clear direction from a broad group of stakeholders representing many perspectives.

NRHI recently launched Affordable Care Together, a national campaign that strives to achieve affordable health care by focusing on three major drivers: 1) health; 2) price; and 3) waste. A key component of this work is developing a better understanding of the specific relationships across health, price and waste in each region and supporting local stakeholders in developing and implementing tailored strategies to increase the likelihood of more affordable health care. The preceding examples illustrate the necessity of gathering locally generated information, applying local market intelligence and leveraging the key role of RHICs, as neutral conveners, to catalyze action and achieve measurable results. The impact of policies that continue to enable and support these types of efforts cannot be underestimated.

As part of this national campaign, NRHI is inviting policymakers, national organizations and health care advocates interested in taking community action to address health care affordability to collaborate with other like-minded change agents across the country.⁶⁷

⁶⁷ Stay up to date on the work NRHI and its members are doing to increase the quality and affordability of health care for everyone by signing up for our email list (<http://affordablecaretogether.com/>) and following us on Twitter (www.twitter.com/reghealthimp).

Prescription Drug Cost Drivers

By Susan Pantely,⁶⁸ Principal and Consulting Actuary, Milliman

Introduction

Prescription drug spending was approximately \$328.6 billion in 2016, accounting for approximately 10% of total health care spending.⁶⁹ The uniqueness of the delivery system, along with unit cost pricing, competition and other characteristics warrants an examination of cost drivers for prescription drugs separate from other health care spending. In recent years, prescription drug cost trends have at times exceeded medical cost trends, driven primarily by the price and utilization of specialty drugs. Although it has leveled off, spending growth for prescription drugs is expected to remain at comparable levels or slightly above medical spending growth.⁷⁰

This paper discusses: 1) relevant prescription drug background information and detail on the role of pharmacy benefit managers (PBMs); 2) the identified cost drivers of prescription drugs, including some insights regarding opioids; and 3) existing and potential actions to address the high costs of prescription drugs.

For the purposes of this paper, prescription drugs are defined as drugs dispensed in a retail setting, excluding drugs administered in a hospital or physician setting. Drugs administered in a hospital or physician setting are typically reimbursed under the medical benefit and, as such, many of the observations for the retail prescription drug market are not applicable. Additionally, the focus here is on the drivers of spending for those enrolled in the private health insurance system. This has the greatest relevance for state insurance regulators. Many of these concepts may also apply to the Medicaid and Medicare markets. However, due to the uniqueness of these state and federal programs, some of these concepts may not be applicable.

Background

Prescription drugs are often used to treat chronic medical conditions like diabetes, high blood pressure or depression, but they are also used to treat more severe diseases like cancers or

⁶⁸ Several additional people contributed to this report. I would like to acknowledge the assistance of Maggie Alston, Brian Andersen, Casey Hammer, Dan Henry, Rebecca Johnson and Chankyu Lee.

⁶⁹ CMS, 2018. "National Health Expenditures 2017 Highlights." Accessed online May 8, 2019, at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf>. Chapter XX of the full report similarly found prescription drugs to be 9.8% of total health care spending in 2017.

⁷⁰ American Academy of Actuaries (Academy), 2018. "Drivers of 2019 Health Insurance Premium Changes," *Issue Brief*. Accessed online May 8, 2019, at https://www.actuary.org/files/publications/Premium_Drivers_2019_061318.pdf.

HIV/AIDS. Surveying the types of drugs, how patients access them, and how they are administered and paid for can be complex and confusing. In this section, we discuss some fundamental basics about the types of drugs prescribed by physicians.

Depending upon the type of drug prescribed, a patient will most often obtain the drug in one of three ways: 1) fill the script at a pharmacy to pick up and take home (retail); 2) fill the script over the phone or via a website and receive the drug in the mail (mail order); or 3) have the drug administered in a clinic, hospital or physician's office (non-retail—again, not falling under our purposes here).

How the patient takes the drug, also known as the route of administration, varies by the type of drug. Drugs are often taken orally, but other routes of administration include, but are not limited to: 1) injection (e.g., intravenously or subcutaneously); 2) breathed into the lungs (e.g., inhalation or nebulization); or 3) applied to the skin (e.g., topical). A single drug may have more than one route of administration, each with a specific purpose and advantages and disadvantages to consider related to convenience and ease of administration, frequency of dosing, safety, and expense.

The types of prescription drugs fall into a handful of broad categories, depending upon their patent status, exclusivity rights and molecular complexity:

- **Single-source brand:** A sole manufacturer holds the patent and rights to sell the drug to a consumer. The average life of single-source protections is 12 years after U.S. Food and Drug Administration (FDA) approval. Because of exclusivity rights and other factors, brand drugs tend to be relatively high-priced.
- **Multi-source brand:** A brand drug that is sold by at least two manufacturers and for which there are also generic equivalents available.
- **Generic:** A drug that has the same active ingredients as a brand drug and is also the same in dosage form, safety, route of administration, and other characteristics. Generic drugs can be sold by manufacturers after brand patent expiration and other exclusivity rights have ended. Generic drug prices tend to be lower than their brand equivalents.
- **Specialty:** No one single definition, but these drugs tend to be high-priced, highly complex biologics derived from living cells that may require special handling (e.g., temperature control), have challenging side effects requiring special risk evaluation and mitigation strategies (REMS), and/or have a challenging route of administration (e.g., injection or infusion).

Regardless of the type, drugs are known by several different names, including their proprietary trademarked names and a generic name assigned by the U.S. Adopted Names (USAN) Council. For example, hydrocodone (generic name), an oral pain reliever (analgesic), is also known by the trademarked name Vicodin (among others).

The distribution of spending among generic, brand and specialty drugs varies by type of payer; i.e., commercial, Medicare, Medicaid or health exchange. However, for all payers, brand and specialty drugs make up two-thirds or more of total prescription drug spending⁷¹ (see Table 1).

Table 1: Components of Per-Member Per-Year Drug Spending (2017)

Payer	Generic	Brand	Specialty
Commercial	23.8%	35.5%	40.8%
Medicare	28.7%	40.2%	31.1%
Medicaid	20.5%	37.2%	42.3%
Health Exchanges	22.8%	28.6%	48.7%

Numbers may not add up to 100% due to rounding.

Source: Express Scripts

Lastly, drugs can be grouped together into drug classes based on varying classification methods:⁷²

- Used to treat similar conditions (therapeutic use).
- Mechanism of action (biochemical reaction).
- Mode of action (body response).
- Chemical structure.

In the U.S., the U.S. Pharmacopeia (USP)⁷³ has developed a classification system that includes 52 different broad categories, such as antidepressants; cardiovascular agents, including beta-blockers; and angiotensin-converting enzyme (ACE) inhibitors and respiratory tract agents, including antihistamines and bronchodilators.

Organizing drugs into therapeutic classes is a key element of a prescription drug formulary—i.e., the list of prescription drugs that a health insurer will cover—which is used by health plans and PBMs to manage benefit access to drugs.

⁷¹ Express Scripts, 2018. “2017 Drug Trend Report.” Accessed online May 8, 2019, at <http://lab.express-scripts.com/lab/drug-trend-report/~media/2b56ec26c9a04ec2bcca0e9bf1ea8ff1.ashx>.

⁷² Bihari, M., 2019. “Drug Classes: Making Sense of Medication Classification.” Accessed online May 8, 2019, at https://www.verywellhealth.com/drug-classes-1123991_

⁷³ The USP Drug Classification schema is available at https://www.usp.org/health-quality-safety/usp-drug-classification-system_

Pharmacy Benefit Managers (PBMs)

PBMs are third-party intermediaries who contract with health plans, employers, government agencies and other payers to manage prescription drug benefits. To understand the role of PBMs, it is also important to understand all the stakeholders in the pharmacy supply chain. There are generally six of them in the prescription drug market: 1) pharmaceutical manufacturers; 2) wholesalers; 3) health insurers; 4) PBMs; 5) pharmacies; and 6) patients (see Table 2). PBMs are involved in nearly every part of the pharmacy supply chain.

Table 2: Key Stakeholders in the Prescription Drug Distribution Chain

Source: Milliman⁷⁴

Stakeholder	Role	Example Organizations
Pharmaceutical Manufacturer	Develop and market prescription medications.	Genentech, Pfizer, Sanofi
Health Insurer (including Medicare Part D plans)	Provide insurance products to patients that cover health care services, including prescription drugs.	Aetna, Cigna, employers, government agencies
Pharmacy	Dispense prescription medications to patients.	Walgreens, Rite Aid, CVS, mail order
PBM	Act as an intermediary between health insurers and pharmacies. Develop and maintain formularies for health insurers. Negotiate rebates and discounts with manufacturers.	Caremark (part of CVS) Express Scripts, OptumRx
Wholesaler	Distribute drugs from the pharmaceutical manufacturer to the pharmacy.	AmerisourceBergen, Cardinal Health, McKesson
Patient	End user for the prescription medication.	

The PBM market is extremely concentrated, with at least 75% of prescription drug claims being handled by just three PBMs: CVS Caremark, Express Scripts and OptumRx.⁷⁵ PBM functions may vary depending upon their contracted role and responsibilities, but they often include:

⁷⁴ Dieguez, G., M. Alston, and S. Tomicki, 2018. "A primer on prescription drug rebates: Insights into why rebates are a target for reducing prices," *Milliman White Paper*. Accessed online May 8, 2019, at www.milliman.com/insight/2018/A-primer-on-prescription-drug-rebates-Insights-into-why-rebates-are-a-target-for-reducing-prices/

⁷⁵ Yu, N.L., P. Atteberry, and P.B. Bach, 2018. "Spending On Prescription Drugs In The US: Where Does All The Money Go?" *Health Affairs*. Accessed online May 8, 2019, at www.healthaffairs.org/doi/10.1377/hblog20180726.670593/full/.

Prescription Drug Cost Drivers

- Formulary management.⁷⁶
- Negotiating pricing, including discounts, dispensing fees, and rebates with manufacturers.
- Contracting with pharmacies.
- Processing and paying claims on behalf of the health plan, employer or other payer.

PBMs may also own and operate pharmacies designed specifically to manage specialty drugs. PBMs typically make their money by: 1) capturing a share of the negotiated rebates; 2) charging administrative fees; 3) negotiating a price spread between what is paid by the payer to the PBM and what the PBM pays the pharmacy; 4) owning and operating mail order and specialty pharmacies that allow for them to profit in the distribution channel; 5) benefiting from the time value of money from the holding rebates and pharmacy payments; 6) reselling claims data; 7) negotiating price protection in the manufacturer contracts; 8) offering invoice discounts via purchasing arrangements; and 9) manufacturer administrative fees for formulary administration.

Prescription drug rebates are generally paid by a pharmaceutical manufacturer to a PBM, who then shares a portion with the health insurer. Rebates are mostly used for brand prescription drugs in competitive therapeutic classes where there are interchangeable products (rarely for generics).⁷⁷ The purpose of rebates is to incentivize PBMs and health insurers to include the pharmaceutical manufacturer's products on their formularies and to obtain preferred tier placement.⁷⁸

A formulary is the list of prescription drugs that a health insurer will cover. It can be arranged in many different ways. A single health plan may use several different formularies, each tied to a specific drug benefit plan design. A formulary assigns particular products to one of several tiers (there are typically two to four tiers in commercial formularies), each with different member cost-sharing. Formulary tiers are often designed to promote low-cost prescription drugs. For example, a low-cost generic prescription drug may require a \$5 copay, a preferred brand prescription drug with a high rebate may require a \$20 copay, and a non-preferred brand prescription drug with a low rebate may require a \$50 copay.

⁷⁶ Formulary management involves placing drugs on various tiers to determine cost-sharing (or whether to cover at all). The purpose of formulary management is to reduce pharmacy costs while maintaining clinical integrity.

⁷⁷ Johnson, N.J., C.M. Mills, and M. Kridgen, 2018. "Prescription Drug Rebates and Part D Drug Costs," Milliman Report. Accessed online May 8, 2019, at www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf.

⁷⁸ Academy of Managed Care Pharmacy (AMCP), 2012. "Maintaining the Affordability of the Prescription Drug Benefit: How Managed Care Organizations Secure Price Concessions from Pharmaceutical Manufacturers." Accessed online May 20, 2018, at www.amcp.org/WorkArea/DownloadAsset.aspx?id=9299.

PBMs typically supplement the drug formulary with a set of utilization management protocols designed to encourage the appropriate use of medications. In addition to the coverage restrictions employed by definition within the formulary, these management protocols include:

- Quantity limit: Restricts the amount of medication (or number of refills) that can be provided to a patient within a specified time period (e.g., 30 days, 60 days or 90 days).
- Step edit: Requires that the patient demonstrate that a lower-cost generic alternative is ineffective prior to approving the use of a more expensive brand drug.
- Prior authorization: Requires the demonstration of medical necessity using evidence-based guidelines prior to approving the use of a drug.

Drivers of Prescription Drug Spending

From an overall perspective, prescription drug spending trends are driven by increases in the average unit cost per script and increases in the number of prescriptions taken, or utilization. The trend in prescription drug average cost per unit is typically measured as the annual increase in cost per script. The unit cost trend is influenced by both inflationary price increases and the mix of the underlying drugs prescribed.

Prescription drug utilization is typically measured by the number of prescription drug orders filled in a retail setting. This definition of utilization is directly related to prescription drug spending, because as more prescriptions are filled, spending on prescription drugs increases. Therefore, prescriptions ordered by a physician, but never filled, are not considered. To normalize for population changes, the prescription drug utilization trend is typically measured using the number of scripts per 1,000 persons.

The total prescription drug spending trend is the combination of the utilization trend and unit cost trend. In recent years, utilization and average unit cost per script have contributed about equally to growth in prescription drug spending. Below, we discuss many of the more specific items that contribute to high prescription drug spending in the U.S. as they relate to the overall cost drivers of average unit cost pricing—i.e., prescription drug pricing, transparency, and copay coupons—and utilization; i.e., non-adherence, polypharmacy, and direct-to-consumer advertising.

Prescription Drug Pricing

Estimates of drug development costs vary widely, but estimates of the out-of-pocket cost of developing a single drug range from about \$350 million⁷⁹ to \$5 billion.⁸⁰ The inclusion of research and development costs increases the single-drug development cost substantially, as less than 10% of drugs entering Phase I clinical trials make it to market.⁸¹ As basic financial principles apply, taking greater risk requires greater return. In order to encourage innovation, the U.S. federal government has designed laws to encourage such innovation.

Patents and exclusivity are mechanisms that the U.S. uses to protect the pharmaceutical research and development investment. These laws allow a manufacturer to be the sole producer of a drug for a period of time following approval. Without competition, manufacturers receive the financial reward of all sales during this period. The exclusivity period varies due to eligibility and timing of protections, but the average market single-source period for newly approved drugs is over 12 years.⁸²

While exclusivity encourages innovation and drug development, it also allows for the manufacturer to have pricing power. There is not an agreed-upon formula or approach for how drugs are priced. Drugs are not priced to simply recoup the cost of the drug. There is no evidence of an association between research and development costs and prices.⁸³ Instead, drugs may be priced at what the manufacturer determines to be the highest price the market is willing to bear, potentially considering the value of the quality of life as a result of the treatment and other market factors.

In addition to research and development, production, and the size of the market; for pricing purposes, manufacturers consider the price of other therapies for the treatment of a condition,

⁷⁹ Herper, M., 2013. "The Cost of Creating A New Drug Now \$5 Billion, Pushing Big Pharma To Change." Accessed online May 8, 2019, at www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/#24afd3e313c3.

⁸⁰ Paul, S.M., et al., 2010. "How to improve R&D productivity: the pharmaceutical industry's grand challenge," *Nature Reviews Drug Discovery* 9(3): 203–14. Accessed online May 8, 2019, at www.nature.com/articles/nrd3078.

⁸¹ *BIO Industry Analysis*, 2016. "Clinical Development Success Rates 2006–2015." Accessed online May 8, 2019, at www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf. Drug development moves through several phases beginning with Phase I clinical trials (primarily safety testing) to Phase II (efficacy testing), Phase III trials (comparison of safety and effectiveness to existing treatments) and finally New Drug Application or Biologic License Application and Phase IV testing (to answer any remaining questions in a large-scale trial) before finally coming to market.

⁸² Kesselheim, A.S., 2017. "Determinants of Market Exclusivity for Prescription Drugs in the United States," *The Commonwealth Fund*. Accessed online May 8, 2019, at www.commonwealthfund.org/publications/journal-article/2017/sep/determinants-market-exclusivity-prescription-drugs-united_

⁸³ Kesselheim, A.S., J. Avorn, and A. Sarpatwari, 2016. "The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform," *Journal of the American Medical Association (JAMA)*. Accessed online May 8, 2019, at www.ncbi.nlm.nih.gov/pubmed/27552619_

how the drug compares to other available treatments, which drugs are in their pipeline to use as a source of capital for future innovation, and insurer willingness to pay for the drug.⁸⁴

Once the patent or exclusivity of a drug expires, generics can enter the market. The entry of a single generic equivalent typically has little effect on the price of a drug, as the generic manufacturer will often shadow-price the brand drug. However, a second entrant tends to decrease the price of the drug by nearly half (52%), and additional entrants may decrease the price of the drug down to 20% or less of the original brand drug.⁸⁵

The average price of physician-administered drugs decreases by 38–48% following patent expiration, and oral drugs decrease by about 25% on average.⁸⁶ In order to avoid the release of a generic version of the drug, manufacturers employ tactics to retain market exclusivity. These tactics include, but are not limited to, ever-greening their patents, paying a generic manufacturer to forestall the release of a generic version of a drug, paying to settle a lawsuit challenging brand drug patents, and not providing samples of the drug to generic manufacturers for bioequivalence testing.⁸⁷ Interestingly, though, it is common for the price of brand drugs to increase upon patent expiration, limiting the overall reduction in average price.⁸⁸

PBMs and payers frequently use the Institute for Clinical and Economic Review (ICER) reports to support their formulary decisions; although, they are not required to do so. ICER is an independent research organization that researches the clinical and economic value of drugs. ICER reviews treatments from a clinical perspective and determines a value-based price of the drug, taking the price per quality-adjusted life year (QALY) and the short-term budget impact into account. Different value frameworks are applied for rare diseases and curative therapies. In a 2016 America's Health Insurance Plans (AHIP) survey, 73% of respondents used ICER reports to evaluate current and/or planned coverage policies.⁸⁹ CVS recently announced that it will allow

⁸⁴ Vokinger, K.N., et al., 2017. "Strategies That Delay Market Entry of Generic Drugs," *JAMA Intern Med*. Accessed online May 8, 2019, at www.ncbi.nlm.nih.gov/pubmed/28975217.

⁸⁵ FDA, 2017. "Generic Competition and Drug Prices." Accessed online May 8, 2019, at www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

⁸⁶ Conti, R.M., and E.R. Berndt, 2014. "Specialty drug prices and utilization after loss of U.S. patent exclusivity, 2001–2007," *National Bureau of Economics Research (NBER) Working Paper No. 20016*.

⁸⁷ Vokinger, K.N. et al., op cit.

⁸⁸ NBER. "Patent Expiration and Pharmaceutical Prices." Accessed online May 8, 2019, at www.nber.org/digest/sep14/w20016.html.

⁸⁹ ICER, 2017. "Survey Highlights Health Plan Use of ICER Reports." Accessed online May 8, 2019, at <https://icer-review.org/blog/ahip-survey/>.

its clients to exclude drugs with launch prices greater than \$100,000 per QALY based on the ICER pricing.⁹⁰

Further, the economics of drug pricing becomes increasingly complex as advancements in curative therapies are made. Many of these therapies significantly improve a patient's quality of life and/or reduce the patient's lifetime financial burden. These drugs come with a high price tag. Although the drugs may represent a great value compared to the lifelong financial burden of the disease, they have a very expensive up-front cost. The highly reported hepatitis C drugs, Sovaldi and Harvoni, initially carrying price tags of \$95,500 and \$84,000 for a 12-week regimen, respectively, fall into this drug class category.⁹¹ Insurers have short one-year cycles for their members, and the cost of these drugs will not likely be recouped by the insurance company in annual premiums.

A new drug targeted at spinal muscular atrophy is expected to cost \$2 million for the one-time treatment.⁹² There is growing discussion surrounding how these expensive therapies will be financed in the future.

Transparency

The published list price is rarely the price that is paid by consumers. A long chain of entities is involved in getting the drugs from the manufacturers to the patients. Manufacturers sell drugs to wholesalers. Wholesalers sell to pharmacies. PBMs negotiate prices between pharmacies and insurers. Insurers are the financial intermediaries between patients and pharmacies. There are negotiations and discounts along the way with each intermediate transaction.

To incentivize sales, manufacturers offer brand drug rebates to PBMs to receive favorable positions or preferred status on drug list formularies. PBMs pass some of the rebates along to the insurance company. However, drug rebate amounts and how they are divided among parties are often unknown.

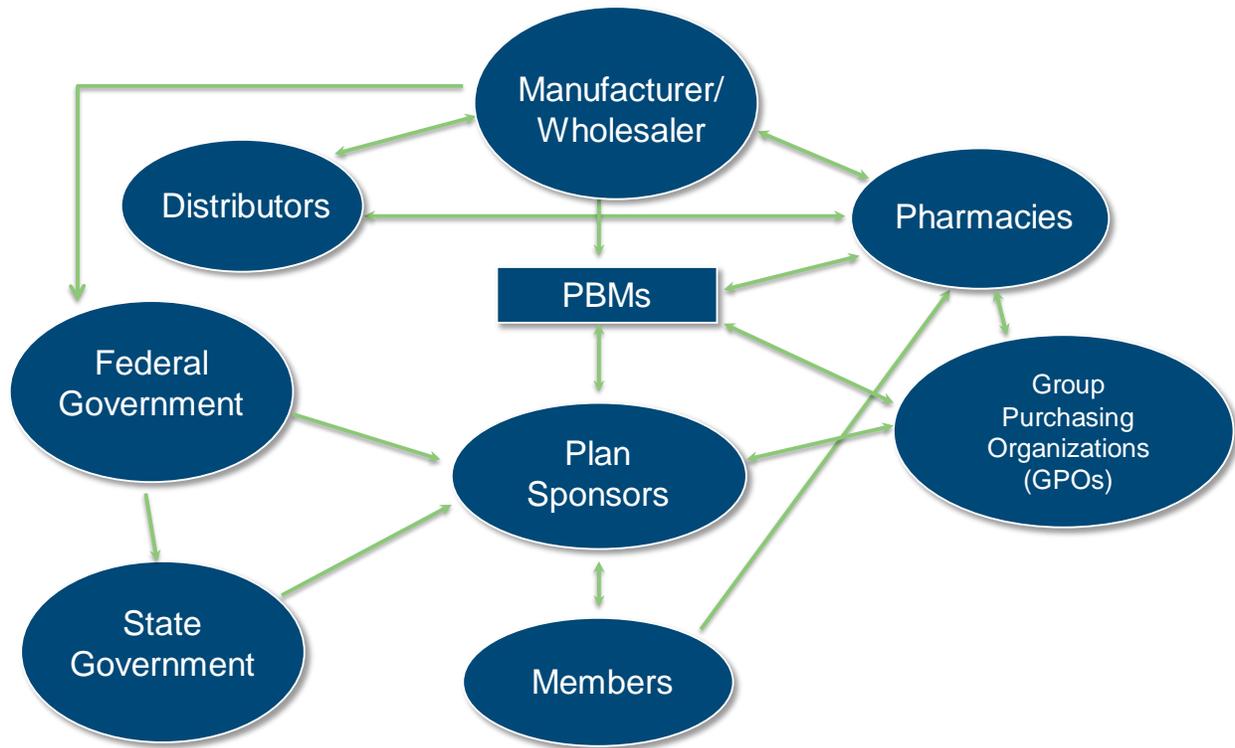
⁹⁰ CVS, 2018. "Current and New Approaches to Making Drugs More Affordable." Accessed online May 8, 2019, at <https://cvshhealth.com/sites/default/files/cvs-health-current-and-new-approaches-to-making-drugs-more-affordable.pdf>.

⁹¹ Sifferlin, A., 2015. "CVS to Cover Expensive Hepatitis C Drugs," *Time*. Accessed online May 8, 2019, at <http://time.com/3654118/hepatitis-c-drug-harvoni-sovaldi-cvs>.

⁹² Roland, D., 2019. "A \$2 Million Drug Is About to Hit the Market," *The Wall Street Journal*. Accessed online May 8, 2019, at www.wsj.com/articles/a-2-million-drug-is-about-to-hit-the-market-11557221401.

Figure 1, below, summarizes the drug benefit dollar flow.

Figure 1: Drug Benefit Dollar Flow



The non-transparent pricing structure can result in misaligned cost reduction incentives. The patient's cost-sharing amount is applied to the gross value of the drug. In some cases, with the patient's cost-sharing and the rebate received, the payer could receive payments greater than the liability. In this situation, it is in the payer's financial best interest to steer the patient toward the more expensive brand drug than a less costly generic or alternative brand drug.

Copay Coupons

In most cases, insurers encourage the utilization of the lowest-cost drug using formularies and a tiered cost-sharing. Generics have the lowest member cost-sharing, and specialty drugs have the highest. Brand drugs fall between these two endpoints.

To circumvent insurers' strategy to lower costs using tiered patient cost-sharing, manufacturers provide commercially insured patients with copay cards or coupons for brand or specialty drugs. These coupons reduce or eliminate patient cost-sharing, sometimes even making their brand drug more affordable to the patient at the point of sale than a lower-cost alternative. Overall, it

is estimated that approximately half of all drugs with a copay coupon have a lower-cost alternative.⁹³ By paying a small portion of the total cost of the drug through copay cards or coupons, a manufacturer is able to increase the utilization of its drug, thus increasing the total revenue.

Non-Adherence

Medication non-adherence can result in serious health complications, including death. It is estimated that 20–30% of prescriptions go unfilled, and 50% of prescriptions for chronic conditions are not taken according to their prescribing orders.⁹⁴ Non-adherence can also result in significant health care spending waste, including avoidable prescription drug spending.⁹⁵ A variety of reasons, including financial, medical, or knowledge-based reasons may cause a patient to be non-adherent.

Patients may not have the knowledge, motivation or resources to follow the prescription orders from their providers.⁹⁶ In these cases, patients may think they are adhering to their prescribing orders when in fact they are overutilizing or underutilizing their medications. Some medications also have side effects, such as nausea and insomnia, which may cause patients to reduce doses or even stop treatment altogether. Some diseases, like heart disease, do not have prominent symptoms; as a result, some patients stop taking their prescriptions because they do not see a visible benefit from the medication. Finally, many patients are not able to afford their medications. As a result, patients may skip doses or take partial doses in order to make prescriptions last longer.⁹⁷ No matter the cause of medication non-adherence, the result is usually detrimental to the patient's health. Medication non-adherence can result in increased emergency and inpatient (IP) utilization, which increases health care costs. Spending on prescription drugs that are not taken or not taken properly, is a source of waste related to prescription drug spending, and this can lead to overspending on prescription drugs.

⁹³ Van Nuys, K., et al., 2018. "A Perspective on Prescription Drug Copayment Coupons," *USC Schaeffer*. Accessed online May 8, 2019, at https://healthpolicy.usc.edu/wp-content/uploads/2018/02/2018.02_Prescription20Copay20Coupons20White20Paper_Final-1.pdf

⁹⁴ Brody, J.E., 2017. "The Cost of Not Taking Your Medicine," *New York Times*. Accessed online May 8, 2019, at www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html?rref=collection%2Fsectioncollection%2Fhealth&action=click&contentCollection=health®ion=stream&module=stream_unit&version=latest&contentPlacement=1&pgtype=sectionfront&_r=1.

⁹⁵ Ibid.

⁹⁶ Alloway, R.R. "Non-Adherence: Definitions – Monitoring – Prevention/Maintenance," University of Cincinnati. Accessed online May 8, 2019, at <https://www.fda.gov/downloads/Drugs/NewsEvents/UCM551735.pdf>.

⁹⁷ Cohen, R.A., W.K. Kirzinger, and R.M. Gindi, 2013. "Strategies Used by Adults to Reduce Their Prescription Drug Costs," *National Center for Health Statistics (NCHS) Data Brief*. Accessed online May 8, 2019, at www.cdc.gov/nchs/data/databriefs/db119.pdf.

Polypharmacy

Polypharmacy is the use of multiple, commonly five or more, prescriptions concurrently. While it is most common in the elderly population, polypharmacy is also associated with certain segments of the non-elderly population, such as adults with intellectual disability or psychiatric disorders. Most studies regarding the risks and implications of polypharmacy have been done on the elderly population. There is a high likelihood of drug interactions and adverse drug events. A team approach of doctors, nurses and pharmacists, as well as caretakers, has shown promising results.

Direct-to-Consumer Advertising

Pharmaceutical direct-to-consumer advertising is only legal in the U.S. and New Zealand. Pharmaceutical companies spent more than \$3 billion in direct-to-consumer advertising in the U.S. in 2012. There is wide agreement that direct-to-consumer advertising increases prescription drug utilization. Of course, for some patients, gaining access to a prescription drug they have seen advertised may improve their health and prevent higher future medical costs. However, it may also be that direct-to-consumer advertising can lead to unnecessary utilization and/or using higher-cost brand drugs over generic alternatives. The actual impact is difficult to quantify.

Opioids

According to the 2012 National Health Interview Survey (NHIS), over 25 million Americans suffer from daily chronic pain. In the early 2000s, opioid analgesics were increasingly seen as a solution to perceived undertreatment that occurred during the 1990s for those suffering from pain. In 1991, 76 million prescriptions for opioids were filled at U.S. retail pharmacies; in 2011, that number had grown to 219 million.⁹⁸ It is estimated that 1.7 million Americans have a substance use disorder (SUD) involving prescription opioids, and an additional almost 626,000 Americans have an SUD involving heroin.⁹⁹

While the number of opioid prescriptions has fallen since 2011, the number of deaths and the cost of treating opioid use disorder (OUD) have continued to climb. In 2012, 81.3 opioid prescriptions were written per 100 persons, and 8.3 of them were considered high-dosage; by 2016, the numbers were 66.5 prescriptions per 100 persons and 6.1 considered high-dosage, respectively, with continued declines in 2017.¹⁰⁰ According to the Centers for Disease Control

⁹⁸ Davenport, S., and K. Matthews, 2018. "Opioid use disorder in the United States: Diagnosed prevalence by payer, age, sex, and state," *Milliman White Paper*. Accessed online May 8, 2019, at www.milliman.com/insight/2018/Opioid-use-disorder-in-the-United-States-Diagnosed-prevalence-by-payer--age--sex--and-state/.

⁹⁹ Kaiser Family Foundation (KFF), 2018. "Medicaid's Role in Addressing the Opioid Epidemic," *Infographic*. Accessed online May 8, 2019, at www.kff.org/infographic/medicaids-role-in-addressing-opioid-epidemic/.

¹⁰⁰ Centers for Disease Control and Prevention (CDC), "Prescription Opioid Data." Accessed online at www.cdc.gov/drugoverdose/data/prescribing.html.

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and Prevention (CDC), there were 63,632 drug overdose deaths in the U.S. in 2016, a 21% increase from 2015. Of these, 42,249 were classified as opioid deaths,¹⁰¹ an increase of 28% over 2015.¹⁰² Prescription opioids were involved in 17,087¹⁰³ deaths; heroin in 15,469¹⁰⁴ deaths; and synthetic opioids, including fentanyl, in 19,413¹⁰⁵ deaths (the total is greater than the reported total due to some deaths resulting from multiple types of opioids, such as heroin combined with fentanyl.) As awareness of the rising opioid death rate grew and access to opioid prescriptions became more difficult, many people with OUDs substituted heroin or synthetic opioids, such as fentanyl, for oxycodone and hydrocodone. While deaths from prescription opioids increased by 59% from 2008 to 2016, the increases for heroin and synthetic opioids over the same period were 409% and 742%, respectively.¹⁰⁶

Opioid Utilization/Abuse Metrics

Looking at the statistics from the perspective of insurance coverage, among people who are commercially insured, the diagnosed prevalence rate for opioid misuse was 3.28 per 1,000 persons; for the Medicare population, 5.39 per 1,000 persons; and for those with Medicaid, 8.9 per 1,000 persons. Across all insurance types, the prevalence of diagnosed opioid misuse is 4.91 per 1,000 persons.¹⁰⁷ However, researchers estimate that there are 5.5–9.4 times as many people without a diagnosed OUD as there are with a diagnosis, who have opioid use levels exceeding key usage thresholds, such as a 360-day supply of pills or prescriptions totaling 200 morphine milligram equivalents per day across the full year.¹⁰⁸

In 2016, an estimated 29% of adults with opioid addiction received any treatment, with 16% receiving IP treatment and 25% receiving outpatient treatment. These numbers were higher for those with Medicaid coverage (43% total and 24% for IP) and lower for those with commercial insurance and the uninsured.¹⁰⁹

¹⁰¹ CDC, “Drug Overdose Deaths.” Accessed online at www.cdc.gov/drugoverdose/data/statedeaths.html.

¹⁰² Davenport, S., and K. Matthews, op cit.

¹⁰³ Ibid.

¹⁰⁴ CDC, “Heroin Overdose Deaths.” Accessed online at www.cdc.gov/drugoverdose/data/heroin.html.

¹⁰⁵ CDC, “Synthetic Opioid Overdose Data.” Accessed online at <https://www.cdc.gov/drugoverdose/data/fentanyl.html>.

¹⁰⁶ Medicaid’s Role in Addressing the Opioid Epidemic, op cit.

¹⁰⁷ Davenport, S. and K. Matthews, op cit.

¹⁰⁸ Davenport, S., A. Weaver, and M. Caverly, 2018. “Opioid prescription drug patterns in diagnosed and non-diagnosed opioid use disorder populations,” *Milliman White Paper*. Accessed online May 8, 2019, at <http://us.milliman.com/uploadedFiles/insight/2018/opioid-prescription-patterns.pdf>.

¹⁰⁹ Orgera, K., and J. Tolbert, 2018. “The Opioid Epidemic and Medicaid’s Role in Facilitating Access to Treatment,” *KFF Issue Brief*. Accessed online May 8, 2019, at www.kff.org/medicaid/issue-brief/the-opioid-epidemic-and-medicaids-role-in-facilitating-access-to-treatment/.

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Total commercial spending in 2016 on opioid prescriptions was \$1.4 billion, down from \$1.9 billion in 2009. About 19% of this was paid out-of-pocket by members. Also, in 2016, total spending on opioid addiction and overdose treatments was \$2.6 billion, with \$300 million paid out-of-pocket. This compares to \$646 million in spending on addiction and overdose treatments in 2009. As with the addiction and mortality patterns noted above, most spending on overdoses and addiction is for members in the age group of 18–34, and it is higher for males than females. Of the total commercial spending, 53% is for children of employees, 18% for employee spouses, and 29% for employees themselves.

Curbing Prescription Drug Costs: Current and Potential Actions

Current State Initiatives

The following are some of the recent actions the states have taken to combat the high prescription drug cost trend.

Drug Price Transparency

As of 2018, six states (California, Connecticut, Maine, Nevada, Oregon and Vermont) have passed legislation requiring drug manufacturers to justify price increases over certain thresholds. Several states have explored imposing penalties if the price increases are excessive, Maryland became the first state to pass such a law

Louisiana proposed a regulation that required drug sales representatives to disclose the price of the drug during sales discussions at physicians' offices. However, this regulation did not pass.

Drug Importation

In 2018, Vermont became the first state to pass a drug importation bill to import wholesale prescription drugs from Canada. Several steps remain before the program can go into effect, including securing federal approval and providing a funding mechanism for the program. The law applies to 17 high-impact products, excluding biologics or infused products. The law is expected to only be implemented for commercial plans, as Medicaid drug prices are typically lower than prescription drug prices in Canada.

Generic Drugs

Maine implemented legislation requiring brand drug manufacturers to make samples of drugs available to generic drug manufacturers with the intention of shortening time until a generic becomes available.

PBMs

At least 25 states, including California and Connecticut, have implemented laws aimed at more transparency regarding drug rebates and other concessions.

From these recent state actions, we see that the primary focus of the legislative actions is generally on either the transparency of drug prices and/or the cost increases in drug prices. While this is certainly a step forward, it is unlikely that transparency alone will have a significant impact on the high prescription drug costs in the U.S.

Other Potential Actions

The following actions may be part of an effort to balance the goals of keeping insurance affordable while providing high quality of care.

Value-Based Contracts

The pharmaceutical industry is facing increasing public pressure over the prices and value of their products.¹¹⁰ Fee-for-service (FFS), the current arrangement under which most pharmaceuticals are currently reimbursed, is no longer perceived as providing value. These traditional financial arrangements are also not likely to be financially sustainable, given the already large share of the economy consumed by health care.¹¹¹ As a result, insurers and pharmaceutical manufacturers are beginning to explore alternative contracting arrangements, including value-based contracts.

Value-based contracts are nontraditional payment arrangements that aim to reduce costs and improve patient outcomes. These arrangements facilitate the sharing of risk between pharmaceutical manufacturers and payers for patients' treatment costs and outcomes. They also align incentives between payer and pharmaceutical interests with financial and other advantages for both parties.

The definition of value is different for each stakeholder. For some, value is primarily qualitative—better patient outcomes, high patient satisfaction, and a positive societal impact. For others, value is primarily quantitative—drug cost effectiveness and enhanced reimbursement for a given product.

There are three main approaches of value-based contracts: 1) financial contracts; 2) adherence contracts; and 3) outcomes contracts. All three value-based contract approaches have their

¹¹⁰ Pollack, A., 2015. "Drug Prices Soar, Prompting Calls for Justification." Accessed online at www.nytimes.com/2015/07/23/business/drug-companies-pushed-from-far-and-wide-to-explain-high-prices.html.

¹¹¹ Hartman, M., et al., 2017. "National Health Care Spending In 2016: Spending And Enrollment Growth Slow After Initial Coverage Expansions." Accessed online at www.healthaffairs.org/doi/10.1377/hlthaff.2017.1299.

purpose, and the type of value-based contract used will depend on the drug and goals of the contract (e.g., better patient outcomes, cost containment, etc.). Table 3 provides more information on these categories of value-based contracts and examples of how they can be utilized in practice.

Table 3: Value-Based Contracts

Source: Value-Based Contracting for Pharmaceuticals and Device Manufacturers¹¹²

Approach	Type	Example
Financial	Aggregate Patient Utilization Cap	PBM does not pay for macular degeneration drug scripts after patients hit the preset average cap of seven scripts.
	Free or Discounted Scripts	Health plan does not pay for a patient’s irritable bowel syndrome (IBS) drug scripts if that patient stops taking the drug within three months of starting treatment.
	Individual Patient Utilization	PBM does not pay for macular degeneration drug scripts after patients hit the preset individual cap of 10 scripts.
	Per Member Per Month (PMPM) Contracting	Health plan pays a fixed PMPM for a portfolio of heart failure drugs produced by the manufacturer, which allows patients to receive as many scripts as necessary.
	Regimen-Based Pricing	Two lung cancer drugs that are supposed to be taken together are priced lower if purchased in a bundle versus individually.
Adherence	Daily Average Consumption (DACON)	Manufacturer of an insulin drug pays a lower rebate if the DACON is less than the maximum units per day on the label.
	Medication Possession Ratio (MPR)	Manufacturer of a heart medication pays a lower rebate if 80% of patients have an MPR of at least 80% in a given year.
	Persistency	Manufacturer of a diabetes drug pays a lower rebate if 80% of new patients fill a script at least 180 days after the first script.
	Proportion of Days Covered (PDC)	Manufacturer of a blood pressure medication pays a lower rebate if 80% of patients have a PDC of at least 80% in a given year.

¹¹² Dieguez, G., and M. Alston, 2017. “Value-Based Contracting for Drugs and Medical Devices,” *Society of Actuaries (SOA)*. Accessed online May 8, 2019, at www.soa.org/globalassets/assets/files/e-business/pd/events/2017/annual-meeting/pd-2017-10-annual-session-181.pdf.

Approach	Type	Example
	Scripts Per Patient	Manufacturer of an HIV drug pays an additional rebate for each patient who uses more than seven scripts in a given year.
Outcomes	Absolute Outcomes Targets	Manufacturer of an antidiabetic drug pays an additional rebate if the average HbA1C level for eligible patients was above 8.0.
	Event Metrics	Manufacturer of a cholesterol-lowering drug pays an additional rebate if more than 10% of eligible patients experienced a myocardial infarction.
	Head-to-Head	Insurer does not pay for diabetes medication if patients do not experience lower HbA1c levels in comparison to patients on a competing product.
	Non-Response Metrics	PBM does not pay for a patient's weight-loss medication if they do not lose 3% of their body weight after three months of treatment.
	Proportion of Patients Reaching a Target	Manufacturer of an antihypertension drug pays an additional rebate if less than 75% percent of eligible patients reached their target blood pressure.
	Utilization Metrics	Manufacturer of a multiple sclerosis drug pays an additional rebate if eligible patients did not have a 5% decrease in hospital admissions

Value-based contracts are likely more prevalent than they appear to be because contracts are often not announced publicly. To date, 40 value-based contracts have been announced publicly in the U.S. since 2015.¹¹³ These contracts have included 15 payers, 17 disease areas, and 16 pharmaceutical manufacturers. Harvard Pilgrim has announced 10 value-based contracts that cover nine disease areas, including diabetes, multiple sclerosis, rheumatoid arthritis and retinal disease. Other key payers include Cigna, which has announced five value-based contracts, as well as Prime Therapeutics and Express Scripts, which have both announced three value-based contracts. In terms of pharmaceutical manufacturers, AstraZeneca has engaged in the most value-based contracts (six), followed by Amgen with five, and Novartis and Biogen with four each.¹¹⁴

¹¹³ Pharmaceutical Research and Manufacturers of America (PhRMA), 2018. "Value-Based Contracts: 2009 – Q3 2018." Accessed online May 8, 2019, at http://phrma-docs.phrma.org/files/dmfile/PhRMA_ValueBasedContracts_Q3.pdf.

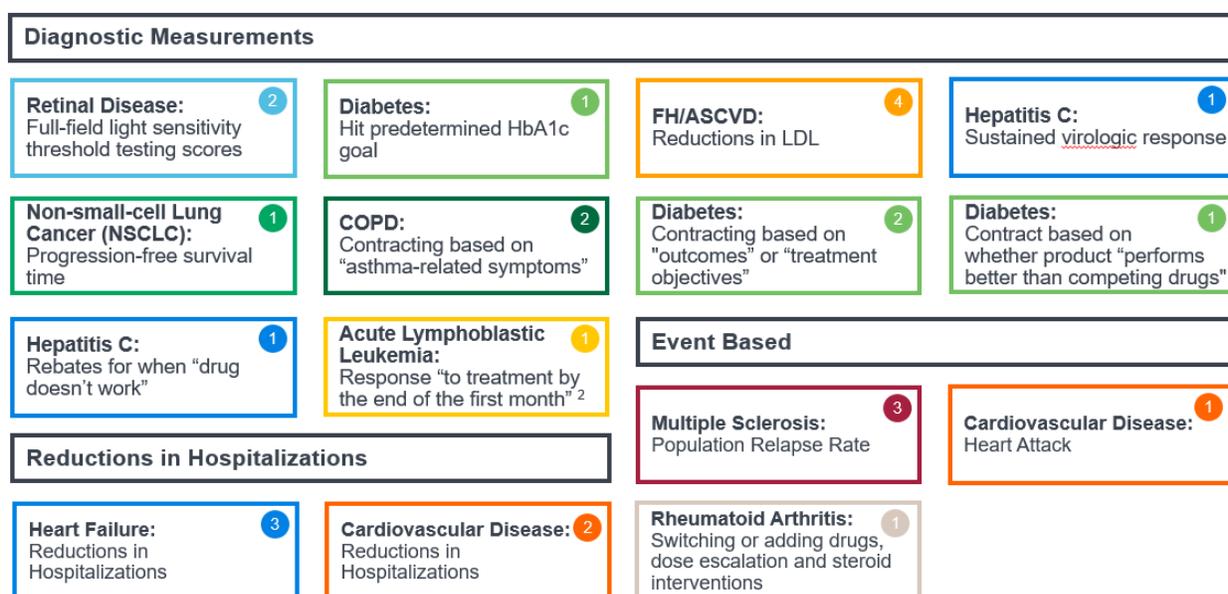
¹¹⁴ Ibid.

Most value-based contracts cover chronic disease areas, with lots of competition, and rare disease areas, with high-cost drugs. Diabetes and high cholesterol (atherosclerotic cardiovascular disease and familial hypercholesterolemia) have the most value-based contracts (six each). Contracts for these diseases include outcomes and total cost of care. There have also been value-based contracts for cancer, particularly non-small-cell lung cancer, lung cancer, and acute lymphoblastic leukemia.

Outcomes contracts are by far the most common type of value-based contract, of those that have been publicly announced, with 26 arrangements. These outcomes contracts cover a wide range of topics because they are product-specific and disease-specific, but the most common outcomes metrics include reductions in hospitalizations, reductions in low-density lipoproteins (LDLs) for high cholesterol or HbA1c for diabetes, and “comparison to clinical trials.” See Figure 2 for a breakdown of the outcomes-based metrics announced to date.

Figure 2: Outcomes-Based Contract Metrics in Publicly Announced Contracts

Source: Pharmaceutical Research and Manufacturers of America (PhRMA) Value-Based Contracts: 2009 – Q3 2018



Some value-based contracts combine more than one contract type. For example, a value-based contract may have an outcomes component and a PMPM component. Combining contract types allows a contract to cover multiple stakeholder interests and potential concerns; i.e., patient compliance and overall costs. To date, three types of combined value-based contracts have been publicized: adherence and utilization cap, outcomes and adherence, and outcomes and utilization cap.

Value-based contracts are more nuanced and resource-intensive than traditional FFS contracts. Logistical challenges that value-based contracts face include data availability for patient attribution, setting spending and outcomes targets, and measuring outcomes.

Payers and pharmaceutical manufacturers are likely trying to accomplish different goals through a value-based contract. As a result, they may differ on their desired parameters for a given contract, such as patient eligibility and outcome measurement. While payers and pharmaceutical manufacturers work out the details of these parameters, they also need to consider data availability and how the data supporting the value-based contract will be collected, processed and analyzed.

Metrics in clinical trials may only be available via electronic medical records or manual chart reviews, which could have a significant impact on the number of patients in a value-based contract and, therefore, the contracts' overall viability. If value-based contracts are resource-intensive and have small sample sizes, the cost of administering them may be higher than the dollars at stake in the contract.

A more cost-effective data option for value-based contracts could be using proxy metrics (e.g., reductions in unplanned hospitalizations) that are available in administrative claims data. Administrative claims and beneficiary data are already used by payers, so systems are already in place to extract, vet and process the data. These processes would also allow for more patients to be included in a contract because this information is available for all paid transactions for a payer's patient population.

Regardless of the type of data used to execute a value-based contract, personal health information (PHI) will be used; therefore, processes will need to be set up in order to protect this data. This issue will be particularly important for pharmaceutical manufacturers, whose contracting departments typically do not work with PHI.

Value-based contracts currently face several potential regulatory hurdles, including Medicaid terms for best price, average sales price (ASP), rebate reporting, and 340B ceiling price.¹¹⁵ These challenges are primarily faced by pharmaceutical manufacturers, and they could have implications for large portions of their business operations, not just those in the value-based contract.

Below is a summary of the impact of value-based contracts on several key regulations that affect pharmaceutical manufacturers:

¹¹⁵ Dieguez, G., and M. Alston, op cit.

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- ASP, which is used to reimburse providers for Medicare Part B drugs, could be reduced, which would impact all providers, not just those participating in a value-based contract.
- Medicaid best price, which allows state Medicaid agencies to purchase drugs at the lowest price available, could be reset to a new, lower amount.
- 340B ceiling price, which is used to provide outpatient drugs at significantly reduced prices to safety net hospitals and other covered entities in Medicaid, could be reset to a new, lower rebate.
- Any discounts that result in a new 340B ceiling price.
- Coverage and formulary requirements under state and federal requirements, such as state mandated preferred drug lists, Medicare Part D, and the federal Affordable Care Act (ACA).

Federal anti-fraud policies, based on the federal Anti-Kickback Statute, prohibit offering or receiving remuneration to induce or reward referrals for items or services paid for by federal health care programs.¹¹⁶ Stark Law prohibits physicians from referring patients for items or services reimbursable by the federal government to a health care entity with which the physician has a financial relationship. There is some concern that value-based contracts could be seen as remuneration to encourage favorable formulary placement and access. In particular, if a physician were to enter into a value-based contract where reimbursements were tied to the performance of a drug they prescribe, then prescribing that drug to a Medicare or Medicaid patient could potentially be a violation of these laws. At this time, the Office of Inspector General (OIG) has not issued guidance on this subject.

Finally, there is concern that value-based contracts could promote the off-label use of drugs. This is particularly a concern for oncology products and in pediatrics where drugs can be prescribed outside of label indications.

The number of value-based contracts will likely increase in the coming years as payers and pharmaceutical manufacturers continue to look for ways to demonstrate “value” and contain costs. In a recent speech, the U.S. Department of Health and Human Services (HHS) Secretary Alex Azar stated that value-based contracts would be a part of a "multifactor solution" to address high drug costs.¹¹⁷ During this speech, Mr. Azar also voiced support for allowing pathways for manufacturers to offer value-based contracts.

¹¹⁶ Dieguez, G., and M. Alston, op cit.

¹¹⁷ Azar speech.

However, not all value-based contracts will be successful, such as the canceled Centers for Medicare & Medicaid Services (CMS) pilot for Kymriah.¹¹⁸ Still, the CMS has indicated that it is interested in pursuing value-based contracts. In particular, the Center for Medicare & Medicaid Innovation (CMMI) expects to begin demonstration models in the near future.¹¹⁹ It is clear that payers and pharmaceutical manufacturers are still testing value-based contracts and there are still a lot of obstacles to overcome in order to make these arrangements sustainable. Part of this learning curve comes from the need to understand what can be measured through a contract in a cost-effective manner. The other key component is ensuring transparency about which regulations apply to value-based contracts.

As the health care industry moves from paying for volume to paying for value, the pharmaceutical industry will likely need to follow suit. These contracts are complex, and measurement can be challenging. However, support for value-based contracts has the potential to more effectively spend our health care dollars as well as improve outcomes.

Reporting

While this paper has focused on prescription drugs, the total cost of care is the most important value. In many cases, the increased cost of prescription drugs may lead to a reduction in medical costs, as well as improved outcomes. This is difficult to assess by standard utilization and average unit cost reports. Measurements over time by chronic condition may be more meaningful to understand the interaction of medical and prescription drug costs. While it may be unrealistic to report on all chronic conditions, reporting on high cost and/or high prevalence conditions can provide additional insight.

Innovations

Many organizations are interested in evaluating medication adherence as a way to assess patients' health care. Optimal adherence varies by medication, and the best way to measure adherence will vary depending on how the medication is administered. Patient medication adherence can be measured in several indirect ways. Some examples include PDC, MPR and persistency. These adherence measures have been included in value-based contracts, and they are also included in the Consumer Assessment of Health Plans Survey (CAHPS) and Medicare star ratings.

¹¹⁸ Sagonowsky, E., 2018. "CMS quietly cancels plan for indication-based pricing on Novartis's Kymriah," *FiercePharma*. Accessed online May 8, 2019, at www.fiercepharma.com/pharma/cms-cancels-value-based-pricing-plan-novartis-kymriah-report.

¹¹⁹ Pink sheet CMMI article.

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Still, these measures only evaluate whether the patient received the medication; they do not measure whether or not the patient actually took the medication. Pharmacy processes, like 90-day prescriptions, mail prescriptions, and auto-refill prescriptions may make access to prescriptions easier, but they make measuring medication adherence more challenging because they likely result in overestimations. The only way to ensure that a patient takes a medication as prescribed is via direct observation, which is not feasible in the real world. Instead, at this time, payers and providers will have to rely on indirect measures as a way to understand patient medication adherence.

Technological advances may offer new solutions. A pill that can tell your doctor if you have taken it was approved by the FDA for the first time. Abilify MyCite is a digital pill that contains an electronic sensor that is activated upon contact with stomach fluid and sends a message to a patch worn by the patient. The system can then remotely inform the doctor (or caretaker) whether the patient is adhering to the medication.¹²⁰ Of course, privacy concerns may limit rapid adoption of this type of technological advance.

As technology improves, there may be additional tools that can be leveraged to improve non-adherence.

Direct-to-Consumer Advertising

It is apparent that direct-to-consumer advertising increases utilization. Providing consumers with more information on drugs, costs, and alternatives may be valuable educational material. Additional and higher visibility disclosures in the advertisements may moderate utilization.

Compounded Drugs

Drug compounding is a process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Compounding includes the combining of two or more drugs. Compounded drugs are not FDA-approved. Compounded drugs can be essential for patients who cannot tolerate an FDA-approved drug. For example, a patient may have an allergy to a component in a drug, such as a dye, and seek a compounded version.

Compounded drugs can often cost significantly less than the manufacturer's version. However, current regulations only allow drugs to be compounded under limited circumstances: to address a drug shortage or to meet a medical need. The FDA recently proposed taking some drug

¹²⁰ FDA, 2017. "FDA approves pill with sensor that digitally tracks if patients have ingested their medication," *News Release*. Accessed online May 8, 2019, at www.fda.gov/news-events/press-announcements/fda-approves-pill-sensor-digitally-tracks-if-patients-have-ingested-their-medication.

ingredients off the list approved for bulk compounding. Pharmaceutical companies have filed lawsuits to stop entities from compounding drugs in large volumes.

Drug compounders have grown over the years, with some able to produce large quantities of certain drugs to sell to hospitals and clinics. However, the FDA and pharmaceutical companies point out that the lack of federal scrutiny can put patient safety at risk. In 2012, there was an outbreak of fungal meningitis that killed at least 64 people who were given pain drugs mixed at a large compounding facility. Since then, certain manufacturing, quality and labeling standards have been implemented. Approximately 70 facilities are registered with the FDA to compound drugs in bulk.

One of the newest ventures seeking to sell cheaper compounded drugs is venture-backed start-up Osh's Affordable Pharmaceuticals (Osh's) of Littleton, Colorado. The company, which is marketing drugs for pulmonary arterial hypertension and rare diseases, does not bulk-produce the drugs but it says it has agreements with pharmacies in 30 states to make the low-cost versions.

Osh's markets a compounded version of Syprine, a Wilson disease treatment from Bausch Health Companies Inc. (Bausch). Syprine lists for as much as \$21,000 per month for certain patients according to wholesale-acquisition cost data from IBM Watson Health. A generic version made by Teva Pharmaceutical Industries Ltd. (Teva) costs about \$18,000.¹²¹ Osh's version will cost about \$120 for the same prescription, said founder, Dr. Alex Oshmyansky.¹²² Dr. Oshmyansky said Osh's would satisfy FDA requirements by ensuring that patients have prescriptions for a custom-made drug. Bausch and Teva declined to comment. Compounding facilities may play a role in lowering the cost of prescription drugs. However, that role will have to be balanced with patient safety regulations.

Cost Reduction Action Conclusion

A variety of tools are available to stakeholders to affect the key drivers of prescription drug costs. Increasing transparency for all stakeholders, improving information and incentives for both consumers and providers, and encouraging manufacturer competition and innovation can contribute to the goal of lowering prescription drug costs while maintaining or improving outcomes.

¹²¹ Mehr, S., 2018. "Teva's Syprine Generic Priced 14% Below Jacked Up Valeant Product Price," *Biosimilars Review & Report*. Accessed online May 8, 2019, at <https://biosimilarsrr.com/2018/02/26/tevas-syprine-generic-priced-14-below-jacked-up-valeant-product-price/>

¹²² <https://oshpharma.com/>



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Center for Insurance Policy and Research
1100 Walnut Street, Suite 1500
Kansas City, MO 64106-2197
Phone: 816-842-3600
Fax: 816-783-8175

<http://cipr.naic.org>

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