Statement for the Record  
Council for Affordable Health Coverage  
Senate Committee on Health, Education, Labor and Pensions  
Hearing on The Cost of Prescription Drugs: How the Drug Delivery System Affects What Patients Pay  
October 17, 2017
Introduction

Chairman Alexander, Ranking Member Murray, and Members of the Committee, the Council for Affordable Health Coverage (CAHC) respectfully submits this statement for the record for the Committee’s hearing on the costs of prescription drugs. Below we outline a series of reforms that would lower national health expenditures by as much as $71 billion annually when fully implemented. These benefits will accrue to taxpayers and consumers in the form of lower premiums and out of pocket costs.

CAHC is a broad-based alliance with a singular focus: bringing down the cost of health care for all Americans. Our membership reflects a broad range of interests—organizations representing insurers, PBMs, drug manufacturers, small and large employers, patient groups, consumers, and physician organizations. We run several solutions-oriented campaigns to promote affordability, including an effort to lower costs and improve patient adherence to medications.

Already, this Committee and this Congress have taken steps to lower drug costs by passing FDARA, which will help clear the backlog of drug applications at the FDA. Doing so will increase competition in the brand and generic markets and save billions for consumers. We urge you to do more by passing additional reforms that allow enhanced communications between manufacturers and payers, better benefit designs through modern insurance products, and value based arrangements in Medicare and other federal programs. We believe such market based, incentive driven changes will do more to lower costs than any government program.

Background

As health costs rise, consumers struggle to access health care coverage, services, and treatment. In fact, because costs are rising faster than wages, a dangerous gap continues to widen between health care needs and what can reasonably be afforded. Lately, many have focused on a subset of health costs for the most frequently accessed potion of health care – prescription drugs.

The current deadlock and finger pointing across industries and politicians has produced inertia that does nothing to lower costs for consumers. CAHC has brought together a cross-industry collaboration of stakeholders to break the stalemate and advance reforms that will lower costs for prescription drugs. We hope to impact the debate by educating and raising awareness about drug costs and value and by developing and advocating for a set of credible, actionable policy solutions designed to increase value in health care.

Most recognize the healthcare system is undergoing a monumental shift as payers move aggressively to reward value. CAHC supports accelerating the shift to a value based system in three specific areas:

1. **Allow more and better information sharing in designing value based payment models.** Information before and after to a drug’s approval is important in anticipating impacted populations, designing appropriate coverage and incentivizing use in relevant populations through alternative payment model design and uptake.
2. **Promote benefit design and insurance modernization.** Allowing flexibility for insurers to design plans for those with chronic illnesses or high drug needs will enhance the value of coverage, and make insurance more useful to consumers in affording their medicines.

3. **Accelerate models that pay based on value (lower costs and better outcomes) versus volume.** In such value-based systems, payment for a medicine is linked to patient outcomes, rewarding affordability and quality if certain targets are met. Uptake of these approaches have been needlessly slow for prescription drugs, hindered by laws that were built for an era that discouraged coordination and team based approaches.

As policy makers look for reforms that address rising costs of treatment, we believe any changes should be rooted in patient- and market-oriented principles that promote — not unintentionally inhibit – competition, value, innovation, and appropriate access to treatment. These solutions are outlined below.

**Communications Between Payers and Manufacturers**

Needless and avoidable uncertainty is a result of artificial barriers to communications between manufacturers and other parties both before and after approval, which negatively impacts the design of value based payment models, planning for and incorporating new drugs onto formularies, and premium setting because plans may lack the information necessary to make good determinations or to set accurate rates. It is impossible to design new value models prior to a new drug approval due to these restrictions, even though new models and protocols might help accelerate cures and lower costs.

For example, new hepatitis C treatments cure the disease. Had better information on new hepatitis C treatments been available to payers prior to approval, plans might have designed medication adherence protocols to ensure impacted plan enrollees not only accessed medicines but were assisted in completing treatment, a necessary step to curing the virus. If patients fail to complete the regimen, the money spent on treatment is wasted, the disease progresses, and premiums are likely greater for all plan enrollees. Improving communication between manufacturers and payers will thus enable better coverage determination and pricing accuracy.

Congress created a safe harbor to allow for the proactive dissemination of health care economic information by manufacturers to formulary committees or other similar entities on medications post-FDA approval. While recent FDA guidance regarding expansion of Section 114 made by 21st Century Cures has opened the door for more communication between manufacturers and payers concerning the safety, efficacy, and value of medicines, more certainty is needed for stakeholders to improve and facilitate communication, including:

1. **Create Certainty.** The FDA guidance allows the proactive communication of certain information by biopharmaceutical manufacturers to payors prior to FDA approval, but the guidance is non-binding and may be revoked or changed by FDA. Congress should formalize the standards in law.

2. **Pre-Approval Communications.** Congress should create a legislative safe harbor to clarify that economic and clinical communications pre-approval do not violate the labeling,
misbranding and intended use provisions of the FDA law. Such changes are included in legislation (H.R. 2026) introduced by Congressman Brett Guthrie (R-KY).

3. **Post-Approval Communications.** Post-approval sharing of information should be expanded to additional entities, such as population health decision makers, including those who create or operationalize value based payment arrangements and alternative payment models. These include entities that bear financial risk for patients, including payers, PBMs, ACOs and other integrated delivery networks.

Such efforts will result in lower costs by helping plans and manufacturers effectively negotiate formulary coverage and design, and creation of value based arrangements.

**Benefit Design and Insurance Modernization**

Patients are not uniform; their needs are as diverse as their diseases. Flexible benefit designs enable consumers to choose plans that best meet their health needs and budgets. Current federal and state policies limit plan flexibility and consumer choices, and fall short in leveraging the latest technology and access to data. Congress should work to enact the following reforms:

1. **Expand HSAs.** For those with chronic conditions, certain drug costs are unavoidable, such as insulin for diabetics. Federal law, however, requires Health Savings Account (HSA)-compatible health plans to impose cost-sharing requirements even for routine and predictable drug related health expenses. Allowing health plans, including consumer-directed health plans that are HSA compatible, greater benefit design flexibility to cover these expenses would improve access to medications. Insurers should be allowed to market and tailor plans to meet the needs of individuals with specific conditions or adopt VBID within HSA-compatible plans to provide first-dollar coverage of certain high-value medications and treatments, such as statins for individuals with coronary heart disease.

2. **Allow Insurance Modernization.** Some insurers have experimented with creating specialized plans that target and improve care for consumers with higher-cost conditions such as diabetes, mental health, and heart disease in the individual market. For example, a plan might have lower cost-sharing for drugs commonly used to treat depression while also incorporating mental health care coordination within its core services to help prevent comorbidities or condition deterioration. Such specialized plans can help insurers keep enrollees with higher-cost illnesses healthier, thereby positively impacting premiums while also lowering consumer out-of-pocket costs. These specialized plans are not available to consumers in states such as California or the District of Columbia that prohibit variation from rigid standardized benefit designs on their state exchanges. Policies that inhibit the design of and access to innovative benefit structures should be prohibited.

3. **Empower consumers to take charge of their health.** Consumer needs are as diverse as the treatments and plans available to them. They must have access to relevant, understandable, and actionable information to make optimal decisions about their health needs. Consumer engagement over health management, treatment decisions, and coverage selection can help improve access and adherence to treatment, slow or halt disease progression, and lower out-of-pocket and system costs. Such engagement is often difficult for both providers and
insurers to successfully accomplish, however. Strategies for engagement vary, but technology is increasingly becoming a major part of engagement solutions. Done well, these tools and data can help consumers choose plans to best meet their needs and make treatment compliance easier and communication between insurers, providers, and consumers more effective. Done poorly, however, engagement efforts can be frustrating, ineffective, and costly.

4. **Better information for consumers.** Encouraging more and better benefit designs requires effective means of communicating relevant information to consumers so that they can adequately assess how a plan might suit their individual needs. Government sites used by consumers to evaluate and learn about coverage options such as public health insurance exchanges and Medicare Plan Finder should integrate web-based support tools optimized to the consumer’s personal circumstances, considering factors such as the type of health coverage, total potential out-of-pocket costs (premiums, deductibles, and cost-sharing), eligibility for financial assistance and tax benefits, preferred providers, and prescribed medications. Information about formulary design and appeals rights should also be easily accessible and understandable. Congress ought to reexamine the value of government run information web sites, and turn to private sector options that are updated and upgraded more frequently. This helps gear sites toward consumer engagement that increases access to state of the art tools and reaches consumers that government sites may not.

**Promote Value Based Reimbursement Arrangements**

Value Based Payment Arrangements (VBAs) create payment metrics by which drug makers receive higher reimbursements when a medication has the desired therapeutic impact, and lower (or no) reimbursement if the treatment doesn’t work or work well. Despite their growing use in the private sector, federal programs and their enrollees (and the taxpayers who support them) are unable to benefit from rewarding value.

While CMS recently announced it would test paying for a high cost medicine used to treat certain pediatric and young adult patients with B-cell precursor acute lymphoblastic leukemia, CMS must use its demonstration authority to waive laws and regulations to implement this money-back guarantee payment model. Why? Federal law otherwise stands in the way of CMS lowering drug costs through more aggressive discounting or paying for a drug only if it works. The main barriers are Medicaid’s “best price” law and the anti-kickback statute. Reforms here could save billions for consumers and taxpayers and include:

1. **Reform pricing models that inhibit value-based arrangements.** Manufacturers and payers are reluctant to enter into value-based arrangements, in part, because of the challenge of squaring such innovative approaches with the inflexible complexities of rebate liabilities under Medicaid’s “best price” reporting requirements. If a manufacturer offers a discount that is below the best price threshold, it triggers Medicaid rebate liability. Manufacturers are understandably reluctant to enter into pricing arrangements that discount products below the threshold. Numerous CBO and GAO reports have documented the limiting impact the Best Price law has had on drug discounts. Additionally, other drug reporting programs also hinge reimbursement on sales prices, which compounds the chilling effect on value-based systems.
by setting artificial pricing floors. The result is that many innovative, lower cost arrangements simply are not pursued. We recommend Congress enact clear exceptions to Medicaid best price, Average Sales Price, and Average Manufacturer Price reporting be established for value-based arrangements, coupled with clear guidance to reduce current ambiguity about how to capture value-based pricing for reporting purposes.

2. **Reform Anti-Kickback restrictions.** The Anti-kickback statute prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce or reward the referral of federal health care program business. Although the law has historically been effective in capturing true misconduct, its approach has also had the unintended consequence of hampering the adoption of innovative arrangements that reward value, consumers and health care broadly. Regrettably, the Department of Health and Human Services has, thus far, provided little guidance to payers, manufacturers, providers, and other entities regarding how the Anti-Kickback laws might apply to modern value-based systems of care. This has resulted in considerable uncertainty and has impeded adoption of these arrangements. TO clarify the environment and facilitate value, Congress should create a statutory safe harbor to:

   a. Allow value-based arrangements and other innovative care models, particularly for those involving prescription drugs and biologics.
   b. Allow for medication adherence programs.

3. **Use Data and Technology.** Facilitating the use of data requires a reliable, standards-driven health information technology infrastructure that providers can use to easily report data to payers and manufacturers. Greater access to and better standardization of clinical data in electronic health records (EHRs) and claims data are essential elements in supporting value-based care. Congress should expressly exempt from the anti-kickback law investments necessary to implement a value-based pricing mechanism, including any investment in equipment and software necessary to monitor and assess compliance by a seller as reasonable and necessary to implement a VBA.

These changes will lower the costs of value-based arrangements, aid employers and payers in establishing and operating these arrangements, empower consumers to choose more efficient and effective treatments, and inform providers about the efficacy of various treatment options. These are necessary steps in the shift toward value and cost containment.

**Cost Impact**

We estimate these changes cumulatively would lower national health expenditures by as much as $71 billion annually when fully implemented.

In terms of federal cost savings between 2017 and 2026, we estimate that:

- Allowing pre-approval communication to facilitate VBAs for new drugs would save taxpayers about $860 million over the ten-year period;
- Creating a “safe harbor” or exception for VBAs from anti-kickback regulations would save approximately $1.1 billion over that period; and
Exempting VBAs from Medicaid’s “best price” rule would save more than $2 billion over the ten-year period, although some of that savings would be offset by increases in estimated Medicaid costs.

Most importantly, we believe aggressively moving to VBAs will begin to shift focus from selling pills to selling outcomes and impact the top 1 percent of drugs that account for one-third of expenditures. Ultimately, patients will benefit through dedication to therapies that work, and we believe consumers will benefit from falling premiums.

**Conclusion**

Bipartisan commitments from Congress and the White House to address drug cost and access issues have created new opportunities to promote innovation and value in prescription drug coverage, development, and access. We hope that policy makers will look to positive solutions that promote these principles rather than policies that seek to punish one stakeholder or another through greater government intervention, which will only serve to reduce innovation and hamper access to effective treatments.

While there is no one solution that will lower costs for drugs or health care more broadly, we believe the policies presented here will help put our system, and the consumers who rely on it, on a better, more sustainable path.

Already, the typical family spends 30 percent of their income on health care. If current trends continue, that family will spend more than 50 percent of their income on care within 14 years. Congress can help families avoid this future, but you must be ready and willing to act.