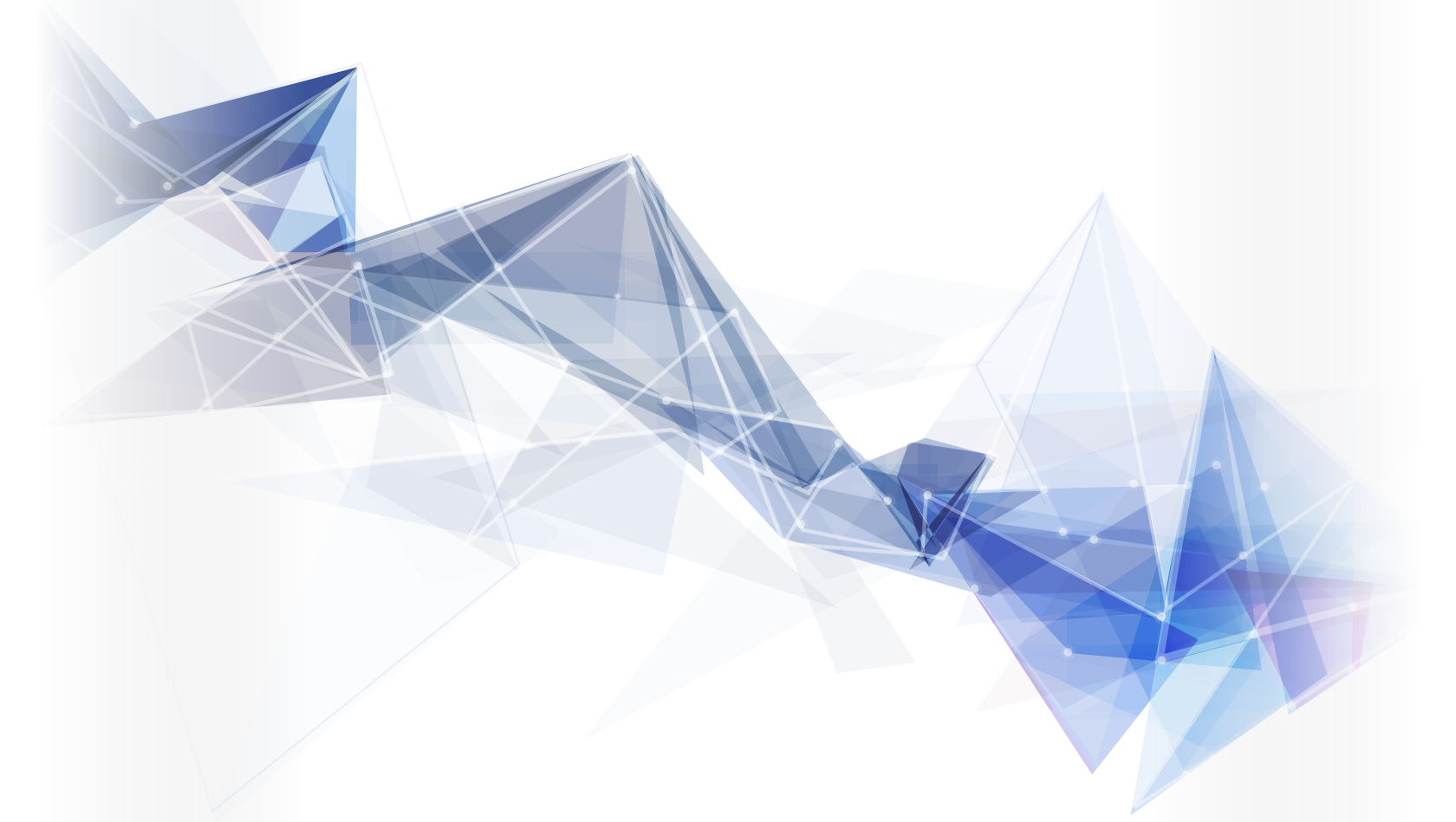
COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

Prescriptions for Competition, Value, and Innovation

Positive Reforms to Increase Access and Affordability for Prescription Drugs

Policy Proposals from the Council for Affordable Health Coverage



Introduction

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 increasing health costs for the most frequently accessed potion of health care – prescription drugs. As policy makers look for solutions to address rising costs for treatment, we believe it is important to offer new policies and incentives that are firmly rooted in patient- and market-oriented solutions to promote — not unintentionally inhibit – competition, value, innovation, and appropriate access to treatment.

For nearly two decades, the Council for Affordable Health Coverage has been laser focused on making health care more affordable for all Americans. This year, we are proposing a set of positive, common sense policy solutions to address the issues around prescription drug access and affordability.

Despite spirited debate from all areas of industry and among policy makers, we have yet to see a consensus-based effort that engages a full range of health care stakeholders who are concerned about rising drug costs and overall health care spending. The Council for Affordable Health Coverage brings together insurers, benefit managers, drug manufacturers, consumers, patients, employers, health technology organizations, and health care providers to advance reforms that 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 lower costs, improve patient access, and increase value in health care.

Through collaboration, we can build broad support for common sense solutions grounded in the principles of competitiveness and economic efficiency, leading to improved patient care and savings for the entire health care system.

Our policy solutions focus on:

- **Increasing Competition:** ***Bring more generics and brands to market to drive down costs and increase choice.***
- **Rewarding Value:** ***Reward improved outcomes and lower costs by reforming outdated laws that inhibit value-based arrangements for prescription drugs.***
- **Improving Data Infrastructure and Utilization:** ***Create better infrastructure and streamline processes needed to bring value-based arrangements and higher value treatments to market.***
- **Preserving What Works:** ***Reject policies that undermine functioning markets, hamper innovation, or jeopardize safety or access.***

Outlined below, these reforms will help increase competition in the marketplace and shift the current system of paying for drugs based on prescription drug volume and cost to one based on patient outcomes and efficiency. Collectively, these changes will save billions, lower health care premiums and out-of-pocket costs, and ensure patients have access to the treatments they need. While these solutions are not the “silver bullet” to tackle rising costs, we believe they are a positive step toward injecting greater efficiency and value into the system, ultimately lowering costs and improving access to needed therapies.

1. Increasing Competition

Consumers and the system benefit, quality improves, and greater efficiency is created when drug manufacturers compete to attract consumers. The more products on the market, the more pharmaceutical manufacturers compete for market share and better placement on plan formularies, which leads to more competitive prices. Greater competition in the pharmaceutical sector not only promotes lower out-of-pocket costs and greater treatment access and choice for consumers, but it can also increase access to health coverage through lower premiums and plan availability.

Removing barriers to bring more and better products to market, while maintaining the Food and Drug Administration's (FDA) gold standard for safety and efficacy will foster competition. Additional policies to streamline governmental processes and facilitate greater and more informed choice where patients and consumers reward market participants for higher quality and greater efficiency should be encouraged.

- ***Address communication barriers between manufacturers and payers to enable better coverage determination and pricing accuracy.*** While recent FDA guidance 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. Needless and avoidable uncertainty is a result of these polices, which negatively impacts coverage, premium setting, and formulary design because plans may lack the information needed to make coverage determinations or to set accurate rates. Clear statutory and regulatory guidelines should be established for drug manufacturers and plans to proactively communicate prior to approval, including relevant drug features, expected patient populations, dosing, and potential pricing. Information showing the full range of research outcomes – positive, negative, and inconclusive – should be confidentially shared to help drive the most accurate evaluations for a treatment. After drug approval, communication between stakeholders on information-sharing concerning clinical and economic outcomes should be encouraged and any guidelines surrounding them should also be clarified. Such efforts will result in lower costs by helping plans effectively negotiate with manufacturers and design formularies while also increasing the likelihood of less costly treatment options for patients.

- ***Improve competition through better and more efficient drug development and FDA review.*** A spate of breakthroughs in the power of tools, such as massive parallel cloud computing, super-microscopy, and new approaches to statistical analysis has opened the door to rapid gains in scientific understanding on a range of the biological processes that govern health. The drug development and review process has yet to take full advantage of these gains, however.

  Ensuring that drug developers and FDA work together to adopt new approaches that shorten the time of development and reduce the size, time, and cost of clinical trials is essential. Commitments and resources under the Prescription Drug User Fee Act can help bring consensus on innovative clinical trial design, the use of computer modeling to inform clinical studies needed for new drug approval, incorporation of patient perspectives in regulatory decisions, and the use of real world evidence for both safety and effectiveness information. Such consensus can help reduce the time it takes to move from an initial promising concept to the submission of an application to FDA and its ultimate approval.

  The cost of bringing a drug to market, which has risen significantly over the last fifteen years, slows the pace of medical improvement and innovation. FDA approval takes significant time and effort for branded, biosimilar, and generic products. For example, more than 4,300 generic drug applications, alone, await review and approval at FDA. In many cases, the resulting long approval times are attributable to the regulatory system's lack of capacity for throughput as well as inconsistent and confusing approval processes.

  While FDA has significantly improved its time and efficiency since the enactment of the Prescription Drug User Fee Act and now ranks as both more efficient and timely when compared to similar regulatory agencies in other advanced health systems, improvements are still needed, particularly in regards to consistency, clarity, and coordination with effected entities. Streamlining and speeding up the process to bring more generic and brand drugs to market can help shorten the timeframe for access to more affordable and effective treatments as plans leverage negotiating power for lower costs and manufacturers compete to bring higher quality products to market and get placement on plan formularies.

Reforms designed to speed up the approval process and decrease the time and cost to bring drugs to market include:

- Requiring more consistent and reliable review processes.
- Providing more resources to FDA for application review and approval.
- Establishing expedited timeframes for FDA review of generic and biosimilar applications.
- Creating a generic priority review voucher for products addressing medical shortages or sole-source markets that requires review and action within 150 days.
- Facilitating the use of real world evidence in product development and regulatory decisions.
- Encouraging the development and use of centralized Institutional Review Boards.
- Encouraging efficient qualification and use of validated biomarkers.
- Ensuring that innovative tools and approaches to designing and conducting clinical trials can be used to their full advantage by updating standards to reflect and translate the application of best practices and new technological developments.

2. Rewarding Value

Health care is undergoing a monumental shift as payers move to aggressively reward value defined by lower costs and better outcomes. Bundled payments, accountable care organizations, evidence-based medicine, and value-based insurance design (VBID) have become key tools in a system-wide movement away from traditional volume-based, fee-for-service payment models. In such value-based systems, payment for a service or treatment is linked to real medical outcomes, rewarding lower cost and higher quality – not quantity. Current law has inhibited this move in the prescription drug space, however.

Key reforms must be made to enable this shift toward value-based reimbursement. Ultimately, this kind of approach will more effectively encourage resources to be allocated to treatments that provide the most benefit at the lowest cost to consumers and society, enabling consumers and governments alike to make the most of their available resources.

- ***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. 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 that 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.
- ***Reform Anti-Kickback and Stark restrictions.*** The Anti-Kickback and Stark laws are intended to prevent fraudulent and abusive practices by prohibiting arrangements where organizations, individuals, and physicians could receive inappropriate payments for referring a product or service that would be paid for by federal health programs. Although the laws have historically been effective in capturing true misconduct, their broad and relatively inflexible approach has also had the unintended consequence of hampering the adoption of innovative arrangements and patient engagement efforts that can truly benefit consumers and the health care system. This is especially relevant to value-based and care coordination arrangements.

Regrettably, the Department of Health and Human Services has, thus far, provided little guidance to payers, providers, and other entities regarding how the Anti-Kickback and Stark laws might apply to modern value-based systems of care. This has resulted in considerable uncertainty and has impeded adoption of these arrangements. It is important to create and provide clarity on clear safe harbors that explicitly allow and encourage value-based arrangements and other innovative care models, particularly for those involving prescription drugs and biologics.

- ***Clarify anti-discrimination provisions.*** While anti-discrimination laws were rightly created to prevent discrimination based on health history status, these laws may also inhibit insurer ability to create VBID plan designs. VBID is a mechanism for altering cost-sharing based on higher value clinical treatments to enable and incentivize treatment adherence. For instance, biopharmaceuticals can vary widely in their effectiveness for different patients, and the benefit delivered by any given medication may also vary markedly depending on the particularities surrounding its use and patient condition. VBID can align the use of these relatively expensive and complex specialty medications with appropriate patients by basing consumer cost-sharing on a treatment's clinical value – not just negotiated rates. Current anti-discrimination rules are ambiguous as to whether these types of arrangements are permitted. Policy makers should establish clear guidelines that support VBID and similar value-based arrangements while maintaining appropriate consumer protections.

- ***Permit more flexible and better targeted benefit designs.*** 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 and better plan options. 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.

  Similarly, 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 be designed to have lower cost-sharing for drugs commonly used to treat depression and mental health providers while also incorporating care coordination for the condition within its core services to help prevent comorbidities or condition deterioration. Evidence has shown that consumers enrolled in coverage on exchanges have greater medical needs than the general population, which has resulted in an unbalanced risk pool with higher premiums and lower plan participation in most of the country. Such specialized plans can help insurers keep enrollees with higher-cost conditions healthier, 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 that can help improve health and lower consumer costs should be prohibited.

- ***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.

As payment and delivery reforms produce incentives for better value, such as through bundled payments, health care providers will seek out more effective tools to engage and educate consumers on strategies to help improve or halt disease progression. Current incentives, however, are often meager and limited to discrete programs like Medicare physician payment schedules. This must be changed to drive true system reform. More focus should be devoted to developing effective consumer engagement tools to both evaluate options and maintain an active role in treatment and prevention, including medication adherence and wellness activities. Policy makers should look to innovative pilots to test effective tools for populations that could benefit the most from engagement programs, such as lower income consumers with chronic conditions.

At the same time, focus should be given to provide consumers with the tools necessary to select optimal coverage options. 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. Unfortunately, current federal and state efforts are generally not effectively leveraging the latest technology and available data to achieve these goals.

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. Policies should be reformed to leverage innovation geared toward consumer engagement in the private sector to augment or replace government run sites when possible and appropriate to increase access to state of the art tools and reach consumers that government sites may not.

3. Improving Data Infrastructure and Utilization

Lack of consistent and readily available information is an enormous barrier to targeted treatment regimens, value-based arrangements, and other alternative payment and benefit structures. At present, value-based arrangements for drugs are difficult to implement and operate. At the same time, the savings that flow from arrangements that do get operationalized must generally be reinvested into paying for tracking and data systems used to implement and maintain the arrangement. Overhead costs related to operationalizing these arrangements can be reduced and data and measures should be improved to accurately pinpoint patients and record and track their progress and outcomes.

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. 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.

- ***Advance appropriate value measurement.*** Moving from a volume-based reimbursement system toward a valued-based one requires value to be appropriately measured and evaluated. Rapid clinical progress has outpaced our progress in measures development, however. Steps must be taken to align these two more closely or innovation and care may suffer. Greater investment and focus should be shifted toward developing appropriate outcomes measures rather than procedural measures, which tend to dominate most quality measurement systems today. At the same time, measurement systems and requirements should be updated in a timely manner and aligned across programs.

  Consumers should be a key element in determining value. Reporting and metrics that capture the consumer perspective of value should be developed and used to help inform consumer and provider decision making and evaluation of value-based arrangements. To the greatest extent practicable, objective measures should be used in place of subjective measures.

- ***Improve and encourage data infrastructure, sharing, and availability.*** Value-based arrangements rely on information about a consumer's health and a treatment's efficacy so that value can be evaluated appropriately and the arrangement can be implemented effectively. This includes clinical and claims data, and, increasingly, real-world evidence from surveys, registry information, and other sources. Without quality, accurate information at the individual and population levels, such arrangements are less effective.

  Incentives to use health information technology, share data appropriately and securely, and protect privacy are all critical elements of a successful value-based arrangement. Unfortunately, most clinical data is inconsistently reported and frequently locked away in silos. Standards that encourage and improve data and its exchange across providers and systems are needed to promote value-based arrangements and treatment targeting. Incentives to include all providers and other relevant entities in information-sharing arrangements are necessary to ensure success. Laws, programs, and operating standards should be updated to improve data and foster its use in such arrangements.

  Data, metrics, and methodologies related to cost and quality from public programs such as Medicare and Medicaid, respecting the need to protect patient privacy and commercially sensitive information, should also be made publicly available in accessible formats. Medicaid data should be made standard across states and communicated to the federal government where deidentified data can be made available publicly for research and other purposes.

- ***Drive the revolution to precision medicine.*** Value-based care can be used to advance personalized care. At present, we often think of drugs as being "valuable" if they are effective and at a lower cost for the "typical" consumer. Such notions of value may be naïve as there is no such thing as a typical consumer. Science and medical advances are permitting life science manufacturers and clinicians to pinpoint treatment regimens and target therapies for individual needs. This should reduce clinical inefficiencies, improve outcomes, and reduce side effects and morbidity. Improving data infrastructure for drug development, identification of disease risk and presence, appropriate treatment markers, and outcome and process measurements are necessary to bolster and hasten precision medicine. Real world evidence from EHRs and other sources should be leveraged to inform drug and treatment regimen development and innovative care coordination and reimbursement structures. This infrastructure must also be adaptable, flexible, and scalable to fit the changing needs of evolving health and technology systems.

  As quality measurements improve and treatment options become more targeted toward individual needs, greater investment in decision support tools to help providers and consumers filter through various options and make better informed treatment decisions will be necessary.

- ***Lower the cost of bringing drugs to market by creating greater efficiencies for and facilitating enrollment in clinical trials.*** Nearly sixty percent of the cost of clinical trials comes in the early stages of drug development and includes the cost of matching, recruiting, and retaining the right individuals for the right clinical trials. Better use of interoperable medical records could more effectively match potential subjects to clinical trials. Greater and more consistent use of innovative technologies could also more easily predict how potential medications could work at lower costs and less risk. Such policies can not only increase access to life-saving treatments and improve outcomes, but they can also lower the cost of bringing drugs to market.

  Congress should fund a cost-efficient upgrade to the ClinicalTrials.gov database that would allow for electronic patient trial matching and provide for a more centralized, easily acceptable source for clinical trial information. The solution would standardize trial inclusion and exclusion criteria (e.g., patient demographic, clinical, and geographic information) in the database so that EHRs could query ClinicalTrials.gov to determine suitability. Such automatic matching would drive patient-doctor decision making to the clinical setting, address lingering privacy concerns, and lower front-end development costs.

  Additionally, regulatory requirements for clinical trials should be evaluated and reformed as needed to better foster innovation, reduce inefficiencies, and speed access to therapies while maintaining strict standards for safety and efficacy.

4. Preserving What Works

Several aspects of the system are working relatively well, with lower than expected costs and greater satisfaction and access for consumers for both insurance coverage and prescription drugs. Policies have been proposed that seek to address perceived problems with drug access and cost, but many of these "solutions" would only serve to drive up costs further, hamper innovation, and create additional access and competition challenges.

Policy makers should aggressively protect aspects of the system that are working well – those that promote robust competition, access, and innovation. Common sense reforms to help advance, improve, and preserve these programs over the long-term should be adopted while policies that could undermine them should be opposed.

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. As a group of united and diverse stakeholders, we stand ready and willing to serve policy makers in their search for solutions to the complex challenges facing our health system today.