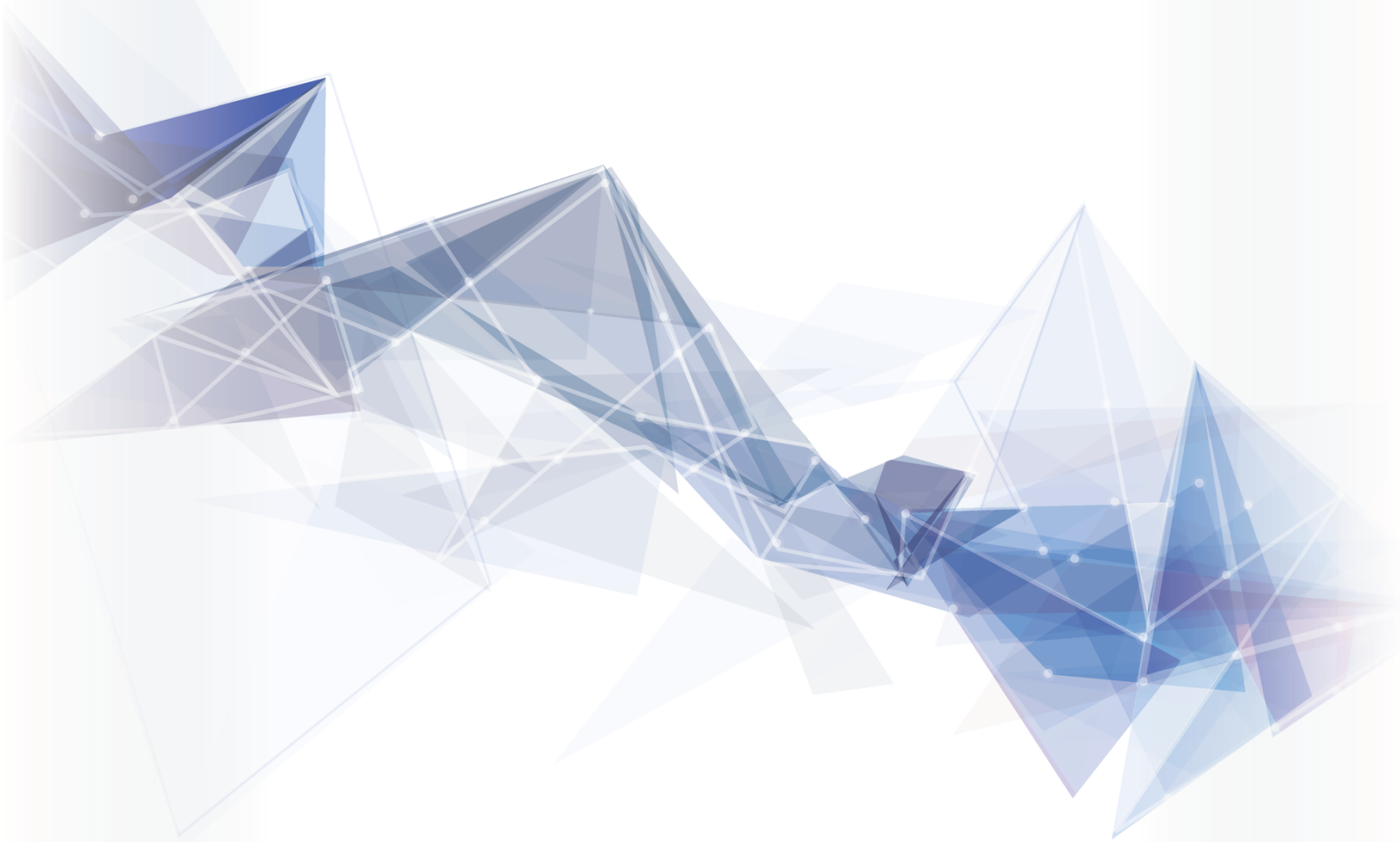
COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

# Prescriptions for Savings

## Policies to Increase Patient Access and Improve Affordability for Prescription Drugs



*Policy Proposals from the Council for Affordable Health Coverage*

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# Overview

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. As policymakers look for solutions to address rising costs for treatment, it is important for Congress to adopt policies and incentives that are firmly rooted in patient- and market-oriented solutions that promote access to treatment, value, competition and innovation.

Despite spirited debate from all areas of the health care system and in Washington, we have yet to see a consensus-based approach that engages a wide range of affected stakeholders in a concerted effort to address drug costs and overall health care spending. In this paper we propose a set of positive, common sense policy solutions to address the issues around prescription drug access and affordability. These proposals are broken into four broad categories: better coverage; pay for value; better markets and competition; and improved transparency.


Outlined below, these reforms will save billions, lower health care premiums and out-of-pocket costs, and ensure patients have access to the treatments they need. It does so by improving markets, not by imposing access restrictions on patients, or by arbitrarily capping benefits, reimbursement, or prices.

# Summary

## Improve Coverage to Lower Patient Out-of-Pocket and Taxpayer Costs

1. *Establish a budget neutral out-of-pocket cap for beneficiaries in Part D that does not raise premiums.* We propose an annual cap on out-of-pocket expenses, indexed to inflation, to protect beneficiaries in case of catastrophic drug expenses.

2. *Modernize Medicare Part D reinsurance payments to ensure premiums do not increase.* Medicare Part D's reinsurance payments above the catastrophic threshold would be reduced from 80 percent under current law, and Medicare's direct subsidy to Part D insurers would increase correspondingly to ensure premiums do not increase.

3. *Allow beneficiaries to pay their Part D cost sharing over time.* Some beneficiaries may have difficulty paying their deductible or other out-of-pocket costs in a lump sum. Those with incomes between the Low-Income Subsidy (LIS) threshold and 250 percent of poverty could apply for added help to pay this amount over time with no impact on premiums.

4. *Bring 340B discounts directly to patients to reduce cost sharing.* 340B discounts flow to eligible entities, typically big health systems, hospitals and contract pharmacies. These discounts are not required to flow directly to patients to help them cover their medical bills.

5. *Allow plans to offer better coverage of medications for chronic conditions.* Health Savings Account (HSA) or High Deductible Health Plans are required by law to have cost-sharing requirements even for routine and predictable drug-related health expenses. Easing these requirements would allow greater benefit design flexibility to cover patients' expenses and improve access to critical medications.

## Encourage Payment for Value

1. *Reform government barriers that inhibit Value-Based Arrangements (VBAs) in federal programs*.
   - Establish clear exceptions to Medicaid best price and Average Manufacturer Price (AMP) reporting
   - Reform Anti-Kickback and Stark restrictions
   - Clarify Anti-Discrimination Laws for to allow a consumer's cost sharing to reflect a medicine's clinical value
   - Create clear measures of patient outcomes and programmatic successes to be evaluated through a GAO study

2. Improve and encourage data infrastructure, sharing, and availability. Value-based arrangements rely on information about a consumer's health outcomes and a treatment's efficacy so that value can be evaluated appropriately, and the arrangement can be implemented effectively. 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.

## Promote Competition and End Anti-Competitive Practices

1. *Address so-called 'evergreening'*. A branded drug's exclusivity should not be extended due to a simple change to how a drug is administered or other non-innovative applications.

2. *Reduce barriers to generic and biosimilar drug development by ensuring access to samples necessary to develop products is granted.* Pass the CREATES Act.

3. *Give the FDA authority to expedite brand drug approval when there is limited competition in a class*. FDA has existing authority to expedite approval for a branded drug that should be expanded in cases where a class of drugs has limited or no competition. The cost for this process would be borne by the company requesting the approval.

4. *Provide incentives for developing generics amid drug shortages or significant price increases.* Some of the most controversial drug price increases have taken place in markets with expired patents for older generics. In these cases, the FDA should create a process that speeds up approval of generics and lifts any Risk Evaluation and Mitigation Strategies (REMS) barriers.

5. *Eliminate pay-for-delay patent settlements.* Drug companies should not be allowed to offer an inducement or payment to another drug company that stops lower cost generics from entering the market.

6. *Allow for streamlined interchangeability of biosimilars.* Interchangeability allows for substitution at the pharmacy counter and ensures biologic/biosimilar competition is more accessible to more consumers, which leads to increased access and lower costs.

7. *Reform Medicaid to more closely reflect market-based Medicare Part D tools*. Medicaid often reimburses pharmacies at government mandated rates that do not reflect market competition for ingredient costs or dispensing fees, resulting in higher costs to federal and state governments.

### Increase Transparency

1. *For Prescribers and Patients: Require cost information and any coverage restrictions to be available at the point of prescribing.* Require real-time benefit tools (RTBT) in Medicare to fully inform the prescriber and patient of their drug coverage options and costs (including pharmacy-specific costs) before a prescription is submitted.

2. *For Patients: Require plans to provide their enrollees the cost sharing and list of covered medicines*. Plans should show each enrollee specific information about their drug coverage, including cost sharing and any utilization review tools such as prior authorization requirements. Plans should also provide clear notice of a consumer's appeal and exceptions rights for medicines that are either denied or not covered.

## Background and Detailed Description

### Improve Coverage to Lower Patient Out-of-Pocket and Taxpayer Costs

More than 91 percent of people have some form of health coverage, whether through private insurance, employer coverage, Medicare, Medicaid or other public programs. Improvements to health insurance and public coverage will help to lower costs and enhance access. Because prescription drug utilization increases with age, our reforms primarily focus on improvements to Medicare, but will also benefit those with private coverage.

1. *Establish budget neutral out-of-pocket caps for beneficiaries in Part D.* Under current law, beneficiaries are responsible for 5 percent of spending above the Catastrophic Threshold ($5,100 in 2019), while plans are responsible for 15 percent, and taxpayers pay 80 percent.

   Congress created this shared liability structure to ensure: 1) plans would participate in Part D by limiting their risk above a threshold; and 2) beneficiaries would retain "skin in the game" above the threshold. While these policies made sense in 2003, we now have the benefit of 15 years of Part D experience. 901 plans currently participate in all geographic areas of the country. In addition, many beneficiaries are abandoning drugs (primary non-adherence) above the catastrophic threshold because of cost. Rather than skin in the game, the 5 percent cost sharing is facilitating disease progression by causing many to forgo treatment due to cost. The rationale for the 5 percent contribution no longer makes sense as it has a disproportionate impact on the sickest beneficiaries who need expensive but extraordinarily valuable drug therapies and no longer aligns with private sector coverage.

   Medicare's spending above the catastrophic limit became the largest component of program spending in 2014. According to MedPAC, is the fastest growing component of Part D spending, rising at an average annual rate of nearly 18 percent between 2007 and 2016. High cost enrollees make us more than 57 percent of Part D program

costs. The lack of a catastrophic coverage cap runs counter to trends in commercial private insurance where, according to Kaiser Family Foundation, 99 percent have an out-of-pocket maximum. MedPAC and others have suggested simultaneously eliminating liability on beneficiaries after they reach a catastrophic limit and imposing more risk on plans and manufacturers above the threshold.

*Proposal: Beginning in 2021, create an annual cap for beneficiary obligations, set at $2,750 to approximate the current amount of patient spending necessary to reach existing catastrophic threshold. This new cap would be indexed to the average per capita increase in drug spending in future years (which is a common indexing method for other Part D parameters).*

*There are several ways to achieve this policy: (1) Establish a threshold above which Medicare beneficiaries would no longer pay out-of-pocket; (2) Reduce taxpayer liability above the catastrophic threshold to incent lower costs; (3) Redirect taxpayer savings from reduced liability above the catastrophic threshold into direct subsidies to ensure premiums do not increase; and (4) Ensure plans have tools to manage costs above the threshold.*

*Taxpayer liability in the catastrophic threshold could be reduced in multiple ways. Reducing reinsurance payments and increasing Part D plan liability could create better incentives for plans to manage costs. The magnitude of savings will depend on what additional management tools are permitted and the resulting behavioral changes. Moving manufacturer liability from the coverage gap to the catastrophic phase could improve incentives to keep prices down as their liability will also increase as prices rise.*

*This proposal would remake Part D to look more like private plans by adding a true cap on enrollees' out-of-pocket costs while ensuring premiums do not increase as a result. Plans, manufacturers, and patients should all have incentives, tools and information that maximizes cost saving opportunities. Doing so would improve access to medications for millions of enrollees while improving incentives to manage drug costs. These principles should guide Congressional policy in establishing a true out of pocket limit on costs.*

2. *Allow beneficiaries to pay their Part D cost sharing over time.* Some beneficiaries who do not qualify for low income assistance still face difficulties meeting their deductible and cost sharing obligations at the beginning of the year. Deductible amounts reset every year, creating an affordability challenge every January for some beneficiaries. Combined with co-payments and co-insurance, these financial obligations create access barriers for some beneficiaries.

   *Proposal: Create a new category of beneficiaries, called Added Help Beneficiaries, who can separately apply to have all, or a portion of their annual deductible paid over the course of the year without impacting their premium or a plan's bid. Beneficiaries with income between the LIS threshold and 250 percent of poverty could apply for Added Help.*

3. *Bring 340B discounts directly to patients to reduce cost sharing.* The federal 340B program requires manufacturers to pay discounts to health care providers based on a complicated formula tied to the low-income patients they treat and the drugs they use. Currently, 340B discounts flow to eligible entities- typically big health systems, hospitals and contract pharmacies- and are spent on whatever the entity wants. Money does not, and is not required to, flow directly to patients to help them cover their medical bills.

   *Proposal: This section would require discounts to follow the patient and be paid to them (instead of 340B entities) to lower their medical costs.*

4. *Eliminate barriers to offer more generous drug coverage in a Health Savings Account (HSA) or High Deductible Health Plans.* About 25 million Americans have an HSA. HSAs are accounts that are paired with insurance plans. For those with chronic conditions, certain drug costs are unavoidable, such as insulin for diabetics. Federal law, however, requires 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.

   *Proposal:* Allow HSA qualified health plans to provide first dollar coverage of prescription drug costs within the deductible.

## Encourage Payment for Value

1. *Reform pricing models and government barriers that inhibit value-based arrangements in federal programs*. Health care is undergoing a monumental shift as payers move to aggressively reward value, defined by lower costs and improved patient 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 inhibits the move to value models in the prescription drug space. Key reforms must be made to enable this shift toward value-based reimbursement.

   - Establish clear exceptions to Medicaid best price and Average Manufacturer Price reporting. 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. As manufacturers lower prices, they must pay more to state Medicaid programs, creating a powerful disincentive to discount. Since the law was enacted in 1990, discounts have decreased significantly. Additionally, other drug reporting programs 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.

     *Proposal: Require clear exceptions to Medicaid best price and Average Manufacturer Price reporting 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. Value based arrangements are growing in prominence in the commercial markets. They rely on coordination between payers, providers, drug makers, and patients. The Anti-Kickback Statute (AKS) and Stark laws prevent such collaboration around value in federal programs in drug pricing and outcomes. These 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. Congress created exceptions that allow physicians and hospitals to collaborate in Medicare as part of Accountable Care Organizations. Congress should also allow payers, drug manufacturers, providers, and patients to collaborate on value-based payment efforts in federal programs.

*Proposal: Value-based and care coordination arrangements should have a clear safe harbor from AKS and Stark to allow payers, providers, drug makers, and patients to enter into these arrangements.*

2. 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 precision medicine. Incentives to include all providers and other relevant entities in information-sharing arrangements are necessary to ensure success.

   *Proposal: Laws, programs, and operating standards should be updated to improve data and foster its use in value-based arrangements.*

   - *Establish a safe harbor to allow manufacturers and payers to share or donate technology (both hardware and software) that is necessary to monitor, track patient progress and automatically report outcomes to facilitate payments in value-based arrangements.*
   - *HHS should finalize rules to prevent information blocking and to specifically allow information sharing in value-based payment arrangements.*
   - *Congress and HHS do not need to build value-based programs from whole cloth. Examples of successful programs abound in commercial markets. Congress should direct the Government Accountability Office (GAO) to conduct a study documenting measures of patient outcomes, identifying gaps in measures, and reporting on examples of existing commercial programs' successes. GAO should evaluate these programs and report to Congress within 12 months on what makes them successful.*

## Promote Competition and End Anti-Competitive Practices

1. *Address so-called 'evergreening'.* Evergreening occurs when brand-name companies patent "new inventions" that are really just slight modifications of old drugs in order to increase exclusivity timelines. While patenting is a key mechanism of the United States' free market system, those who game the system and prolong monopolies when there are no true new innovative additions should be discouraged.

   *Proposal: Congress should authorize FDA to deny the practice of evergreening patents for new delivery systems, mixtures and/or other related non-innovative applications. Companies should only receive new protections on truly new innovations and not on the total product, just the incremental improvement.*

2. *Reduce barriers to generic and biosimilar drug development by passing* CREATES. Generic products lower costs by promoting price competition and creating new access to previously protected intellectual property. Some have argued that branded drug makers withhold samples of their medicines from generic makers in an effort to delay or prevent generics from coming to market. This legislation would legally require brands to sell "sufficient quantities" at "commercially reasonable" prices to generic competitors who need samples for bioequivalency testing as part of their Abbreviated New Drug Applications. Additionally, the bill would create a legal framework to provide generics with the ability to get injunctive relief quicker from courts and allow judges to award payments to generics to deter sample withholding. It also allows the FDA to approve alternative Risk Evaluation and Mitigation

Strategy (REMS) programs if a generic or biosimilar developer and the innovator company are unable to arrive at a single shared system.

3. *Give the FDA authority to expedite brand drug approval when there is limited competition in a class.* When a therapeutic class of drugs has limited competition or one branded drug in a class, there is no countervailing market force to keep costs down. Brand-to-brand competition is a critical factor in keeping prescription drug costs low. Once competing drugs are available in a class, prices and net costs tend to decrease, resulting in lower costs for patients, taxpayers and employers. The FDA currently has four ways to streamline and expedite approvals for certain types of new branded drugs:

   a. Breakthrough therapy designations for drugs in clinical trials that show greater promise than available products for treating serious conditions;
   b. Fast track designations for drugs that address an unmet medical need;
   c. Priority review for New Drug Applications (NDAs) and Biologics License Applications (BLAs) that demonstrate significant improvement over available treatments; and
   d. Accelerated approval for drugs with an intermediate clinical endpoint that indicates the likelihood of substantial clinical benefit.

   *Proposal: This section would grant authority to the FDA commissioner to expedite approval of a branded drug where there is limited or no competition in a class. Specifically, it would:*

   - *Allow for the Commissioner to grant a "priority review" path of approval to "NDAs or BLAs when a therapeutic class is limited to a single sole source drug or has limited competition";*
   - *Such a determination would be at the discretion of the Commissioner; and*
   - *Any additional funds required to conduct the "priority review" will be assessed on the companies making the request for expedited approval.*

4. *Provide incentives for developing generics in the case of a shortage or significant price increase of a drug.* Some of the most publicly controversial drug price increases have taken place in markets with expired patents. Natural monopolies allow generic manufacturers to increase price above production cost and can be substantial for drugs that do not have substitutes. Reformulation of generic drugs reintroduces market exclusivity and creates barriers to generic entry.

   *Proposal:*

   - *Require the FDA to prioritize the review of certain generic drug applications and act on them within 150 days. This generic fast track review applies to applications for drugs: (1) that are not under patent or for which patents will expire soon; (2) for which there is no marketing exclusivity in effect; and (3) for which a generic has not recently been introduced to the market by more than one manufacturer.*
   - *Require the FDA to create a process where the incumbent and generic entrant can share a REMS system.*
   - *Allow the FDA to require the incumbent to grant access to proprietary REMS systems to any follow-on products on a case-by-case basis.*

5. *Eliminate pay-for-delay patent settlements.* Drug companies should not be allowed to offer an inducement or payment to another drug company that stops lower cost alternatives from entering the market.

   *Proposal: Impose penalties on manufacturers who engage in "pay-for-delay" that forestall market competition for their products, including termination of exclusivity for brands and loss of first filer status for generics who engage in settlements that include any terms other than the date of generic entry.*

6. *Allow for streamlined interchangeability of biosimilars.* Interchangeability allows for substitution and ensures biologic/biosimilar competition is more accessible to more consumers, which leads to increased access and lower costs. An interchangeable biosimilar is expected to produce the same clinical result as the reference biologic product in any given patient. It may be substituted for the biologic (reference product) without prescriber intervention. Currently, the FDA has not approved any interchangeable biosimilars.

   *Proposal: In order to create a sustainable and competitive biosimilar market, the FDA should streamline requirements for interchangeability.*

7. *Reform Medicaid to more closely reflect market-based Medicare Part D tools*. Medicaid often reimburses pharmacies at mandated rates set by individual state governments that do not reflect market competition for neither ingredient costs nor dispensing fees, resulting in higher costs to federal and state governments. Even with managed care penetration increasing in Medicaid, frequently the drug benefit is 'carved out' or cost saving tools are significantly pared back by the state. The result is many state Medicaid drug benefits have not modernized, and still abide by antiquated government established fee-for-service rules.

   Medicare Part D has been the most successful government established health program that consistently comes in under budget each year and is extremely popular with beneficiaries. This public-private partnership is a model that takes advantage of market-based tools to increase competition and lower costs.

   *Proposal: Establish 'best practices' minimum benchmark ingredient cost reimbursement rate for pharmacies, as well as a minimum benchmark dispensing fee that reflects an average Part D plan reimbursement rate. States would have the flexibility to exceed the benchmark but would have their federal matching rate deducted by that amount.*

## Increase transparency

1. *Require real-time benefit tools at the prescriber level.* According to a survey of 1,000 patients, half did not fill a prescription because it cost too much when they arrived at the pharmacy. Price transparency at the point of prescribing is largely missing. Information on formulary and benefit (F&B) coverage information, patient assistance, pharmacy cost and cash price options – among other cost-contributing factors - are rarely available. Real-time benefit tools (RTBTs) are technology innovations that deliver prescription benefit details, such as patient out-of-pocket costs, drug alternatives and prior authorization (PA) information at the point of care, enabling patients and their providers to make informed medication choices. An effective RTBT solution facilitates discussion between a provider and patient about the most clinically appropriate and affordable medication for the patient. By providing true price and coverage transparency, the patient is less likely to be surprised at the pharmacy and more likely to remain adherent.

   *Proposal: This section requires real time benefit tools to be used by all MA-PD and Part D Plans by 2021.*

2. *Require plans to show their enrollees the cost sharing amount and coverage of their medicine before they get to the pharmacy*. Consumers need better and more succinct information to inform how they choose their plan based on coverage and costs. In today's health market, transparency—on price, quality and plan choices—can help reduce health costs and improve health outcomes by empowering consumers to make better health decisions. Plan choice is important because it can lead to lower beneficiary and taxpayer costs. For example, a 2016 study found that most seniors often did not select a Part D plan that offered the best value, with the number of enrollees making the best plan choice declining from 11% in 2006 to 2% in 2009. For beneficiaries re-enrolling in a plan, almost 90% of enrollees opt to remain in the same plan, preferring inertia over change. Availability of clear information and plan selection tools is a critical feature to identify the least-expensive coverage options most

closely tailored to an applicant's financial circumstances and medical needs, while minimizing the risk of poor plan selection.

Plans should be able to show each enrollee their specific information about their drug coverage including cost sharing and any utilization review tools. For those who lack coverage, information on the list price (WAC) and average, estimated, or typical patient out-of-pocket costs, and other context about the potential cost of the medicine, should also be provided on a public facing web site.

*Proposal: Because most Americans have coverage, this section requires their payer – public or private – to provide information directly to consumers- including list of covered drugs, network pharmacies, patient out-of-pocket cost, prior authorization (PA) information and exceptions and appeals rights.*

## Conclusion

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.

### About the Council for Affordable Health Coverage

*The Council for Affordable Health Coverage (CAHC) brings together insurers, pharmacy benefit managers, drug manufacturers, consumers, patients, employers, health technology organizations, and health care providers to advance commonsense reforms that lower health costs. Most recently, CAHC members have shaped the prescription drug pricing debate by championing actionable policy solutions that reward value and improve affordability and access for patients.*

*Working across industry lines and with leaders in both parties, CAHC builds broad support for solutions grounded in the principles of competitiveness and economic efficiency, leading to improved care and savings for the entire health system. Learn more at* CAHC.net.