COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

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July 16, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

RE: 0991-ZA49; *Submitted Electronically to regulations.gov*

Dear Secretary Azar:

The Council for Affordable Health Coverage (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 appreciate the opportunity to comment on the Request for Information included in the *American Patients First* blueprint.

Already, the Trump Administration has taken significant steps to lower drug costs, including clearing the backlog of drug applications at the FDA, blocking pharmacy gag clauses, increasing competition in the brand and generic markets, and other programs that will save billions for taxpayers and consumers.

Unfortunately, the sad truth is that we still have laws on the books that were enacted more than three decades ago, which are blocking lower prices for prescription drugs and team-based, coordinated care. These laws should be reformed or repealed to facilitate flexible benefit designs and value-based payment arrangements in Medicare and other federal and state health programs. Such market-based, incentive-driven changes will do more to lower costs than any government program.

As such, we estimate that three of the proposals CAHC discusses below would lead to annual health system savings of nearly $50 billion after ten years. Federal budgetary savings would be about $3.7 billion over the 10-year budget window. These proposals are: (1) H.R. 2026, the Pharmaceutical Information Exchange Act, which would allow pre-approval communication between drug manufacturers and health plans; (2) safe harbors from anti-kickback regulations for VBAs and medication adherence programs; and (3) exemptions for VBAs from Medicaid's "best price" and Average Manufacturer Price rule. If enacted, these policies will ease barriers to access for much needed medications and help to improve the lives of Americans across the country. We look forward to working with your administration on this effort.

Background

As health costs rise, consumers struggle to access health care coverage, services, and products. 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 portion of health care – prescription drugs. The current deadlock and finger pointing across industries and by 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 promote affordability through lower costs for prescription drugs.

Health spending has grown faster than our economy for decades. In 2017, the U.S. spent $3.57 trillion on health care.[1] These soaring costs pose a burden on individuals, families and businesses, and requires bold reforms that bring competition and market incentives to bear on runaway spending.

American Patients First tailors its focus to prescription drug costs. This is appropriate considering that is the sector of health spending that consumers interact with most directly and often. At the same time, any conversation on affordability must recognize the real drivers of the health care cost curve. More than half of federal health care spending is on hospital, physician and clinical care.[2] More specifically, hospital costs contribute to nearly one-third of all health spending. Appropriate use of prescription medicines can help lower hospital and other service spending.

Conversely, prescription drugs make up 10% of health spending.[3] In 2017, spending on medicines grew by a net rate of 0.6 percent, while spending on retail and mail-order drugs actually declined by 2.1% – a shift driven in part by price declines for some generic drugs, which now account for 90 percent of the more than 4 billion prescriptions filled annually at pharmacies nationwide. [4]

While these trendlines are encouraging and the context important, CAHC, like the administration, recognizes that costs for prescription drugs still present a barrier for too many patients and the status quo is unacceptable. High out-of-pocket costs have exacerbated a crisis of medication nonadherence, something the *New York Times* calls "an out-of-control epidemic … that costs more and affects more people than any disease Americans currently worry about."[5]

Indeed, poor adherence is estimated to result in some $300 billion in avoidable annual healthcare spending.[6] This is largely due to increased hospitalizations – making these various streams of health care spending interconnected. Improving prescription drug access and affordability can tackle the growing problem of nonadherence and ultimately address one of the root drivers of skyrocketing health care costs.

Recommendations

CAHC recommends the administration to:

1. *Pay for value.* 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 by promoting value-based payment arrangements in Medicare and other government programs;

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[1] https://altarum.org/altarum-estimates-2017-national-health-spending-growth-at-4-7
[2] Health Sector Economic Indicators Spending Brief. Altarum. 2018. https://altarum.org/sites/default/files/uploaded-related-files/SHSS-Spending-Brief_June_2018.pdf
[3] https://altarum.org/sites/default/files/uploaded-related-files/SHSS-Spending-Brief_June_2018.pdf
[4] Medicine Use and Spending in the U.S. April 2018. IQVIA. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf?_=1529619143517
[5] https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html
[6] https://cvshealth.com/thought-leadership/cvs-health-research-institute/cost-biggest-barrier-medication-adherence

2. *Expand Biosimilars.* Foster a robust market for biosimilars and expand patient access to all biologic products; and
3. *Lower Consumer Prices*. Reform Medicare Part D to encourage lower costs and fewer subsidies. HHS should test approaches to provide consumers access to lower negotiated prices.

Our suggestions, which reflect those of the Council and not necessarily those of our individual members, are outlined below.

Value-Based Arrangements

Today, our nation's healthcare system is undergoing a monumental shift as payers move aggressively to reward value and deliver affordable, quality care to consumers. In such value-based systems, payment for a medicine is linked to patient outcomes, rewarding affordability and quality.

As medicines are becoming more personalized and effective, manufacturers and payers are increasingly exploring innovative payment and coverage approaches in the competitive market that can help improve affordability and access. Sadly, old laws and rules on the books prevent these private sector innovations from flourishing in federal health programs. This shortchanges taxpayers and, most importantly, patients.

While CAHC supports demonstration projects to test value-based arrangements for drugs, we believe that permanent changes need to be made outside of CMMI's demonstration authority to provide certainty to payers, manufacturers and patients about the rules of the road. The main barriers to value-based arrangements are Medicaid's "best price" law and the anti-kickback statute (AKS). These laws stand in the way of adopting commercial models in government programs, lower drug prices and more coordinated care.

To address this, 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 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 to be greater for all plan enrollees. Improving communication between manufacturers and payers will thus enable better coverage determination and pricing accuracy. We laud FDA's recent guidance[7] on recommendations to facilitate this appropriate communication and support FDA moving forward with additional reforms in this area.

Such efforts will result in lower costs by helping plans and manufacturers effectively negotiate formulary coverage and design to create 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. CAHC supports 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 and lower costs. HSA-compatible health plans are currently permitted to cover preventive drugs before the deductible is met, but should be allowed to market and tailor plans to meet the needs of individuals with specific conditions or adopt value-based insurance design (VBID) within HSA-compatible plans, including covering chronic care medications, generics, or even all drugs outside of the deductible if they so choose. The Administration can achieve this goal immediately through Internal Revenue Service (IRS) action to update existing HSA guidance.

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

[7] https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537130.pdf

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. *HHS should ensure consumers have access to choices by conditioning exchange funding on access to coverage options.*

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 does not work or does not 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. Federal law otherwise stands in the way of 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. *HHS should enact clear exceptions to Medicaid best price 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 (AKS) and civil monetary penalties (CMP) law 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. Regrettably, HHS has, thus far, provided little guidance to payers, manufacturers, providers, and other entities regarding how the AKS and CMP 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, HHS should create AKS safe harbors and broaden the CMP exceptions 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; and*
    c. *Allow for technology and data donations to make value-based programs more effective.*

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. *HHS 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 government programs in adopting new payment models, 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

CAHC has endorsed three proposals that would foster additional value-based arrangements (VBAs) for drugs in federal health programs: (1) H.R. 2026, the Pharmaceutical Information Exchange Act, which would allow pre-approval communication between drug manufacturers and health plans; (2) safe harbors from anti-kickback regulations for VBAs and medication adherence programs; and (3) exemptions for VBAs from Medicaid's "best price" and Average Manufacturer Price rules.

The estimates below include federal budgetary costs and savings, changes in private health insurance premiums, and potential changes in national health expenditures from 2019 through 2028.

We estimate that this set of proposals would increase the share of drugs under VBAs substantially over the next ten years. On balance, additional VBAs would foster greater access to and utilization of prescription drugs but at lower costs per dose or treatment. Thus, the overall health system costs for prescriptions under VBAs would be mostly unaffected, as higher utilization would be offset by lower consumer prices. However, the broader and better targeted use of drugs under VBAs would lead to savings in other "downstream" health costs, particularly hospital and physician costs due to improved outcomes for patients. We estimate overall health system savings of nearly $50 billion dollars, which would be coupled with significant gains in access to treatments. Federal budgetary savings would be about $3.7 billion over the 10-year budget window. For a detailed explanation of the budget estimates, please appendix A.

CAHC Rx Value Proposals -- Summary
(calendar years)

	2019-2023	2019-2028
Net Federal Budget Cost (+) or Savings (-) (millions of dollars)		
1. HR 2060 (PIE Act). Allow pre-approval communication between manufacturers and health plans	-309	-1,089
2. Create a safe harbor for Rx Value-Based Arrangements and medication adherence programs under Anti-Kickback regulations	-355	-1,181
3. Adjust Medicaid "Best Price" and Avg. Man. Price rules to exempt Rx Value-Based Arrangements	-391	-1,421
Total	-1,055	-3,691

	Change in National Health Expenditures (billons of dollars)	
	2023	2028
Combined Proposals	-10	-47

Source: Council for Affordable Health Coverage (CAHC).
Note: Costs or Savings may include direct spending, appropriated amounts, and revenues.

Improving Transparency

CAHC has long supported better transparency for consumers as a key means to promoting competitive markets. While we support making price, quality, safety and cost more transparent, and support the HHS drug pricing dashboard, we believe HHS' focus should be on providing accurate information to the 90 percent of Americans with coverage. These consumers want to know whether their drug is covered, what their cost sharing obligation may be, and what their appeal rights are.

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. *HHS 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.*

Biosimilars

CAHC supports the development and delivery of safe and effective drugs, including biologics and biosimilars. Biosimilars are bioequivalent copies of branded biologics as determined by the FDA.[8] They vary from "generics" in that they can have minor differences in clinically inactive components because they are made from living organisms. Despite these differences, biosimilars still act as competitive products that help to lower prices and improve access. Because biologics account for nearly 40% of US prescription drug spending- despite only 1-2% of patients using the drugs, access to biosimilars will have a significant impact ($54 billion over 10 years) on direct spending for biologic drugs.[9]

Biosimilar uptake has been relatively slow in the United States as compared to other markets in developed countries. CAHC supports improving the pathways for biosimilar development and approval by the FDA. We also support policies that crack down on efforts of withholding reference products for biosimilar development. Eliminating barriers or protections for cases involving product sample access issues should be a priority of the FDA. Finally, CAHC supports including biosimilars for purposes of LIS cost sharing and non-LIS catastrophic. This will encourage biosimilar use among beneficiaries by lowering cost sharing, while generating more price competition, expanding access for beneficiaries, and helping to restrain growth in program spending, especially in the catastrophic benefit.

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[8] FDA Purple Book, https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/ucm411418.htm

[9] Biosimilar Cost Savings in the United States. Rand Corporation. 2017. https://www.rand.org/content/dam/rand/pubs/perspectives/PE200/PE264/RAND_PE264.pdf

Medicare Part D

CAHC appreciates CMS' request for information and proposal to require plans to pass through a percentage of manufacturer rebates and pharmacy price concessions to beneficiaries at the point of sale. We support CMS' goal of reducing beneficiary cost burdens and encourage you to continue to explore the dynamics and trends in drug and pharmacy pricing, manufacturer rebates and the impact of plan and manufacturer behavior on Part D affordability, especially the impact of these trends on beneficiaries and taxpayers.

When Congress enacted the Part D benefit, the authors did not want CMS to micromanage plans or benefits, instead preferring a reliance on competition to drive beneficiary choices. Mandating plan rebates at the point of sale would lower out of pocket costs for some beneficiaries, but it would also raise beneficiary premiums and taxpayer costs.

Congress also believed plans would compete on both premium and cost sharing. Congress required plans to provide access to negotiated prices, which take into account negotiated price concessions, including discounts, rebates, DIR and dispensing fees. When manufacturer rebates and pharmacy price concessions are not reflected in the price of a drug at the point of sale, the concessions are realized in lower premiums. Based on data submitted by plans and required by law, between 2010 and 2015, the amount of all forms of price concessions received by Part D sponsors and their PBMs increased nearly 24 percent per year, about twice as fast as total Part D gross drug costs. The DIR data show similar trends for pharmacy price concessions.

While price concessions have lowered beneficiary premiums, they have not generally been passed on at the point of sale in lower cost sharing. As a result, average plan premiums increased just 1 percent per year between 2010 and 2015 and are decreasing in 2018. But also, as a result, some beneficiaries are paying higher cost sharing at the point of sale. Higher DIR has also shifted a greater proportion of drug spend into the catastrophic phase of the benefit. This has shifted more costs onto taxpayers as plans are only responsible for 15 percent of costs in the catastrophic phase of the benefit.

We encourage you to carefully consider requiring point of sale rebates, recognizing the trade-offs inherent in the proposal across out-of-pocket costs, premiums, taxpayer costs, incentives for all players, and increasing government requirements on plans. We suggest the following reforms*:*

1. *Testing the concept of requiring point-of-sale rebates as the next logical step to gauge how plans, manufacturers and beneficiaries will react to mandated point-of-sale discounts. Based on the results of the demonstration, CMS could make a better-informed decision on next steps.*

2. *CMS should also test the approach presented by MedPAC to evaluate and test whether the actuarial equivalence model could incorporate a portion of expected DIR so that cost sharing reflects some of the rebates not currently reported in plan bids. CMS should test this approach for a subset of plans using a revised bid-pricing tool.*

3. *Such testing should also seek to maximize benefits to consumers.*

4. *CMS should take great care to ensure that if point-of-sale rebates are required, Part D plans do not seek to make up revenue through expanded DIR fees from pharmacy providers.*

Conclusion

With your administration's efforts through *American Patients First* and ongoing RFIs as well as interest from Congress on addressing drug cost and access issues, new opportunities are being created that can promote innovation and value in prescription drug development, coverage 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 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 polices presented here are a positive step forward to help put our system- and the consumers who rely on it- on a better, more sustainable path.

We appreciate your consideration of our comments and stand ready to serve as a resource as you further develop policies to make health care more affordable and accessible for all Americans.

Sincerely,

Joel White
President
Council for Affordable Health Coverage

APPENDIX A – DETAILED COST ESTIMATE AND EXPLANATION

Estimating the Impact of the Council for Affordable Health Coverage's Proposals to Increase Access and Affordability of Prescription Drugs

This report analyzes a set of proposals from the Council for Affordable Health Coverage (CAHC) that seek to increase access and affordability for prescription drugs by promoting policies that would improve competition, value, and innovation in the prescription drug space. CAHC has brought together insurers, benefit managers, drug manufacturers, consumers, patients, employers, health technology organizations, and health care providers to advance reforms that will lower costs for prescription drugs. This paper analyzes the subset of policies that would foster additional value-based arrangements (VBAs) between pharmaceutical manufacturers and health insurance plans and enhance consumer tools to analyze plan and treatment choices. The estimates include federal budgetary costs and savings, changes in private health insurance premiums, and potential changes in national health expenditures from 2019 through 2028, under two alternative assumptions about the impact of VBAs on consumer cost and utilization.

Table 1. Rx Value Campaign Policy Proposals Analyzed

1. Allow pre-approval and post-approval communication between drug manufacturers and health plans (H.R. 2026).
2. Create a safe harbor for VBAs and medication adherence programs under Anti-Kickback regulations.
3. Exempt Rx VBAs from Medicaid "Best Price" and Average Price rules.

Explanation of Analysis on Fiscal Costs and Savings

Table 2 shows fiscal estimates of the proposal's key elements, where policies that would be considered savings for the federal budget (i.e., reductions in outlays or increases in revenues) are shown with a negative (-) sign, and items that would increase the federal deficit (i.e., increases in outlays or reductions in revenues) have a positive sign. For purposes of this estimate, we assumed that the proposal would be implemented in full in January 2019; however, the VBA proposals were assumed to take effect on a phased-in basis over the first four years, 2019 through 2022. The estimates are compiled on a calendar year basis.

Table 2 shows the federal costs and savings under the assumption that VBAs reduce prices by an average of five percent and increase the number of prescriptions by a corresponding five percent. Under this assumption, the net fiscal impact from enacting this set of proposals would save the federal government over $1 billion over the five-years from 2019-2023 cumulatively, and would result in ten-year cumulative net savings between 2019 and 2028 of approximately $3.7 billion.

The largest elements of savings stem from the proposal's impact on the ability of health plans and manufacturers to more easily form VBAs, particularly for newer, high-cost, specialty medications with no competitors. Allowing pre-approval communication between health plans and manufacturers is estimated to save about $1.1 billion over the ten-year period from 2019-2028, largely by speeding the inclusion of new drugs on plan formularies. Under the assumption that VBAs increase prescription volumes by 5 percent, creating a "safe harbor" or exception for VBAs and medication adherence

programs from Anti-Kickback regulations would save approximately $1.2 billion over the ten-year period. We estimate that exempting VBAs from Medicaid's "best price" rule would save more than $2.7 billion over the ten-year period, although some of those savings would be offset by increases in estimated federal Medicaid costs.

Table 2.
Rx Value Proposals -- Assuming VBAs Reduce Price 5% and Increase Volume 5%; Med Adherence Programs Increase Volume 5%
Summary Net Federal Cost (+) or Savings (-)

(calendar years, millions)	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2019-2023	2019-2028
Value-Based Arrangements for Prescription Drugs												
1. HR 2060 (PIE Act). Allow pre-approval communication between manufacturers and health plans	-15	-35	-60	-93	-107	-121	-138	-155	-173	-193	-309	-1,089
2. Create a safe harbor for Rx Value-Based Arrangements and medication adherence programs under Anti-Kickback regulations												
Additional VBAs	-18	-43	-76	-118	-137	-159	-182	-207	-234	-264	-392	-1,438
Medication Adherence Programs	1	2	6	12	17	24	31	42	54	69	38	257
3. Adjust Medicaid "Best Price" and Avg. Man. Price rules to exempt Rx Value-Based Arrangements												
Health Insurance Impact	-34	-80	-142	-222	-258	-297	-341	-388	-439	-495	-736	-2,697
Medicaid Impact	16	37	67	104	121	140	161	184	209	236	345	1,276
Total	**-50**	**-118**	**-207**	**-317**	**-363**	**-414**	**-468**	**-524**	**-584**	**-647**	**-1,055**	**-3,691**

Source: Council for Affordable Health Coverage (CAHC).
Note: Costs or Savings may include direct spending, appropriated amounts, and revenues.

Impact on Private Insurance Premiums and Out-of-Pocket Spending

Table 3 shows the impact of CAHC's proposals on private health insurance premiums, based on the fiscal estimates in Table 2. The premium impacts of each individual item are small, in some cases only a tiny fraction of a percentage point. The overall impact, however, can be quite large.

Under the assumption of a five percent increase in prescription volumes, the policy proposals would reduce premiums for private insurers by about one-tenth of a percent as these policies are implemented, rising to a reduction of 0.15 percent in year ten.

Table 4 below shows the impact on aggregate private health insurance premiums and out-of-pocket costs from the perspective of total national health expenditures. For this illustration, we assumed that the potential reduction in out-of-pocket costs was proportionate to that of private health insurance premiums under both scenarios about the impact of VBAs.

Possible Impact on Medicare and Medicaid

The fiscal estimates presented in Table 2 for CAHC's proposals do not include direct federal savings to the Medicare and Medicaid programs. This is not necessarily because we believe such savings are not possible, but instead because the analyzed proposals would generally not impact Medicare and Medicaid payments and reimbursement methods directly, and, therefore, might not "score" in the usual ways in which federal cost estimates are performed.

If Congress authorized or even incentivized private entities in Medicare to enter into similar VBAs, savings along the lines of those we discuss below for private health plans could potentially be activated. Reimbursement laws and regulations would have to be changed to allow savings to flow to the federal budget, and we do not make any such assumptions here.

However, Table 4 does illustrate the potential reductions in overall Medicare and Medicaid expenditures if those programs' total spending was impacted in proportion to that of private health insurance. Under that assumption, the total reduction in national health spending associated with CAHC's proposals could range as high as $47 billion per year by the tenth year of implementation. Broader effects on the health system could potentially increase these savings.

Table 3.
Rx Value Proposals -- Assuming VBAs Reduce Price 5% and Increase Volume 5%; Med Adherence Programs Increase Volume 5%

Impact on PHI Premiums (percent)	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
1. HR 2060 (PIE Act). Allow pre-approval communication between manufacturers and health	0.00%	0.00%	-0.01%	-0.02%	-0.02%	-0.02%	-0.03%	-0.03%	-0.03%	-0.03%
2. Create a safe harbor for Rx Value-Based Arrangements and medication adherence programs under Anti-Kickback regulations	0.00%	-0.01%	-0.01%	-0.02%	-0.03%	-0.03%	-0.03%	-0.03%	-0.03%	-0.03%
3. Adjust Medicaid "Best Price" and Avg. Man. Price rules to exempt Rx Value-Based Arrangements	0.00%	-0.01%	-0.03%	-0.05%	-0.06%	-0.06%	-0.07%	-0.07%	-0.08%	-0.08%
Sum, Technical Proposals	**0.00%**	**-0.02%**	**-0.05%**	**-0.10%**	**-0.10%**	**-0.11%**	**-0.12%**	**-0.13%**	**-0.14%**	**-0.15%**

Source: Council for Affordable Health Coverage (CAHC).

Table 4. Impact on National Health Spending
Rx Value Proposals -- Assuming VBAs Reduce Price 5% and Increase Volume 5%; Med Adherence Programs Increase Volume 5%

	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Baseline										
PHI Total (billions)	1,286	1,349	1,411	1,473	1,544	1,620	1,698	1,776	1,858	1,944
PHI Growth (percent)	3.4%	4.9%	4.6%	4.4%	4.9%	4.9%	4.8%	4.6%	4.6%	4.6%
Impact on PHI Premiums										
PHI Total (billions)	1,286	1,348	1,410	1,471	1,540	1,614	1,689	1,765	1,844	1,926
PHI Growth (percent)	3.4%	4.9%	4.6%	4.3%	4.7%	4.8%	4.7%	4.5%	4.5%	4.5%
PHI Savings (in billions)	0	0	-1	-2	-4	-6	-8	-11	-14	-17
Impact on Out-of-Pocket										
OOP Total (billions)	398	417	436	459	481	504	528	552	577	603
OOP Growth (percent)	4.9%	4.8%	4.6%	5.1%	4.9%	4.9%	4.8%	4.5%	4.5%	4.5%
OOP Savings (billions)	0	0	0	-1	-1	-2	-3	-3	-4	-5
Potential Impact on Medicare										
MCR Total (billions)	808	873	942	1,014	1,090	1,172	1,247	1,358	1,479	1,610
MCR Growth (percent)	8.0%	8.1%	7.9%	7.7%	7.5%	7.5%	6.4%	8.9%	8.9%	8.9%
MCR Savings (billions)	0	0	-1	-2	-3	-4	-6	-8	-11	-14
Potential Impact on Medicaid										
MCD Total (billions)	656	696	738	781	826	874	928	990	1,056	1,126
MCD Growth (percent)	5.5%	6.1%	6.0%	5.9%	5.8%	5.8%	6.2%	6.7%	6.7%	6.6%
MCD Savings (billions)	0	0	0	-1	-2	-3	-4	-6	-8	-10
Total	**0**	**-1**	**-2**	**-6**	**-10**	**-15**	**-21**	**-28**	**-37**	**-47**

Source: Council for Affordable Health Coverage (CAHC).

Data, Assumptions, and General Estimating Approach

The fiscal estimates are grounded in ten-year projections of national health expenditures (NHE) by the Office of the Actuary at CMS.[10] Table 5 shows the NHE projection of total prescription drug spending by private insurers, broken into five categories:

- The "Top 1%" – These are estimated insured costs of specialty drugs and other very expensive treatments.
- No competition – These are single-source drugs that do not have a generic substitute or similar drug in the therapeutic category that would provide a source of competition.
- 1 competitor – Drugs that have only one similar or generic competitor.
- 2-4 competitors – Drugs that have 2 to 4 similar or generic substitutes.
- 5 or more competitors – Drugs with many sources of competitive substitution.

[10] Gigi A. Cuckler, Andrea M. Sisko, John A. Poisal, Sean P. Keehan, et al. "National Health Expenditure Projections, 2017–26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth" Health Affairs (February 14, 2018), available at: https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2017.1655 ; additional data from https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.

This categorization is based on preliminary discussions with pharmacy experts at health plans. The projection over the ten-year estimating period reflects an assumption that the fastest-growing category in recent years—the Top 1%—will continue to gain as a share of overall spending. Importantly, this categorization is by spending, not volume. Thus, most prescriptions may be in categories with many competitors and relatively low prices. In fact, the Top 1% category is so named precisely because it generally reflects one percent of volume – but about one-third of costs.

Table 5.
Rx Value Proposals -- Breakout of NHE Rx Spending

Baseline Rx Spending (billions of dollars)	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Top 1%	56	60	66	72	79	87	95	104	114	124
No competition	27	28	30	31	33	35	36	38	40	42
1 competitor	31	32	33	35	37	39	41	43	46	48
2-4 competitors	23	23	24	26	27	28	29	31	32	34
5+ competitors	23	23	24	26	27	28	29	31	32	34
Total NHE Rx PHI	159	167	178	189	202	216	231	247	264	283

Baseline Rx Spending (percent of total)	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Top 1%	35%	36%	37%	38%	39%	40%	41%	42%	43%	44%
No competition	17%	17%	17%	17%	16%	16%	16%	16%	15%	15%
1 competitor	19%	19%	19%	19%	18%	18%	18%	18%	17%	17%
2-4 competitors	14%	14%	14%	14%	13%	13%	13%	13%	12%	12%
5+ competitors	14%	14%	14%	14%	13%	13%	13%	13%	12%	12%
Total NHE Rx PHI	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Source: Council for Affordable Health Coverage (CAHC).

A second key element is the estimated reduction in costs when a new competitive product is approved. Again, based on discussions with health plans, we assumed the following schedule for determining pricing by category.

- The "Top 1%" Pricing not affected.
- No competition Pricing not affected.
- 1 competitor 15% reduction in price.
- 2-4 competitors 25-30% reduction in price.
- 5 or more competitors 50% reduction in price.

H.R. 2060 would work toward accelerating the introduction of competitor products by decreasing the gap in time between approval and appearance of the drug on health plans' formularies. Savings from those policies are based, in part, on the assumed reductions in costs from additional competitors shown above.

Another key element of savings come not from drug costs but via the impact of VBAs for prescription drugs on hospital and medical costs. In general, we assumed that when manufacturers and health plans enter into a VBA, average prices are reduced by about 5 percent, while quantities prescribed increase by about the same percentage. Thus, total drug spending is unchanged by the increased adoption of the VBAs, with lower prices offset by higher volumes.

The Congressional Budget Office (CBO), however, has studied the issue of prescription drug availability in the context of Medicare's Part D prescription drug benefit, and the summary of CBO's reasoning is worth quoting directly at length:[11]

> *"Prescription drugs affect people's health and their need for medical services. For example, overuse or inappropriate use of prescription drugs may raise the risk of adverse reactions, triggering a need for medical treatment. But most often, pharmaceuticals have the effect of improving or maintaining an individual's health. Taking an antibiotic may prevent a more severe infection, and adhering to a drug regimen for a chronic condition such as diabetes or high blood pressure may prevent complications. In either of those circumstances, taking the medication may avert hospital admissions and thus reduce the use of medical services.*
>
> *After reviewing recent research, the CBO estimates that a 1 percent increase in the number of prescriptions filled by beneficiaries would cause Medicare's spending on medical services to fall by roughly one-fifth of 1 percent. That estimate, which applies only to policies that directly affect the quantity of prescriptions filled, represents a change in the agency's estimating methodology.*
>
> *Previously, CBO had found insufficient evidence of an offsetting effect of prescription drug use on spending for medical services. Thus, for example, CBO's cost estimate for the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (which established Medicare's Part D prescription drug benefit) did not include an offset, nor did its estimates of the cost of the Affordable Care Act (which includes provisions closing the Part D coverage gap).*
>
> *In estimating the budgetary impact of future legislation or proposals that would directly affect prescription drug use in the Medicare program, CBO will apply an offsetting effect on medical spending. The agency will first estimate a proposal's direct effect on prescription drug costs; then, the agency will estimate the effect on the number of prescriptions filled and any resulting offsetting effect on spending for medical services.*
>
> *For example, a policy that increased prescription drug copayments for certain Medicare beneficiaries might save $4 billion in federal drug costs in a given year but reduce the number of prescriptions filled that year by 1 percent. That reduction in use would result in a one-fifth of 1 percent increase in the affected population's total spending for medical services. If that total spending would otherwise be $250 billion in that year, then those costs would increase by $0.5 billion. The net effect of the policy, combining the savings on drug costs and the costs of increased use of medical services, would be a savings for the federal government of $3.5 billion in that year."*

We extrapolated CBO's reasoning to VBAs between manufacturers and private health plans in the following manner: a one percent increase in the volume of prescriptions via new VBAs for prescription drugs was assumed to cause a one-fifth of one percent decline in insured spending for hospitalization and physician costs. Thus, value-based arrangements for drugs – which we assume would lower prices and increase volumes of prescriptions, particularly for the newest, most innovative drugs that are the subject of VBAs – would slightly lower non-drug health costs.

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[11] Congressional Budget Office. *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (November 2012). Available at: https://www.cbo.gov/publication/43741.

CBO has indicated that it would use this drug volume versus non-drug health cost relationship only for estimates involving Medicare Part D. However, the underlying research would likely apply to non-Medicare patients as well, and we have assumed as much.

While privately insured patients often switch health plans when they change jobs or re-enroll, we assumed that the system-wide savings in an overall reduction in follow-on hospital and physician services resulting from greater access to medications would remain the same. It is certainly possible that the short tenure of some patients in particular health plans could create a disincentive for health plans to enter into VBAs in the first place, since the downstream savings could be captured by a different health plan. However, we believe health plans still have powerful incentives to undertake such efforts.

Reductions in privately insured health costs impact the federal budget in two ways:

- Reductions in the cost of employer-based coverage are reflected in higher taxable wages, raising federal revenues.
- Reductions in the cost of individual coverage lower federal subsidies for people purchasing via state health exchanges.

When employers provide health benefits, the cost is not included in employees' taxable incomes. However, CBO and the Joint Committee on Taxation (JCT) assume that employees' total compensation is determined by their productivity, and changes in productivity or overall economic activity are usually reflected in basic fiscal estimates. Thus, a change in employer health benefit costs (not taxed) is assumed to be reflected as an equivalent change in employee wages (taxed). When benefit costs fall, CBO and JCT assume wages rise equivalently. (Technically, the savings could be funneled instead to other non-taxed benefits, or held as corporate surplus, but we assume workers' preference for wages limits the former possibility and competition for labor limits the latter.)

For example, if employer costs for health benefits were reduced by $1, we assume that taxable wages would increase by $1, and payroll and income tax revenues would increase by 30 cents, based on a marginal payroll tax rate of 15 percent and a marginal income tax rate of 15 percent. Since the vast majority of privately insured people obtain coverage through employers, rather than state health exchanges, the revenue effect of employer health benefit costs would dominate. For simplicity, we assumed that the effective overall subsidy rate for private insurance purchased individually (either through state exchanges or directly from insurers) was also 30 percent, so that the total cost of private health insurance could be used as the basis of the estimates. In effect, this means we did not have to separate insurance costs between the employer, exchange, and direct purchase markets.

These assumptions and estimating conventions are further explained in the following sections describing each element of CAHC's policy proposals.

Value-Based Arrangements for Prescription Drugs

Value-based reimbursements are sweeping through other parts of the health sector, spurred by efforts to hold down health costs while improving care. Medicare – historically the largest fee-for-service payer in the country – is also pushing toward value-based payment arrangements, particularly with hospitals and physicians. By its sheer size, Medicare's interest in shifting away from fee-for-service payments toward VBAs has created a great deal of momentum for change.

Even so, the switch toward VBAs in the pharmaceutical sector has been slow. Several initiatives have been launched, with notable efforts from health plans Aetna, Cigna, and Harvard Pilgrim and manufacturers Amgen, Merck, and Novartis, among others.[12] These efforts are newsworthy because they are not yet commonplace. A key goal of CAHC's proposals are to make VBAs for pharmaceuticals more widespread, even routine, and for drug manufacturers and insurers to work more collaboratively toward ensuring that patients get the highest-value medications at an affordable cost.

Most payments for pharmaceuticals remain based on fee-for-volume or fee-per-dose basis. Health plans have focused on setting up multiple tiers of copayments in an attempt to steer patients toward lower-priced preferred drugs and generics. Health plans place "preferred" drugs on lower copayment tiers based on rebates negotiated with manufacturers. Thus, a manufacturer may offer a larger rebate to a health plan in return for placement on a preferred, low copayment tier on the plan's formulary in order to gain a higher volume of enrollees.

While these tiering systems sharpen competitive prices for drugs and have helped raise the share of generic drug purchases over the last two decades, they have not necessarily fostered the highest-value use of drugs. They have helped reduce the insured costs of medications, but they haven't necessarily shifted the overall therapeutic value of the medications.

Unlike the current fee-for-dose system, VBAs would switch payment toward drug therapies that improve patients' health or have the desired therapeutic impact. VBAs require performance on a pre-agreed metric for determining success of the drug therapy, typically based on a therapeutic measure or clinical outcome. They would create incentives for manufacturers to work with health care providers to ensure

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[12] Modern Healthcare, "Harvard Pilgrim cements risk-based contract for pricey cholesterol drug Repatha" (November 9, 2015) available at: http://www.modernhealthcare.com/article/20151109/NEWS/151109899; Barlas S. "Health Plans and Drug Companies Dip Their Toes Into Value-Based Pricing: The Pressure Is on P&T Committees to Monitor Utilization." *Pharmacy and Therapeutics* (January 2016), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4699485/; Silverman, E. "Another big insurer will pay for key drugs based on patient outcomes," *STATnews.com* (June 27, 2016), available at: https://www.statnews.com/pharmalot/2016/06/27/harvard-pilgrim-eli-lilly-novartis/; Wall Street Journal, "Health Insurers Push to Tie Drug Prices to Outcomes, Cigna reaches value-based contracts for entire new class of cholesterol drugs," (May 11, 2016), available at: http://www.wsj.com/articles/health-insurers-push-to-tie-drug-prices-to-outcomes-1462939262; Modern Healthcare, "Insurers, drugmakers wrestle with how to build value-based contracts," (February 20, 2016), available at: http://www.modernhealthcare.com/article/20160220/MAGAZINE/302209963; Reuters, "Novartis sets heart-drug price with two insurers based on health outcome" (February 9, 2016), available at: http://www.reuters.com/article/us-cigna-novartis-drugpricing-idUSKCN0VH25K; For an updated list of publicly announced VBAs, see: https://www.phrma.org/fact-sheet/value-based-contracts-2009-q1-2018. Since the first version of this estimate was published by CAHC, a few research and background articles on Rx VBAs have been published, although none have strong evidence of the impacts of VBAs. See, for example: Elizabeth Seeley and Aaron S. Kesselheim, "Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending?" *The Commonwealth Fund* (September, 2017), available at: https://www.commonwealthfund.org/publications/issue-briefs/2017/sep/outcomes-based-pharmaceutical-contracts-answer-high-us-drug, Rachel Sachs Nicholas Bagley Darius N. Lakdawalla, "Innovative Contracting for Pharmaceuticals and Medicaid's Best-Price Rule," *Journal of Health Politics, Policy and Law*, Vol. 43, No. 1, (February 2018), available at: https://read.dukeupress.edu/jhppl/article-abstract/43/1/5/132803/Innovative-Contracting-for-Pharmaceuticals-and?redirectedFrom=fulltext, and Amy M. Duhig, Soumi Saha, Stacie Smith, Stew Kaufman, and Janet Hughes, "The Current Status of Outcomes-Based Contracting for Manufacturers and Payers: An AMCP Membership Survey" *Journal of Managed Care & Specialty Pharmacy JMCP* (May 2018), available at: https://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.16326.

that drugs are prescribed more appropriately rather than receiving the same payment per dose regardless of effectiveness.

Based on all the policies in CAHC's policy set, we estimate that VBAs would account for an additional 16 percent of private health insurance prescription drug spending in 2022, growing to more than 25 percent by 2028 (see Table 6).

Table 6.
Rx Value Proposals -- Breakout of NHE Rx Spending

	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Additional Percentage of PHI Drug Spending in VBAs										
Top 1%	5%	12%	20%	29%	31%	34%	36%	39%	42%	44%
No competition	3%	6%	10%	14%	16%	17%	18%	20%	21%	22%
1 competitor	1%	3%	5%	7%	8%	8%	9%	10%	10%	11%
2-4 competitors	1%	1%	2%	4%	4%	4%	5%	5%	5%	6%
5+ competitors	1%	1%	2%	4%	4%	4%	5%	5%	5%	6%
Additional percent of all drugs in VBAs	3%	6%	10%	16%	17%	19%	21%	22%	24%	26%

Source: Council for Affordable Health Coverage (CAHC).

Specific Policies Related to Value-Based Arrangements for Prescription Drugs

H.R. 2016. Allow pre-approval communication between drug manufacturers and health plans.

Under current law, manufacturers face limitations on communications about drugs that are undergoing the FDA approval process. These regulations are designed to restrict pre-approval promotion to healthcare providers or patients, so that public claims of safety or effectiveness are not made until final FDA approval and labeling is in place. However, these restrictions are not intended to restrict scientific communication.

Health plans may benefit from knowing details about drugs in the FDA pipeline so that they can have both the opportunity to develop VBAs and also better plan and set premiums accurately. However, in-depth pre-approval communications between health plans and manufacturers could be interpreted as both scientific and promotional, and they may thus fall into a grey area under the current rules. Such ambiguity can have a negative impact on rate setting and formulary design, as was seen in 2014 with the mid-year release of several high-priced drugs that cured Hepatitis C.

We estimate that allowing pre-approval communication between manufacturers and health plans would raise the share of drug spending subject to VBAs by 2 percent for the "Top 1%" drug category, and by 0.75 percent for the "no competition" category. Thus, this proposal would potentially affect approximately $1.6 billion in privately insured drug costs in these categories in 2019. If we assume spending in these categories is impacted by a 5 percent price reduction and a 5 percent volume increase due to the additional VBAs, the corresponding savings in physician and hospital spending by the spending offset (one-fifth of the volume increase) is about $90 million.

By allowing health plans and manufacturers to undertake business communications prior to approval, this proposal would also allow health plans to be ready on the first day of FDA approval. Based on discussion with health plans, we believe this would typically shave three months off the process of getting newly approved drugs on a plan's formularies.
We estimate that this proposal would thereby speed the introduction of lower prices when competitive drugs are approved. For drugs in the "no competition" category, we assumed a three month speed up of

first competitors, triggering a price reduction of 15% more quickly than would have otherwise been the case. For drugs in the 1 competitor category, we assumed a quicker triggering of the price reduction of 25-30% that is indicated when a drug gets a second competitor.

The quicker price reductions cause corresponding volume increases ranging from 10-25 percent in the categories affected, based on a price elasticity of demand of approximately -0.5. That is, a 1% reduction in price is expected to cause roughly a 0.5% increase in volume. These volume increases, in turn, lead to reductions in hospital and physician spending in the same manner as the additional VBAs.

This timing effect is estimated to cover a relatively small share of the markets for these drugs, but the total impact of price reductions, volume increases, and hospital and medical cost offsets is estimated to save about $106 million in 2019. The $106 million savings from the timing effect, plus the VBA effect of about $90 million equals a total reduction in costs of about $196 million in 2019. Assuming that reduction passes through to wages that are taxed at the margin at 30%, the total 2019 federal revenue increase (fiscal "savings") from this proposal is estimated to be $59 million. We phased in the proposal's impact over four years, so Table 2 shows a 2019 savings of $15 million, reflecting one quarter of the $59 million estimated savings had the proposal been fully phased in.

Create a safe harbor for VBAs and medication adherence programs under Anti-Kickback regulations.

Under current law, healthcare providers and suppliers are not allowed to offer or accept remuneration for prescribing treatments. Some statutory and regulatory safe harbors have been enacted, but it is unclear whether these would apply to VBAs for prescription drugs. This provision would provide a space for health plans and manufacturers to negotiate VBAs without the uncertainty.

We estimate that providing a safe harbor for prescription drug VBAs from anti-kickback regulations would raise the share of drug spending subject to VBAs by an additional 6 percent for the "Top 1%" drug category, by 3 percent for the "no competition" category, and by smaller percentages in the competitive categories. Thus, this proposal would potentially affect approximately $5.3 billion in privately insured drug costs in 2019. Assuming spending in these categories is impacted by a 5 percent price reduction and a 5 percent volume increase due to the additional VBAs, the corresponding savings in physician and hospital spending by the spending offset (one-fifth of the volume increase) would be about $240 million in 2019 fully phased in, and the federal fiscal savings would be $72 million. Assuming the four-year phase-in lowers the estimated savings to $18 million in 2019, $43 million in 2020, $76 million in 2021, and so on.

A safe harbor for medication adherence programs would have a similar impact, except that we assume that prices would not be reduced when adherence programs are run by drug manufactures. Those programs are assumed to increase volumes by 5 percent, particularly in the drug categories with little or no price competition, with downstream savings in reduced hospitalizations and physician spending as with VBAs. However, with no price reductions, the extra drug spending would only be partially offset by those reductions in downstream costs. Although medication adherence programs run by health insurance plans would be likely to result in overall reduced costs (drugs plus follow-up health costs), we did not assume any impact from increases in insurer-led adherence programs in this estimate. The ten-year federal cost of the safe harbor for medication adherence programs is estimated to be about $250 million.

Create safe harbors for VBAs from Medicaid best price and other price reporting reimbursement system reporting requirements.

Under current law, manufacturers must submit pricing data for inclusion in the computation of Average Manufacturers' Price (AMP), a measure that is used as a benchmark for rebates to the Medicaid program. Likewise, manufacturers must provide the maximum of a percentage rebate (often 23.1% of AMP), or their "best price" rebate to the Medicaid program.[13] Similar reporting requirements are pegged to reimbursement for some drugs in the Medicare program. These policies create artificial pricing floors, disincentivizing VBAs.

These rules were based on the idea that all reimbursements would be based on fee-for-dose. VBAs that allow different discounts or rewards based on how well the therapy worked were not considered when best price and other similar policies were enacted.

For example, if a manufacturer agreed to provide a deep discount or rebate to the health plan in cases were the drug therapy did not meet the therapeutic goal, the best price rule would be triggered and might require that deep discounts be applied to all Medicaid reimbursement. We believe the best price rule has a substantial chilling effect on the formation of VBAs.

On the other hand, if VBAs were excluded from best price *and* AMP, then the resulting Medicaid rebate amount if a new VBA is introduced is fairly indeterminate; it would depend on spread in prices to different plans and which plan does the VBA (a plan paying high prices versus a near-best or best price plan). So, while intuitively, it would seem that repealing a law that requires Medicaid to get the "best" or lowest price would automatically raise Medicaid's costs, the arithmetic of the price setting system doesn't guarantee that outcome.

This portion of the estimate has two components. First, the proposal would enhance the spread of prescription drug VBAs; second, the proposal could affect Medicaid costs. We estimate that providing an exemption for VBAs from Medicaid's best price rule would raise the share of drug spending subject to VBAs by an additional 12 percent for the "Top 1%" drug category, by 6% for the "no competition" category, by smaller percentages in the competitive categories. Thus, this proposal would potentially affect approximately $9.9 billion in privately insured drug costs in 2019. Assuming spending in these categories is impacted by a 5 percent price reduction and a 5 percent volume increase due to the additional VBAs, the corresponding savings in physician and hospital spending by the spending offset (one-fifth of the volume increase) is about $450 million in 2019, and the fully phased-in federal fiscal savings from this aspect of the proposal would be $134 million.

The estimate of the Medicaid impact starts with the average price reduction from the total additional induced VBAs because of the other proposals in CAHC's policy set. We then estimated the Medicaid share of that market as a proportionate share of Medicaid's total prescription drug spending. Next, we assumed that the actual Medicaid impact would be a percentage of this stylized "maximum" impact. Our

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[13] HHS on Best Price https://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/medicaid-drug-rebate-program.html ; Association of Community Health Plans on Medicaid Best Price http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=18692 ; https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/64xx/doc6481/06-16-prescriptdrug.pdf ; CBO Effects of March Health Legislation on Drug Prices https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/116xx/doc11674/11-04-drug_pricing.pdf ; CBO Budget Option https://www.cbo.gov/budget-options/2013/44899 ; CBO Rx pricing in the private sector https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf ; CBO letter to Grassley https://www.cbo.gov/sites/default/files/109th-congress-2005-2006/reports/06-21-medicaidrebate.pdf ; CBPP http://www.cbpp.org/research/reducing-medicaid-and-medicare-drug-costs-could-help-pay-for-health-reform

preliminary modeling indicates that under certain conditions, the Medicaid rebate could increase or be reduced (and Medicaid's costs go down or up) after a VBA is introduced. Therefore, we assumed that only 25 percent of the maximum potential for Medicaid cost increases would actually materialize.

We estimate that federal Medicaid costs would rise by about $109 million in 2019 based on exempting VBAs from the best price rule if the proposal were fully phased in. Assuming the four-year phase-in period yields Medicaid costs of $16 million in 2019, as shown in Table 2. Federal Medicaid is estimated to be 57 percent of overall Medicaid costs; the remainder is paid by the states.

This estimate of Medicaid costs is particularly uncertain for two reasons. First, the arithmetic of the Medicaid best price rebate, the default percentage rebated, and the average manufacturer price is complex. In some cases, exempting VBAs from the best price rule could lower Medicaid rebates and raise the program's cost. In other cases, it might not. It depends on the distribution of prices/rebates associated with all health plans in a state, which we do not know.

Our estimates are intended to be separable – that is, one can look at individual estimates of elements of CAHC's policy proposals as an indicator of that policy's impact, regardless of whether other elements of the whole proposal were also enacted. In this case, Medicaid can't possibly get higher rebates (lower costs) based on exempting VBAs from the best price rule if those VBAs had never been established in the first place due to the best price rule.

On balance, we believe the estimate of increased costs to Medicaid is probably appropriate, but the magnitude of the estimate is possibly quite conservative (too high). However, in combination with the added VBAs we believe would be induced by exempting them from the best price rule, the net impact of this policy would be a fiscal savings, with the added revenue effect of more VBAs only partially offset by potentially higher Medicaid costs.