

Attachment: Recommendations to Reduce Health Care Costs

High and rising health care costs have profound implications for household budgets, employers, and taxpayers alike. State and Federal governments alone spend over a trillion dollars per year on health care,¹ straining budgets and consuming resources that could be directed towards other worthwhile purposes. Premiums – which now average nearly \$20,000 for family health coverage and \$7,000 for single coverage – consume large portions of their total compensation, reducing what workers take home in cash wages.² These realities make controlling health care costs a pressing priority.

The Senate Committee on Health, Education, Labor, and Pensions has recently heard from several witnesses who emphasized that much of current spending reflects inefficiencies in our current health care market. This past December, you followed up on what was presented in those hearings by soliciting recommendations from health policy experts at the American Enterprise Institute and the Brookings Institution for policies that would begin to address this difficult problem.

We believe that many policies have potential to make the market for medical care more efficient through a combination of pro-competitive reforms and the use of regulation. Many such policies are relatively well-understood but have not been pursued for a variety of reasons, including stakeholder opposition.

What follows are cost-reducing policy proposals that are broadly supported by our group of health policy scholars—a group which includes experts holding a variety of political perspectives. Some of these proposals would require explicit Congressional approval while others could be implemented by federal agencies through administrative action but which might be advanced by an explicit endorsement by Congress. We also include policies that states are best positioned to pursue. We believe these proposals would meaningfully slow the growth of health care costs.

Improving Incentives for Cost-Effective Private Insurance

Over 150 million Americans obtain health insurance through an employer. As noted above, the high and rising cost of health insurance has contributed to the slow growth of take-home pay. Those costs are driven in part by government policies. In this section we highlight ways policymakers could stimulate competitive forces to reduce the costs of these policies.

Limit the tax exclusion of employer-sponsored insurance

The exclusion of premiums for employment-based health insurance from income and payroll taxes reduced federal revenues by about \$300 billion in 2018.³ By lowering the net price of health insurance, the tax exclusion promotes the purchase of more generous coverage than if health insurance were taxed like cash compensation. Limiting the exclusion would increase federal revenue, encourage the purchase of lower-cost health insurance, and slow the growth of health spending.

The most direct approach would cap the amount of employer and employee health insurance payments that can be excluded from the employee's taxable income. Capping, rather than

¹ National Health Expenditure Accounts, 2017.

² Kaiser Family Foundation Employer Health Benefits Survey, 2018.

³ Congressional Budget Office, Federal Subsidies for Health Insurance Coverage for People Under Age 65: 2018-2028.

eliminating, the exclusion would maintain incentives for employers to continue offering coverage to their employees. It would also encourage employers to seek lower-cost plan options, but would not drive employers to offer only low-cost plans.

The Affordable Care Act (ACA) adopted a different approach to limiting the tax preferences for employer coverage. It imposed an excise tax (the “Cadillac” tax) on employer-sponsored health insurance with premiums exceeding certain thresholds. The tax was set to take effect in 2018, but Congress delayed implementation until 2022, when it will be levied on employer-sponsored plans with premiums exceeding \$9,800 for individual coverage and \$28,300 for family coverage. The amount of the tax is 40 percent of the excess of premiums over those thresholds.⁴

We urge Congress either to allow the Cadillac tax to take effect or to legislate a cap on the tax exclusion, so that premiums above the cap would be treated as income to covered workers. CBO estimates that setting the cap to the 75th percentile will reduce the 10-year deficit by \$256 billion and will slightly narrow insurance coverage, with fewer than 500,000 people becoming uninsured.⁵

A second strategy would modify provisions of the Cadillac tax. Congress should consider allowing for variations in health insurance costs that reflect local market conditions and setting an inflation index that reduces the chance that plans that are not unduly generous would be taxed. These and other policies could make the Cadillac tax more sustainable in the future.

Further delays, or repealing the tax outright without a substitute that limits the tax exclusion, would leave in place the current incentives that increase spending rather than value in health care.

Limit the tax exclusion of employer-sponsored insurance

We recommend that Congress pass legislation capping the tax exclusion for employer-sponsored insurance at the 75th percentile of premiums. If this is not feasible, we recommend that Congress allow the Cadillac tax to take effect.

Ensure effective anti-trust enforcement

Many segments of the health care market are becoming increasingly consolidated. While some consolidation offers the potential of greater efficiency, too much consolidation can lead to higher prices and lower quality.

Legislation enacted more than a century ago recognized these dangers and authorized review of horizontal mergers between businesses that provide similar services and are actual or potential competitors. But funding constraints lead antitrust agencies to make tough choices about which mergers to challenge and discourages venturing into newer, but potentially more difficult areas, such as vertical mergers.

For example, the Federal Trade Commission has yet to challenge a hospital acquisition of a physician practice on vertical grounds, despite growing evidence that consolidation of this kind tends to lead to higher prices and less competition in other areas of the market. More funding for

⁴ Fiedler, Matthew. 2018. “How to interpret the Cadillac tax rate: A technical note.” USC-Brookings Schaeffer on Health blog. <https://www.brookings.edu/blog/usc-brookings-schaeffer-on-health-policy/2018/02/01/how-to-interpret-the-cadillac-tax-rate-a-technical-note/>.

⁵ Congressional Budget Office, Options for Reducing the Deficit: 2019 to 2028.

antitrust enforcement could have a large return in lower prices paid by consumers and employers, which in turn would increase federal revenues through the tax exclusion. The Congress should provide substantial increases in funding for the Federal Trade Commission and the Department of Justice Antitrust Division.

Indeed, some believe that the way antitrust cases are handled today, with requirements for substantial quantitative evidence, may preclude opportunities to consider newer types of vertical combinations where there is little experience to analyze. For example, insurers and pharmacy benefits managers tend not to be competitors, but with all of the PBMs having been acquired by insurers, entry into both of those industries may now be impossible. Bringing expert judgment on these issues to bear might require amendments to the original laws.

Some states have shielded hospital systems from federal antitrust scrutiny with the promise of state oversight through Certificates of Public Advantage (COPA). But experience shows that states rarely have the resources (or the will) to make sure that the merged entity does not abuse its new market power. States should not pursue this tool.

Fostering a competitive environment goes beyond challenging inappropriate mergers. Providers or insurers often pursue anti-competitive practices. For example, anti-tiering and anti-steering clauses in contracts between providers and insurers tend to extend provider dominance. “Most favored nation” clauses tend to extend the dominance of insurers. Some states, such as Massachusetts and Michigan, have passed legislation to address these practices. More states should do so. Empowering the FTC to study the insurance industry, enforce antitrust laws in the insurance industry and enforce antitrust laws with respect to nonprofit health care organizations could enable it to work against anticompetitive practices as well.

Ensure effective anti-trust enforcement

We recommend that Congress increase funding for the Federal Trade Commission (FTC) and the Department of Justice Antitrust Division. We also recommend that Congress direct the FTC to study the insurance industry.

Create pathway to encourage development of APCDs

One significant barrier to both public and private sector efforts to reduce health care spending is a lack of detailed and comprehensive data on provision and consumption of health care services, particularly among people enrolled in private insurance. Without high-quality, comprehensive data, it is difficult to obtain an accurate picture of how the health care system is operating today, which in turn makes it challenging to devise strategies to make it work better. In recent years, many states have aimed to address this problem by establishing all-payer claims databases (APCDs), repositories that collect claims records from all public and private payers operating within a state. Sixteen states have established APCDs to date and several more are in the process of implementation.⁶

State efforts to establish APCDs were dealt a significant blow by the Supreme Court’s 2016 ruling in *Gobeille v. Liberty Mutual*. In that case, the Court held that the Employee Retirement Income Security Act (ERISA) bars states from requiring self-insured health plans to report to the state’s

⁶ For a list of state APCD initiatives, see <https://www.apcdouncil.org/state/map>.

APCD. This leaves a large gap in states' APCDs as self-insured plans account for around half of all enrollment in private health insurance nationwide.

The federal government should take action to enable state APCDs to collect data for self-insured plans. It has at least two options for doing so. First, the Department of Labor likely has the authority to create a standardized national process that state APCDs could use to collect data from self-insured plans without running afoul of ERISA.⁷ Congress could direct the Department to use that authority. Second, Congress could clarify that ERISA was not intended to bar state APCDs from collecting data from self-insured plans and thereby permit states to move ahead without additional federal action.

Create pathway to encourage development of APCDs

We recommend that the Department of Labor use its authority to create a standardized process that state APCDs could use to collect data from self-insured plans or that Congress amend ERISA to allow states to move ahead on their own.

Remove State Regulatory Barriers to Provider Market Competition

State governments have authority to regulate a number of features of local health care markets. Policymakers can, for example, regulate the supply of new health care facilities or conditions of state licensure for health care providers. In this section, we outline pro-competitive policies that Congress should encourage states to pursue.

Repeal any willing provider laws

As of 2014, around half of states had so-called “any willing provider” laws, which generally require insurers to allow any interested provider to join its network on the same terms offered to other in-network providers.⁸ Many states also have similar restrictions known as “freedom of choice” laws, which require insurers to pay for care delivered by out-of-network providers. The types of providers included in these laws vary widely from state to state, with some targeting only specific provider categories (e.g., pharmacies) and others targeting a broad swath of health care providers.

Insurers' main source of leverage in negotiations with providers is their ability to exclude providers from their networks, so these restrictions tend to increase the prices insurers pay for health care services.^{9,10,11} Those increases in provider prices in turn increase consumers' premiums and out-of-pocket costs.

⁷ Ario, Joel. And Kevin McAvey. 2018. “Transparency In Health Care: Where Do We Stand And What Policy Makers Can Do Now.” *Health Affairs Blog*. <https://www.healthaffairs.org/doi/10.1377/hblog20180703.549221/full/>; Bagley, Nicholas. 2016. “A Modest Proposal for Fixing Gobeille,” *36 Yale J. On Reg.: Notice & Comment*. <http://yalejreg.com/nc/a-modest-proposal-for-fixing-gobeille-by-nicholas-bagley/>.

⁸ For a list of which states had any willing provider laws as of 2014, see <http://www.ncsl.org/research/health/any-willing-or-authorized-providers.aspx>.

⁹ Vita, Michael G. 2001. “Regulatory Restrictions on Selective Contracting: An Empirical Analysis of ‘Any-Willing-Provider’ Regulations.” *Journal of Health Economics*. 20(6), 955-966. <https://www.ncbi.nlm.nih.gov/pubmed/11758054>.

¹⁰ Klick, Jonathan and Joshua D. Wright. 2015. “The Effect of Any Willing Provider and Freedom of Choice Laws on Prescription Drug Expenditures.” *American Law and Economics Review*. 17(1), 192-213. <https://academic.oup.com/aler/article-abstract/17/1/192/212392>.

¹¹ Durrance, Christine P. 2009. “The Impact of Pharmacy-Specific Any-Willing-Provider Legislation on Prescription Drug Expenditures.” *Atlantic Economic Journal*. 37(4), 409-423.

In light of these negative consequences, states that have these laws should repeal them. Federal policymakers could consider tying the repeal of any willing provider laws to federal funding. States do have a legitimate interest in ensuring that insurance products offer reasonable access to providers, but there are more targeted approaches for achieving that objective. For example, if carefully crafted, network adequacy standards can safeguard access to care without creating the same degree of upward pressure on the prices of health care services.

Repeal any willing provider laws

We recommend that Congress encourage states to repeal any willing provider laws.

Certificate of need reform

Many states enacted laws in the early 1970s to create “certificate of need” programs, which required hospitals and sometimes other facilities to get permission from a state board to pursue major construction projects or equipment purchases. The rationale was that if too many beds were built they would nevertheless be filled and, even if not, cost reimbursement systems would automatically pass the cost of unfilled beds to patients. For a while, the federal government required states to implement CON programs.

However, a lot about the health system has changed since then, including a shift from cost-based to prospective payment and insurers requiring authorization for hospital admissions and major tests and procedures. Research has shown that CON programs do not save money. In fact, they may raise spending by blocking new competitors, such as hospital systems or physicians seeking to set up ambulatory facilities, from entering markets. The Federal Trade Commission and the Department of Justice have urged states to repeal these laws and not enact new ones, based both on empirical evidence from the research literature and the economic argument that market entry (or the threat of it) can make consolidated markets function more like competitive ones.¹²

What should the federal government do to discourage CON laws? Just as it required states to enact CON in the 1970s, it could take steps to make it attractive for states to repeal them. This could include tying elimination of CON laws to federal funding.

Repeal certificate of need laws

We recommend that Congress encourage states to repeal certificate of need laws.

Surprise billing reform

Too often, patients receive surprise medical bills from providers outside their health plan network. This may arise in an emergency situation or when treated by an out-of-network ancillary physician (an anesthesiologist, radiologist, pathologist, or assistant surgeon) at an in-network hospital. Surprise bills can be large. Furthermore, patients are liable for the difference between

https://www.researchgate.net/publication/227451073_The_Impact_of_Pharmacy-Specific_Any-Willing-Provider_Legislation_on_Prescription_Drug_Expenditures.

¹² “Joint Statement of the Federal Trade Commission and the Antitrust Division of the U.S. Department of Justice on Certificate-of-Need Laws and South Carolina House Bill 3250,” January 11, 2016.

the health plan's allowed amount for the service(s) and the out-of-network providers' billed charges (or the "balance"), which are much larger than typical contractual payment rates.

An estimated one in five emergency department (ED) visits result in a potential surprise balance bill from an out-of-network physician and roughly one in ten scheduled stays at an in-network hospital involve treatment from an out-of-network provider, most commonly an anesthesiologist.¹³ Prevalence appears similar in both the employer and individual markets and across plan types.¹⁴

The market for emergency and ancillary physician services is skewed because there is no price-volume trade-off in negotiations with health plans as is the case when bargaining with other medical providers. Patients do have some voice in which hospital they go to, but little or none over the individual physicians who treat them in the ED. Similarly, for nonemergency care, insured patients typically take care to select an in-network facility and primary physician, such as a surgeon, but do not select their ancillary physician(s). A similar dynamic exists for hospitalists and ambulance companies.

As a result, ED and ancillary physicians, as well as hospitalists and ambulance companies, have a lucrative out-of-network billing arrangement unavailable to other providers. Not surprisingly, emergency and ancillary physicians tend to have much higher billed charges (also known as "list prices") relative to Medicare payment rates, compared to other specialties.¹⁵ Not only are surprise out-of-network bills harmful to those directly receiving them, but the ability to routinely treat and bill unsuspecting patients on an out-of-network basis allows ED and ancillary physicians to demand higher in-network rates (in order to forgo this option), increasing premiums for everyone. Studies find that emergency medicine physicians and anesthesiologists receive in-network rates, on average, in the range of 300% of Medicare rates, whereas commercial insurer payments to other physicians appear to average roughly 125% of Medicare rates.¹⁶

The more natural market negotiation for ED and ancillary clinician services is between those specialists and the facility (typically a hospital), for which there is a price-volume trade-off. The most straightforward solution is to require facilities to contract with insurers over a bundle of services that includes any associated ED or ancillary clinician services. Legislatively, accomplishing this would require prohibiting ED and ancillary physicians, as well as hospitalists, from billing independently for their services. Facilities would then negotiate with insurers over payment for these bundled services, and ED and ancillary physicians would negotiate with facilities for payment. Alternatively, a similar outcome could be achieved by limiting out-of-network charges for these provider types to or near the Medicare rate.

¹³ Cooper, Zack and Fiona Scott Morton. 2016. "Out-of-Network Emergency-Physician Bills—An Unwelcome Surprise." *New England Journal of Medicine*. 2016; 375:1915-1918. <https://www.nejm.org/doi/full/10.1056/NEJMp1608571>; Garmon, Christopher and Benjamin Chartock. 2017. "One in Five Inpatient Emergency Department Cases May Lead to Surprise Bills." *Health Affairs*. 36(1). <https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0970>.

¹⁴ Garmon and Chartock, 2017.

¹⁵ Adler, et al. 2019. "State Approaches to Mitigating Surprise Out-of-Network Billing," USC-Brookings Schaeffer Initiative for Health Policy. <https://www.brookings.edu/research/state-approaches-to-mitigating-surprise-out-of-network-billing/>.

¹⁶ Trish, et al. 2017. "Physician Reimbursement in Medicare Advantage Compared with Traditional Medicare and Commercial Health Insurance." *JAMA Internal Medicine*. 2017; 179(9):1287-1295 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5710575/>; Stead, Stanley W. and Sharon K. Merrick. 2018. "ASA Survey Results for Commercial Fees Paid for Anesthesia Services—2018." *ASA Monitor*. 82:72-79 <http://monitor.pubs.asahq.org/article.aspx?articleid=2705479>; MedPAC. 2017. "Report to the Congress: Medicare Payment Policy." March 2017. http://medpac.gov/docs/default-source/reports/mar17_entirereport.pdf.

This solution would eliminate surprise out-of-network bills received from treatment at in-network facilities, but would leave unaddressed surprise bills from emergency services at an out-of-network facility and out-of-network ambulances. Addressing these instances would generally require a mechanism for limiting out-of-network charges for emergency department facility fees and ambulance services, combined with a requirement on insurers to hold their enrollees harmless for any costs above their normal in-network cost-sharing amounts. The authors of this letter share an interest in addressing these cases, but have yet to reach a consensus with regards to a preferred policy remedy.

Surprise billing reform

We recommend that Congress prohibit independent physician billing for emergency, ancillary, and hospitalist services. We further recommend that Congress consider options to address surprise billing by out-of-network emergency departments and ambulances.

Improving Incentives within Medicare

Medicare provides insurance for nearly 60 million beneficiaries and now represents roughly 15 percent of total federal spending.¹⁷ Net outlays for the program are projected to rise to \$1.26 trillion by 2028.¹⁸ In this section we outline several specific policy options which would reduce program costs and improve efficiency throughout Medicare.

Expand site-neutral payments where clinically feasible:

Historically, Medicare has paid a higher rate for the same service when performed in a hospital outpatient department (HOPD) than in a freestanding physician's office. While this differential may sometimes be clinically justified, it often is not. Some services can be performed as safely at a physician's office as in an HOPD. Providing services in a needlessly costly setting is expensive for both Medicare and patients (through higher coinsurance). The differential also increases the incentive for hospitals to acquire physician practices, which often makes the hospital and physician markets less competitive.

Congress took an important first step in addressing site of service payment differentials as part of the Bipartisan Budget Act of 2015 (BBA) by reducing Medicare payments for services delivered at newly-built off-campus HOPDs to rates intended to approximate those in the physician fee schedule. And recently, the administration took the additional step, through rulemaking, of aligning payment rates for clinic visits at off-campus HOPDs built before the BBA with physician fee schedule rates.

But the move toward site-neutral payment between HOPDs and physician offices remains incomplete. In addition to exempting HOPDs that started construction before November 2, 2015, the BBA (as amended by subsequent provisions) exempts certain sites of care, such as

¹⁷ Cubanski, Juliette and Tricia and Neuman. 2018. "The Facts on Medicare Spending and Financing," *The Kaiser Family Foundation*. Issue Brief. <https://www.kff.org/medicare/issue-brief/the-facts-on-medicare-spending-and-financing/>.

¹⁸ Congressional Budget Office. 2018. "The Budget and Economic Outlook: 2018 to 2028." <https://www.cbo.gov/publication/53651>.

freestanding emergency departments, ambulatory surgical centers, and all on-campus HOPDs. The administration addressed the exemption for certain services (clinic visits) at grandfathered off-campus HOPDs, but left the remaining exemptions intact. As a result, much of the unjustified excess spending on services delivered at HOPDs that could be safely provided at physician offices remains.

Moving forward, policymakers should apply site-neutral payment for all services delivered in HOPDs – both off- and on-campus – that can safely be delivered outside of a hospital. The Medicare Payment Advisory Commission (MedPAC) has identified a list of services for which the additional payment for delivery at a HOPD appears unjustified, and a further list of services where only a small differential should exist.¹⁹

Expand site-neutral payments where clinically feasible

We recommend that Congress eliminate the grandfathering of off-campus HOPDs built before November 2015 from the BBA reforms and apply Medicare site-neutral payments for services delivered at on-campus HOPDs when clinically feasible, in line with MedPAC's recommendations.

Balancing incentives in Medicare Physician Fee Schedule

In all of the enthusiasm for expanding the use of alternative payment models, many lose sight of the fact that most of these models are built on a fee-for-service (FFS) architecture, specifically the Medicare Physician Fee Schedule (MPFS), which is used not only by Medicare, but by most Medicaid programs and private insurers as well.^{20,21} The MPFS was created in the late 1980s to address chronic imbalances in payment rates between physicians who spend most of their time providing procedures and those whose time is taken up with patient visits. While the fee schedule led to large relative gains in payments for visits that benefited specialties such as primary care, these gains eroded over time as the process to update the relative values was flawed and CMS devoted insufficient staff resources to refinement of relative values. The upshot has been increasing incentives to provide procedures and growing unattractiveness of primary care and other specialties that rely heavily on visits. The latter is a particular problem for alternative payment, which often involves a larger role for these specialties to coordinate care and manage chronic diseases.

The Medicare Payment Advisory Commission (MedPAC) has periodically urged Congress to take steps to diminish these distortions in relative payment, the most recent of which is included in its June 2018 report. In addition to many technical changes to bring more accurate data into the process of updating relative values, the Commission called for an across-the-board increase for all outpatient evaluation and management services to be funded by cuts in payment for other services. In a February 2019 article in *Health Affairs*, one of the authors of this letter (Ginsburg) outlined the importance of revising the MPFS as a part of a strategy to further alternative payment

¹⁹ MedPAC. 2014. "Hospital Inpatient and Outpatient Services." Report to the Congress: Medicare Payment Policy. March 2014. http://www.medpac.gov/docs/default-source/reports/mar14_ch03.pdf?sfvrsn=0.

²⁰ Clemens, Jeffrey and Joshua D. Gottlieb. 2017. "In the Shadow of a Giant: Medicare's Influence on Private Payment Systems." *Journal of Political Economy*, 125(1): 1-39.

https://www.researchgate.net/publication/227451073_The_Impact_of_Pharmacy-Specific_Any-Willing-Provider_Legislation_on_Prescription_Drug_Expenditures.

²¹ Clemens, Jeffrey and Joshua D. Gottlieb, J., and Timea L. Molnar. 2017. "Do Health Insurers Innovate? Evidence from the Anatomy of Physician Payments." *Journal of Health Economics*, 55C: 153-167. <https://www.sciencedirect.com/science/article/abs/pii/S0167629616305628?via%3Dihub>.

and called for ending the separation within CMS of the staff that manages the MPFS and the Centers for Medicare and Medicaid Innovation.²²

Balancing incentives in Medicare Physician Fee Schedule

We recommend that Congress increase Medicare fee schedule rates for evaluation and management services, offset by decreases elsewhere in the fee schedule.

Reforming Medigap cost sharing and Medicare benefit design

Medicare requires beneficiaries to pay part of the cost of their care through deductibles, copayments, and other cost-sharing requirements. These charges are intended to promote cost-consciousness and reduce unnecessary use of services. Beneficiaries are responsible for a separate Part A deductible for each hospitalization, daily copayments for extended stays in hospitals and skilled nursing facilities, an annual Part B deductible, and 20 percent coinsurance under Part B after the deductible is met.

This complex structure exposes beneficiaries in fee-for-service Medicare to unpredictable and potentially catastrophic expenses. About 80 percent of those beneficiaries have additional coverage through commercial Medigap plans, employer-sponsored retiree plans, or Medicaid, which pay for most of the required out-of-pocket costs.²³ Moreover, because Medicare's cost-sharing requirements are complex, they do not always provide a clear incentive to beneficiaries or their providers to select the most cost-effective approach to treatment.

Two policy modifications would improve the effectiveness of cost-sharing in promoting cost-awareness among beneficiaries in fee-for-service Medicare: simplifying the program's cost-sharing rules and restricting Medigap insurance.

Congress could adopt a simplified Medicare cost-sharing structure similar to that of most commercial insurance. Medicare's current requirements would be replaced by a single annual deductible, a uniform coinsurance rate for all spending above the deductible, and an annual out-of-pocket cap on beneficiary liability. This would increase incentives for beneficiaries to use medical services more prudently, but would also protect those with serious illness from high medical costs.

Congress should prohibit Medigap plans from providing full first-dollar coverage, either as a stand-alone policy or in conjunction with simplifying Medicare's benefit design. The Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") took the first step in this direction. It banned Medigap policies that cover the Part B deductible for Medicare beneficiaries who first become eligible in 2020. However, under that provision, beneficiaries who already have Medigap plans that cover the deductible can maintain that insurance. One option would extend the MACRA provision to all Medigap plans, including those that have been grandfathered in. However, that leaves in place first-dollar coverage for Part A services and the potential for zero cost-sharing

²² Berenson, Robert and Paul B. Ginsburg. 2019. "Improving the Medicare Physician Fee Schedule: Make it Part of Value-Based Payment." *Health Affairs*, 38(2), 246-252.
<https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05411>.

²³ Cubanski, Juliette, Anthony Damico, Tricia Neuman, and Gretchen Jacobson. 2018. "Sources of Supplemental Coverage Among Medicare Beneficiaries in 2016." *The Kaiser Family Foundation*.
<https://www.kff.org/medicare/issue-brief/sources-of-supplemental-coverage-among-medicare-beneficiaries-in-2016/>

liability for Parts A and B services above the deductible. A more effective approach would bar all Medigap policies from providing first-dollar coverage for Part A or Part B services, and further restricting Medigap so that it does not pay the full cost-sharing amount until the beneficiary's expenses exceed a specific level.

There are many potential versions of reforms like those described above, some of which would reduce the overall generosity of the Medicare benefit and some of which would not, and our group has not reached consensus on which version should be pursued. Nevertheless, policy changes in this area have received broad support among health policy experts for decades and changes like these could be an important step towards improving the Medicare program. To that end, we applaud Congress' recent efforts to alter Medigap coverage of Part B deductibles while urging them to build on this recent success.

Reforming Medigap cost sharing and Medicare benefit design

We recommend that Congress (1) reform Medicare's benefit design to include a combined deductible for Part A and B services, uniform coinsurance for services above the deductible, and an out-of-pocket maximum to protect beneficiaries from catastrophic costs; and (2) restrict Medigap plans from filling in the Medicare deductible(s) or covering the entirety of patient coinsurance.

Reforming protected classes in Medicare Part D.

The Medicare Part D program uses private insurance plans to cover non-physician administered drugs (i.e. those picked up at a pharmacy). Medicare enrollees can choose among a variety of available plans, thus incentivizing insurers to reduce costs and improve quality. However, competitive forces are severely limited by the program's "protected classes" – the rule requiring participating Part D plans to cover every available drug in six major therapeutic categories.

Completely eliminating this designation would carry the risk that insurers could alter formulary design to discourage sicker, and more expensive, beneficiaries from enrolling. The potential of encouraging this type of "cream skimming" argues against fully eliminating protected classes.

We suggest that Congress support the reforms to the protected class requirements in CMS' Part D Drug Pricing Proposed Rule (CMS-4180-P). Those reforms would maintain the six designated protected classes, but 1) allow insurers to exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold; 2) allow the exclusion of a protected class drug from a formulary if the drug represents only a new formulation of an existing drug; and 3) expand the use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications.

HHS has estimated that this proposal would save the Medicare trust fund roughly \$1.2 billion in the next ten years.²⁴ Thus, this proposal balances savings from additional flexibility, while avoiding undesirable incentives to attract only healthy patients through formulary design.

²⁴ Centers for Medicare & Medicaid Services, HHS. 2018. "Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses." *83 Fed. Reg. 62152*.
<https://www.federalregister.gov/documents/2018/11/30/2018-25945/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses>.

Reforming protected classes in Medicare Part D

We recommend that Congress support modifications to the Medicare Part D protected class designation. One option is to support CMS' Part D Drug Pricing Proposed Rule (CMS-4180-P) to increase flexibility in Medicare Part D protected classes.

Revising the Medicare Part D reinsurance program

The federal government subsidizes 74.5 percent of the cost of Part D coverage. But the subsidy comes in two forms—a direct subsidy to premiums and through reinsurance. For any beneficiary's spending in the catastrophic range (after the coverage gap), Medicare reinsurance pays for 80 percent of spending. Over time as more very expensive drugs have come into use and prices for brand name drugs have increased, reinsurance has grown from 31.3 percent of basic benefits in 2007 to 72.5 percent.

Between the 80 percent reinsurance and beneficiary coinsurance in this range of 5 percent, insurers are responsible for only 15 percent of drug spending in the catastrophic range. This is on top of diluted incentives for prudent spending in the coverage gap, where pharmaceutical manufacturers are now required to offer a 70 percent discount. The two together have the potential to severely distort insurer incentives. Insurers have little incentive to manage drug use through prior authorization, to secure lower list prices for expensive drugs used by their sickest patients, or to encourage the use of generic drugs or less expensive therapeutic alternative branded drugs.

MedPAC has proposed reducing the reinsurance percentage from 80 percent to 20 percent, while revamping the risk adjustment model used. This would substantially increase incentives on Part D insurers to contain costs, with the government reaping 74.5 percent of the savings and beneficiaries getting the remaining 25.5 percent.²⁵

Revising the Medicare Part D reinsurance program

We recommend that Congress adopt MedPAC's proposal to lower federal reinsurance in Medicare Part D to 20 percent.

Remove incentive to prescribe higher cost drugs in Medicare Part B

Currently, the Medicare Part B program pays physician offices and other providers for the drugs and biologics that they infuse or inject into their patients in their offices or outpatient clinics. Medicare pays for these drugs and biologics based on a weighted Average Sales Price (ASP) formula, which is tied to the prices (net of rebates and discounts) charged by manufacturers to all public and private purchasers (with some exceptions). In addition, Medicare pays physicians an additional 6 percent fee to compensate them for administering these drugs for their patients.

²⁵ MedPAC. 2018. "The Medicare Prescription Drug Program (Part D): Status Report." Report to the Congress: Medicare Payment Policy, Chapter 14. March 2018. http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec_rev_0518.pdf?sfvrsn=0.

The Medicare Payment Advisory Commission (MedPAC) has reported that, for large numbers of Part B-covered drugs and biologics, the ASP is well in excess of the prices paid by the office acquiring the products. In effect, these offices are able to use the sometimes large difference between the prices they pay for these drugs and the amount of reimbursement from Medicare to substantially increase their practice revenue. Further, the 6 percent add-on may encourage practices to use higher-priced products because the payment add-on increases commensurate with increases in the price of the product.

We support MedPAC’s recommendation to supplement a reformed ASP formula with a market-based pricing approach, which would be a voluntary option in its initial phase. The market-based option would solicit vendors to negotiate directly with the manufacturers to obtain the lowest prices possible for their products. The vendors would be permitted to use formularies with preferred tiers to increase their pricing leverage. Physicians would be allowed to select from among the competing vendors, and would acquire the products at the prices their selected vendors have secured from the manufacturers. Medicare would reimburse them for this expense, and provide a reasonable administration fee not tied to the price. Physicians would also get to share in whatever savings the vendors are able to produce, which would serve as the incentive for joining the program.

Physicians would have the option to stay in the ASP reimbursement program, but the add-on would need to be reduced. Further, it is important to require universal reporting of price data by all manufacturers selling products covered by Part B, and to assign biologics and their biosimilar competitors to the same billing code to ensure maximum price competition.

Remove incentive to prescribe higher cost drugs in Medicare Part B

We recommend that Congress enact the 2017 MedPAC proposal to reform payment for physician-administered drugs in Medicare Part B.

Reform the low-income subsidy under Part D to encourage greater use of generic drugs

Beneficiaries enrolled in the Medicare Part D low-income subsidy (LIS) face relatively similar copayments for generic and brand drugs (\$3.40 for generics and \$8.50 for a brands).²⁶ As a result, there may be less incentive to choose the therapeutically-equivalent generic drug when available, and we have seen notably lower usage of generic drugs among LIS beneficiaries. (However, this difference may stem, at least in part, from greater usage of drugs without generic equivalents available in the LIS population.)²⁷

To encourage greater use of generic drugs and reduce program spending, generic copayments should be reduced close to zero and brand copayments should be increased from current levels for LIS beneficiaries. The higher brand copayments would not apply to drugs without a generic equivalent or where therapeutic substitution with the generic is not deemed clinically-

²⁶ NCOA. 2019. “Part D LIS Eligibility and Benefits Chart.” <https://www.ncoa.org/wp-content/uploads/part-d-lis-eligibility-and-benefits-chart.pdf>.

²⁷ MedPAC. 2012. “Report to the Congress: Medicare Payment Policy.” March 2012, p.xxi. <http://www.medpac.gov/docs/default-source/reports/march-2012-report-to-the-congress-medicare-payment-policy.pdf>.

appropriate. Some of the savings from this proposal could be used to reduce other costs for low-income Medicare beneficiaries.

Reform the low-income subsidy under Part D to encourage greater use of generic drugs

We recommend increasing the spread between generic and brand drug copayment requirements in the Part D low-income subsidy in order to encourage greater generic drug utilization.

Expand bundled payments through legislation

In recent years, both the Medicare program and private payers have been experimenting with “bundled” payment approaches in which a fixed payment is made for all care associated with an episode of medical care; some bundled payment models also adjust payment based on quality performance. Evidence to date has suggested that such models can, at least in some instances, reduce spending without impairing the quality of care patients receive.^{28,29,30,31} This evidence suggests that bundled payments may be more effective for some conditions than others, but provides little evidence that they have done harm in any context.

In light of this evidence, Congress should mandate that Medicare use bundled payments for episodes similar to those included in the Bundled Payment for Care Improvement (BPCI) initiative operated by the Center for Medicare and Medicaid Innovation (CMMI). To ensure that this system of bundled payments creates strong incentives for providers to become more efficient and generates savings for the federal government, the bundle amount should be set at an empirically-justified level and providers should be responsible for any spending in excess of the bundle amount.

Pending Congressional action, the Administration should reverse its 2017 decision to cancel or scale back CMMI demonstrations that were testing bundled payments on a mandatory basis, and it should expand those tests to encompass additional episode types. When the relevant statutory criteria are met, the Administration should use its authority to expand those models throughout the Medicare program.

²⁸ Barnett, Michael L., et al. 2019. “Two-Year Evaluation of Mandatory Bundled Payments for Joint Replacement”. *New England Journal of Medicine*, 380(3), 252-262. <https://www.nejm.org/doi/full/10.1056/NEJMsa1809010>.

²⁹ Finkelstein, Amy, et al. 2018. “Mandatory Medicare Bundled Payment Program for Lower Extremity Joint Replacement and Discharge to Institutional Postacute Care Interim Analysis for the First Year of a 5-Year Randomized Trial.”. *JAMA*, 320(9), 892-900. <https://jamanetwork.com/journals/jama/article-abstract/2698927>.

³⁰ Joynt Maddox, Karen E., John Orav, Jie Zheng, and Arnold M. Epstein. 2018. “Evaluation of Medicare’s Bundled Payments Initiative for Medical Conditions.” *New England Journal of Medicine*, 379(3), 260-269. <https://www.nejm.org/doi/full/10.1056/NEJMsa1801569>.

³¹ Dummit, Laura, et al. 2018. “CMS Bundled Payments for Care Improvement Initiative Models 2- 4: Year 5 Evaluation & Monitoring Annual Report.” <https://downloads.cms.gov/files/cmmi/bpci-models2-4-yr5evalrpt.pdf>.

Expand bundled payments through legislation

We recommend that: (1) Congress mandate that Medicare use bundled payments for a set of episodes similar to those included in the Bundled Payment for Care Improvement initiative; and (2) the Administration move forward with testing bundled payments in additional contexts.

Improving the choice environment for Medicare enrollees

Medicare beneficiaries have numerous coverage enrollment options but the process through which they make their coverage decisions doesn't allow for clear cost comparisons. Currently, Medicare beneficiaries are allowed to select between traditional Medicare and Medicare Advantage. Separately, they may select a drug coverage plan, and then also a supplemental insurance plan offered in the private market.

It is not easy for the beneficiaries to see the full cost consequences of the various combinations of these options because they involve separate enrollment processes. To make informed decisions, Medicare should set up an enrollment system that allows the beneficiaries to see what the different combinations of options available to them would mean for their premium and out-of-pocket costs over the following year.

Improving the choice environment for Medicare enrollees

We recommend that Medicare adopt more comprehensive plan-finder tools that give beneficiaries better information on the likely cost of their enrollment options.

Promoting Competition in the Pharmaceutical Market

The Drug Price Competition and Patent Term Restoration Act (or "Hatch-Waxman Act") established a period of exclusivity for novel therapeutics, while substantially lowering barriers to entry once this expired. Over time, drug makers have used strategic behavior to block or delay entry of lower-priced generic drug competitors. We urge lawmakers to re-evaluate the net effect of the full set of tools now available to drug manufacturers for delaying generic entry and pursue reforms to encourage generic competition and lower drug spending. In particular, we outline below a series of specific policy reforms to consider.

Restricting REMS abuse

Manufacturers of dangerous drugs are required by the FDA to develop Risk Evaluation and Mitigation Strategies (REMS). Today, 40 percent of newly approved drugs require a REMS,³² which can include monitoring protocols or, in stringent cases, restrictions on the distribution of drugs. Branded drug manufacturers have exploited REMS by arguing that safety considerations prevent them from selling their drug to generic manufacturers. This can delay or prevent competitors from creating a generic alternative.

³² Zelnick Kaufman, Beth. 2016. "Statement of Beth Zelnick Kaufman." Senate Judiciary Subcommittee on Antitrust, Competition, Policy, and Consumer Rights. <https://www.judiciary.senate.gov/imo/media/doc/06-21-16%20Zelnick-Kaufman%20Testimony.pdf>.

The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2018 would address this by allowing generic and biosimilar makers to bring civil lawsuits if insufficient quantities of a branded drug are not made available. CBO estimates this bill would reduce the federal budget deficit by \$3.8 billion over 10 years and reduce system wide costs by a larger amount.³³

Restricting REMS abuse

We recommend that Congress pass the CREATES Act of 2018, or similar legislation aimed at reducing delays of generic competitors into drug markets due to insufficient samples of branded products.

Restricting the use of the orphan drug designation

The Orphan Drug Act introduced various additional incentives for drugs treating rare conditions. Over time, however, some these policies have had perverse incentives and boosted drug spending. In part, these unintended effects arose from interactions with the 340B program, which was introduced to provide discounted drugs to hospitals serving large portions of low-income Americans.

Notably, if a drug is granted orphan status for a single indication, it is exempted from the 340B discount drug program for all sales. In addition, drugs may gain successive orphan drug designations on subtypes of a given disease, giving it an orphan drug exclusivity for various subpopulations far beyond the initial 7 years. Both of these activities increase drug spending. We recommend that orphan drugs only be exempted from the 340B program for the condition(s) for which they have orphan status and that any secondary orphan designations be limited to 6 months of exclusivity each (rather than the current 2 years). Allowing for an additional 6 months of exclusivity would retain an incentive to investigate further uses of an existing drug, while limiting the ability to indefinitely “game the system.”

Restricting the use of the orphan drug designation

We recommend that Congress pass legislation which exempts orphan drugs from the 340B program for conditions which initially established their orphan status. We further recommend that secondary orphan designations be granted only 6 months of additional exclusivity.

Reforming the 340B Program

We recognize that the 340B program has grown beyond its initial purpose. Because 340B providers may purchase drugs at large discounts while billing much higher rates to patients and insurers, there is a strong incentive for providers to qualify for the program. Close to half of hospitals now participate.³⁴ In addition, this ability to inflate mark-ups encourages hospitals to

³³ Congressional Budget Office. 2018. “Cost Estimate of S. 974 Creating and Restoring Equal Access to Equivalent Samples Act of 2018.” <https://www.cbo.gov/system/files/2018-09/s974.pdf>.

³⁴ GAO. 2015. “Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.” GAO-15-442: Published: Jun 5, 2015. Publicly Released: Jul 6, 2015. <https://www.gao.gov/products/GAO-15-442>

employ physicians (particularly oncologists), which diminishes competition in the physician market.

We propose that Congress amend the 340B program to tie discounted drug prices to the status of individual patients, not entire facilities. For example, providers should be granted 340B prices only for drugs administered to Medicaid patients or those without insurance.

Reforming the 340B program

We recommend that the 340B designation be tied to patient status rather than being determined at the facility level.