



Institute For Policy Innovation

ISSUE BRIEF

BUDGETS FIRST, PATIENTS LAST:

MEDPAC'S PLAN TO UNDERMINE MEDICARE PART B'S DRUG BENEFIT

by Merrill Matthews, Ph.D.

The Medicare Part B prescription drug program is one of the few federal programs that has worked reasonably well. MedPAC recently proposed several extensive changes that would fundamentally alter the program—and not for the better. The result will almost surely be fewer participating doctors, reduced access and higher costs. Any reform plan should put patients' needs before the government's budgets.

Synopsis

The Medicare Part B prescription drug program is one of the few federal programs that has worked reasonably well over the years, both for health care providers and for some of the sickest and most vulnerable patients. So when the Centers for Medicare and Medicaid Services (CMS) proposed changing the program's reimbursement policy last year, it set off alarm bells.¹

Introduction

More recently, the Medicare Payment Advisory Commission (MedPAC) proposed several more-extensive changes.² While one was similar to the CMS recommendation, others would fundamentally alter the way the Part B prescription drug program works—and not for the better. While MedPAC frames its proposals as an effort to make Part B more market-driven, they would have the opposite effect by imposing price controls on Part B medicines. These ill-informed proposals ignore how price controls could reduce access, hinder innovation and even increase costs.

The Part B drug program has undergone reform fairly recently—through the Medicare Modernization Act (MMA) of 2003. These reforms made the program more market-based and have helped control costs while beneficiaries continue to benefit from access to growing medical innovation.

1. Centers for Medicare and Medicaid Services, "CMS proposes to test new Medicare Part B prescription drug models ...," March 8, 2016. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-08.html>

2. Medicare Payment Advisory Commission, "Report to Congress: Medicare and the Health Care Delivery System," June 2017.

Government programs should strive to fulfill their missions in as efficient and cost-effective way as possible. But fundamentally changing programs that are working well and serving an important function can be counterproductive. More government regulation, bureaucratic micromanagement and price controls, which is what MedPAC has proposed, often have the unintended result of increasing costs and reducing access to care.

What Medicare Part B Does

Medicare pays for prescription drugs in several ways. Part D, which was created by the Medicare Modernization Act, is the largest and best-known program. It provides outpatient prescription drugs for some 41 million Medicare beneficiaries.³

Medicare Part B, the program that pays for most physicians' services, also covers prescription drugs that are administered in the physician's office or in a hospital outpatient setting. While about 50.7 million people have chosen to participate in Part B, only a relatively small percentage are receiving prescription drugs through the program.⁴ These mostly seniors often have debilitating and life-threatening medical conditions, such as cancer, rheumatoid arthritis and end-stage renal disease.

Why MedPAC Is Concerned

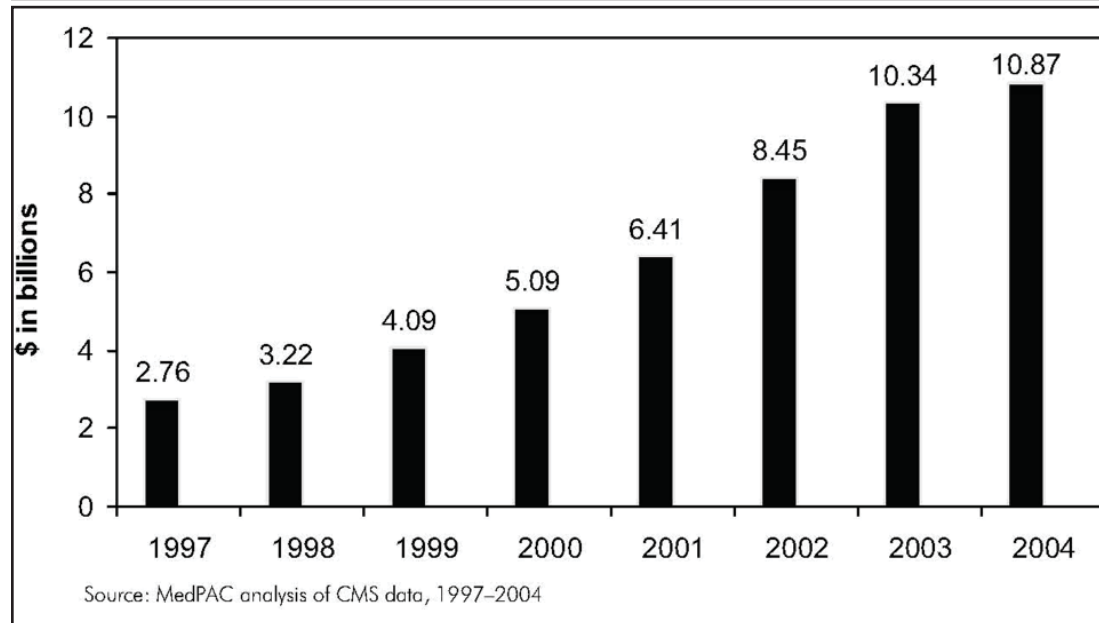
Congress created MedPAC as part of the Balanced Budget Act (BBA) of 1997. It is an independent body of 17 health policy experts who provide Congress with analysis and policy advice on ways to improve Medicare. Congress may or may not choose to act on any of MedPAC's recommendations.

The BBA established Part B reimbursement guidelines, requiring Medicare to reimburse 95 percent of the average wholesale price (AWP) or the actual charge, whichever was lower, for each drug that physicians billed.⁵ Then-executive director of MedPAC, Mark E. Miller, explained in 2006 congressional testimony that under the 1997 policy, "Expenditures for Part B drugs increased rapidly, more than 25 percent every year from 1998 to 2003."⁶ (see Figure 1)

In order to address Part B's drug spending growth and better align reimbursements with prices paid in the market, the MMA changed the reimbursement policy to the average sales price (ASP) plus 6 percent. This was a significant reform, because it shifted the reimbursement rate from a list price set by manufacturers to a price that incorporates the discounts that are privately negotiated in the market. These reforms were successful in generating significant savings for the program and permanently tying reimbursement to a private market mechanism.

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3. Henry J. Kaiser Family Foundation, "The Medicare Part D Prescription Drug Benefit," September 26, 2016. <http://www.kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/>
 4. National Committee to Preserve Social Security & Medicare, "Medicare Fast Facts." <http://www.ncpssm.org/Medicare/MedicareFastFacts>
 5. Centers for Medicare and Medicaid Services, "Historical Part B Drug Price Files." <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/HistPartBDrugPricingFiles/Overview.html>
 6. Mark E. Miller, "Medicare Part B Drugs and Oncology," Statement before the Subcommittee on Health, Committee on Ways and Means, July 13, 2006, p. 2. http://www.medpac.gov/docs/default-source/congressional-testimony/071306_testimony_part-b_oncology.pdf?sfvrsn=0

**FIGURE 1:
MEDICARE SPENDING AND ANNUAL GROWTH RATES FOR PART B DRUGS**



In a report examining reimbursement of Part B drugs, the Government Accountability Office (GAO) agreed with CMS “that ASP is a practical data source for setting and updating rates for drug[s],” ensuring “that Medicare pays appropriately—neither too much nor too little—and ensuring beneficiary access to these innovative pharmaceutical products.”⁷

Part B drugs are often complex biologics that account for about 65 percent of Part B drug spending.⁸ Administering them, usually by infusion or injection, requires trained health care professionals. Physicians purchase them and then bill Medicare for reimbursement. While various factors affect what physicians pay for the drugs—for example, physicians with smaller practices and less purchasing power may have to pay more—reimbursement is always set at ASP plus 6 percent.

Relying on physicians to provide Part B drugs in their offices or clinics is more efficient and much less costly than administering them in the hospital, which is where patients would go if doctors were unwilling or unable to provide the care. Any proposal that discourages physicians from providing and administering Part B drugs in situ will necessarily increase Medicare Part B spending, not reduce it.

Both CMS and several MedPAC members believe the current Part B drug reimbursement model encourages physician overspending on high-cost drugs. Some of this concern comes from the rise in Part B drug spending in recent years, increasing from \$21.5 billion in 2014 to \$24.6 billion in 2015. However, Part B drugs remain just 3 percent of overall Medicare spending.⁹

7. United States Government Accountability Office. “Medicare Hospital Pharmaceuticals: Survey shows price variation and highlights data collection lessons and outpatient rate-setting challenges for CMS,” April 2006. <http://www.gao.gov/assets/250/249967.pdf>

8. MedPAC, “Report to Congress,” p. 37.

9. “Medicare Monday: A Closer Look at Part B Spending,” Pharmaceutical Research and Manufacturers Association, March 13, 2017 <http://catalyst.phrma.org/medicare-monday-a-closer-look-at-part-b-spending>

In its Part B reform proposal, CMS claimed, “Physicians often can choose among several drugs to treat a patient, and the current Medicare Part B drug payment methodology can penalize doctors for selecting lower-cost drugs, even when these drugs are as good or better for patients based on the evidence.”¹⁰ Based on CMS and MedPAC’s recent stated concerns, one might conclude that doctors are disproportionately prescribing the most expensive drugs. This concern may represent something of a shift from the recent past. In 2015, MedPAC member Dr. Francis J. Crosson mentioned, “I don’t think we actually have evidence in front of us that what we think might be an adverse incentive actually is ...”¹¹

Yes, there are some costly patients using Medicare Part B prescription drugs, but that’s exactly what one would expect given the Part B population’s age and health challenges. Even so, MedPAC says that only a “small number” use the most expensive drugs.

What MedPAC Is Proposing

Last year, CMS proposed reducing the 6 percent add-on fee to 2.5 percent of ASP plus a flat \$16.80.¹² The agency argued that the current model incentivizes doctors to prescribe more expensive drugs and that the proposed change, to be tested in a pilot program, would reduce that economic incentive.

However, after hearing from a number of physicians and patients groups, CMS dropped its proposal in December 2016.¹³

Then in April of 2017, MedPAC weighed in with a wider and more extensive set of Part B drug reimbursement changes. Proposals intended to go into effect in 2018 are:

- Make several changes to the current ASP model by requiring manufacturers to submit ASP data (and penalize them if they don’t), pay Medicare a rebate if prices exceed a certain government-imposed benchmark, and use a common billing code for both reference biologics and their biosimilars.
- Change the WAC (wholesale acquisition cost, or “list price”) payment model by reducing providers’ reimbursement from WAC plus 6 percent to WAC plus 3 percent.

MedPAC also proposed long-term changes to begin in 2022 that are even more ambitious—and harmful. The commission wants to implement what it calls a “Drug Value Program” (DVP), in which “Medicare contracts with a small number of private vendors to negotiate prices for Part B products.”¹⁴ MedPAC describes its Drug Value Program this way: “The intent of the DVP would be to obtain lower prices for Part B drugs by permitting private vendors to use tools (such as a formulary) to negotiate with manufacturers and improve incentives for provider efficiency through shared savings opportunities.”¹⁵

10. Centers for Medicare and Medicaid Services, “CMS proposes to test new Medicare Part B prescription drug models ...”

11. Medicare Payment Advisory Committee, Public Meeting, Washington DC, March 5, 2015, p. 168. <http://www.medpac.gov/docs/default-source/meeting-materials/march-2015-public-meeting-transcript.pdf?sfvrsn=0>

12. “CMS proposes to test new Medicare Part B prescription drug models ...,” March 8, 2016.

13. Zachary Brennan, “CMS Drops Medicare Part B Drug Payment Pilot,” Regulatory Affairs Professional Society, December 16, 2016. <http://www.raps.org/Regulatory-Focus/News/2016/12/16/26388/CMS-Drops-Medicare-Part-B-Drug-Payment-Pilot/>

14. MedPAC, “Report to Congress,” p. 32.

15. *Ibid.*, p. 35.

Explaining Part B's Spending Growth

MedPAC sees spending—which is not the same as prices—rising for Part B prescription drugs and so proposes implementing more regulations and price controls.

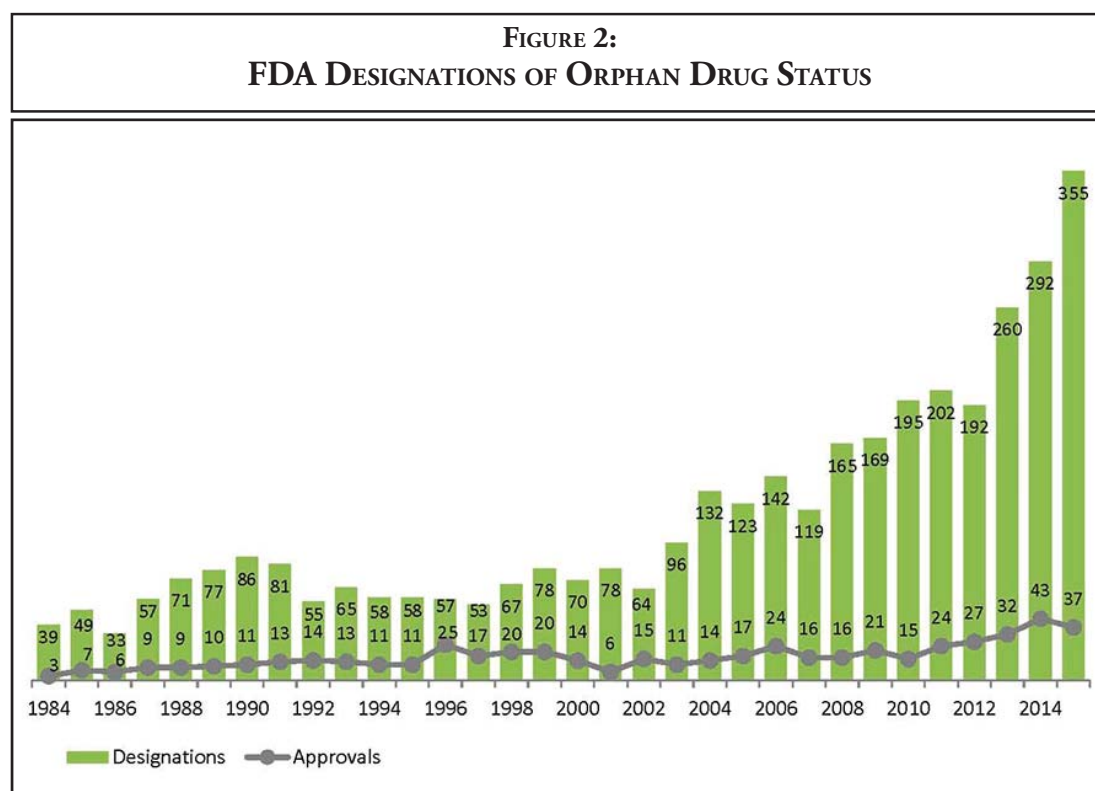
According to the GAO, total Medicare Part B drug spending “grew at an average annual rate of 4.4 percent from 2007 to 2013, and this growth was driven primarily by new Part B drugs.”¹⁶ Patients who previously lacked treatment options getting access to newly developed medicines is not the same as pure price growth.

What non-price factors could be driving Part B spending?

Aging Population — The U.S. has an aging population; there are more seniors—an estimated 10,000 baby boomers are retiring every day—and they are living longer.¹⁷

Medical Advancements — Innovator drug companies are increasingly targeting unmet medical needs and rare diseases where there are few or no treatment options. (Rare diseases are defined as those affecting fewer than 200,000 people, and the resulting drugs are referred to as “orphan drugs.”) (See Figure 2)

The GAO notes, “New Part B drugs are more likely than new non-Part B drugs to have used an FDA expedited program or to have received an orphan designation which applies to drugs that treat rare conditions and are received by a relatively small number of people.”¹⁸



16. Government Accountability Office, “Medicare Part B: Expenditures for New Drugs Concentrated Among a Few Drugs, and Most Were Costly for Beneficiaries,” November 20, 2015. <https://www.gao.gov/products/GAO-16-12>

17. Glenn Kessler, “Do 10,000 baby boomers retire every day?,” Washington Post, July 24, 2014. https://www.washingtonpost.com/news/fact-checker/wp/2014/07/24/do-10000-baby-boomers-retire-every-day/?utm_term=.d5057408ff7a

18. Government Accountability Office, “Medicare Part B: Expenditures for New Drugs Concentrated Among a Few Drugs, and Most Were Costly for Beneficiaries,” November 20, 2015.

And yet research costs and regulatory hurdles continue to mount, even as the target patient population for many new drugs continues to shrink, which means those R&D costs must be spread over a very small number of patients, raising the per-person cost.¹⁹ (See Figure 3)

**FIGURE 3:
AVERAGE COST OF DRUGS APPROVED BY YEAR**

Year	R&D (Billions)	Approved per year	Cost per Approved Drug (Millions)
2007	\$47.9	18	\$2,661.1
2008	\$47.4	24	\$1,975.0
2009	\$46.4	25	\$1,856.0
2010	\$50.7	21	\$2,414.3
2011	\$48.6	30	\$1,620.0
2012	\$49.6	39	\$1,271.8
2013	\$51.6	27	\$1,911.1
2014	\$53.3	41	\$1,300.0
2015	\$58.8	45	\$1,306.7
2016	\$65.5	22	\$2,977.3
Totals:	\$519.8	293	\$1,774.1

The key point is that new drugs addressing unmet medical needs will almost certainly add to drug spending because these patients had no effective options prior to the new drug(s). But that is a policy and medical success, not a failure. As MedPAC member Dr. William J. Hall has said, “The biologics, I would argue, [and] some of the newer antibiotics have made a huge increase in the quality of life for Medicare recipients. So we fool with this at our peril...”²⁰

Single-Source Drugs — MedPAC says of Part B drugs, “of the top 10 products in 2015, 8 were biologics and none faced biosimilar or generic competition.”²¹

To foster innovation, the federal government grants intellectual property protection for a limited time. While competitors can produce drugs in the same therapeutic class, they cannot release a copy of a drug until its patent expires. Drugs typically cost more while the patent is still in effect—a financial incentive to allow companies to recoup the money spent on research and development. The large number of single-source drugs used in Part B puts upward pressure on total spending. However, when a generic version appears, the price will likely drop, along with spending, if providers view the biosimilar as comparably effective as the reference drug. In fact, biosimilars are starting to enter the market, and many of the most expensive Part B products will soon be subject to competition from biosimilars.

19. See Merrill Matthews, “The High Cost of Inventing New Drugs—And of Not Inventing Them” and “Explaining the High Cost of Prescription Drugs,” Institute for Policy Innovation, IPI Ideas Nos. 65 (April 2015) and 69 (November 2015).

20. Medicare Payment Advisory Committee, Public Meeting, p. 158-9.

21. MedPAC, “Report to Congress,” p. 37.

Others Determine the Prices — MedPAC wants to focus on ASP as if drug companies control the final sales price of their drugs; they often don't. They may control their initial price—the wholesale acquisition cost—but the government, pharmacy benefit managers (PBMs), insurers, hospitals and pharmacies play a major role in determining the final sales price. The fact that ASP incorporates these discounts and rebates has consistently moderated Part B prices over time.

Problems with MedPac's "Solutions"

MedPAC proposes to reduce Part B drug spending in several ways, but most of them depend on various forms of restricted access and price controls.

Using Formularies and Rebates — A formulary is a list of approved drugs. While formularies are widely used, those imposed by the government are designed to be restrictive in an effort to reduce spending.

MedPAC is pushing that same dynamic for Medicare Part B, which it considers a "key feature" of the DPV. "Permitting vendors to *exclude drugs or biologics from the formulary* when other products with similar health effects exist would often give them leverage to negotiate lower prices on these products."²² (Emphasis added)

Under the DPV the government, or some quasi-governmental body, would set a predetermined cap on the price. If the ASP were to exceed that cap, drug manufacturers would have to rebate the difference. Since the cap is arbitrary, it can—and likely would—be lowered if the government is facing budget constraints or political pressure, or if it just wants more savings.

However, a government-mandated drug company rebate is really just a form of corporate tax increase. And here's the irony: Most economists argue that companies don't pay taxes; they pass those costs on, often to consumers in the form of higher prices. Similarly, economic theory would suggest that rebate costs, like taxes, may also be passed on in the form of higher prices.

Rebates also shift costs. MedPAC recognizes its rebate scheme could lead to cost shifting. "The Medicaid 'best price' policy, which requires makers of innovator drugs to provide a rebate equal to the greater of 23.1 percent of the average manufacturer price (AMP) or the difference between AMP and the manufacturer's 'best price' to any customer ..., *can increase costs to other payers, including Medicare.*"²³ (Emphasis added)

Thus, MedPAC's proposed rebates would distort the market and could have the perverse effect of driving prices higher, which would lead to state governments that purchase those drugs demanding even more rebates, which would drive prices even higher.

Negotiating Prices — MedPAC's version of "negotiated prices" really means the government dictates prices and drug makers accept them. Just look at other Medicare reimbursement systems. The federal government dictates what it will pay for hospital services under Part A and for physician services under Part B. In fact, MedPAC cites Part A and B's price controls *as a feature* of those programs, and concludes that imposing something similar on Part B drugs would create an internal consistency. Both Parts A and B price control laws were initially sold as ways to increase competition, improve efficiency and, most importantly, lower total spending. They have achieved none of the above.

22. MedPAC, "Report to Congress," p. 61.

23. Ibid., p. 39.

Shared Savings — “Shared savings” simply means that the government wants to make it lucrative for doctors to set aside what they think is best for their patients and prescribe what the government thinks is best. And that’s what MedPAC is proposing for Part B— for those physicians who are willing to practice medicine the way Washington wants them to.

The Patient Protection and Affordable Care Act’s Accountable Care Organizations (ACOs) had a similar purpose, using shared savings as bait. As Healthcare Infomatics explained from a 2016 CMS report: “[W]ith six of 12 (50 percent) Pioneer ACOs generating shared savings, and 119 of 392 (30 percent) MSSP [Medicare Shared Savings Program] ACOs generating shared savings last year, 279 of the 404 total Medicare ACOs, or 69 percent, did not generate savings outside a minimum savings rate to earn shared savings.”²⁴ In other words, the results were decidedly mixed, and certainly no panacea of savings or improved care. There is little reason to think the DPV’s shared savings proposal would fare any better.

Step Therapy — Another MedPAC solution is “step therapy,” sometimes referred to as “fail first.” It encourages physicians prescribing drugs to begin with the least expensive drug in the same therapeutic class. If that drug doesn’t work, then the next least expensive drug on the formulary is prescribed. If several of the lower-priced drugs are not effective, then the doctor is allowed to prescribe a more expensive drug.

The problem with step therapy is that it is inefficient, not to mention costly, forcing physicians to prescribe drugs that they may not think are in the best interests of their patients. More importantly, patients using Part B prescription drugs can be very sick, and they may not have the time or the strength, let alone the finances, to work through a list of drugs that bureaucrats, who have never examined the patient, think they should try first. Step therapy for many Part B patients would be a death sentence.

Combined Coding — The government currently uses one billing code for a biologic drug and a separate code for each of its biosimilars, if any exist. MedPAC proposes placing both the biologic and its lower-priced biosimilar(s) in the same code for ASP purposes. That change would have an averaging effect—i.e., reducing the reimbursement for the biologic and increasing the reimbursement for the biosimilar, relative to the status quo.

This proposal offloads part of the costs onto physicians treating Part B patients. That’s because physicians’ cost to buy the reference biologic wouldn’t necessarily change, but their reimbursement would likely be lower. MedPAC’s goal is to encourage physicians to prescribe the biosimilar rather than the biologic. “Thus, clinicians could earn more net revenue than they otherwise would on lower cost products ...”²⁵ For those products that have a biosimilar, MedPAC tries to put physicians’ financial interests above their patients’ interest.

MedPAC’s proposal places the physician in an ethical dilemma: It might cost the physician more to prescribe a needed drug than he or she receives from the government. Not to worry, MedPAC says, “A payment exception process might also mitigate any risk of beneficiaries’ access being adversely affected.” In other words, patients might not be harmed IF physicians were willing to take the time and effort to go through an approval process.

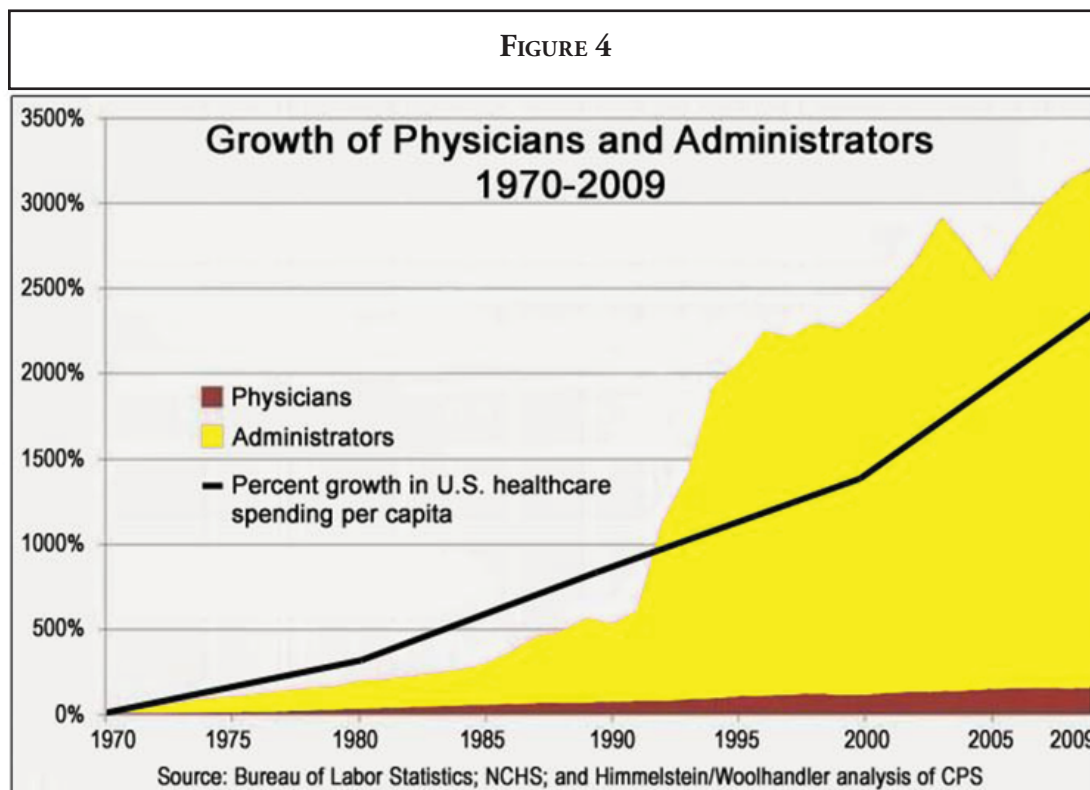
24. Rajiv Leventhal, “Medicare ACOs Saved \$466M in 2015, but Nearly Half Failed to Generate Any Savings,” Healthcare Infomatics, August 25, 2016. <https://www.healthcare-informatics.com/article/payment/breaking-nearly-half-medicare-acos-failed-generate-savings-2015>

25. MedPAC, “Report to Congress,” p. 57.

Other Problems with MedPac’s Proposal

Besides the specific problems mentioned above, MedPAC’s proposals create a number of other challenges.

Adding Middlemen — The U.S. health care system is filled with middlemen, including companies such as pharmacy benefit managers that have little or no role in providing care. They mostly negotiate prices and discounts, and take a chunk of the savings for themselves. Both of MedPAC’s recommended changes invest even more power in middlemen, primarily to negotiate lower prices, but it isn’t clear how much patients would benefit from the change.²⁶ (See Figure 4)



Medicare’s Low Reimbursement Rates — The fundamental problem with several of MedPAC’s proposals is that they are variations of a price control scheme, wrapped in the language of choice and competition.

Price controls distort economic incentives and often lead to unintended consequences. With respect to Medicare, one of the clear unintended consequences has been doctors limiting their Medicare patient load.

Medicare typically pays physicians, on average, about 20 percent less than private health insurance, according to Medicare’s Office of Chief Actuary.²⁷ And under the Affordable Care Act, reimbursements will continue to decline for decades to come.

26. See Merrill Matthews and Peter Pitts, “Selective Transparency: Transparency Efforts Obscure Real Health Care Pricing Issues,” Institute for Policy Innovation Issue Brief, May 2017.

27. John D. Shatto and M. Kent Clemens, “Projected Medicare Expenditures under an Illustrative Scenario with Alternative Payment Updates to Medicare Providers,” CMS Office of the Actuary, July 22, 2015, pp. 7-8. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrust-Funds/Downloads/2015STRAlternativeScenario.pdf>

MedPAC makes it very clear that its goal, especially under the DVP, is to reduce what physicians are currently receiving from Medicare Part B prescription drug administration. Medicare's low reimbursement rates—which would be exacerbated by MedPAC's proposals—would force many physicians to limit their Medicare patient load, making it harder for seniors to find a doctor.

MedPAC points out that Part B drug spending is now growing much faster in hospital outpatient departments (HOPDs). “Between 2009 and 2015, average annual growth was roughly 16 percent in HOPDs and 7 percent for physicians.”²⁸ No one should be surprised. Low Medicare reimbursement rates, made even lower if MedPAC is successful, will result in physicians cutting back and even more patients having to go to the hospital for their Part B drugs, which will have the unintended effect of driving up Part B spending.

Conclusion

MedPAC is following the path of all countries that spend significant amounts of taxpayer dollars on health care: looking for ways to reduce that spending. In short: budgets first, patients last.

The result will almost surely be fewer doctors participating in Part B drug administration. And those who remain would be turning to the oldest drugs first—because MedPAC is pushing them in that direction—before trying the newest and most advanced therapies. Or they may just send their patients to the hospital for the drugs, which, ironically, will cost the government significantly more money.

Government-devised systems usually empower the wrong people—in this case, bureaucrats and middlemen—and reduce access to care, especially for the sickest and most vulnerable patients. Medicare's Part B drug program has a disproportionate share of those patients.

Any reform plan should be guided by the patients' needs, not the government's budgets. Dramatic changes from the current system, like those being proposed by MedPAC, would put patients' lives at risk.

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28. MedPAC, “Report to Congress,” p. 37.