

# PRESCRIPTION DRUG COVERAGE IN THE MEDICARE PROGRAM

---

## HEARING BEFORE THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED SIXTEENTH CONGRESS FIRST SESSION

APRIL 30, 2019

**Serial No. 116-27**



Printed for the use of the Committee on Energy and Commerce  
[govinfo.gov/committee/house-energy](http://govinfo.gov/committee/house-energy)  
[energycommerce.house.gov](http://energycommerce.house.gov)

U.S. GOVERNMENT PUBLISHING OFFICE

39-904 PDF

WASHINGTON : 2021

## COMMITTEE ON ENERGY AND COMMERCE

FRANK PALLONE, JR., New Jersey  
*Chairman*

|                                               |                                    |
|-----------------------------------------------|------------------------------------|
| BOBBY L. RUSH, Illinois                       | GREG WALDEN, Oregon                |
| ANNA G. ESHOO, California                     | <i>Ranking Member</i>              |
| ELIOT L. ENGEL, New York                      | FRED UPTON, Michigan               |
| DIANA DeGETTE, Colorado                       | JOHN SHIMKUS, Illinois             |
| MIKE DOYLE, Pennsylvania                      | MICHAEL C. BURGESS, Texas          |
| JAN SCHAKOWSKY, Illinois                      | STEVE SCALISE, Louisiana           |
| G. K. BUTTERFIELD, North Carolina             | ROBERT E. LATTA, Ohio              |
| DORIS O. MATSUI, California                   | CATHY McMORRIS RODGERS, Washington |
| KATHY CASTOR, Florida                         | BRETT GUTHRIE, Kentucky            |
| JOHN P. SARBANES, Maryland                    | PETE OLSON, Texas                  |
| JERRY McNERNEY, California                    | DAVID B. McKINLEY, West Virginia   |
| PETER WELCH, Vermont                          | ADAM KINZINGER, Illinois           |
| BEN RAY LUJAN, New Mexico                     | H. MORGAN GRIFFITH, Virginia       |
| PAUL TONKO, New York                          | GUS M. BILIRAKIS, Florida          |
| YVETTE D. CLARKE, New York, <i>Vice Chair</i> | BILL JOHNSON, Ohio                 |
| DAVID LOEBSACK, Iowa                          | BILLY LONG, Missouri               |
| KURT SCHRADER, Oregon                         | LARRY BUCSHON, Indiana             |
| JOSEPH P. KENNEDY III, Massachusetts          | BILL FLORES, Texas                 |
| TONY CARDENAS, California                     | SUSAN W. BROOKS, Indiana           |
| RAUL RUIZ, California                         | MARKWAYNE MULLIN, Oklahoma         |
| SCOTT H. PETERS, California                   | RICHARD HUDSON, North Carolina     |
| DEBBIE DINGELL, Michigan                      | TIM WALBERG, Michigan              |
| MARC A. VEASEY, Texas                         | EARL L. "BUDDY" CARTER, Georgia    |
| ANN M. KUSTER, New Hampshire                  | JEFF DUNCAN, South Carolina        |
| ROBIN L. KELLY, Illinois                      | GREG GIANFORTE, Montana            |
| NANETTE DIAZ BARRAGÁN, California             |                                    |
| A. DONALD McEACHIN, Virginia                  |                                    |
| LISA BLUNT ROCHESTER, Delaware                |                                    |
| DARREN SOTO, Florida                          |                                    |
| TOM O'HALLERAN, Arizona                       |                                    |

---

### PROFESSIONAL STAFF

JEFFREY C. CARROLL, *Staff Director*  
TIFFANY GUARASCIO, *Deputy Staff Director*  
MIKE BLOOMQUIST, *Minority Staff Director*

SUBCOMMITTEE ON HEALTH

ANNA G. ESHOO, California  
*Chairwoman*

|                                                                |                                           |
|----------------------------------------------------------------|-------------------------------------------|
| ELIOT L. ENGEL, New York                                       | MICHAEL C. BURGESS, Texas                 |
| G. K. BUTTERFIELD, North Carolina, <i>Vice</i><br><i>Chair</i> | <i>Ranking Member</i>                     |
| DORIS O. MATSUI, California                                    | FRED UPTON, Michigan                      |
| KATHY CASTOR, Florida                                          | JOHN SHIMKUS, Illinois                    |
| JOHN P. SARBANES, Maryland                                     | BRETT GUTHRIE, Kentucky                   |
| BEN RAY LUJAN, New Mexico                                      | H. MORGAN GRIFFITH, Virginia              |
| KURT SCHRADER, Oregon                                          | GUS M. BILIRAKIS, Florida                 |
| JOSEPH P. KENNEDY III, Massachusetts                           | BILLY LONG, Missouri                      |
| TONY CARDENAS, California                                      | LARRY BUCSHON, Indiana                    |
| PETER WELCH, Vermont                                           | SUSAN W. BROOKS, Indiana                  |
| RAUL RUIZ, California                                          | MARKWAYNE MULLIN, Oklahoma                |
| DEBBIE DINGELL, Michigan                                       | RICHARD HUDSON, North Carolina            |
| ANN M. KUSTER, New Hampshire                                   | EARL L. "BUDDY" CARTER, Georgia           |
| ROBIN L. KELLY, Illinois                                       | GREG GIANFORTE, Montana                   |
| NANETTE DIAZ BARRAGÁN, California                              | GREG WALDEN, Oregon ( <i>ex officio</i> ) |
| LISA BLUNT ROCHESTER, Delaware                                 |                                           |
| BOBBY L. RUSH, Illinois                                        |                                           |
| FRANK PALLONE, JR., New Jersey ( <i>ex</i><br><i>officio</i> ) |                                           |



## C O N T E N T S

---

|                                                                                                             |      |
|-------------------------------------------------------------------------------------------------------------|------|
|                                                                                                             | Page |
| Hon. Anna G. Eshoo, a Representative in Congress from the State of California, opening statement .....      | 1    |
| Prepared statement .....                                                                                    | 2    |
| Hon. Larry Bucshon, a Representative in Congress from the State of Indiana, opening statement .....         | 3    |
| Prepared statement .....                                                                                    | 4    |
| Hon. Frank Pallone, Jr., a Representative in Congress from the State of New Jersey, opening statement ..... | 5    |
| Prepared statement .....                                                                                    | 7    |
| Hon. Greg Walden, a Representative in Congress from the State of Oregon, opening statement .....            | 8    |
| Prepared statement .....                                                                                    | 9    |
| Hon. Eliot L. Engel, a Representative in Congress from the State of New York, prepared statement .....      | 66   |
| WITNESSES                                                                                                   |      |
| James E. Matthews, Ph.D., Executive Director, Medicare Payment Advisory Commission .....                    | 10   |
| Prepared statement .....                                                                                    | 12   |
| Answers to submitted questions .....                                                                        | 67   |



## **PRESCRIPTION DRUG COVERAGE IN THE MEDICARE PROGRAM**

**TUESDAY, APRIL 30, 2019**

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON HEALTH,  
COMMITTEE ON ENERGY AND COMMERCE,  
*Washington, DC.*

The subcommittee met, pursuant to call, at 10:30 a.m., in room 2322 Rayburn House Office Building, Hon. Anna G. Eshoo (chairwoman of the subcommittee) presiding.

Members present: Representatives Eshoo, Engel, Butterfield, Matsui, Castor, Sarbanes, Luján, Schrader, Kennedy, Cárdenas, Welch, Ruiz, Dingell, Kuster, Kelly, Barragán, Blunt Rochester, Rush, Pallone (ex officio), Burgess (subcommittee ranking member), Upton, Shimkus, Guthrie, Griffith, Bilirakis, Long, Bucshon, Brooks, Mullin, Hudson, Carter, Gianforte, and Walden (ex officio).

Staff present: Jacquelyn Bolen, Counsel; Waverly Gordon, Deputy Chief Counsel; Tiffany Guarascio, Deputy Staff Director; Josh Krantz, Policy Analyst; Una Lee, Chief Health Counsel; Aisling McDonough, Policy Coordinator; Joe Orlando, Staff Assistant; Kaitlyn Peel, Digital Director; Samantha Satchell, Professional Staff Member; C. J. Young, Press Secretary; Mike Bloomquist, Minority Staff Director; Jordan Davis, Minority senior Advisor; Caleb Graff, Minority Professional Staff Member, Health; Peter Kielty, Minority General Counsel; Ryan Long, Minority Deputy Staff Director; Brannon Rains, Minority Staff Assistant.

Ms. ESHOO. The Subcommittee on Health will now come to order.

Good morning, everyone. I am going to recognize myself for five minutes for an opening statement.

### **OPENING STATEMENT OF HON. ANNA G. ESHOO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA**

Our subcommittee continues its work to lower drug prices for seniors and for families across our country. Last month the members of the subcommittee passed six bipartisan bills to make prescription drugs more affordable by increasing market competition. Today, we are going to take a close look at the Medicare program to understand what is leading to high prescription drug costs for the 60 million Americans who get their drugs through Medicare.

To inform our work, we have present at hand, Dr. Matthews, the Executive Director of MedPAC, the Medicare Payment Advisory Commission. MedPAC provides valuable nonpartisan advice to Congress on the Medicare program.

We need expert advice. Drug prices are skyrocketing and Congress must act, and wants to act. Before we do, we have to, I believe, do as best we can to do a deep dive to understand the Medicare program and its challenges.

Medicare accounts for one out of every three dollars spent on prescription drugs, and drug spending is growing rapidly each year. Whether a patient gets their drugs at the hospital under the Part B program, or the pharmacy counter through the Part D program, costs are rising.

In the Part B program, Medicare drug spending doubled from 2009 to 2017. We spent \$32 billion, that's with a B, on Part B drugs in 2017. Part D drug spending has also nearly doubled over the past ten years. We spent \$80 billion in the Part D program in 2017.

These rising costs are putting, I believe, unsustainable pressure on the Medicare program and on America's families. In a recent Kaiser Family Foundation poll, 23 percent of seniors say it is difficult to afford their medications. I know it is true for my constituents, and for all of my colleagues constituents as well.

We hear from people on a consistent basis. They are worried that when they leave their doctors' office appointments with a new prescription written out for them, they are not sure whether they can pay for it, afford it or not.

America leads the world in innovative healthcare, but soon, few people will be able to afford this cutting-edge care. This committee, through our work on the 21st Century Cures Act, promoted development of novel, breakthrough treatments. But, with the development of these treatments has come increased spending.

Spending on drugs in specialty tiers has grown nearly 1,000 percent over ten years, from \$3.4 billion in 2007 to \$37.1 billion in 2017.

Because Medicare has no limit on out-of-pocket spending, people who rely on specialty drugs are hit especially hard. One study found needing a single specialty drug could cause people on Medicare to spend anywhere from \$2,000 to \$16,000 out-of-pocket annually.

Every senior deserves high-value, innovative medicine to improve their lives, but rapidly increasing costs affect their ability to get the drugs they need. We need solutions.

Today's hearing is yet another step closer to our, well, I would say it is a very important step towards our bringing forward solutions to what I just described.

Welcome to Dr. Matthews. I look forward to your expert advice on improving the Medicare Part D program.

[The prepared statement of Ms. Eshoo follows:]

#### PREPARED STATEMENT OF HON. ANNA G. ESHOO

Today, this Subcommittee continues its work to lower drug prices for seniors and families.

Last month, the members of this Subcommittee passed six bipartisan bills to make prescription drugs more affordable by increasing market competition.

Today, we are taking a close look at the Medicare program to understand what is leading to high prescription drug costs for the 60 million Americans who get their drugs through Medicare.

To inform our work, we have Dr. Mathews, the executive director of MedPAC, the Medicare Payment Advisory Commission. MedPAC provides valuable nonpartisan advice to Congress on the Medicare program.

We need expert advice—drug prices are skyrocketing, and Congress must act.

Before we do, we must understand the Medicare program and its challenges.

Medicare accounts for one out of every three dollars spent on prescription drugs, and drug spending is growing rapidly each year.

Whether a patient gets their drugs at the hospital under the Part B program or the pharmacy counter through the Part D program, costs are rising.

In the Part B program, Medicare drug spending doubled from 2009 to 2017. We spent \$32 billion on Part B drugs in 2017. Part D drug spending has also nearly doubled over the past ten years. We spent \$80 billion in the Part D program in 2017.

These rising costs are putting unsustainable pressure on the Medicare program and American families. In a recent Kaiser Family Foundation poll, 23 percent of seniors say it is difficult to afford their medications.

I know it's true for my constituents. I've heard from people that are worried when they leave their doctors appointment with a new prescription and no way to pay for it.

America leads the world in innovative healthcare, but soon, few people will be able to afford cutting-edge care.

This Committee, through our work on the 21st Century Cures Act, promoted the development of novel, breakthrough treatments. But, with the development of these treatments has come increased spending.

Spending on drugs in specialty tiers has grown nearly 1,000 percent over ten years—from \$3.4 billion in 2007 to \$37.1 billion in 2017.

Because Medicare has no limit on out-of-pocket spending, people who rely on specialty drugs are hit especially hard.

One study found needing a single specialty drug could cause people on Medicare to spend anywhere from \$2,000 to \$16,000 out-of-pocket annually.

Every senior deserves high-value, innovative medicine to improve their lives, but rapidly increasing costs affect their ability to get the drugs they need.

We need solutions. Today's hearing will get us another step closer.

Welcome to Dr. Mathews and I look forward to your expert advice on improving the Medicare Part B and D programs.

Ms. ESHOO And with that, I will now recognize Mr. Bucshon, who will—is taking the place of Mr. Burgess this morning, who has to be at the Rules Committee.

Ms. ESHOO Welcome. It is nice to sit next to you.

Mr. BUCSHON. Thank you. It is nice to sit next to you, also.

#### **OPENING STATEMENT OF HON. LARRY BUCSHON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF INDIANA**

Madam Chairwoman, thank you for holding this important hearing today. I appreciate this opportunity to members to take a deeper look at the drug coverage offered to seniors under Medicare Part B and Part D. These programs provide critical healthcare coverage for American seniors. And getting a better understanding of where these programs are today will help ensure that we can—they can meet the needs of seniors tomorrow.

As we have been exploring drug pricing in this subcommittee and in the committee, this is an important opportunity to hear from the Medicare Payment Advisory Commission, a nonpartisan organization that is tasked with providing technical advice to Congress. MedPAC is an important resource for Congress as we look to address challenging issues, such as Medicare's ability to provide adequate and affordable drug coverage to seniors, and the impacts any programmatic changes may have on beneficiaries, providers, and taxpayers.

Medicare Part B covers drugs that are administered by a physician through infusion or injection in an office or outpatient setting. These drugs include many high-cost chemotherapy agents, and other critical lifesaving medications.

Medicare Part D provides a prescription drug benefit to beneficiaries, and participation is voluntary. The Part D program has been a success. According to a recent MedPAC report, it has improved beneficiaries' access to prescription drugs.

Generic drugs now account for nearly 90 percent of the prescriptions filled. Enrollees' average premiums for basic benefits have remained around \$30 per month for many years. More than 8 in 10 Part D enrollees reported they are satisfied with the program. Furthermore, because of the deliberate structure of Part D, which incentivizes private health insurers to compete against one another, the program has been wildly successful in holding down costs to taxpayers.

In 2016, Part D expenditures were approximately \$100 billion, which was less than half of the \$205.5 billion projected by the CBO in 2006. In fact, over the first ten years that Part D was in operation, CBO data shows that the program cost taxpayers \$555.8 billion less than originally projected.

While Part B and Part D operate differently and cover different medications, they both provide seniors with access to necessary treatments and lifesaving drugs. It is important that any suggested changes to these program be well understood, and the impacts on patients, providers, and taxpayers be carefully considered.

The Trump administration has made a vow to lower costs of drugs, and has proposed changes to both Medicare Part B and D, to address the rising list prices, out-of-pocket costs for patients, and costs to the Federal Government. These proposed changes to how Medicare operates and provides drugs under Part B and D should be carefully analyzed to understand their full impact.

It is important that members of Congress on both sides of the aisle work together and, with the Administration, find solutions to lower list prices and out-of-pocket costs while maintaining robust access to seniors, without penalizing physicians, taxpayers, or stifling innovation.

As the Energy and Commerce Committee considers legislative proposals to address the high cost of drugs, I appreciate the important resource that MedPAC provides Congress. I want to thank our witness Dr. Matthews for being here today and I look forward to your testimony.

I yield back.

[The prepared statement of Mr. Bucshon follows:]

#### PREPARED STATEMENT OF HON. LARRY BUCSHON

Madame Chairwoman, Thank you for holding this important hearing today.

I appreciate this opportunity for members to take a deeper look at the drug coverage offered to seniors under Medicare Part B and D. These programs provide critical healthcare coverage for American seniors and getting a better understanding of where these programs are today will help ensure that that can meet the needs of seniors tomorrow.

As we have been exploring drug pricing in this committee, this is an important opportunity to hear from the Medicare Payment Advisory Commission, a non-partisan organization that is tasked with providing technical advice to Congress.

MedPac is an important resource for Congress as we look to address challenging issues, such as Medicare's ability to provide adequate and affordable drug coverage to seniors, and the impacts any programmatic changes may have on beneficiaries, providers, and taxpayers.

Medicare Part B covers drugs that are administered by a physician through infusion or injection in an office or outpatient setting. These drugs include many high cost chemotherapy agents, and other critical life-saving medications.

Medicare Part D provides a prescription drug benefit to beneficiaries, and participation is voluntary. The Part D program has been a success, according to a recent MedPac report, "It has improved beneficiaries' access to prescription drugs. Generic drugs now account for nearly 90 percent of the prescriptions filled. Enrollees' average premiums for basic benefits have remained around \$30 per month for many years. More than 8 in 10 Part D enrollees report they are satisfied with the program." Furthermore, because of the deliberate structure of Part D—which incentivizes private health insurers to compete against one another—the program has been wildly successfully in holding down costs to taxpayers. In 2016, Part D expenditures were approximately \$100 billion—which was less than half the \$205.5 billion projected by CBO in 2006. In fact, over the first ten years that Part D was in operation, CBO data shows that the program cost taxpayers \$555.8 billion less than originally projected.<sup>1</sup>

While Part B and Part D operate differently and cover different medications, they both provide seniors with access to necessary treatments and life-saving drugs. It is important that any suggested changes to these programs be well understood, and the impacts on patients, providers, and taxpayers be carefully considered.

The Trump Administration has made a vow to lower the cost of drugs and has proposed changes to both Medicare Part B and D to address the rising list prices, out-of-pocket costs for patients, and cost to the Federal Government. These proposed changes to how Medicare operates and provides drugs under Part B and D should be carefully analyzed to understand their full impact. It is important that Members of Congress on both sides of the aisle work together, and with the Administration to find solutions to lower list prices and out-of-pocket costs while maintaining robust access for seniors without penalizing physicians and taxpayers, or stifling innovation.

As the Energy and Commerce Committee considers legislative proposals to address the high cost of drugs, I appreciate the important resource that MedPac provides to Congress.

I thank our witness, Mr. Matthews for being here today, and I look forward to your testimony. I yield back.

Ms. ESHOO. I thank the gentleman for his statement, and now I recognize Mr. Pallone, chairman of the full committee, for five minutes for his opening statement.

**OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY**

Mr. PALLONE. Thank you, Madam Chair.

Today we are continuing this committee's important work in providing Americans relief when it comes to the skyrocketing price of prescription drugs. We have already passed several bills that will remove barriers that delay cheaper generic drugs from coming to market. Today we are focusing on the rising costs of prescription drugs in the Medicare program so we can begin to think about solutions to drive down costs for America's seniors and for the Federal Government.

We have all heard the stories about Americans who cannot afford their medications, who are rationing their life-saving therapies, or choosing not to fill their prescriptions because they instead need to put food on the table. At the same time, we have watched as pre-

<sup>1</sup> <https://www.americanactionforum.org/research/medicare-part-d-advancing-patient-health-private-sectorinnovation/>

scription drug spending continues to cost the Federal Government more and more each year. And we simply can't afford to wait any longer to fix this broken system.

The way drug prices are set, and the opaque drug supply chain, has fostered a system that can be gamed for profit at the expense of seniors who need access to affordable medicines.

I want to thank James Matthews, the Executive Director of MedPAC, for testifying. MedPAC is a critical resource to Congress and provides invaluable nonpartisan policy recommendations on how to improve the Medicare program for beneficiaries. MedPAC has conducted significant work on prescription drug pricing in the Medicare program. I look forward to hearing from Dr. Matthews on how we pay for drugs under Parts B and D, and how we can lower drug costs.

But this is particularly concerning in the Part D program, where high cost specialty drugs represent a large and growing share of Part D spending. According to MedPAC, spending for specialty drugs has grown more than ten times since the beginning of the Part D program. That growth resulted in specialty drug claims making up nearly a quarter of all gross Part D spending in 2017. It is now estimated that between 2019 and 2023, nearly two-thirds of newly-launched drugs will be considered specialty drugs.

These high cost specialty drugs are partly responsible for the fact that each year more beneficiaries are reaching the catastrophic phase of the Part D benefit. In 2016, over 360,000 Medicare beneficiaries reached the catastrophic limit of \$4,850 out-of-pocket, that threshold, in just one visit to the pharmacy. That's a significant jump from only 33,000 beneficiaries in 2010, and this leaves beneficiaries, particularly those with serious, chronic, or life-threatening diseases at risk for substantial out-of-pocket costs.

I look forward to hearing from Dr. Matthews about MedPAC's proposal to add an out-of-pocket limit to the Part D program. I hope we can work together on a bipartisan basis to implement some of these ideas in order to provide seniors with peace of mind that they will be protected if they need these high-cost therapies.

MedPAC has also noted that the current structure of the Part D program may be eroding incentives for Prescription Drug Plans to control costs. Currently, the Federal Government pays 80 percent of the costs for Part D benefits in the catastrophic phase of coverage. This means that payors may not be incentivized to effectively manage costs for their most expensive enrollees since the Government is footing most of the bill.

We will also discuss Part B drug spending, which has increased at an average rate of almost 10 percent annually for the past decade. These increases are primarily driven by rising drug prices, which have a direct impact on out-of-pocket costs for beneficiaries, because most beneficiaries are responsible for paying a 20 percent coinsurance on their Part D drug—Part B drugs. I look forward to examining proposals to slow rapid price growth and increase competition in the Part B drug program as well.

While most groundbreaking drugs are coming to market, they really are saving lives, increasing quality of life, and helping seniors to better manage diseases; but these therapies often come with price tags that are unaffordable for the average American. And

these prices represent a significant long-term financial challenge to the Federal Government and to the Medicare program. We have to find solutions that promote greater affordability and access. I look forward to that discussion today.

I don't think anybody else wants my time, Madam Chair, I yield back. Thank you.

[The prepared statement of Mr. Pallone follows:]

#### PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Today we are continuing this Committee's important work in providing Americans relief when it comes to the skyrocketing price of prescription drugs. We have already passed several bills that will remove barriers that delay cheaper, generic drugs from coming to market. And today we're focusing on the rising costs of prescription drugs in the Medicare program, so we can begin to think about solutions to drive down costs for America's seniors and for the Federal Government.

We have all heard the stories about Americans who cannot afford their medications, who are rationing their life-saving therapies, or choosing not to fill their prescriptions because they instead need to put food on the table. At the same time, we have watched as prescription drug spending continues to cost the Federal Government more and more each year. We cannot afford to wait any longer to fix this broken system.

The way drug prices are set, and the opaque drug supply chain, has fostered a system that can be gamed for profit at the expense of seniors who need access to affordable medicines.

I'd like to thank James Mathews, the Executive Director of the Medicare Payment Advisory Commission, for testifying today on this important issue. MedPAC is a critical resource to Congress and provides invaluable nonpartisan policy recommendations on how to improve the Medicare program for beneficiaries. MedPAC has conducted significant work on prescription drug pricing in the Medicare program, and I look forward to hearing from Dr. Mathews on how we pay for drugs under Parts B and D and how we can lower drug costs.

This is particularly concerning in the Part D program, where high cost specialty drugs represent a large and growing share of Part D spending. According to MedPAC, spending for specialty drugs has grown more than ten times since the beginning of the Part D program. That growth resulted in specialty drug claims making up nearly a quarter of all gross Part D spending in 2017. It is now estimated that between 2019 and 2023, nearly two-thirds of newly launched drugs will be considered specialty drugs.

These high cost specialty drugs are partly responsible for the fact that each year more beneficiaries are reaching the catastrophic phase of the Part D benefit. In 2016, over 360,000 Medicare beneficiaries reached the catastrophic limit of \$4,850 out-of-pocket threshold in just one visit to the pharmacy. That's a significant jump from only 33,000 beneficiaries in 2010. This leaves beneficiaries, particularly those with serious, chronic, or life-threatening diseases at risk for substantial out-of-pocket costs.

I look forward to hearing from Dr. Mathews about MedPAC's proposal to add an out-of-pocket limit to the Part D program. I hope we can work together on a bipartisan basis to implement some of these ideas in order to provide seniors with peace of mind that they will be protected if they need these high cost therapies.

MedPAC has also noted that the current structure of the Medicare Part D program may be eroding incentives for Prescription Drug Plans (PDPs) to control costs. Currently, the Federal Government pays 80 percent of the costs for Part D benefits in the catastrophic phase of coverage. This means that payors may not be incentivized to effectively manage costs for their most expensive enrollees since the Government is footing most of the bill.

We'll also discuss Part B drug spending, which has increased at an average rate of almost 10 percent annually for the past decade. These increases are primarily driven by rising drug prices, which have a direct impact on out-of-pocket costs for beneficiaries because most beneficiaries are responsible for paying a 20 percent coinsurance on their Part B drugs. I look forward to examining proposals to slow rapid price growth and increase competition in the Part B drug program.

While more groundbreaking drugs are coming to market that are saving lives, increasing quality of life, and helping seniors to better manage diseases, these therapies often come with price tags that are unaffordable for the average American. These prices also represent a significant, long-term financial challenge to the Fed-

eral Government and to the Medicare Program. We must find solutions that promote greater affordability and access, and I look forward to the discussion today.

Ms. ESHOO. The gentleman yield back, and now I'm pleased to recognize Mr. Walden, the ranking member of the full committee, for five minutes for his opening statement.

**OPENING STATEMENT OF HON. GREG WALDEN A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON**

Mr. WALDEN. Thank you, Madam Chairman. Thank you for holding this hearing.

This hearing continues this committee's important work on bringing down the costs of prescription drugs for seniors, frankly for all Americans, and patients across the country, but especially seniors in the Medicare program.

I want to thank our witness. Doctor, we are delighted to have you here as Executive Director of Medicare's Payment Advisory Commission, more commonly known as MedPAC. The work you do there, and your team, is really important. MedPAC provides a really valuable service to lawmakers. As an independent nonpartisan commission, provides data analysis and policy recommendations to improve the Medicare system, which we all care deeply about.

We value this input and we really appreciate the work of the Commission.

Today, we call on MedPAC's expertise with respect to rising prescription drug costs in the Medicare system. This committee has a long history on this issue, including the creation of Part D, which some of us were on the committee then and did the full overnight mark-up, and 60 amendments, and a lot of back and forth, but we got it done. That was back in 2003.

Nearly 44 million Medicare beneficiaries use Medicare Part D today. I remember there was talk then that nobody would write one of those plans, it will never get off the ground, it will cost a fortune. And, actually, it has worked pretty well. Now there are some tweaks all these years later we need to look at.

It is important to note the overwhelming majority of seniors who have Part D are satisfied with their plan. The premiums have remained stable and, frankly, relatively low throughout the program's history. The program has largely been a good success, and harnessing the power of competition to create a working market has given consumers more choices than anybody thought possible, and has helped keep prices down.

Now, there are challenges to Medicare Part D that have grown over time and have saddled some beneficiaries with significant increases in their out-of-pocket costs. Additionally, the share of Medicare Part D spending attributable to the catastrophic stage of coverage, has increased from 14 percent of the program costs in 2006 to 40, 4 zero, percent in 2017. We should confront these issues now to modernize Part D and keep drugs affordable for seniors and address misaligned incentives to drive up costs.

The same goes for Part B where a small number of drugs represent a large percentage of Government and beneficiary spending on the program. As others have noted, Part B drug spending has increased almost 10 percent per year since 2009. While there has been tremendous development, especially drugs, that can effec-

tively treat cancer and other diseases in amazing ways, these rising costs must also be confronted.

I look forward to hearing from our witnesses, or our witness, on whether the current structure of how Part B drugs are reimbursed—can and should be modified to foster competition and to lower prices. One consistent concern I hear about from my constituents in Oregon, and I have done 20 town halls so far this year, is the high cost of prescription drugs. I know that my colleagues on both sides of the aisle have heard similar concerns in their districts as well.

We have worked in a bipartisan manner on lowering drug costs over the last several years. During my tenure as chairman of this committee and during the first few months of this year we have continued those efforts. I believe that that should continue. This hearing will help us further our bipartisan work to lower drug costs for American consumers and seniors who rely upon Medicare.

Thanks again, Doctor, for being here today and the good work you do at MedPAC.

With that, Madam Chair, I yield back.

[The prepared statement of Mr. Walden follows:]

#### PREPARED STATEMENT OF HON. GREG WALDEN

Thank you, Chairwoman Eshoo for holding this hearing today. This hearing continues this committee's important work on bringing down the cost of prescription drugs for patients across the country, including seniors in the Medicare program.

I'd like to thank our witness, Dr. James Matthews, Executive Director for the Medicare Payment Advisory Commission, more commonly known as MedPAC. MedPAC provides a valuable service to lawmakers in Congress, as an independent, nonpartisan commission providing data analysis and policy recommendations to improve the Medicare system. We value this input and appreciate the work of the Commission.

Today, we call on MedPAC's expertise with respect to rising prescription drug costs in the Medicare system. This Committee has a long history on the issue, including the creation of the Part D benefit back in 2003 that nearly 44 million Medicare beneficiaries use today. It's important to note that the overwhelming majority of seniors who have Part D are satisfied with their plan, and premiums have remained stable and relatively low throughout the program's history. The program has largely been a success, harnessing the power of competition to create a working market that gives consumers choice and keeps prices down.

There are challenges in Part D, however, that have grown over time and have saddled some beneficiaries with significant increases in their out-of-pocket costs. Additionally, the share of Part D spending attributable to the catastrophic stage of coverage has increased from 14% of program costs in 2006 to 40% in 2017. We should confront these issues now to modernize the Part D benefit, keep drugs affordable for seniors and address misaligned incentives that drive up costs.

The same goes for Part B, where a small number of drugs represent a large percentage of Government and beneficiary spending on the program. As others have noted, Part B drug spending has increased almost 10% per year since 2009. While there has been tremendous development of specialty drugs that can effectively treat cancer and other diseases in amazing ways, these rising costs must also be confronted. I look forward to hearing from our witness on whether the current structure of how Part B drugs are reimbursed can be modified to foster competition and lower prices.

One consistent concern I hear about from my constituents in Oregon as I hold town halls and other meetings is the high cost of prescription drugs. I know that my colleagues on both sides of the aisle have heard similar concerns in their districts as well.

We have worked in a bipartisan manner on lowering drug costs over the past several years, during my tenure as Chairman and during the first few months of this year. I believe that should continue, and this hearing will help us further our bipartisan work to lower drug costs for American consumers and seniors who rely on Medicare.

Thank you again to our witness for being here today, and I look forward to a productive hearing.

Ms. ESHOO. The gentleman yield back.

Now I would like to remind Members that, pursuant to committee rules, all Members' written opening statements shall be made part of the record. So, get them in.

I would now like to introduce our witness for today's hearing, Dr. Jim Matthews. He serves as the Executive Director of the Medicare Payment Advisory Committee, and a very important position, a very important commission. And once again, thank you for being here today to be instructive to us. And we certainly look forward to your testimony.

You have testified many times in Congress, so I don't think I need to explain the lighting system to you. The most important one is when it turns red, because that is when your five minutes are up.

So, Dr. Matthews, thank you again. You are now recognized for five minutes of testimony.

**STATEMENT OF JAMES E. MATTHEWS, PH.D., EXECUTIVE DIRECTOR, MEDICARE PAYMENT ADVISORY COMMISSION**

Mr. MATTHEWS. Thank you. Good morning, Chairwoman Eshoo, Dr. Bucshon, and distinguished committee members. On behalf of MedPAC, a nonpartisan, independent congressional advisory agency, I am here to convey information on Medicare's payments for prescription drugs.

First, I will describe how Medicare pays for drugs under Part B and discuss recent trends in spending and utilization.

Second, I will do the same with Part D.

Lastly, I will touch briefly on commission recommendations that address these trends.

I will start with Part B. Part B covers drugs that are typically administered by a provider, such as infused chemotherapy drugs. Medicare pays for Part B drugs based on the average sales price that manufacturers report for a drug, net of most rebates and discounts. Medicare pays providers the actual sales price, plus a six percent add-on, regardless of how much the individual provider has spent to purchase the drug. Medicare makes a separate payment to the provider for administering the drug.

Part B spending has grown roughly 10 percent a year since 2009, reaching \$32 billion in 2017. Growth in Medicare spending for drugs under Part B is driven largely by rising prices, which account for two-thirds of overall spending growth, and which reflect manufacturers' significant pricing leverage. Under the current payment system, as drug prices rise, Medicare's payments will follow. And Medicare has few tools to affect prices under Part B.

Part D uses private plans to deliver Medicare's outpatient prescription drug benefit. Part D plans negotiate with pharmacies over payment rates for filling prescriptions, and with drug manufacturers for post-sale rebates. Medicare is prohibited from interfering in these negotiations.

There are two components of Medicare's payments to plans for Part D basic benefits.

First, there is a per-enrollee payment based on plans' bids, which reflects their expected costs for the Part D benefit for an average enrollee.

The second is individual reinsurance, which are cost-based payments to plans for which Medicare covers 80 percent of the costs in the catastrophic phase of the benefit.

Part B—Part D spending grew at about 7 percent annually between 2010 and 2017, reaching \$80 billion. But Medicare's reinsurance payments for Part D enrollees who had drug spending high enough to reach the catastrophic phase grew almost 20 percent annually over the same period. Again, high cost therapies drive these trends. Part D spending for high-priced specialty tier drugs grew tenfold between 2007 and 2017. And, again, this growth is driven by price.

In 2017, 370,000 beneficiaries filled a single prescription that was so expensive it would push them into the catastrophic phase of the benefit, up from just 33,000 such beneficiaries in 2010.

When plans have financial responsibility for insurance risk, they face greater incentives to manage costs. However, growth in reinsurance, recent changes to the coverage gap, and the growth in high-cost medicines may be eroding plans' incentives to and ability to control costs. In fact, Part D's benefit structure may give plans a financial incentive to play certain high-cost, high-rebate drugs on their formularies, even when lower cost alternatives are available.

Growth in drug prices substantially affects Medicare drug spending. This growth reflects both higher prices for existing products and the launch of new high-price drugs. Yet, again, Medicare has very limited influence over drug prices.

Recent commission recommendations attempt to address the growth in Medicare drug spending. In Part B we would give clinicians an alternative to the "buy and bill" environment, and provide incentives for them to use this approach.

In Part D we would shift more liability for costs in the catastrophic phase of the benefit to plans. In exchange, we would give plans more tools and flexibility to manage enrollees' utilization. We would also eliminate beneficiary cost-sharing in the catastrophic phase.

In sum, prescription drugs are essential to treating many medical conditions, and Medicare must ensure that beneficiaries have access to appropriate medication therapies. At the same time, high prices for drugs make it difficult to ensure this access, while protecting the taxpayers and beneficiaries who funds the program. We hope the committee regards the Commission as a resource as you develop policies to address these critical issues.

Thank you.

[The prepared statement of Mr. Matthews follows:]



TESTIMONY

## Payment policy for prescription drugs under Medicare Part B and Part D

April 30, 2019

Statement of  
James E. Mathews, Ph.D.

Executive Director  
Medicare Payment Advisory Commission

Before the  
Subcommittee on Health  
Committee on Energy and Commerce  
U.S. House of Representatives

Chairwoman Eshoo, Ranking Member Burgess, distinguished Committee members, I am James E. Mathews, Executive Director of the Medicare Payment Advisory Commission (MedPAC). I appreciate the opportunity to be here with you this morning to discuss prescription drug payment policy under Medicare Part B and Part D. In my testimony I will provide:

- a brief overview of how Medicare currently pays for drugs under Part B and Part D and a description of what the Commission has identified as problems with the incentives of those payment systems,
- a look at evidence of rising drug spending and drug prices within Medicare, and
- a brief description of the Commission's standing recommendations for changes to drug payment policies in Part B and Part D.

### **The Commission's role**

MedPAC is a small congressional support agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to provide independent, nonpartisan policy and technical advice to the Congress on issues affecting the Medicare program. The Commission's goal is to achieve a Medicare program that ensures beneficiary access to high-quality, well-coordinated care; pays health care providers and health plans fairly, rewarding efficiency and quality; and spends taxpayer and beneficiary dollars responsibly.

Prescription drugs are an essential component of health care. Because of their role in medical treatment, it is important that Medicare make sure beneficiaries have access to appropriate medications. However, it is becoming increasingly difficult to ensure that access to medicines remains affordable for beneficiaries and financially sustainable for taxpayers. For this reason, the Commission has devoted considerable attention to the issue of drug spending in recent years. In 2016, the Commission recommended major changes in the payment system for outpatient prescription drugs delivered by private plans in Part D. In 2017, we also recommended substantial changes to the payment system for provider-administered drugs under Medicare Part B. As I will describe in a few minutes, both sets of

recommendations would improve payment incentives while using market competition to constrain growth in drug prices. Even after those recommendations, the Commission has continued to examine other potential changes with the goal of better ensuring that appropriate prescription drug treatments are affordable to beneficiaries and sustainable for the Medicare program.

### **Overview of how Medicare pays for drugs**

Medicare accounts for about one-third of U.S. retail pharmaceutical sales. The program also pays for drugs and biologics provided in nonretail settings, including medicines provided in hospitals, physician offices, skilled nursing facilities, and other providers.<sup>1</sup> Across all Medicare sectors, we estimate that spending for drugs and biologics grew from about 20 percent of total Medicare spending in 2007 to 23 percent by 2016.<sup>2</sup>

Medicare pays for drugs in different ways across its various payment systems. Most institutional providers receive prospective payments, typically for a bundle of services that includes drugs. Physicians and outpatient hospitals are generally paid separately for higher-priced Part B–covered drugs. Under Part D, Medicare pays private drug plans a combination of capitated payments based on plan bids and cost-based reinsurance subsidies.

In each payment system, Medicare’s influence over drug pricing is limited. For example, when CMS administratively sets a bundled payment rate (e.g., as with the hospital inpatient and dialysis facility prospective payment systems), it is providers who negotiate the price of the drugs they administer. Medicare then sets payment rates that take into account the agency’s estimates of providers’ drug costs. Similarly, Medicare payments for high-cost Part B drugs are based on the manufacturer’s average sales price (ASP) to physicians, hospitals,

---

<sup>1</sup> Biologics are large-molecule medicines derived from living organisms that are used to treat serious diseases such as cancer, rheumatoid arthritis, and multiple sclerosis. The term *biologics* encompasses a wide range of products including vaccines, blood and blood products, allergenics, somatic cells, gene therapy, tissues, and therapeutic proteins. Examples of biologics include monoclonal antibodies, therapeutic proteins, human insulin, recombinant hormones, and growth factors. Biologics can be purified from natural substances, produced through recombinant DNA technology, or manufactured through other methods. Hereafter, we use the term *drugs* to refer to drugs and biologics unless otherwise noted.

<sup>2</sup> This analysis determined drug and total spending under the inpatient and outpatient hospital, skilled nursing facility, home health, and hospice payment systems; the physician fee schedule, Part B ASP-based system, and other Part B providers (e.g., dialysis facilities); Part A and Part B benefits administered by Medicare Advantage plans; and Part D.

and other purchasers plus a 6 percent add-on (ASP + 6 percent).<sup>3</sup> In the case of Part D, private plans negotiate prices for drugs, not the Medicare program.<sup>4</sup>

#### **Part B drugs paid on the basis of ASP**

Part B covers drugs that are administered by infusion or injection in physician offices and hospital outpatient departments, as well as certain drugs furnished by suppliers. Medicare Part B drug spending has been growing rapidly, more than doubling between 2009 and 2017. Medicare Part B spending (including beneficiary cost sharing) grew from \$15.4 billion in 2009 to \$32.0 billion in 2017, increasing at an average rate of 9.6 percent per year.

Medicare pays physicians and outpatient hospitals for most separately payable Part B–covered drugs they furnish to beneficiaries at a rate of 106 percent of the manufacturer-reported ASP. A product’s ASP reflects the average price realized by the manufacturer for sales to all purchasers net of rebates, discounts, and price concessions with certain exceptions.<sup>5</sup> Medicare pays providers 106 percent of ASP for the drug regardless of the actual price a given provider pays for it. CMS updates the Medicare Part B drug payment rates for each product with available ASP data on a quarterly basis; these payment rates are publicly available on CMS’s website. There is a two-quarter lag in the data used to set ASP + 6 percent payment rates. This lag is

---

<sup>3</sup> Under the hospital outpatient prospective payment system, certain Part B–covered drugs (e.g., those that are low cost) are bundled into the payment for other services rather than separately paid. In addition, by statute, certain vaccines and blood products are paid based on 95 percent of average wholesale price (AWP) instead of ASP + 6 percent.

<sup>4</sup> Details about each of Medicare’s payment systems can be found in the Commission’s *Payment Basics* series of publications available at <http://medpac.gov/-documents/-payment-basics>.

<sup>5</sup> Manufacturers calculate ASP based on sales to all purchasers, excluding nominal sales to certain entities and prices that are exempt from the determination of Medicaid best price (e.g., sales or discounts to other federal programs, 340B-covered entities, state pharmaceutical assistance programs, and Medicare Part D plans, as well as manufacturer coupons to consumers meeting certain criteria). Bona fide service fees are not considered price concessions for the purposes of ASP. Bona fide service fees are fees paid by the manufacturer to entities such as wholesalers or group purchasing organizations that are fair market value, not passed on in whole or part to customers of the entity, and are for services the manufacturer would otherwise perform in the absence of the service arrangement.

necessary to permit time for manufacturers to submit ASP data and for CMS to calculate and implement the new payment rates.<sup>6</sup>

The ASP system enacted by the Medicare Modernization Act of 2003 represents a significant improvement over the prior payment method that set a drug's payment rate at 95 percent of the average wholesale price (AWP). Under the ASP-based system that Medicare has used since 2005, the program's payment rates for Part B drugs are closer to the prices that providers pay than under the prior AWP-based payment method. Despite its name, AWP does not represent the average wholesale price. Rather, it can be thought of as a manufacturer's suggested list price, which does not have to correspond to any market-based transaction price and does not reflect discounts. Under AWP-based payment, expenditures for Part B drugs increased rapidly, more than 25 percent per year from 1998 to 2003. One of the most significant factors driving spending growth was the AWP payment method. A series of reports by the Department of Health and Human Services Office of Inspector General (OIG) and the Government Accountability Office (GAO) showed that Medicare payment rates under the AWP-based payment system were well above providers' acquisition costs.

In addition to paying ASP + 6 percent for the drug, Medicare makes a separate payment to providers for administering the drug to the patient (e.g., for infusing or injecting the product) under the physician fee schedule or the hospital outpatient prospective payment system. Medicare pays a dispensing or supplying fee to pharmacies that dispense inhalation drugs and oral anticancer, oral antiemetic, and immunosuppressive drugs to beneficiaries; Medicare also pays a fee to providers when they furnish clotting factors.

If a drug lacks ASP data, Medicare has alternative methods for paying for the product. For new single-source drugs that initially lack ASP data, Medicare pays a rate of wholesale acquisition cost (WAC) plus 3 percent for the first two to three quarters the product is on the

---

<sup>6</sup> Manufacturers are required to report ASP data for a calendar quarter within 30 days after the close of that quarter. CMS then takes the data submitted by manufacturers and uses it to calculate the ASP + 6 percent payment rates for the next calendar quarter. For example, ASP data for 4<sup>th</sup> quarter of 2018 were used to set the ASP + 6 percent payment rates for 2<sup>nd</sup> quarter of 2019. Manufacturers were required to report ASP data for 4<sup>th</sup> quarter of 2018 by January 30, 2019. CMS then had two months to calculate, publish, and operationalize the new payment rates so they would go into effect at the start of the next calendar quarter, which began April 1, 2019.

market. For drugs that lack ASP data for reasons other than being new, such as the manufacturer not reporting ASP data or the manufacturer having no sales in a particular reporting quarter, the payment method varies and may be 106 percent of WAC, 95 percent of AWP, or invoice priced. WAC- or AWP-based payment methods generally result in Medicare paying more for drugs than it otherwise would under the ASP-based formula. These alternative payment methods do not incorporate rebates, discounts, and other price concessions. Most, but not all, Part B drug manufacturers are required to report ASP data to CMS. A recent Commission recommendation to require all manufacturers to report ASP data would be an important step to ensure that it is not possible for overpayments to occur as a result of manufacturers not reporting ASP data.

Payments for single-source drugs and originator biologics, multiple-source drugs, and biosimilars are set differently. Each single-source drug and originator biologic is paid under its own billing code at 106 percent of its own ASP; brand and generic versions of a drug are assigned to the same billing code and paid the same rate equal to 106 percent of the volume-weighted average ASPs; and each biosimilar is paid under its own billing code at a rate of 100 percent of its own ASP plus 6 percent of the originator biologic's ASP.

An individual provider may purchase a drug for more or less than ASP for a number of reasons. ASP is the average price from the manufacturer's perspective. Generally, some purchasers pay more than ASP and some pay less. For example, prices can vary across purchasers of different sizes (e.g., due to volume discounts) or across types of purchasers (e.g., physicians, hospitals, and pharmacies). In addition, the two-quarter lag in ASP data can result in the average provider acquisition cost for a drug being different from the ASP used to set the Medicare payment amount for a quarter. When prices increase or decrease, it takes two quarters before that price change is reflected in the ASP data used to pay providers.

The Secretary does not routinely collect providers' acquisition costs for Part B drugs.<sup>7</sup> To get a sense of how physicians' drug acquisition costs compared to Medicare's payment rate, in our June 2016 report to the Congress, we analyzed proprietary invoice price data for 34 high-expenditure Part B drugs from IMS Health Incorporated for the clinic channel of purchasers (e.g., physicians and outpatient hospitals). That analysis found that for two-thirds of the 34 drugs, at least 75 percent of the volume was sold to clinics at an invoice price below 102 percent of ASP.<sup>8</sup> In addition, the analysis found evidence suggesting that some manufacturers responded to the federal budget sequester that began in 2013 by changing their pricing patterns in a way that mitigated the effect of the sequester for some providers. The sequester effectively reduced Medicare's payment rate for Part B drugs from 106 percent of ASP to 104.3 percent of ASP. Analysis of the IMS data found that across the 34 drugs, the median 75th percentile invoice price as a percent of ASP fell when the sequester was implemented (from around 103 percent of ASP before the sequester to 101.5 percent of ASP in 2nd quarter 2013). This suggests that providers' ability to purchase Part B drugs was generally maintained following the implementation of the sequester because manufacturers appear to have adjusted their prices to take into account the lower Medicare payment amount.

Although the ASP-based method is an improvement over the prior AWP-based method, the ASP-based payment method has raised several concerns. There is concern about the overall price Medicare Part B pays for drugs and the lack of price competition among drugs with similar health effects. There is concern that the ASP-based payment method does not consider evidence about a drug's comparative clinical effectiveness, which means that a drug's payment rate is not related to whether it is clinically comparable to, better than, or

---

<sup>7</sup> On a few occasions, the OIG compared the acquisition costs of selected drugs among a sample of providers to Medicare's payments rates under ASP. In the first quarter of 2010, OIG estimated that physician acquisition costs for Lucentis was on average 5 percent below the Medicare payment rate. In the first quarter of 2009, acquisition costs for end-stage renal disease drugs among independent dialysis facilities averaged 10 percent below Medicare payment rates.

<sup>8</sup> The IMS Health Incorporated data were available by channel of purchaser. We examined the clinic channel, which included physician offices, hospital outpatient departments, dialysis clinics, nonhospital surgical centers, and public health service clinics. The IMS data for the clinic channel included discounted sales to 340B entities. To avoid reflecting 340B prices in our estimates, we did not use data on the average invoice price. Instead, we focused on invoice prices at the 75<sup>th</sup> percentile (i.e., the 75<sup>th</sup> percentile reflects the price at which 75 percent of the volume of a drug is sold at or below that price). The prices in the IMS data reflect all on-invoice discounts and rebates but not off-invoice rebates. As a result, in some cases the IMS data overstate the actual end-price paid by the purchaser.

worse than its relevant alternatives. There is also concern about the financial incentives providers face under the ASP payment system. In particular, the 6 percent add-on to ASP may create incentives for some providers to choose higher-priced drugs over lower-priced drugs. Since 6 percent of a higher-priced drug generates more revenue for the provider than 6 percent of a lower-priced drug, selection of the higher-priced drug may generate more profit, depending on the provider's acquisition costs for the two drugs. For example, the 6 percent add-on of a drug with an ASP of \$1,000 is \$60; by comparison, the add-on of a drug with an ASP of \$100 is \$6. It is difficult to know whether the percentage add-on to ASP is influencing drug prescribing patterns because few studies have looked at this issue.

#### **Part D**

Part D is a voluntary prescription drug benefit in which Medicare beneficiaries obtain outpatient prescription drug coverage through competing private plans. Between 2007 and 2017, Part D program spending increased from about \$46 billion to about \$80 billion (average annual growth of 5.6 percent). In addition to those taxpayer-financed amounts, in 2017 Part D enrollees paid \$14 billion in premiums and nearly \$17 billion in cost sharing.

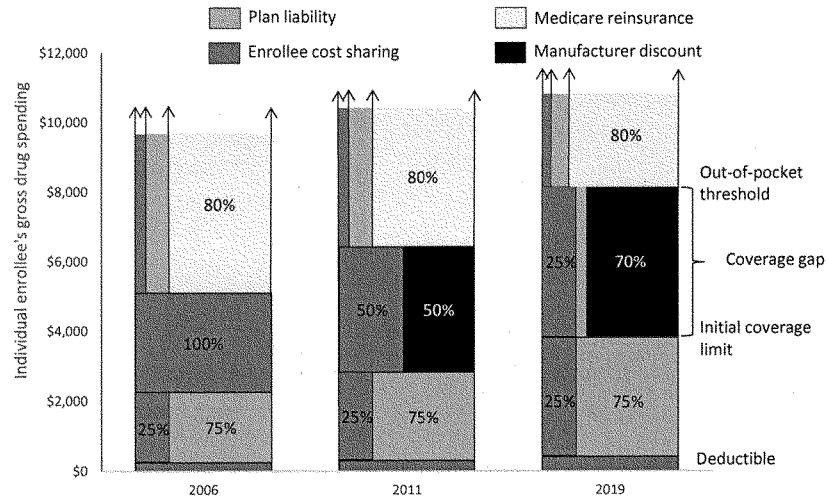
Part D was designed to rely on competition among plans that bear insurance risk to manage drug use and keep spending in check, while offering a benefit package that is attractive to enrollees. Rather than Medicare setting prices administratively, Medicare pays Part D plan sponsors that, through their pharmacy benefit managers (PBMs), contract with pharmacies over payment rates for each prescription filled by an enrollee and negotiate with drug manufacturers for prices and post-sale rebates. The Part D statute includes a "noninterference" provision that says the Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP [prescription drug plan] sponsors." The law also says that the Secretary "may not require a particular formulary or institute a price structure for the reimbursement of covered Part D drugs."

Part D plan sponsors submit bids annually to CMS by the first Monday in June. Those bids reflect plan sponsors' expected benefit costs for an enrollee of average health. CMS adjusts payments to plan sponsors based on the actual health status of the plans' enrollees. Medicare's payments to Part D plan sponsors consists of two components: 1) the direct

subsidy, which is a per enrollee capitated payment based on plans' bids and 2) individual reinsurance in which Medicare pays for 80 percent of an enrollee's drug spending above Part D's out-of-pocket (OOP) threshold (cost-based payment). Together, the two forms of Medicare payments are intended to cover 74.5 percent of the expected costs of standard benefits, with enrollee premiums making up the remaining 25.5 percent. Part D also includes a low-income subsidy (LIS) that pays plans certain premium and cost-sharing amounts on behalf of about 12.5 million individuals who have low incomes and assets.

Medicare shares risk with Part D plan sponsors in three ways to counteract incentives for sponsors to avoid enrollees who have high spending. First, CMS risk adjusts direct subsidy payments to reflect each enrollee's predicted spending. Second, Medicare pays individual reinsurance for enrollees who reach the OOP threshold. Third, Medicare establishes symmetric risk corridors unique to each plan. Under risk corridors, Medicare limits a plan's overall losses (or profits) by financing some of the higher-than-expected costs (or recouping excessive profits).

The original design of the Part D benefit was intended to provide both basic coverage for most enrollees who have relatively low drug spending as well as some catastrophic protection for enrollees with high drug costs. In 2006, the defined standard basic benefit covered 75 percent of drug spending above the deductible and all but 5 percent coinsurance once an enrollee reached the OOP threshold (Figure 1). The benefit also included a coverage gap in which enrollees paid 100 percent of the cost of prescriptions. The standard benefit was later modified by the Patient Protection and Affordable Care Act to phase out the coverage gap by 2020—in part, by requiring manufacturers of brand-name drugs to provide a discount on prescriptions filled by non-LIS enrollees in the coverage gap.

**Figure 1. Part D's defined standard benefit structure has changed over time**

Note: "Gross drug spending" refers to amounts paid at the pharmacy before post-sale rebates and discounts. The amount of drug spending at which a beneficiary reaches the out-of-pocket (OOP) threshold in 2011 and 2019 depends on the mix of brand-name and generic prescriptions he or she fills in the coverage gap. The coverage-gap phase (between the initial coverage limit and OOP threshold) is depicted as it would apply to brand-name drugs for an enrollee who does not receive Part D's low-income subsidy (LIS). Non-LIS enrollees' cost sharing for generic drugs in the coverage gap was 100 percent in 2006, 93 percent in 2011, and 37 percent in 2019.

Source: MedPAC depiction of Part D benefit structure as set by law.

The law also required that the manufacturers' discount be counted as though it were the enrollee's own OOP spending for determining when he or she reached the OOP threshold. That change lowered OOP costs for some beneficiaries, but it also increased the number of non-LIS enrollees who reached the OOP threshold—the point at which Medicare begins to pay individual reinsurance.

A 2018 change in law quickened the timeframe for closing the coverage gap from 2020 to 2019 by increasing the manufacturers' discount on brand-name drugs from 50 percent to 70 percent. This change also reduced the portion of benefits that plans must cover for brand-name drugs in the coverage gap from 25 percent to 5 percent. Because the discount is counted as though it were the enrollee's own spending, the increase in that discount lowered

the OOP costs non-LIS enrollees must incur to reach Part D's catastrophic phase. This means that more enrollees are likely to reach the OOP threshold.

Medicare's reinsurance (which covers 80 percent of enrollees' spending in the catastrophic phase of the benefit after rebates) has been the fastest growing component of Part D program spending, with average increases of nearly 17 percent annually between 2007 and 2017. Over time, a growing share of Medicare's payments to plans have taken the form of cost-based reinsurance subsidies rather than capitated payments. Between 2007 and 2017, the portion of the basic benefit payments paid to plans through capitated direct subsidies fell from 55 percent to 21 percent, while the portion paid through Medicare's reinsurance grew from 25 percent to 54 percent. Despite significant growth in catastrophic benefits, average premiums for basic Part D benefits have remained low, in part reflecting the effects of Medicare's reinsurance subsidy. As a result, taxpayers—not plans—bear an increasing share of the insurance risk for Part D spending.

The Commission has highlighted how Part D's unique benefit design, Medicare's cost-based reinsurance payments, and plan sponsors' focus on premium competition can affect which drugs a plan covers on its formulary. Because plan sponsors are not liable for much benefit spending in the coverage gap, Part D's structure may provide a financial advantage to sponsors when they select certain drugs with high prices and large postsale rebates over lower-cost alternatives. The dollar amount of rebates for certain drugs can be larger than a plan sponsor's liability for the associated benefit spending. For example, during the coverage-gap phase, a plan could increase its net revenue by encouraging use of a brand-name drug that received a rebate of 20 percent because the plan would only be liable for 5 percent of the prescription's cost. In this sense, Part D's benefit design may contribute to growth in drug spending. The recent changes to the coverage gap, which further reduced plan sponsors' liability, heighten those concerns.

### **Rising spending for prescription drugs in Part B and Part D**

In recent years, growth in Medicare's spending for prescription drugs under both Part B and Part D has been driven by increases in average price per claim, particularly for high-cost

brand-name therapies. Those increases reflect both higher prices for existing products and high launch prices for new drugs.

**Part B drugs**

Price growth is the largest driver of Medicare Part B spending growth. Almost two-thirds of the growth in Part B drug spending between 2009 and 2016 was accounted for by price growth. Growth in Medicare's ASP-based payment rates for individual drugs is driven by manufacturer pricing policies. There is no statutory or regulatory constraint on how much Medicare's ASP-based payment rate for an individual drug can increase over time.

For separately payable drugs (excluding vaccines), Medicare Part B drug spending grew at an average annual rate of 10.7 percent between 2009 and 2016, with 6.9 percentage points of the growth due to an increase in price (as measured by the average annual payment per drug per user) (Table 1). This 6.9 percent increase reflects a combination of factors—increased prices for existing products, the launch of new high-priced products, and other changes in the mix of drugs used.

**Table 1. Payments and utilization for separately payable Part B drugs, 2009–2016**

|                                                                                                    | 2009      | 2016      | Annual average change, 2009–2016 |
|----------------------------------------------------------------------------------------------------|-----------|-----------|----------------------------------|
| <b>Total payments: Separately payable Part B drugs excluding vaccines (in billions of dollars)</b> | \$12.8    | \$26.1    | 10.7%                            |
| Number of beneficiaries receiving Part B drug                                                      | 2,840,166 | 3,750,634 | 4.1                              |
| Average payment per beneficiary                                                                    | \$4,524   | \$6,962   | 6.4                              |
| Average number of drugs per beneficiary                                                            | 1.41      | 1.36      | -0.5                             |
| Average annual payment per drug (price increase)                                                   | \$3,206   | \$5,119   | 6.9                              |

Note: This analysis includes all Part B drugs paid the average sales price plus 6 percent (ASP + 6 percent) as well as the small group of Part B drugs that are paid based on the average wholesale price or reasonable cost or that are contractor priced. "Vaccines" refers to the three Part B–covered preventive vaccines: influenza, pneumococcal, and hepatitis B. Total payments include Medicare payments and beneficiary cost sharing. Data include Part B drugs furnished by physicians, hospitals paid under the outpatient prospective payment system, and suppliers. Excluded from the analysis were any Part B drugs that were bundled or packaged in 2009 and/or 2016 (i.e., drugs that were packaged under the outpatient prospective payment system, regardless of the setting where they were furnished, and drugs furnished by dialysis facilities), drugs billed under not-otherwise-classified billing codes, blood and blood products (other than clotting factor), and data for critical access hospitals and Maryland hospitals. The average annual growth rates displayed in the table may differ slightly from the average annual growth rates calculated using the 2009 and 2016 values displayed in the table due to rounding.

Source: MedPAC analysis of Medicare claims data for physicians, hospital outpatient departments, and suppliers.

Part B drug spending is concentrated in a small number of expensive products. In 2017, Medicare spending (including beneficiary cost sharing) for the top 10 drugs paid under the ASP system totaled about \$13.6 billion, about 43 percent of all Part B drug spending that year. Notably, all 10 of these products are biologics. Many of these products are used to treat cancer or its side effects, while some treat macular degeneration, rheumatoid arthritis, and other immunologic diseases.

The patterns of spending growth within the top 10 highest-expenditure products illustrate two pricing factors driving spending growth: new products with high launch prices, and existing products with price inflation. For example, two products—Opdivo and Keytruda—are recent market entrants (approved in late 2014) and belong to a new class of immuno-oncology biologics. Spending on these products in 2017 reached \$1.5 billion and \$1 billion,

respectively, reflecting the products' substantial launch prices. Average 2017 Medicare spending per user for these products was about \$51,000 and \$48,000, respectively.<sup>9</sup>

Price growth among biologics that have been on the market longer has also driven spending growth. For example, over the eight years between 2009 and 2017, the ASPs increased 44 percent for Remicade (which treats certain immunologic diseases such as rheumatoid arthritis), 53 percent for Rituxan and Herceptin (which treat certain cancer types), and 89 percent for Neulasta (which stimulates the growth of white blood cells after chemotherapy). Although we lack data on Medicare expenditures beyond 2017, we do have ASP-based payment rates through first quarter 2019. In the two years between January 2017 and January 2019, the ASPs for 5 of the top 10 products increased by more than 10 percent. Although price declines have occurred among a few of the top 10 products, these declines have been modest given the existence of competing products and the magnitude of spending on these products. For example, Eylea and Lucentis are competing products used to treat macular degeneration and related eye conditions, and they accounted for \$3.5 billion of 2017 Part B drug spending. Eylea's ASP declined 2 percent since its launch and Lucentis' ASP declined 11 percent between 2009 and 2019.

With biologics accounting for more than two-thirds of Part B drug spending and all 10 of the highest-expenditure products, biosimilar approval and entry may offer savings potential, but to date the effects have been modest. Two originator biologics paid under Part B—Remicade and Neupogen—have faced biosimilar entry in recent years.<sup>10</sup> We have observed little decline in the ASPs of Remicade and Neupogen, but we have seen lower and declining ASPs for their biosimilars.<sup>11</sup> As of the first quarter of 2018 (the most recent calendar quarter for which complete utilization data are available), the use of biosimilars under Part B has been mixed. Use of the more costly originator product Remicade accounted for 94 percent of

---

<sup>9</sup> Because some beneficiaries begin treatment mid-year and treatment carries into the following year, average spending per user in any given year understates the cost of a full year of treatment with the product.

<sup>10</sup> Neupogen is used to stimulate the growth of white blood cells after chemotherapy.

<sup>11</sup> The ASP for the originator product Neupogen has remained roughly the same between the first quarters of 2016 and 2019 while the ASP for its biosimilar Zarxio has declined by 34 percent. The ASP for the originator biologic Remicade declined 7 percent between 2017 and 2019; however, that decrease followed a 55 percent increase in Remicade's ASP between 2005 and 2017. The ASP for Remicade's biosimilar Inflectra has declined by 43 percent between the first quarters of 2017 and 2019.

utilization while use of its biosimilars accounted for only 6 percent of utilization. By contrast, utilization has shifted away from the more costly originator biologic Neupogen, with its biosimilars accounting for 63 percent of the market in the first quarter of 2018.

In recent years, drugs furnished in physician offices account for the majority of Part B drug spending, but spending on drugs furnished in hospital outpatient departments (HOPDs) has grown more rapidly than drug spending in physician offices. Of total Part B spending in 2017 (including beneficiary coinsurance), about \$18.4 billion was for drugs administered in physician offices, about \$12.3 billion was for drugs administered in HOPDs, and \$1.8 billion was for drugs furnished by suppliers. Between 2009 and 2017, Part B drug spending increased at an average annual rate of 15 percent in HOPDs and 7 percent in physician offices. The greater spending growth in HOPDs partly reflects a shift in site of service from physician offices to HOPDs, particularly for oncology drugs.

#### **Part D drugs**

Overall growth in Part D spending is increasingly driven by the relatively few enrollees who reach the catastrophic phase. In 2017, 3.6 million Part D enrollees (about 8 percent) had spending high enough to reach the catastrophic phase of the benefit (high-cost enrollees). High-cost enrollees accounted for nearly 60 percent of all Part D spending in 2017, up from about 40 percent before 2011.

Among high-cost enrollees, nearly all growth in spending was due to increases in the average price per prescription filled (Table 2). That growth reflects inflation of the existing products' prices, greater availability of higher-priced drugs and biologics, and other changes in the mix of medications prescribed. Between 2010 and 2017, the average price per standardized, 30-day prescription for high-cost enrollees grew at an annual rate of 9.4 percent, while the number of prescriptions filled per enrollee per month remained flat. This pattern is in stark contrast to enrollees who did not reach the OOP threshold. The average price of their prescriptions fell 2.9 percent annually, while the number of prescriptions they used grew by 1.3 percent annually.

**Table 2. Spending for high-cost enrollees drove overall Part D spending, 2010-2017**

|                                            | 2010       | 2017       | Average annual growth rate, 2010-2017 |
|--------------------------------------------|------------|------------|---------------------------------------|
| <b>High-cost enrollees</b>                 |            |            |                                       |
| Average price per 30-day prescription      | \$118      | \$221      | 9.4%                                  |
| Prescriptions per enrollee per month       | <u>9.5</u> | <u>9.7</u> | 0.3%                                  |
| Gross drug spending per enrollee per month | \$1,117    | \$2,140    | 9.7%                                  |
| <b>Lower-cost enrollees</b>                |            |            |                                       |
| Average price per 30-day prescription      | \$41       | \$33       | -2.9%                                 |
| Prescriptions per enrollee per month       | <u>3.7</u> | <u>4.1</u> | 1.3%                                  |
| Gross drug spending per enrollee per month | \$151      | \$135      | -1.6%                                 |
| <b>All Part D enrollees</b>                |            |            |                                       |
| Average price per 30-day prescription      | \$55       | \$67       | 2.7%                                  |
| Prescriptions per enrollee per month       | <u>4.2</u> | <u>4.5</u> | 1.1%                                  |
| Gross drug spending per enrollee per month | \$231      | \$302      | 3.9%                                  |

Note: Spending includes all payments to pharmacies, including payments by drug plans, Medicare's low-income subsidy, and beneficiary out of pocket. Changes in the average price per prescription reflects both price inflation and changes in the mix of drugs used.

Source: MedPAC analysis of Part D prescription drug event data and denominator file from CMS.

Early on, the vast majority of spending was attributable to prescriptions for widely prevalent conditions such as high cholesterol, diabetes, hypertension (high blood pressure), asthma, depression, and gastroesophageal reflux. After the 2012 "patent cliff" of small-molecule, brand-name drugs, manufacturers turned to producing orphan drugs, biologics, and other specialty drugs that treat smaller patient populations for conditions such as rheumatoid arthritis, hepatitis C, and cancer.<sup>12</sup> These newer therapies are often launched at very high prices, with annual costs per person sometimes reaching tens of thousands of dollars or more.

<sup>12</sup> The "patent cliff" refers to a year in which manufacturers of widely-used brand-name drugs lost market power over pricing because of expirations of patents and periods of exclusivity.

Most Part D plans have a specialty tier for drugs with high prices.<sup>13</sup> Since the start of Part D, spending for drugs on specialty tiers has grown more than tenfold—from \$3.4 billion in 2007 to \$37.1 billion in 2017. Antineoplastics and antivirals accounted for nearly 10 percent and 7 percent, respectively, of total gross Part D spending in 2017. The price for one of the most frequently used hepatitis C treatments (an antiviral) averaged about \$31,000 per claim, and many cancer therapies had prices that ranged from about \$10,000 to over \$14,000 per claim. Because of their high prices, even a single claim for drugs in those classes would be sufficient to meet the OOP threshold. In 2017, more than 370,000 enrollees filled such a claim, up from just 33,000 in 2010.

Over the past decade, prices of drugs typically placed on specialty tiers have grown rapidly. Between 2007 and 2017, prices of drugs placed on specialty tiers grew by a cumulative 145 percent. The price growth was even greater for some drug classes. For example, between 2007 and 2017, prices of antineoplastics grew by a cumulative 168 percent. While the prices measured do not reflect postsale rebates or discounts, the 168 percent growth likely provides a reasonable approximation of the growth in net prices. This is because, given the protected class status and the general lack of close substitutes, Part D plan sponsors have limited ability to negotiate rebates for antineoplastics.

Changes to Part D's coverage gap and manufacturer discounts combined with the expanding role of high-cost medicines may be eroding plans' incentives for and ability to achieve cost control. The increase in brand-manufacturer discounts to 70 percent beginning this year correspondingly decreases what plan sponsors must cover in benefits and likely weakens sponsors' incentives to manage spending. Going forward, increasing emphasis on specialty drugs in the drug development pipeline will lead to greater use of high-cost medicines. Higher demand for such medications would increase premiums for all enrollees and increase Medicare program costs.

---

<sup>13</sup> Under CMS's current guidance, plan sponsors may place drugs that cost \$670 per month or more on a specialty tier. Before 2017, Medicare's specialty-tier threshold was \$600 per month.

### **Recent Commission recommendations related to drugs**

The Commission recommended to the Congress in 2017 changes to payment policy for Part B drugs, and it recommended changes in 2016 and 2018 to improve Medicare Part D.

#### **Part B drugs (June 2017 chapter<sup>14</sup>)**

In 2017, the Commission recommended a set of policies that seeks to improve the current ASP payment system in the short term while developing, for the longer term, a voluntary, market-based alternative to the ASP payment system. Specifically, the recommended short-term actions would:

- *Improve ASP data reporting.* Currently most, but not all, Part B drug manufacturers are required to report ASP data to CMS. The Commission recommended requiring all manufacturers to report ASP data, with civil monetary penalties for failure to report.
- *Reduce payment rates for drugs paid at 106 percent of wholesale acquisition cost (WAC).* The Commission recommended reducing the payment rate from 106 percent to 103 percent of wholesale acquisition cost for new single-source Part B drugs that initially lack ASP data and for existing drugs that lack ASP data. (CMS has adopted this policy for new drugs but has not adopted it for other drugs that lack ASP data).
- *Establish an ASP inflation rebate.* This policy would require manufacturers to pay the Medicare program a rebate when the ASP for a drug grows at a rate in excess of an inflation benchmark.
- *Establish consolidated billing codes.* This policy would group an originator biologic and its biosimilars into the same billing code to maximize price competition.

Over the longer term, the Commission recommended that Medicare develop the drug value program (DVP) as a voluntary, market-based alternative to the ASP payment system for physicians and outpatient hospitals, replacing the current buy-and-bill payment method. The DVP's intent would be to obtain lower prices for Part B drugs by permitting private vendors

---

<sup>14</sup> Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

to use tools (such as a formulary and, in certain circumstances, binding arbitration) to negotiate prices with manufacturers and by improving incentives for provider efficiency through shared savings opportunities. Under the program, a small number of DVP vendors would negotiate prices for Part B drugs, but vendors would not ship products to providers. Providers that chose to enroll in the DVP would continue to buy drugs in the marketplace but at the DVP-negotiated price, and Medicare would reimburse those providers at the same negotiated price. To encourage enrollment in the DVP, providers would have shared savings opportunities through the DVP while the ASP add-on would be reduced gradually in the ASP system. Savings achieved through the DVP would also be shared with beneficiaries (through lower cost sharing) and with DVP vendors and Medicare.

Taken together, this recommendation takes a balanced, multipronged approach to improving payment for Part B drugs and would achieve savings for beneficiaries and taxpayers. The recommendation includes policies that would improve Medicare payment for Part B drugs, through both a regulatory approach (by reforming the ASP-based system) and a market-based approach (by developing a voluntary alternative DVP) and through policies that would achieve savings not just by modifying provider payment incentives but also by creating pressure for drug manufacturers to reduce or slow the growth of drug prices.

#### **Part D drugs (June 2016 and March 2018 chapters<sup>15</sup>)**

The Commission recommended a combination of changes designed to improve the efficiency and financial sustainability of Part D while maintaining the program's market-based approach.

One set of changes would give plan sponsors greater financial incentives to manage the benefits of high-cost enrollees by shifting more of the plan payments from open-ended reinsurance to capitated payments. Over a transition period, Medicare would significantly lower the amount of reinsurance it pays plans from 80 percent of spending above the OOP threshold to 20 percent, and the insurance risk that plan sponsors shoulder for catastrophic

---

<sup>15</sup> Medicare Payment Advisory Commission. 2016. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC. Medicare Payment Advisory Commission. 2018. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.

spending would rise commensurately from 15 percent to 80 percent. The reduction in the reinsurance would be accompanied by larger capitated payments to plan sponsors, so that Medicare's subsidy of basic Part D benefits would remain unchanged at 74.5 percent.

At the same time, sponsors would be given greater flexibility to use formulary tools. The Commission recommended removing protected status from two of the six drug classes in which plan sponsors must now cover all drugs on their formularies (antidepressants and immunosuppressants for transplant rejection), streamlining the process for formulary changes, requiring prescribers to provide supporting justifications with more clinical rigor when applying for exceptions, and permitting plan sponsors to use selected tools to manage specialty drug use.

Other parts of the Commission's recommendations would exclude manufacturer discounts on brand-name drugs from counting as enrollees' true OOP spending, but would also provide greater insurance protection by eliminating cost sharing above the OOP threshold. Because enrollees who receive the LIS pay nominal cost-sharing amounts that provide little incentive to use lower-cost drugs and biosimilars, the recommended improvements would also moderately increase financial incentives by directing the Secretary of Health and Human Services to modify some LIS copayments.<sup>16</sup>

On net, the Commission's recommendations would restrain Medicare's drug costs and make the benefit more affordable for beneficiaries and taxpayers. The recommendations enhance the Part D benefit so that the program would provide real insurance protection against catastrophic OOP spending. However, the recommendation would also expose some beneficiaries to higher cost sharing in the coverage gap. Because of this, the Commission noted that, to the extent that the adoption of this combined set of recommendations results in

---

<sup>16</sup> In the 2019 Part C & D final rule published on April 2, 2018 (Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program), CMS lowered the maximum copay applicable to biosimilars (and interchangeable biological products) for LIS beneficiaries who are subject to copays and for non-LIS beneficiaries in the catastrophic phase of the benefit.

net program savings, the Congress could consider enhancing protections for beneficiaries facing high cost-sharing burdens.

**Conclusion**

Prescription drugs play a critical role in treating many medical conditions. As such, it is important to ensure that beneficiaries have access to appropriate medication therapies. At the same time, the Commission is concerned that high prices for certain drugs make it increasingly difficult to ensure beneficiaries' access to medications while protecting taxpayers and beneficiaries whose dollars finance the program. The Commission looks forward to continuing to be a resource for the Committee as it deliberates on policies aimed at ensuring access to and the affordability of clinically appropriate medications for beneficiaries and taxpayers.

Ms. ESHOO. Thank you, Dr. Matthews.

We have now concluded the opening statements and we will move to member questions. Each Member will have five minutes to ask questions of Dr. Matthews. I will start by recognizing myself for five minutes.

Again, thank you, Dr. Matthews. In my opening statement I spoke about the increase in spending on specialty drugs. And you, you also have spent part of your testimony on specialty drugs in the Medicare Part D program, and what that means for seniors.

You point out that plans may not have the incentive or the ability to control the costs of specialty drugs. So, what, can you restate for us what exactly MedPAC believes what plans can do to better manage the costs of the new specialty drugs?

And, of course it is not just Medicare being hit by the trend in high-cost drugs. We have—well, I have some other questions, too. Maybe I should just put all my questions out and you can answer them.

Veterans' Affairs, Medicaid, and private plans, how are they managing this trend?

How to other Federal programs like the VA and TRICARE leverage their buying power for these products?

And what is the effect of high-cost drugs—well, we know what the effect of high-cost drugs on beneficiaries is. Does MedPAC have a recommendation relative to an out-of-pocket cap needed for Medicare drug costs?

I know that you said that Medicare has very little authority relative to pricing but, you know, we want to examine everything, every angle of this Rubik's Cube. And so, if we were to implement such a cap, how would that affect the incentive for drug makers in Part D plans that we have discussed?

So, those are my questions. And have at it.

Mr. MATTHEWS. Sure. So, and again thank you for the invitation to testify and to clarify. This is my first testimony before Congress.

Ms. ESHOO. Oh. Well, bravo. It is not so bad, is it?

Mr. MATTHEWS. Not yet.

[Laughter.]

Ms. ESHOO. This is a friendlier hearing room. It is smaller, it is more personal. So, share your wisdom and your expertise with us.

Mr. MATTHEWS. Sure. So, your question has multiple components and I am going to try and get to all of them.

First, as you know, Medicare has made a recommendation in 2016, and slightly modified that recommendation in 2018, to modify the structure of the Part D benefits. And the motivation behind this recommendation hinges on the entry of high-cost, high-rebate drugs into the Part D program, and the incentives that the plans have to place those drugs on their formularies, even when lower cost alternatives are available.

And the incentives are such that the plan can move a beneficiary into the catastrophic phase of the benefits where the plan only has 15 percent liability for those costs under current law. The Medicare program is liable for 80 percent, which it makes on a retrospective cost basis. So, it is counter to the incentives that the plans have to actually manage the benefit above the catastrophic limit.

Plans are not the only actor that might have a role in managing costs at that level. We have started to evaluate additional reforms to the structure of the Medicare Part D benefit that would contemplate a role for the manufacturer to have some financial responsibility above that catastrophic phase, in contrast to current law where the manufacturer is liable for a 70 percent discount on brand name drugs within the coverage gap.

We are contemplating whether or not the incentives might be better for beneficiaries and the program as a whole by shifting that liability above the catastrophic threshold.

Ms. ESHOO. Is there any benefit to the beneficiaries relative to rebates in this?

Mr. MATTHEWS. So, we think that by aligning the incentives for the plans and manufacturers to bargain hard for costs and to manage utilization that that would probably have a more direct and immediate effect on the majority or the totality of Part D enrollees relative to rebates that have distorted effects with respect to any individual beneficiary's utilization and costs.

Ms. ESHOO. And the other, how the other programs, private plans, Medicaid, VA, how are they managing this trend? How do they leverage their buying power for these products?

Mr. MATTHEWS. So, so Medicaid has a couple of tools available to the program. And, again, I am not deep on Medicaid because my expertise is primarily Title 18, so I don't want to stray too far out of what I am able to talk about. But Medicaid benefits from a statutory discount and also from a certain inflation rebate that governs how much manufacturers can increase their prices.

Veterans' Affairs is able to contract directly with manufacturers and suppliers under the Federal Supply Schedule. They can do so because they actually take delivery of products and can guarantee utilization. But it is my understanding that sometimes VA has been criticized in that they have a closed formulary that in some cases has precluded access to certain innovative medications.

Ms. ESHOO. Well, my time has certainly expired. So now I would like to recognize Mr. Bucshon, who is standing in for the subcommittee ranking member, for his five minutes of questions.

Mr. BUCSHON. Thank you, Madam Chairwoman.

Dr. Matthews, MedPAC in the past has recommended a voluntary market-based program for doctors to use third party vendors to obtain drugs in Part D. The Administration, in its advanced notice of proposed rulemaking, proposes setting up a similar system but would make it mandatory for physicians to participate.

I have heard concerns from providers that requiring them to switch to vendors could be very disruptive. Can you discuss why MedPAC opted for a voluntary program, and what features you included to foster competition on drug pricing?

Mr. MATTHEWS. Sure. One of the main reasons that led us to recommend a vendor-based approach to Part D drugs was the potential inflationary incentives inherent in Part B. Where the higher the cost of the drug, the higher the six percent add-on that the provider who administers the drug receives from the program.

And the research is fairly limited as to whether or not providers are actively acting on those incentives but, nonetheless, the incentives are still there. And we feel that getting providers out of the

financial incentives related to “buy and bill” would be better served by having them focus more on selecting the drugs that are most appropriate to the given patient.

And so, we have recommended a modernization of the prior competitive acquisition program that Medicare used several years back under which a vendor would be responsible for negotiating prices with manufacturers, and the vendor would be able to pass on those prices to the individual clinicians or providers who prescribe drugs under Part B.

Mr. BUCSHON. Can I ask a question there?

Mr. MATTHEWS. Sure.

Mr. BUCSHON. Because if you add another middle person, just so you are going to—you might, there might be some savings but you are going to eat some of that up; right?

Mr. MATTHEWS. Under our construct there would be a couple of parameters that would govern the ability of a provider to eat up those savings.

One, under our construct savings would accrue to the vendor, and savings would also accrue to the clinicians who voluntarily elected to participate in that vendor’s negotiated prices.

The second thing that we would do——

Mr. BUCSHON. So that would be the difference between voluntary and mandatory then essentially; right?

Mr. MATTHEWS. Yes, sir, that’s correct.

Mr. BUCSHON. OK.

Mr. MATTHEWS. The second thing we would do is under our recommendation we would have a requirement that the vendor negotiate prices no higher than 100 percent of ASP as currently pertains to the market. So, there would be a couple of ways to govern any potential price increases on the Medicare——

Mr. BUCSHON. Well, couldn’t you, couldn’t you just do that? Couldn’t we just do that without a vendor in the middle? We could just say we are—I mean, that has been tried, right? There was a demonstration project?

Mr. MATTHEWS. Yes, sir.

Mr. BUCSHON. In a previous administration cutting it down to ASP plus I think two point some percent. I can’t remember.

Mr. MATTHEWS. So, the current sequester effectively reduces Medicare payments for Part B drugs from the statutory ASP plus six to ASP plus 4.3 percent.

Mr. BUCSHON. Yes, yes. OK, the demonstration project, which didn’t happen——

Mr. MATTHEWS. Right.

Mr. BUCSHON [continuing]. Was even lower than that.

Mr. MATTHEWS. Right.

Mr. BUCSHON. I have another question, so I will move on from there.

But first of all, as a physician I think there automatically is an assumption that physicians out there will choose higher price, a higher priced product to make more money. And I will just push back on that and say that I think there are maybe people that would do that. But I would argue that the vast majority of physicians make decisions on which medications to use for patients

based on known clinical knowledge based on standard of care in their community. I just want to say that up front.

But we do, but there are incentives. Not disagreeing with that.

In MedPAC's recommendation for Part D it suggests that plan sponsors be given more financial incentives to manage the benefits of high-cost enrollees by shifting more of the plan payments from open-ended reinsurance to capitated payments. As part of a—part of this suggestion, plan sponsors would be given more flexibility to use “formulary tools.”

As a physician I have had some problems with those “formulary tools” such as step therapy and prior authorization for many years. That could delay patient access to timely medications, disrupt treatment regimens for stable patients and create unnecessary physician burden.

Did MedPAC consider these potential impacts to patients and physicians before providing this recommendation?

Mr. MATTHEWS. Yes, sir, we did. And, as always, there is a balance or set of tradeoffs involved in these kinds of decisions where you want to give the plans the leverage with manufacturers to negotiate prices and incentive to manage utilization versus any potential speed bumps that those tools put in front of providers and patients in terms of timely access to the medications.

So, we have talked with stakeholders in the course of developing our recommendations. And we do understand the frustration that some of these utilization management tools create. But, at the same time it is a question of the tradeoffs and the balance that we are trying to achieve for the program as a whole.

Mr. BUCSHON. OK, great. Thank you. My time has expired, and I yield back.

Ms. ESHOO. I thank the gentleman and he yield back.

The Chair now recognizes Mr. Pallone, the full committee chairman, for his five minutes of questioning.

Mr. PALLONE. Thank you. Thank you, Madam Chair. And I wanted to kind of follow up on some of those things that you mentioned, Madam Chair.

Let me start with Part D. MedPAC has analyzed that between 2007 and 2017, Part D program spending increased from \$46 billion to about \$80 billion, for an average increase of 5.6 percent per year, which I think is unsustainable. So, Dr. Matthews, can you explain why we are seeing these steep spending increases in Part D?

And it is my understanding that a smaller portion of high-cost beneficiaries are driving the majority of Part D spending; and is that correct?

Mr. MATTHEWS. Yes, sir, that is correct.

As one of the members said in the opening statements, Part D has been successful in shifting a substantial amount of utilization among Part D enrollees to generics, which the Commission has supported. But at the same time, we are seeing the entry of new high-cost specialty drugs into the program. And over the last several years it is those drugs that have been predominantly driving the increases in spending that we have documented.

Mr. PALLONE. Now, I know you talked a little bit about some of MedPAC's solutions to control spending in response to Chairman

Eshoo. But would you, would you develop that a little more? What are some of MedPAC's solutions to control spending in the future?

Mr. MATTHEWS. OK. So, again, under Part D one of the key elements that we would do is restructure the benefit to give plans more of an incentive to manage utilization above the catastrophic limit. We feel that having the program be responsible for 80 percent of those costs above the catastrophic limit is inconsistent with the notion that Part D was founded on, which was that Part D plans would compete with manufacturers in order to generate the best possible price for the enrollees in order to keep premiums low.

So, we feel that the incentives currently has negated plans' ability to do that somewhat.

As we have been discussing the growth in Medicare spending for drugs under Parts B and D since then, we have become more attuned to the influence of these new, high cost therapies. And we are starting, as I said earlier, to contemplate whether or not manufacturers, who do indeed control the price, should have a greater liability for spending in the catastrophic phase of the benefit.

Again, the Commission has not made any formal recommendation there yet, but it is something that we are very actively engaged in doing.

Mr. PALLONE. Let me get into two more questions. This is the last one on Part D, then I want to ask about Part B.

You talked about generics. You know, we are very proud of the fact that on a bipartisan basis we reported out a package of generic competition bills that I think are going to go to the floor soon. But, of course, if you have these single source drug therapies, there is no competition. Right? So, we know often that these innovative products can change lives, the single source. But without competition how difficult is it to control the cost of those therapies in particular?

Mr. MATTHEWS. We believe it is difficult. And that is one factor that has led us to contemplate going further than our 2016 benefit restructuring recommendation. And again, here the recommendation was to have plans liable for 80 percent of those costs.

But, if we are talking about true sole-source products for which there are no competitors, the plans are going to have fairly limited negotiating leverage with which to negotiate hard on price with the manufacturers.

And that is why we are starting to contemplate whether or not the manufacturers should have some liability for costs above the catastrophic phase.

Mr. PALLONE. All right. Now let me address Part D.

I was struck by the rate of rapid annual growth in Part D drugs mentioned in your testimony, almost 10 percent spending increases annually for the past decade. So, one question.

Could you provide some examples of the most expensive drugs in the Part D program and the conditions they treat? And what are some of the annual per-user costs for these drugs? And what is the beneficiary's responsibility for these costs?

Mr. MATTHEWS. Sure. And just to clarify, this is D?

Mr. PALLONE. D now. This is my only question about D, yes.

Mr. MATTHEWS. Yes, of course.

So, a lot of the high-cost drugs that we have been seeing over the last several years are high-cost specialty drugs, predominantly biologics. All of the top ten drugs for Part D in terms of spending are biologics. They are used to treat conditions such as cancer and its side effects, rheumatoid arthritis, and ocular conditions such as macular degeneration.

Mr. PALLONE. All right. Thank you so much.

Thank you, Madam Chair.

Ms. ESHOO. I thank the gentleman, and he yield back.

The Chair now recognizes Mr. Walden, the full committee ranking member for his five minutes.

Mr. WALDEN. Thank you, Madam Chairwoman.

And again, Doctor, thank you for the work you do, and your team.

We know that a lot of surveys show seniors like Medicare Part D, like a 90 percent approval rating. But we also see some disturbing trends. I wanted to ask you about some of that.

I hear a lot about the rising out-of-pocket costs for seniors. And I have some concerns that some of the changes to the Part D program provide incentives to use brands over generics, and particularly as it relates to true out-of-pocket cost, the acronym TrOOP, calculations.

So, if a senior used only generics they would have to spend about \$5,100 to reach the catastrophic stage of coverage; correct?

Mr. MATTHEWS. Yes, sir. That sounds about right.

Mr. WALDEN. And so, due to the way TrOOP is calculated, I am told a senior would have to spend only \$2,275 in a year to reach catastrophic coverage if they use only brands. Is that?

Mr. MATTHEWS. Without commenting on the specific dollar amounts, I believe the proportions are correct.

Mr. WALDEN. OK. And how have these incentives then affected Part D formularies and plan design? What is happening in this?

Mr. MATTHEWS. So, we do see a trend where plans have in certain instances included high-cost, high-rebate drugs on their formularies even when lower cost alternatives are available.

And the idea here is that the high-cost drug is going to get the beneficiary into the coverage gap sooner than a lower cost brand name drug, or a lower cost generic. And it is above the coverage gap in the current construct where the plan only has 15 percent liability for those costs.

And so, arguably, there are instances where the size of the rebate for certain drugs can be so great as to even begin to offset their 15 percent liability above that catastrophic limit.

Mr. WALDEN. So, what is the effect for taxpayers, and what is the effect for consumers for that?

Mr. MATTHEWS. So, for taxpayers then the fastest growing component of Medicare spending for Part D is the reinsurance payments that the program makes to plans. And these are payments that reflect plans' costs for these extremely high-cost enrollees. But these payments are also funded directly by the Medicare program.

So, the fact that these reinsurance payments have been growing for 20 percent year over year for the last ten years is detrimental to taxpayers. And to the extent that these costs are reflected in the

calculation of Part B premiums, it is detrimental for the beneficiaries who are paying for these premiums.

Mr. WALDEN. All right, thank you very much. I will yield back, Madam Chair.

Ms. ESHOO. I thank the gentleman. He yield back.

The Chair now recognizes the gentlewoman from California, my friend Congresswoman Matsui.

Ms. MATSUI. Thank you so much, Madam Chair.

And thank you, Dr. Matthews for joining us today.

While it is important to focus on lowering the price of prescription drugs to patients and to ensure the sustainability of the Medicare program, we can't lose site of the need to protect beneficiaries' access to necessary medications. As you know, the Administration last fall proposed changes to the protected class policy that would allow Part D plan sponsors to add restrictions or otherwise limit prescription medications in the six protected classes.

The protected class policy is an important safety net for patients who absolutely need potentially life-saving medications to treat a complex medical condition. I am particularly concerned that changing protected class policy will jeopardize Medicare beneficiaries' access to the full range of medicines for treating mental illness.

For example, antidepressant medication impacts individuals differently and, as such, can take time to find the right treatment that works for any given individual. And earlier this month I wrote a letter to my colleagues to CMS expressing this concern.

Dr. Matthews, I understand that MedPAC has recently considered similar changes to two of the six protected classes, including antidepressants. Given my concern around access for Medicare's most vulnerable beneficiaries, I am interested in your thoughts on how we can continue to ensure the availability of needed medications while making changes to protect the classes?

Mr. MATTHEWS. Sure. Yes, ma'am, I'm happy to address that.

As part of our 2016 recommendations on Part D, we did recommend removing two categories of drugs from the protected classes, one of which was antidepressants. The second one was immunosuppressives used after transplant surgery.

The rationale here was that there do seem to be enough alternatives in those two categories that plans could be able to put together a formulary that accommodated the clinical needs of most beneficiaries needing those drugs without being constrained by having to cover every drug on those protected classes.

The Administration's proposal is a little bit different. I don't think they have recommended eliminating any of the protected classes, but have proposed giving plans more ability to use utilization management within those classes.

Again, you know, the balance here is beneficiary access relative to plans' ability to negotiate with manufacturers for price. And if the plan has to cover every single drug in a protected class, they have virtually no leverage in order to negotiate with a manufacturer. So, it is those tradeoffs that led us to the recommendation.

The last thing I would say is we would, in either instance, in our recommendation or with respect to the Administration's proposal,

we would believe that there is a strong need for a well-functioning appeals process that beneficiaries can avail themselves of.

Ms. MATSUI. I agree. Yes, that would be good.

But on the other hand, you know, we have had experience with people with mental illness. And in particular, as you know, the therapy involved there is very difficult to get the right medication. And then to have to go back again to start over since there we know that is not going to work anyway. And I just really hope that whatever process you decide to implement is really going to be very sensitive to that.

Because we would hate to lose the ability for individuals who already found a therapy to be able to continue in some way.

Mr. MATTHEWS. Yes. We are keenly aware of the unique nature of treatments for behavioral disorders.

Ms. MATSUI. OK. I want to talk a little bit about out-of-pocket spending for beneficiaries in Medicare Part D. And I am concerned about patient access issues created by the fact the Part D program does not currently have an out-of-pocket limit. It means that some seniors who have significant drug spending, often those with chronic diseases or those who are severely ill, will continue to pay a cost-sharing obligation even in the catastrophic phase, and even after spending thousands of dollars out-of-pocket.

I know that MedPAC has recommended reforming the Part D benefit to eliminate cost sharing above the out-of-pocket threshold. Can you explain MedPAC's recommendations to cap out-of-pocket expenses for Part D beneficiaries, and how this change might impact premiums and other aspects of the benefit design?

And I only have about 15 seconds here.

Mr. MATTHEWS. Sure. So, we did indeed recommend in 2016 capping the beneficiary's financial obligation above the catastrophic phase. The motivation was that if the beneficiary is incurring that kind of cost, coinsurance is not a drag on inappropriate utilization but it is potentially punitive at that point from the beneficiary's financial perspective.

Ms. MATSUI. OK. I yield back my time. Thank you.

Ms. ESHOO. I thank the gentlewoman. She yield back.

I now would like to recognize the gentleman from Illinois, Mr. Shimkus, for five minutes of questions.

Mr. SHIMKUS. Thank you, Madam Chairman. And I want to thank you for having this hearing today.

Dr. Matthews, welcome. We appreciate your input. And it is very helpful. We just need to take action, and that is what this hearing is.

I also appreciate your comments on trying to clarify the how is VA different. I know that is kind of out of your window. But, that there is a formulary and so the formulary is narrow, so even our veterans may not get the full scope of drugs available in our country because they are purchasing and making contracts. And we always have to try to explain that in this process because sometimes it gets lumped together and say, well, why can't you do it that way? And I guess if you have lower cost, that is good. But if you don't get the drug, the blockbuster drug, then it is bad. So, then there is—there is that balance.

I also appreciated, talking just Medicare D, what benefit was provided to our seniors for health and prescription drugs prior to Medicare D?

Mr. MATTHEWS. There was no real outpatient prescription drug benefit.

Mr. SHIMKUS. There was none. So, I mean, again, for, just for an instruction purpose, we wrestled with how to get Medicare. In fact, a lot of conservative Republicans got beat up quite a bit on this because we expanded in essence an entitlement and mandatory spending program. But modern medicine said prescription drugs has to be part of the fix.

I know the chairman has left, but we had some great fights, and debates, and battles. And Chairman Pallone was most angry about the donut hole provisions which we placed in there for budgetary—to make the numbers work.

So, I was surprised when I met with a constituent because I don't follow this as closely as you all do, and we have a new world of drugs on the market prior to what we did in 2003. They are life-saving drugs, they are biologics, they are especially new blockbuster drugs are very, very expensive.

So, I had a constituent who provided me with this, a biologic. It is actually ant—let me look down there. What was it? Enzyme. Come on, come up here so you can tell me. All right, enzyme deficiency. So, this is at a cost a year of \$348,000.

So, then I was kind of going through how Medicare D got established. And I drew the donut hole. I said, you pay here, you fall into the donut hole, you have to pay it all. And then it was our intent that once you came out of the donut hole that you would be covered. So, I think some of your proposals are trying to address, well, you know, the answers to Doris, Congresswoman Matsui's concerns about end of out-of-pocket cost.

And then I was surprised when he provided me information that the percentage cost. This is 22,000, 348,000 over a year, 22,000 a month. They are still on the hook for a percentage of that.

Mr. MATTHEWS. Yes, sir. Correct.

Mr. SHIMKUS. So for those who were in that room in 2003 thought that once they got out of the donut hole they had kind of gotten home free. That is not true, is it?

Mr. MATTHEWS. No, sir, it is not.

Mr. SHIMKUS. Yes, and it is not true for my constituent either. So, I appreciate him meeting me. We actually met in a bar, you know, as I was traveling through my district, which is very large. Yes, we did have to have a few drinks after I heard that cost of that, they were having the burden.

So, we need to address this, you know, this major expense. And if Medicare D is supposed to be an insurance plan and then there is a catastrophic portion, there is eventually a time when—and I think that is your reinsurance provision and those other proposals, am I correct?

Mr. MATTHEWS. That's correct. Yes, sir.

Mr. SHIMKUS. So, I just thank you for being here. It is my understanding that you are an independent agency and you advise us. So, I would hope, Madam Chairman, that we would take your counsel and try to address especially this end of the process be-

cause Medicare D does—seniors pay in. I mean, so they are part of the solution. They are not just, it is just not all Government solution because it is an insurance plan that they are partners with and they choose. We need to help them on the back end.

So, with that I appreciate your time. Thank you, Madam Chairman. And my time has expired.

Ms. ESHOO. I thank the gentleman. Excellent questions.

I now would like to recognize the gentleman from Oregon, Mr. Schrader, for five minutes of questions.

Mr. SCHRADER. Thank you, Madam Chairwoman, I appreciate it.

Dr. Matthews, thanks—I need some medication myself—thank you for taking time to be here.

As you may or may not know, my State of Oregon is taking steps to increase the number of payments tied to performance in Medicaid. Specifically, they are using an 1115 waiver to work with our coordinated care organizations and network providers to create a plan to have a value-based payment by 2022. Other states are also trying to set up these arrangements.

Has MedPAC evaluated either in specific cases or more broadly whether Medicare may benefit from value-based payments and tying the reimbursement to actual outcomes? What, if any, barriers are in the way for that?

Mr. MATTHEWS. So, we are aware of the emergence of these types of value-based arrangements, both here in the United States and in European countries. It is my understanding that the evidence on the long-term effectiveness of these arrangements simply does not yet exist, that these are new enough that a broad base of evidence hasn't been generated to ascertain that they have, they can exercise the potential that the stakeholders believe is there.

With respect to Medicare, one potential impediment to the broad use of these sorts of value-based arrangements is the voluntary nature of Part D. So, a plan may enter into a contract—an agreement with a manufacturer that is contingent on certain beneficiary outcomes that may not manifest themselves until after the lapse of a period of years. But Part D is a voluntary benefit, and a beneficiary can move from one plan to the next year after year. And so, a plan may not see the benefits of its investment in these arrangements for a particular enrollee.

So that is one potential logistical obstacle in Part D as currently designed.

Mr. SCHRADER. Good point.

With regard to the general Medicare population, you spoke in your testimony about the long-term beneficiaries disproportionately selecting brand drugs sometimes over generic, actually oftentimes brand over generic. What remedy for increasing utilization of generics by this population would you recommend? I know that there are administrations out there trying just to lower the cost of the brands or, excuse me, the generic to zero to make it appealing. What about increasing the cost of the brand? Your thoughts.

Mr. MATTHEWS. So, we have gone on record as recommending that even low income or beneficiaries receiving the low income subsidy should be given incentives to use generics when they are available and clinically appropriate.

As you just mentioned, those incentives can take one of two forms: one is zero copayments or zero financial liability for generics; the second would be some nominal financial liability for the use of brand name drugs when generics are available. And we think that even low income beneficiaries should have to make those kinds of decisions with respect to the therapies that they and their clinicians decide on.

Mr. SCHRADER. So you don't have an opinion as to whether just reducing one or increasing?

Mr. MATTHEWS. Either would achieve the goal of increasing benefit—low income beneficiaries' use of generics.

Mr. SCHRADER. All right. Very good, thank you.

With that, I yield back.

Ms. ESHOO. I thank the gentleman. He yield back.

I now would like to recognize the gentleman from Kentucky, Mr. Guthrie.

Mr. GUTHRIE. Thank you, Madam Chair, for holding this meeting.

And thank you for being here. Doing a good job for your—good job even though it is your first time. I almost said a good job for your first job. But a good job. I appreciate it very much.

And, unfortunately, we should coordinate better with my neighbor in the hallway Mr. Schrader because he asked almost word for word one of the questions I was going to ask. So, let me get to the valued-based. That is interesting to me.

But so, are you supportive of transparency tools like real-time prescription benefit check that could help beneficiaries understand the cost of their prescribed medications before they leave the doctor's office?

Mr. MATTHEWS. Yes, sir. We have been supportive of clinicians' use of electronic tools like real-time benefit check.

Mr. GUTHRIE. So, what policies do you think we should develop to encourage use of these policies, of these tools?

Mr. MATTHEWS. I would need to think about that, with all due respect. It is my understanding that the technology does exist with respect to currently available electronic health records. But the issue is getting the clinician to actually purchase the requisite models or modules to do the real-time benefit check and providing incentives for clinicians to use those.

The Commission does not have a specific proposal in order to do that.

Mr. GUTHRIE. OK. Thank you.

And changing gears, since Mr. Schrader took my thunder, I am told that the physician charge, I am told that a physician charges, that a physician charges per administering drugs are twice as much in hospitals compared to doctors' office. This drives up Medicare costs but also drives up cost-sharing for the patients. Can more be done to address this through site neutral payment reform?

Mr. MATTHEWS. Yes, sir. I believe there is more that can be done. As you know, the Commission has been concerned about the incentives or the undesirable incentives that occur with respect to the differential for a clinician's services in the physician office versus the hospital outpatient department. And we have made recommendations to standardize those payments across settings.

Yet, nevertheless, we think that those incentives still exist and that there are potential broader remedies that could be contemplated.

Mr. GUTHRIE. OK, thank you. And, again, thanks for being here today, and holding the hearing. And I yield back.

Mr. BUCSHON. Will the gentleman yield for a few seconds?

Mr. GUTHRIE. Yes, I will yield the remainder of my time to Mr. Bucshon.

Mr. BUCSHON. Yes, yes.

Mr. GUTHRIE. Dr. Bucshon.

Mr. BUCSHON. Yes. I just want to make a brief comment on what he was talking about—about the patients knowing up front what prices drugs are.

When I was in practice, if I was going to prescribe something, I knew might cost a lot I actually checked myself personally before I would prescribe it for the patient, just to make sure. But I do think in today's electronic world that we should, physicians should be able to determine that up front. And sometimes, depending on the patient, that may very well make you make different decisions on what the options are because if the out-of-pocket is going to be really high to the patient there might be therapeutic alternatives.

So, I do think we can get to a place where electronic records can provide that information at a minimum to the provider. I think it is when you go to the consumer it is more confusing, but for the provider I think that can, that could help, so. Yes, it could pop up on the screen for example when you go to provide, when you go to send an electronic prescription.

So, I yield.

Mr. GUTHRIE. Thanks. I yield back.

Ms. ESHOO. I thank the gentleman. And he yields.

I now would like to recognize the gentleman from California, Dr. Ruiz, for five minutes of questioning.

Mr. RUIZ. Thank you.

Dr. Matthews, I appreciate the position that the Commission is in trying to make recommendations that balance the need to cut down on healthcare costs while also ensuring that patients are getting the care that they need. And I know that patient care is important to you.

In your written testimony you identify one of the Commission's goals is "achieving a Medicare program that ensures beneficiary access to high quality, well-coordinated care."

Last November, CMS proposed a rule that would allow Medicare Advantage plans to use step therapy for Medicare Part B drugs. And, while I understand that step therapy can play an important role in reducing healthcare costs, it often does not take into account a patient's medical history, like whether they have tried the medication previously and failed under a different insurance plan.

Fred Sangiorgio, one of my constituents from La Quinta, California, suffers from psoriasis and psoriatic arthritis and is going through step therapy right now. He has been diagnosed most of his adult life and has tried several treatments over the years. Despite the fact that he already tried one treatment that didn't work, he is currently being forced to go through a similar treatment that his doctor knows won't be effective.

Instead of being able to prescribe an alternative treatment that she thinks will be more effective, his doctor has to wait for this drug to fail, too, despite the fact that both of them know that what is going—what is going to happen.

That is why I have introduced legislation with my friend Congressman Wenstrup, a fellow physician, that would help protect the doctor/patient relationship and help get patients the care that they need. The Safe Step Act creates a list of exemptions that will allow patients to bypass step therapy if their doctor knows that the treatment will not be successful, as is the case with Fred.

As a physician, I want to ensure that all step therapy protocols also include safeguards to help ensure that patients aren't forced to have to try a treatment that their provider knows is not likely to work for them, or even to take a drug that may have already failed for them in the past.

So, can you outline some safeguards that CMS can put into place to protect the patients from unnecessary and potential harmful treatments?

Mr. MATTHEWS. Yes, sir. Again, the Commission has gone on record as supporting giving plans more flexibility to appropriately use these management tools. We do understand that the circumstances of every patient is unique, and that we would not support putting a patient through some of these things, like step therapy, when the clinician knows that they are not going to be effective for a given patient. Therefore, we have said that the greater use of these tools has to be accompanied by a very robust and effective system of grievances and appeals whereby a clinician can request an expedited—

Mr. RUIZ. What are some of these exceptions that you would propose to safeguard patient access?

Mr. MATTHEWS. So, if the clinician is able to document that the patient has previously failed on a therapy that is required by a plan's formulary or step therapy or—

Mr. RUIZ. What does "failed" mean to you?

Mr. MATTHEWS. That the patient's clinical condition has not responded to the treatment that is being required by the plan.

Mr. RUIZ. Does a lack of compliance due to cumbersome regimens like a, you know, every 4-hour treatment and, therefore, that doesn't fit that person's life or work schedule, would that be considered failure to you?

Mr. MATTHEWS. I do not have the clinical basis to answer that question, with all due respect. The Commission hasn't opined at that level of detail.

Mr. RUIZ. Right. In my medical opinion, when it is a compliance issue it is usually a failure in the system to provide the best treatment and follow-up for that patient. It is not the patient's fault per se, which is normally what happens in the medical world.

What other safeguards could we think of that would provide these exceptions so that we can preserve the patient's and the physician's judgment in getting them the medication that is best for that patient; instead of putting them through a rigorous bureaucratic step process in order to save the company money?

Mr. MATTHEWS. Again, if I could ask for the dispensation to think about that and follow up.

Mr. RUIZ. OK. What's the MedPAC strategy to both monitor beneficiary impact and to ensure CMS institutes appropriate safeguards, including those that are lined with number of State laws which serve as models for the Safe Step Act?

Mr. MATTHEWS. So, we believe that the Medicare program is currently monitoring beneficiaries' appeals under Part D. There are a number of steps that patients and their clinicians can go through, and it is my understanding that the majority of those appeals are indeed adjudicated in favor of the patients when clinically warranted.

So, the agency is indeed monitoring whether or not beneficiaries' access to medications under Part D as being unduly compromised.

Mr. RUIZ. Thank you.

Ms. ESHOO. The gentleman yield back.

I now would like to recognize the gentleman from Florida, Mr. Bilirakis, for five minutes of questioning.

Mr. BILIRAKIS. Thank you, Madam Chair. I appreciate it very much. Thanks for holding this very important hearing. I appreciate it.

Dr. Matthews, with Florida's traditionally higher senior population, lowering prescription drug prices, as you can imagine, and Medicare is very important to me. As noted in MedPAC comments on the International Pricing Index, or IPI for short, last year the drug value program recommended previously by MedPAC would give vendors tools to negotiate lower prices.

Under the Administration's IPI proposal they don't include these tools. So it seems like, instead, the Government is just setting the price directly. Am I correct in concluding that MedPAC's proposal is more market-based than the Administration's?

Mr. MATTHEWS. I would not want to comment on whether or not the competing proposals are more market based, one relative to the other. We did identify a number of potential logistical issues with respect to the Administration's proposal that we believe would make it very difficult to implement. These range from things such as the one you just mentioned, that the vendor would not have any tools, such as a formulary, or other mechanisms by which to negotiate with manufacturers.

The vendor under the Administration's model would take title to the drugs, but perhaps not actual physical possession.

Then, lastly, the vendor would be paid at a rate determined by Medicare based on the international price comparison, whether or not they were able to obtain that rate on the market or not. We identified a number of issues that would affect the ability to even calculate that international sales rate, given available data and given the idiosyncratic arrangements between manufacturers and, you know, other countries' Governments.

So, we think there are some substantial implementation difficulties with respect to the IPI proposal that do not present themselves under our proposal, which would give the vendor more ability to negotiate on the basis of being able to help drive manufacturers's volume.

Ms. ESHOO. Excuse me, Doctor. May I please, I just learned that your voice is not carrying well on T.V. so, can you bring your microphone much closer.

Mr. MATTHEWS. Sure.

Ms. ESHOO. And then maybe the staff hearing me will come back in and let us know if you can be heard.

Mr. MATTHEWS. Thank you.

Ms. ESHOO. Thank you.

Mr. MATTHEWS. Sure.

I am sorry, so I was indicating that under our proposal that some of the difficulties engendered by the IPI proposal would be mitigated. And we believe that it would have greater potential to reduce spending for Part B drugs.

Mr. BILIRAKIS. Very good.

I know there are examples in the market where arbitration is used, such as baseball. I am a big baseball fan. But developing breakthrough medicine is a lot different from developing starting pitching. And legislating a Government-defined arbitration process is a lot different from negotiating one through a players' union.

Mr. MATTHEWS. Yes, sir.

Mr. BILIRAKIS. Are there examples of binding arbitration between being used in healthcare? Do any of these examples involve setting prices at a national level or just resolving disputes at an individual level?

Ms. ESHOO. Move your microphone even closer please. Yes, pull it right up.

Mr. MATTHEWS. This is, yes, this is not a natural thing for me to be doing. So I apologize.

Ms. ESHOO. That is all right. We will guide you. It is just a microphone; get it as close as possible so——

Mr. MATTHEWS. All right.

Ms. ESHOO [continuing]. Anyone in the country that is listening in can actually hear you.

Mr. MATTHEWS. Yes. That is not helping but I will——

Ms. ESHOO. OK.

[Laughter.]

Mr. MATTHEWS. We will see.

So, we are unaware of the use of baseball arbitration in the way we have proposed it for Part B.

Mr. BILIRAKIS. Can you describe how you have proposed it, the arbitration?

Mr. MATTHEWS. Right. So, so as I mentioned both in my written testimony and in my oral remarks, one of the vulnerabilities of the Medicare program is that it has little, if any, ability to influence the price that the manufacturer sets for a product and, therefore, the price that Medicare pays. We believe that binding arbitration would give the program a means of influencing that price by bringing the manufacturer to the table with their absolute best offer for a new product.

And then the secretary would be able to make a competing offer if he or she did not think that the evidence supported that manufacturer's price. And that this would be distinct from a scenario where the secretary is negotiating directly with manufacturers for price in that only certain drugs that met a criteria defined under statute or regulation would trigger this binding arbitration process.

But, currently the Medicare program has virtually no means whatsoever to influence price. As I have said in my testimony,

under both B and D price is one of the major drivers of Medicare spending for drugs.

Mr. BILIRAKIS. Very good. Thank you.

I yield back, Madam Chair.

Ms. ESHOO. The gentleman yield back.

And I now would like to recognize the gentlewoman from New Hampshire, Congresswoman Kuster.

Ms. KUSTER. Thank you very much. I am delighted to be here. Thank you for your discussion. It is actually very, very helpful on a complicated topic.

In New Hampshire the nearly 300,000 Medicare beneficiaries, and most of them, many of them do have Medicare Part D for complete drug coverage. But the prices that Granite Staters are facing for prescription drugs are, to say it bluntly, unacceptable and, frankly, unsustainable. They are unsustainable for aging communities that rely on Medicare to be there for them when they turn 65, and for the taxpayers who hard-earned dollars go toward the different payment mechanisms that you have walked us through today.

I am going to cut to the chase. I want to understand specifically on the “buy and bill” program.

Under the current Part B system, a provider is reimbursed at 106 percent of the average sales price, regardless of the actual price that they pay for the drug. So my question is some providers may be getting the drug at a price below the average, and it is possible that some at a price above the average?

Could you explain the original intent behind the 100 percent plus six add-on payment? And what information is available on the provider’s actual acquisition cost, what they pay for the drug?

Mr. MATTHEWS. OK, sure. I will try to answer without deigning congressional intent behind the six percent add-on.

But, the answer to the question, in all candor, is not clear. There are a number of competing alternative explanations for six percent. One is that the six percent helps compensate clinicians and providers for the costs of administering the drug. But, as I mentioned earlier, Medicare pays the clinician separately for that.

Ms. KUSTER. But they get a separate payment for that?

Mr. MATTHEWS. That is correct.

Ms. KUSTER. Right.

Mr. MATTHEWS. So, I don’t think that explanation is quite right.

Another explanation is that the six percent compensates for the provider’s costs related to handling and storing the drug or waste that occurs during the administration of the drug. But, again, under both the outpatient perspective payment system and the physician fee schedule there are components of those payments that reflect providers’ costs of basically running the operation. So I don’t think that is—

Ms. KUSTER. The normal overhead.

Mr. MATTHEWS. That is, that is exactly right.

Ms. KUSTER. Exactly.

Mr. MATTHEWS. Yes, ma’am.

And so the most compelling explanation, from my perspective, is that as you just pointed out, not every purchaser is able to get the drug at the average price. Some are paying more, some are paying

less. And to the extent that volume is driving a provider's ability to obtain a good price, some small, independent practitioners, rural physicians, small hospitals, may not be getting quite a good deal as larger health systems. And so, the six percent add-on could be reflecting the relative purchasing provider base—power based on volume.

Ms. KUSTER. I am glad you brought up volume, and my goal is to have the lowest price for the senior and the lowest price for the taxpayer. I think right now it is safe to say seniors are paying too much, taxpayers are paying too much.

My question is has MedPAC ever examined the impact on the cost of medications to beneficiaries in the Medicare program by authorizing Health and Human Service secretary to negotiate a volume discount on prescription drugs? Have you ever provided recommendations? Could you tell us?

I just don't understand, everywhere else. I have sat for six years on the Veterans' Affairs Committee. I know what Federal employees. I know what Walgreen's. And my constituents don't understand why wouldn't we have a volume discount for the purchase of medication under Medicare?

Mr. MATTHEWS. The Commission has not taken a position on this issue, nor have we made any recommendations.

Ms. KUSTER. So, we don't know, it could bring down the cost for both the taxpayers and seniors?

Mr. MATTHEWS. I don't know that I would opine on that myself because the notion of volume discount in some ways raises the question of the secretary negotiating with manufacturers and basically saying, I, the Medicare program, am going to guarantee a certain amount of volume of your drug and, therefore, you need to give me this volume discount or this lower price.

And, again, the Commission has not taken a position with respect to the secretary's ability to influence price through direct negotiation.

Ms. KUSTER. I would simply say, in every other aspect that is how we bring down the price is negotiating a volume discount.

I very much appreciate your candor.

Mr. MATTHEWS. Sure.

Ms. KUSTER. I yield back.

Ms. ESHOO. The gentlewoman yield back.

I now would like to recognize the gentleman from Georgia, Mr. Carter, for five minutes of questioning.

Mr. CARTER. Thank you very much, Madam Chair. Thank you, Dr. Matthews, for being here, and thank you for the work that you in leading MedPAC and helping and doing your best to keep prices down, as well as providing the best services that we can to the recipients of Medicare. It is extremely important.

Earlier this month in this committee, in a bipartisan fashion, I was able to pass legislation that I sponsored, bipartisan legislation, along with Representative Gianforte, Representative O'Halleran, Representative Welch, called the Payment Commission Data Act.

Mr. MATTHEWS. Yes, sir.

Mr. CARTER. Which is going to allow MedPAC, as you know, to be able to get data relating to prescription drug pricing. And you

in turn will be able to use that data to make recommendations to us here in Congress.

Can you just comment on that firsthand on how that may be able to help you?

Mr. MATTHEWS. Yes, sir. Before I do, I would want to express on behalf of the Commission my appreciation to you and the other co-sponsors of this legislation.

One of the ways that the Commission has been hamstrung in terms of being able to evaluate the effects of the various rebate structures on the Medicare program and its beneficiaries is we do not have access to that level of granular data with respect to rebates on a prescription by prescription or drug by drug basis.

And so, for example, when we commented on the Office of Inspector General's recent proposal to eliminate rebates in the Medicare program, we were only able to evaluate that proposal through its aggregate impacts on the program, on beneficiaries and manufacturers. We simply did not have the level of detail in order to be able to assess; it would affect this group of beneficiaries who are taking this class of medications for this variety of conditions. And so, having this more granular data on rebates would help us do those kinds of analyses and help inform the kinds of deliberations that the committee is having on a regular basis.

Mr. CARTER. Right. I certainly think both of us would be remiss if we did not mention that that information is only going to go to you.

Mr. MATTHEWS. Yes, sir.

Mr. CARTER. You are the only ones who are going to see it. It is not—we get it, it is proprietary information, but it is not going to be released to the public, it will only go to the Commission.

Mr. MATTHEWS. That is correct, sir. MedPAC has a sterling track record in terms of—

Mr. CARTER. Right.

Mr. MATTHEWS [continuing]. Handling proprietary and sensitive data.

Mr. CARTER. Right.

I want to ask you about the DIR fees. You are familiar with DIR fees and you are familiar with what the Administration, what Health and Human Services, CMS specifically, has proposed in changing the rules so that—so that DIR fees or discounts will go directly at the point of sale, as you mentioned earlier. But there were two things that you mentioned in your letter to the Administration, or to HHS, about DIR fees, first of all, that DIR fees had grown from \$229 million in 2013 to \$4 billion in 2017.

Mr. MATTHEWS. Sure.

Mr. CARTER. \$229 million to \$4 billion.

And, of course, for those people who don't know, DIR fees are essentially clawback fees that go to the, the PBMs put on, placed on the pharmacies.

You also mentioned that the amount of the DIR fees that the plan sponsors were recouping actually exceeded what they had proposed and what they really had projected. Can you comment on or explain what that disparity might mean for cost sharing?

Mr. MATTHEWS. Yes. What the short answer is that this means beneficiaries at the point of sale are paying a much greater amount

in cost sharing than they should be relative to the effective transaction price between the manufacturer and the plan.

Mr. CARTER. Exactly. Exactly. But and I know that MedPAC has put out some different solution to the DIR fees, but the point is that you agree that DIR fees are a problem?

Mr. MATTHEWS. Yes, sir, that is correct.

Mr. CARTER. OK, good.

Very quickly in what little time I have left, of course one of the things that we've been talking on this committee and in Energy and Commerce, and specifically on the Oversight and Investigations Committee has been insulin pricing. I just wanted you to comment very quickly that I understand there is a lot of variability in the different plans on how they cover insulin, but can you, can you explain how the Medicare plans cover insulin, particularly for those patients who are in the donut hole?

Mr. MATTHEWS. If I could get you to ask the question just slightly differently?

Mr. CARTER. Well, in other words, I know the different Medicare Part B plans cover it in different ways. But making it affordable, making it accessible is something we are very concerned with, particularly on this committee. How can we do that? How can those plans do that in a better way?

Mr. MATTHEWS. Again, our recommendation to restructure the Part D benefit would mitigate the incentives for plans to use these high-cost, high-rebate drugs, and insulin is one example of those kinds of things. And by better aligning the plans' incentives it would potentially reduce the influence of DIR on the cost that the beneficiary faces.

Mr. CARTER. Right. Again I want to thank you for your work on transparency and accountability within the system, particularly with the third party, the pharmacy benefit managers, the middleman, that is what is going to help us. And, you know, transparency is the best disinfectant out there, and sunlight is, and that is why we need it so bad.

Thank you for your work on this, and I yield back.

Ms. ESHOO. The gentleman yield back.

I now would like to recognize the gentleman from North Carolina, George Butterfield, and happy birthday to you again.

Mr. BUTTERFIELD. I have been multitasking today and I don't have any questions.

Ms. ESHOO. You don't?

Mr. BUTTERFIELD. If you can believe that.

Ms. ESHOO. Isn't that something.

Mr. BUTTERFIELD. Yes.

Ms. ESHOO. Well, a lot of good ones have been asked, so stay tuned.

All right. Well, with that we will move to the gentlewoman from Delaware, Ms. Blunt Rochester, for five minutes of questioning.

Ms. BLUNT ROCHESTER. Thank you, Madam Chairwoman. I would also like to thank you, Dr. Matthews, I am trying to speak into the mike now I am cognizant of it.

Today's hearing is an opportunity for the subcommittee to continue our bipartisan work on lowering prescription drug costs by turning our attention to how skyrocketing prices are impacting

Medicare Part B and D. And it couldn't happen at a more important time. Prescription drug spending accounts for nearly one dollar out of every five spent on Medicare and, according to the Kaiser Family Foundation, was 19 percent of overall Medicare spending in 2016.

The Office of the Actuary at CMS found that the national health expenditures will continue to increase by an annual average of 5.5 percent until 2027. These spending trends mean that it is not just the Federal Government that is paying more but Medicare beneficiaries. In my State that means growing costs for the almost 200,000 Medicare beneficiaries.

Dr. Matthews, I would like to discuss Part B's, Medicare Part B's low-income subsidy which helps provide beneficiaries with limited incomes assistance with their Part D premiums and out-of-pocket expenses.

In 2018, 12.5 million beneficiaries with incomes at or below 100 percent of the Federal poverty level received Federal assistance. In Delaware, 23 percent of beneficiaries received the low-income subsidy. However, MedPAC has found that relative to other Part D enrollees, a higher proportion of LIS enrollees use brand name drugs.

Can you explain why this is happening?

Mr. MATTHEWS. OK. The dominant hypothesis that has guided our thinking here is that the low-income beneficiary whose costs are heavily subsidized is not as sensitive to cost sharing, or the price of the drugs that they take relative to a beneficiary who is paying, you know, the full coinsurance and their full out-of-pocket liability. And so, given the choice between a brand name drug and a generic, many Medicare patients who regard generics as not as good, a low-income beneficiary who is facing zero or minimal cost sharing is going to opt for the brand name when it is available.

Ms. BLUNT ROCHESTER. Right. Opt for the one that they rationally think is the better—

Mr. MATTHEWS. Yes.

Ms. BLUNT ROCHESTER [continuing]. Product.

Additionally, MedPAC found that in 2016, about 8 percent of Part D enrollees reached the out-of-pocket threshold. And of that 8 percent of high cost enrollees, over 70 percent were LIS beneficiaries. Given that it is the Medicare program that pays the largest share of costs out of—above the out-of-pocket threshold, I am concerned that plans may be structuring their benefits in ways that shift costs to Medicare for these, these enrollees in order to shield plans from risk.

Does MedPAC share these concerns?

Mr. MATTHEWS. Our concerns are more with, are even larger than that, not limited just to the low-income beneficiaries. But, again, given the growth in the cost-based reinsurance payments for all Part D enrollees, we believe that is an extremely pressing problem for the program. While in the earlier phases of the Part D benefit LIS enrollees did reach the catastrophic phase at faster rates and in greater proportions, in recent years it is the non-LIS population who is now hitting that cap at much higher rates.

Ms. BLUNT ROCHESTER. I know one of the things that you discussed before were the incentives, you know, to incentivize beneficiaries to pick a cheaper alternative. Can you talk about the op-

tions that you gave, are these evidence-based? Where did these ideas come from? How do you know they will work? You had, you listed, like, zero copayments, you talked about nominal financial incentive. Can you talk about where you got that from and why you think it will work?

Mr. MATTHEWS. Yes, with permission, I would like to be able to follow up.

Ms. BLUNT ROCHESTER. Great.

I appreciate MedPAC's thoughtful analysis on this issue and so many issues within the Medicare program. Low-income Part D beneficiaries on tight incomes, there are many of them, and we must be doing all we can to ensure that they also have access to the medications that they need, while ensuring that there are not perverse incentives that keep drug prices high.

I thank you and I yield back.

Mr. MATTHEWS. Thank you.

Mr. BUTTERFIELD [presiding]. Thank you, Ms. Blunt Rochester.

The gentle lady from California, Ms. Barragán, is recognized for five minutes.

Ms. BARRAGÁN. Thank you.

I want to follow up on the questioning from one of my colleagues on Medicare Part D negotiating. I know that you indicated that MedPAC has not taken a position on that. We had a hearing a few weeks ago, we had the drug manufacturers come in and PBMs come in. I asked them if they were for or against a proposal to have Medicare negotiate. And they were against it. Not surprising to many, concerned about profits and so on and so forth.

I am really glad to see in the committee that we are working on a bipartisan basis to bring down the price of prescription drugs. But I, having heard from my colleagues who sit on other committees for the VA, and everything I have read, it seems to me that—and certainly hearing from you that you have no means to influence price—it seems to me that if that were lifted, it would actually provide some leverage for us to bring down the cost of prescription drugs to the American people.

Has MedPAC done any type of study on how much money the American people would save if Medicare had the ability to negotiate drug prices?

Mr. MATTHEWS. MedPAC has not done its own independent assessment of the viability of direct negotiation between the secretary and manufacturers.

When others, such as our colleagues at CBO, have looked at this issue they have determined that without the secretary having very, very strong leverage, such as Medicare coverage or Medicare payment, or other alternatives that have been proposed related to things outside of my purview such as patent changes, that the secretary is unlikely to achieve substantial savings through direct negotiation without being able to use those kinds of very strong negotiating tactics.

Ms. BARRAGÁN. Can Medicare, rather can MedPAC do a study on this so that Congress has a report to look at—and to look at these factors that you are discussing? Will MedPAC commit to doing something like that?

Mr. MATTHEWS. We could potentially look at some of the issues that would pertain to a direct negotiation scenario. So, you know, for example would this be across-the-board all drugs, all manufacturers? Does the agency have the resources to conduct these kinds of evaluations? What the evidence base is for the secretary's ability to negotiate a given price? We could look at those sorts of issues in a qualitative way.

I don't know that we would have the capacity to or the desire to second guess our colleagues at CBO with respect to calculating potential savings.

Ms. BARRAGÁN. OK. Well, anything you could provide to Congress could be helpful, especially because this has been a bipartisan issue on a bipartisan basis, seems like a way to move forward. So, given that you do, you work on a bipartisan basis—

Mr. MATTHEWS. Yes, ma'am.

Ms. BARRAGÁN [continuing]. I think any information will be helpful. Thank you for that.

I want to chat quickly about the issue of minority health disparities. Across this country, you know, people based on race are treated differently in our healthcare system, we have different health impacts and outcomes. For example, HIV diagnosis rate among Hispanic men is more than 3 times the HIV diagnosis rate among non-Hispanic white men. African Americans are also more than twice as likely as whites to be diagnosed with and die from blood cancer and multiple melanoma.

My district is majority minority. It is about 80 percent Latino/African American. I have the highest rate of diabetes than any other congressional district in the State of California. And we touched a little bit upon low-income communities and how Medicare actually has low-income subsidies for patients. But the annual income is pretty low. I think it is about \$18,735. In California it is easy to miss that a little bit. And they are not qualified.

And my concern is the connection between costs and the continuing impacts and effects on minority health disparities. Has MedPAC or CMS done any type of study to determine whether minority communities have similar outcomes from the Medicare Part D program as non-minority communities?

Mr. MATTHEWS. Not to the best of my knowledge.

Ms. BARRAGÁN. Is that something you could do? I know you mentioned you do a lot of, you look at tradeoff and balances. But, you know, when we are talking about communities of color, racial health disparities is an issue. There shouldn't be really a tradeoff or balance with their health.

Mr. MATTHEWS. Understood. What is outlined here is a fairly broad endeavor though. And with, again with all due respect, if you could grant me the leeway to go back and talk to my staff about what we can and can do with—or can and can't do with the resources that we have available to us we would certainly be willing to take a look at this.

Ms. BARRAGÁN. Great. Thank you. I yield back.

Mr. BUTTERFIELD. Thank you. The gentleman from Montana is recognized for five minutes.

Mr. GIANFORTE. Thank you, Mr. Chairman.

OK, thank you. Drug prices in the Medicare program keep rising and it is making it tougher for seniors in Montana to afford their prescriptions. Dr. Matthews, last August several members of the committee wrote to MedPAC and asked the Commission to examine the trend of hospital consolidation and how much consolidation increases the costs to Medicare, the Medicare program and beneficiaries, including the costs of prescription drugs. So, I want to focus on this issue today.

Since we are discussing prescription drug prices, can you please update us on MedPAC's findings, specifically the impact of hospital consolidation and acquisition of physician practices on the cost of prescription drugs to the Medicare program and seniors' out-of-pocket expenses?

Mr. MATTHEWS. Yes, sir. So, I don't have any update with respect to work we have currently underway in response to the most recent request. But as you know, a couple of years back we did a chapter in a June report looking at the effects of consolidation on Medicare spending, and looked at the impacts of both vertical integration where different levels of the healthcare system form single entities or horizontal integration such as where all cardiologists integrate under a single organization.

And so both of those types of consolidation do have the potential to increase spending for the Medicare program.

Mr. GIANFORTE. So, that request that was made, the work is still ongoing?

Mr. MATTHEWS. Yes, sir, that is correct.

Mr. GIANFORTE. OK.

Mr. MATTHEWS. And we anticipate starting to roll that out in the fall of this year.

Mr. GIANFORTE. OK, thank you.

How do significant payment differences for identical medical services performed in Medicare at hospital outpatient departments versus independent physician practices impact seniors' out-of-pocket costs for Part B drugs?

Mr. MATTHEWS. It has the potential to substantially impact their out-of-pocket costs. But I use the word "potential" deliberately. And the reason I do that is because most Medicare beneficiaries in fee-for-service Medicare do have some secondary coverage. They are dual-eligibles, they have employer-sponsored wrap-around insurance, or they purchase Medigap.

And so, to some extent they are insulated from the direct effects of these payment differentials across settings. But nonetheless, all Medicare beneficiaries are experiencing these effects through higher Part D premiums. And those beneficiaries who elect to purchase Medigap are paying higher Medigap premiums as a result.

Mr. GIANFORTE. OK. And has MedPAC made any recommendations to address this differential?

Mr. MATTHEWS. We have. It's been several years now where we identified a set of services meeting certain criteria: if they are majority provided in physicians' offices, they are majority not associated with emergency care, and identified services that are appropriate candidates for a Medicare site mutual payment policy.

Mr. GIANFORTE. OK. If Congress required Medicare to pay the same amount for services regardless of where they are performed,

would seniors' out-of-pocket prescription drug costs decrease? What effect would it have on Medicare overall costs?

Mr. MATTHEWS. Off the top of my head I could not venture an answer with respect to the effects on their drug costs. It is something we could think about.

Mr. GIANFORTE. OK. So that is something you could look into additionally. Because this is the concern we hear back home is—

Mr. MATTHEWS. Understood.

Mr. GIANFORTE [continuing]. The overall cost, and prescription drugs area big piece of that. So, we very much appreciate your, your help to—

Mr. MATTHEWS. Yes, sir.

Mr. GIANFORTE [continuing]. Chart a path for us.

Mr. MATTHEWS. Yes, sir.

Mr. GIANFORTE. I thank you for your testimony today. With that, Mr. Chairman, I yield back.

Mr. BUTTERFIELD. Thank you.

The gentle lady from Illinois, Ms. Kelly, is recognized for five minutes.

Ms. KELLY. Thank you, Mr. Chair. Dr. Matthews, thank you for being here, and thank you for your testimony and sharing MedPAC's work on these important issues.

As you point out in your testimony, there is a handful of expensive drugs driving spending in the Part D program, with consumers responsible for significant out-of-pocket costs. The top ten highest expenditure drugs accounted for about 43 percent of Part D drug spending in 2017. All of these project—products, excuse me, are biologics. Some of these drugs have competitors and others do not.

I would like to learn more about the impact a biosimilar entry into the market had to date on the price of the originator biologics driving costs in Part D. You have shared what drugs a program is spending the most money on and the conditions these drugs treat. But how many of the top ten highest expenditure drugs in Part D face competition from a biosimilar?

Mr. MATTHEWS. As I recall, there are two products out of that top ten list that have biosimilar competitors. The biosimilars have not had a substantial impact on the price that Medicare pays for the originator biologics. In part, this probably reflects the way Medicare pays for the biosimilars relative to the innovator biologic.

The innovator biologic gets its own payment code and its own six percent add-on. The biosimilar gets its own payment code, even if it is at a lower price, but it gets the six percent add-on that is associated with the innovator product.

So, from the prescriber's perspective, the physician who administers the drug, it is a neutral decision whether to use the innovator product or the biosimilar.

MedPAC has recommended that instead of those two products having unique codes, that you would potentially influence price to a much greater extent by combining them and having the program pay the average of the sales prices of those two products.

Ms. KELLY. OK. I understand what you are saying that there has only been a modest impact on prices—

Mr. MATTHEWS. That is right.

Ms. KELLY [continuing]. To date and your recommendations for what we can do about it.

Can you discuss how original biologics and biosimilars are currently grouped, and what the Commission has recommended to result in price reduction there?

Mr. MATTHEWS. Yes. Again, under current payment policy the innovator biologics and each biosimilar get their own payment code. And, again, in an attempt to make the decision financially neutral from the prescriber's perspective, the 6 percent add-on for any of those products if the add-on associated with the originator product.

So, again, our recommendation would be that instead of having, let's say, a \$1,000 drug that gets a \$60 add-on, and then a \$100 drug or biologic that gets a \$60 add-on, that instead we would average the \$1,000 bio—referenced biologic and the \$100 biosimilar and have Medicare pay that rate, which would give providers a much greater incentive to use the biosimilar and potentially start to move the price of the referenced biologic down in a way that we have not yet seen.

Ms. KELLY. Is there, as we have been sitting here, is there anything that we haven't asked you that you want to tell us?

Mr. MATTHEWS. No, ma'am. I do not want to venture any of my own questions here, so.

Ms. KELLY. Well, thank you. A major goal of this committee in our drug pricing work to date has been to remove the barriers to generic competition and stop anticompetitive practices. It is important for us to continue to examine policies that would support competition in all markets to lower costs facing consumers. Everyone should have access, as you know, to the care and medication they need.

And thank you, and I yield back.

Ms. ESHOO[presiding]. The gentlewoman yield back.

And I now would like to recognize the gentleman from Vermont, Mr. Welch.

Mr. WELCH. Thank you.

Ms. ESHOO. Happy birthday to you.

Mr. WELCH. Well, thank you.

Ms. ESHOO. Thank God you were born.

Mr. WELCH. Some people agree with that. Thank you.

Dr. Matthews, really good testimony, so thank you very much, and really good work.

It is really frightening, the cost of prescription drugs, and it is really frightening how the market power that is out there is so aggressively used no matter how much pain is inflicted on folks. I was here when Mr. Bucshon was raising some questions about a formulary. And a lot of people have that question: is that going to impede access. I was talking to Senator Grassley. He had that concern.

One of the approaches that we took in Vermont, because here is the dilemma as I understand it, if you have a strict formulary you tend to get more savings but less patient choice. But if you have a wide-open formulary with patient choice you get no savings. So how do you, how do you deal with that?

What we did in Vermont is we basically made it pretty easy for a doctor to override what the formulary was because it might be

that Mr. Bucshon, or Dr. Bucshon and I have the same condition but the medication that works for him is different than the one that works for me. I mean, is that a possible way to try to thread the needle here where we maintain patient choice but get the benefit where in the vast majority of time medication A is probably going to be good for Dr. Bucshon as well as good for me? Is that a possible path forward on this?

Mr. MATTHEWS. Potentially, and as I said in my comments earlier, we do think that there should be very robust exceptions and appeals avenues available for Part D enrollees and their physicians. But at the same time, you know, we are trying to balance the plan's ability to leverage price from the manufacturer. And—

Mr. WELCH. Right. I agree with that. But the fact is that there is going to be a lot of resistance if there is an apprehension that a patient can't get the medication he or she needs. So it has to be simple.

But the incentives that are built into the system right now that you outlined are totally in favor of higher prices. You know, if you can get somebody into the specialty drug program, then that is a real burden on the taxpayer. The patient has no clue really, because we rely on what the doctor tells us.

I would just urge us to try to look for some way where we address this patient choice issue, because I know a lot of my colleagues have that concern. I have that concern.

Mr. MATTHEWS. Sure.

Mr. WELCH. But we've got to get the benefit of that formulary.

Now, the other thing is we are the only Government that I am aware of that really doesn't play an active role in trying to provide some pricing protection to benefit our taxpayers and consumers. And you gave the shocking statistics about the specialty drugs and how a while ago what was it, 33,000 people went immediately into—

Mr. MATTHEWS. Yes, sir. That was in 2010. The number in 2017 is now 370,000.

Mr. WELCH. Yes. So it is one prescription—

Mr. MATTHEWS. Sure.

Mr. WELCH [continuing]. Gets them into that high pay, high taxpayer pay situation.

Now, would you be supportive of legislation which would have price negotiation available as a tool for MedPAC and, in the event that failed, have arbitration to come up with a price that is "fair"?

Mr. MATTHEWS. The Commission has not weighed in on the broader question of direct negotiation. Our standing recommendation would include binding arbitration as part of our DVP proposal, which we recommended in 2017. We are currently exploring whether or not binding arbitration could have a potentially greater role in the Medicare program. But we have not—

Mr. WELCH. You could have the binding arbitration in some of the highest cost specialty drugs.

Mr. MATTHEWS. Yes, sir. That is correct.

Mr. WELCH. And that would have a huge impact on the cost of the overall to the taxpayer and to the plans. Correct?

Mr. MATTHEWS. Yes, sir, that is correct.

Mr. WELCH. Yes, I mean, you know, again I am going to focus on Dr. Bucshon here a minute because I know what a dedicated physician he has been. We just have this dilemma: you just can't have it all. OK. You just can't have it all, and the cost side on healthcare is where all the pain is. If we just have these costs go out of control, continue to go out of control, that cuts off access.

So there has got to be some tradeoffs is my view here. Would you agree with that, Dr. Matthews?

Mr. MATTHEWS. Yes, sir. It is all about tradeoffs.

Mr. WELCH. There is some argument that is always made by the pharma companies that if there is some pushback on their pricing power, that somehow means they are not going to innovate. I find that to be bogus because they are spending more on advertising than they are on research. There is an enormous amount of research funded by taxpayers through the National Institute of Health. There is an enormous amount of research funded by taxpayers through the research and development tax credit.

Do you see that if we have reasonable interaction by the Government to negotiate prices or to have an arbitration system with neutral parties that that would have—that would impede innovation?

Mr. MATTHEWS. As we have contemplated binding arbitration, we do not believe that it would stifle R&D for true innovative new products where the manufacturer would have an opportunity to come before a neutral arbiter, or arbitrator, I never know which the right word is, but present evidence in terms of R&D costs, in terms of foregone additional spending for the use of their product. And—

Mr. WELCH. And you would get some transparency out there?

Mr. MATTHEWS. Yes.

Mr. WELCH. Again, Madam Chair, I think that is why this hearing is so important. I mean, this is not a he said/she said deal. We are all losing on this thing.

I appreciate that testimony and the good work you have done over the years. And, hopefully, this committee can start moving forward to help bring these prices down.

I yield back.

Ms. ESHOO. I thank the gentleman, and he yield back.

I also want to acknowledge, and I think I was leaving the hearing room to run downstairs to the other hearing, and I did not get to wish our colleague Congresswoman Robin Kelly a happy, blessed, wonderful birthday, because you are all 3.

With that, I am pleased to recognize the gentleman from Florida, Mr. Soto, for five minutes of questioning.

Mr. SOTO. Thank you, Madam Chairwoman.

We saw in our committee analysis we are paying 104.3 percent average sales price to providers, down from 1.6 percent because of sequester. We all realize this is an incentive to purchase drugs at a higher average sales price and receive a higher reimbursement.

We saw CMS roll out a plan recently last year to have pharmaceutical vendors purchase and sell directly to patients, circumventing this provider cost escalation incentive, providing flat fees to providers and time reimbursements to international pricing.

For my constituents at home will this do the job or are there other things we should be doing going along with what Congress-

man Ruiz talked about potential arbitration or other ideas? What is MedPAC advising?

Mr. MATTHEWS. OK.

Mr. SOTO. Just broad points.

Mr. MATTHEWS. Yes, sir. So, I am not familiar with the proposal to have manufacturers sell directly to patients, if I understood your question correctly. So, again I would ask for the dispensation to come back to you on that point.

With—

Mr. SOTO. So, basically it is saying allow private sector pharmaceutical vendors to buy and bill Medicare for drugs and supply those drugs to providers, rather than the providers doing so directly?

Mr. MATTHEWS. Yes. So, this is part of the IPI proposal that the Administration has put forward. And again, while we do support the Administration's desire to reduce the prices that Medicare beneficiaries pay for prescription drugs, particularly in light of prices that citizens of other countries are paying, but at the same time we think there are certain logistical and implementation issues with respect to the Administration's proposal that would make it less likely to succeed than—

Mr. SOTO. What are those specifically?

Mr. MATTHEWS. So, again, under the Administration's proposal, Medicare would set a price that it will pay the vendor based on the international reference price. And it is incumbent upon the vendor to try and obtain that price from manufacturers.

But the proposal, if I recall correctly, does not give the vendor much by way of negotiating tools in order to extract that price.

Mr. SOTO. So, that is where this arbitration idea that is being mulled around in this committee—

Mr. MATTHEWS. Yes, sir.

Mr. SOTO [continuing]. Is so critical because that could create a more arms-length transaction to get the most efficient price. Is that correct?

Mr. MATTHEWS. That is correct.

Mr. SOTO. I wanted to move into some other ideas pitched by HHS, particularly step therapy and higher authorization. Certainly with lesser conditions these can be cost saving. But I worry when you apply it to cancer and other potentially fatal conditions that this step therapy and prior authorization, particularly step therapy, leads to time running out and people dying, literally, of cancer because they are given less effective drugs earlier on in the step therapy. And that we end with a death that could have been prevented.

Do you think there should be a carve-out for cancer and other fatal conditions with regard to step therapy?

Mr. MATTHEWS. The Commission has not contemplated the need for a carve-out or exceptions based on medical condition or a patient's diagnosis. But we have recognized, again, the need for a very robust and very expeditious exceptions and appeals process as part of the use of utilization management tools on the part of plans.

Mr. SOTO. And going into another issue that we continue to see is in the private market drug prices going 3, 4, 10 times the

amount of increases. What role should we play in stopping this from happening? How does that affect Medicare when we see a drug that has been around for 20 years that has a 10—10 to 20 percent—10 to 20 times increase? What are you advising us to do?

Mr. MATTHEWS. Right. So that is actually an insightful distinction that if I could take a minute.

Mr. SOTO. Yes.

Mr. MATTHEWS. So, one, you know, we have seen the entry of truly revolutionary blockbuster products on the market that cure things like Hep C. So, the Sovaldis, the Harvonis where the benefits of the medication potentially warrant the prices that the manufacturer is charging.

But we also see, and the Commission is extremely concerned about instances that you just alluded to where you have products that have been on the market for decades where there is no real active research and development to increasing the efficacy of these products. And yet, the prices continue to increase year over year.

While there may be costs and R&D going on beyond, behind the scenes that people like me don't see, we still think that those kinds of cost increases are not warranted, given our responsibility to a public program like Medicare. And so, we have recommended an inflation rebate that would check the ability of manufacturers to increase their prices on a year over year basis in excess of some defined rate of inflation.

Mr. SOTO. Thank you. I yield back.

Ms. ESHOO. The gentleman yield back.

It is a pleasure to recognize the gentleman from Maryland, Mr. Sarbanes, for five minutes of questioning.

Mr. SARBANES. Thank you.

Thank you, Dr. Matthews, your testimony today has been excellent. You are definitely going to get called back by many, many committees in the future.

Mr. MATTHEWS. I am sorry to hear that.

Mr. SARBANES. You did a great job.

I wanted to pick up actually right where Congressman Soto left off because you mentioned this inflation rebate as a way of trying to get to some of these significant price—

Mr. MATTHEWS. Yes, sir.

Mr. SARBANES [continuing]. Increases. And it seems to me that, arguably, is the other side of a coin where you could think about setting, or we could think about setting upper limits on the prices of some of these drugs. It is just a different way of accomplishing the same thing.

Would you agree with those as sort of two sides of the same coin potentially?

Mr. MATTHEWS. Potentially, yes.

Mr. SARBANES. Yes. I note that there is a number of States which have begun to explore regulating prescription drug pricing within their own jurisdictions. Maryland recently created, the Maryland General Assembly passed legislation.

I think it is the first State to actually get this passed, it is now subject to the Governor's signature, that would create a prescription drug affordability board. The board would have the authority to review drug cost data that manufacturers submitted, and then

they could set an upper payment limit on those prescription drugs. And I think there are six or seven other States that are exploring the same sort of approach.

We have talked about a number of strategies to address drug pricing. We have also talked about how you have made recommendations on how Medicare can try to manage the situation downstream a little bit, if you view the original pricing that the manufacturers are setting as kind of the ultimate upstream point in the continuum.

There are all these efforts downstream, bringing the plans in, trying to incentivize them more to manage costs so the program isn't taking as big a hit, et cetera. But if we go to the source, which is the pricing that the manufacturers are setting, there is increasingly I think a sense in this Congress on both side of the aisle that we have to take some pretty dramatic steps to control the costs and the price setting at that end.

But what is your view of this concept of regulating or setting upper limits on the prices of these various categories of prescription drugs?

Mr. MATTHEWS. OK. So, so again, the Commission hasn't taken a position with respect to setting a specific cap on a price. Although, I do see the analogy between setting a hard cap on a price versus setting a cap on the rate that a price can increase over time.

I am also not personally familiar with the details of the State efforts that you have just described, but it is something we can start to look at and see if there is any model there.

But, with respect to our inflation rebate, it is guided by the notion that for drugs that have been on the market for some period of time where they are established therapies whose indications are known, and their effects are known, that to some extent these are commodities, and the expectation of commodity prices is that they should go down over time.

When you look at things like computers or wide screen T.V.'s you are getting better and better technology with each passing year at lower prices. The question is why these trends work in reverse for prescription drugs, especially these therapies that are, again, long-extant on the market?

And so, we think that at a minimum, setting a limit that those prices can increase year over year is a step in moderating these effects that we have seen that have very detrimental effects on the Medicare program.

Mr. SARBANES. Well, I think we need to put every option on the table. The rebate is, I would say, a step in the right direction, an inflation rebate. But we need to be looking at negotiating power on the part of the Medicare program. Many have talked to that. The arbitration approach is another. Maybe some form of, like, public auction around the pricing of these drugs, and even the notion of regulating these, these drugs as a utility.

I mean, if you look at there is a lot of—there is a lot of analogies you can draw between the public good aspect of how drugs are delivered to pretty much every American and the way electricity is delivered, or water is delivered, or, you know, healthcare premiums are set. I think there is going to be a lot more activism on our part here in Congress with respect to the pricing of drugs.

Thank you for your testimony today. This was extremely helpful. I yield back.

Mr. MATTHEWS. Thank you. Thank you.

Ms. ESHOO. The gentleman yield back.

I am going to recognize myself for an additional five minutes, and also the ranking member as well for a couple of follow-up questions.

First, Dr. Matthews, again thank you. I think it is very clear that the committee on a bipartisan basis clearly has more than an interest in addressing drug prices.

I would encourage MedPAC to go back and continue to make recommendations on how to protect patient access. I know that in the original legislation that created MedPAC, when Medicare Part D was created so was MedPAC. But to leave out patients in this, I mean, this is not just a program where numbers are shifted around. The numbers apply to people, to human beings, and I don't see how that element can be left out of your deliberations.

As we work to reduce costs, that too has an effect on, as we have heard from questions and your responses, that too has an effect on patients.

Now, this whole issue of step therapy, I don't see how MedPAC can just stick with what seems to me a conversation about tools and the kit, et cetera, et cetera, when people have actually died because they don't have access to what they need. We can't ignore that, nor can MedPAC. So, while this step therapy has been created so that, as you describe it more tools in the kit to reduce and control pricing and whatever, when people are dying because they can't get what they need, and they are pushed back to step one.

Step 1 the doctor knows is not going to work, step 2 the doctor knows is not going to work, but you never get to 3 because you haven't lived long enough, that doesn't make sense. It just doesn't. I mean, it is not defensible in my view and I think in other members' views as well.

I don't know who supports this thing. It is from the both side of the aisle you have heard about it. We have heard from our constituents. They don't identify themselves to us as Republicans or Democrats, they are our constituents.

The issue that you have raised since the program was founded, was put together, that there has been a 20 percent increase in D, if I heard you correctly, a 20 percent increase on an annual basis relative to drug pricing is, to say it is a jaw-dropper doesn't begin to describe it.

I think we have our work cut out for us, but I think you do as well. I think that MedPAC needs to step its game up, so to speak, in these, in these areas. And that you do it in a timely fashion so that you can make recommendations and some of these changes be recommended in these key areas.

With that, I would like to recognize Mr. Bucshon and thank him for his support of an additional five minutes for myself and for himself as well. Thank you again.

Mr. BUCSHON. Thank you, Madam Chairwoman.

I will make a few comments about the step therapy and prior authorization. I mean, I have been a physician for years, for many years, and this has been a concept that has waxed and waned for

the 30 years or so that I have been in medicine. And, you know, it is a concept that waxes and wanes because at the end of the day I would argue it ultimately doesn't save anybody any money because the delay—it has a potential to delay therapy.

And then as a cardiovascular surgeon I saw people in tertiary care situations in their lives, and I just, I have always had concerns about that. I don't know if anyone has, has looked at the long-term implications of that, and it may not be—it is probably out of the scope of what you look at.

Mr. MATTHEWS. Yes, sir.

Mr. BUCSHON. But looking at delay in therapy, potential delay in therapy—and, again, my argument that physicians generally will make the decision to treat their patients based on what they think is the best individual therapy for that patient. And do consider cost. Don't get me wrong. As I mentioned, I considered cost if there was equivalent therapy.

The one thing I—on the prior authorization, a number of years ago, maybe 10 or 15 years ago, there was one of the major private sector insurance companies that decided to drop their prior authorization program. Do you recall that at all?

Mr. MATTHEWS. I do not. I am sorry.

Mr. BUCSHON. It might have been UnitedHealthcare. I can't recall. Don't quote me on that, but I just—and then it has been, I think it has been reinstituted. But the reasoning behind that, I remember when that happened, was is because they found that whoever this was, and I am not saying it was them, is that at the end of the day it didn't save them anything because they were authorizing about 98 or 99 percent and the administrative costs to deny the 1 or 1.5 percent didn't outweigh the savings.

Have you heard of that type of concept?

Mr. MATTHEWS. I have heard similar anecdotes. Again, I can't attribute them to a specific—

Mr. BUCSHON. Right.

Mr. MATTHEWS [continuing]. Instance, but yes.

Mr. BUCSHON. Yes. I would argue that that is probably the case. The administrative costs if you are going to, you know, if you are going to deny 10 percent or something I—I get that. I would say I would have an ethical problem with that. But if you were, then it might save you money. I don't know what the finances are on that.

But there is a perception that it saves money, and I am not sure that that is actually true.

So, I want to comment, that is my comment on those two things.

Do you know if CBO has ever done studies on out-of-pocket cost caps? Like, say, if there was a cap set at a certain level what the, what the CBO score would be? There will be a score, right, because there will be a potential number of people that would go over, that would normally be over that level, whatever that cap is.

Mr. MATTHEWS. I believe that is correct, yes.

Mr. BUCSHON. Is that something that you think would be interesting to know for your purposes?

Mr. MATTHEWS. This would be for?

Mr. BUCSHON. For Medicare Part D. Like an out-of-pocket cost cap; right?

Mr. MATTHEWS. Yes. And this is something that MedPAC has recommended as part of our package of Part D recommendations.

Mr. BUCSHON. Right. The question would be is what level that the out-of-pocket costs are capped at.

Mr. MATTHEWS. That is correct.

Mr. BUCSHON. So the question would be is a CBO score on that at differing levels might be interesting information to know. Would you agree or disagree with that, or have they done it?

Mr. MATTHEWS. I am not aware that they have done this. But I don't disagree that it would be an interesting thing to know the effects at different level.

Mr. BUCSHON. Because if you were going, if Congress was going to say, OK, we are going to set an out-of-pocket cost cap at X dollars, right? The first thing we would do is get a CBO score.

Mr. MATTHEWS. Right.

Mr. BUCSHON. And see, well, what is that going to—what is that going to cost; right? Because there will be a cost if you set it, if you set it low enough there would be a cost?

Mr. MATTHEWS. Right.

Mr. BUCSHON. And so, maybe preemptively having a multitude of different cost levels known to Congress before we try to make some of these decisions might—could be helpful. Would you think that would be the case?

Mr. MATTHEWS. Without committing my colleagues—

Mr. BUCSHON. I understand. I am not asking—

Mr. MATTHEWS [continuing]. To doing this work.

Mr. BUCSHON [continuing]. You for any commitment at all. Right.

Mr. MATTHEWS. That is correct, yes.

Mr. BUCSHON. Yes. I think that might very well be helpful.

With that, Madam Chairwoman, I yield back.

Ms. ESHOO. The gentleman yield back.

Again I would like to thank you, Dr. Matthews, for your participation. I hope that you didn't need to take any pain medication to come here today or anything else due to your testimony. But a first time out I think that we would all say that you presented your case very well.

I want to remind Members that pursuant to committee rules they have ten business days to submit additional questions for the record to be answered by the witness who has appeared. We would appreciate your timely response to those, Dr. Matthews.

As I said, we really appreciate prompt responses to the question that you may receive.

So, at this time, the subcommittee is adjourned.

[Whereupon, at 12:43 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

## PREPARED STATEMENT OF HON. ELIOT L. ENGEL

Thank you Madame Chairwoman Eshoo for holding today's important hearing on Medicare drug pricing. Nearly 130,000 of my constituents depend on this vital federal health program for drug coverage.

A growing share of the program's expenditures are going to prescription drugs. According to the nonpartisan Kaiser Family Foundation, Medicare's share of nationwide prescription drug spending jumped from 18 percent in 2005 to 30 percent in 2017.

While some of this increase was for innovative drugs—which save future Medicare dollars—much of the growth stems from price spikes.

I am pleased that this committee has taken steps in the past to curb Medicare drug spending. The bipartisan 21st Century Cures Act included provisions from my bill to expand access to infusion drugs under the Medicare Part B program. These expanded benefits will give beneficiaries the ability to receive life-saving therapies in the comfort of their own home while avoiding costlier care in institutional settings. These past efforts demonstrate that Medicare can be leveraged to reduce drug costs.

My constituents are outraged that the 2003 Prescription Drug, Improvement, and Modernization Act, which I voted against, contains the so-called “non-interference clause.”

This horrendous policy prevents Medicare from using its clout to negotiate lower prescription drug prices.

Empowering Medicare to do so would bring immediate relief to hard-working American families, who often are being forced to choose between filling life-saving prescriptions or purchasing groceries.

James E. Mathews, Ph.D.  
Medicare Payment Advisory Commission  
Page 1

**Questions for the Record**  
**Subcommittee on Health**  
**Hearing on**  
**“Prescription Drug Coverage in the Medicare Program”**  
**April 30, 2019**

**James E. Mathews, Ph.D.**  
**Medicare Payment Advisory Commission**

**The Honorable Gus M. Bilirakis**

1. Dr. Mathews - With Florida’s traditionally higher senior population, lowering prescription drug prices in Medicare is very important to me. As noted in MedPAC comments on the International Pricing Index (or IPI for short) last year, the “Drug Value Program” recommended previously by MedPAC would give vendors tools to negotiate lower prices. Under the Administration’s IPI proposal, they don’t include these tools, so it seems like instead the government is just setting the price directly.
  - Can you talk more about these differences, and—in particular—how your proposal would spur lower prices without direct government price-setting?

**Answer:**

The Commission shares your concern about the prices Medicare and its beneficiaries pay for prescription drugs. To address concerns about the prices for drugs covered under Medicare Part B, in 2017 the Commission recommended reforming Medicare’s payment system. One part of that recommendation would establish a drug value program (DVP) in which private vendors—not physicians—negotiate prices for Part B drugs from manufacturers. The DVP seeks to use increased competition and market forces to lower Medicare spending and beneficiaries’ cost sharing liability. The Administration’s international pricing index (IPI) model also uses a vendor-based approach, but in contrast to the DVP, seeks to reduce Medicare spending for those drugs by aligning Medicare payments with international prices.

While the Commission appreciates the IPI’s goal of reducing Medicare’s payments for Part B drugs, we believe that the DVP model has several components that make it more likely to succeed than the IPI model. First, the DVP would give several important tools to private vendors to use in negotiating lower prices from manufacturers, including authority to establish a formulary, apply utilization management tools like prior authorization and step therapy, and the ability to use binding arbitration under certain circumstances. Second, vendors in the DVP

James E. Mathews, Ph.D.  
 Medicare Payment Advisory Commission  
 Page 2

would not take ownership of the drug, and so the supply channels that providers use for procuring drugs would not be interrupted. Third, the DVP could offer shared savings to providers that chose to participate, which would give incentives for more providers to participate and give the DVP vendors greater negotiating leverage to get lower prices. The IPI does not contain these types of elements, and we believe that it would be difficult for a private vendor to succeed in lowering drug prices under Medicare Part B without them.

The Commission staff would be happy to assist your office with any additional questions you have about how the DVP model can lower Medicare's spending and beneficiaries' cost sharing liability for Part B drugs.

2. I'm a baseball fan. I know there are examples in the market where arbitration is used, like baseball. But developing breakthrough medicines is a lot different from developing starting pitchers and legislating a government-defined arbitration process is a lot different from negotiating one through a players' union.
  - Do any of these examples involve setting prices at a national level, or just resolving disputes at an individual level?

**Answer:**

Arbitration is a process by which two parties agree to accept the decision of a neutral third party in a dispute. Arbitration is used to settle disputes in a range of areas such as labor, communications, health care, and international taxes. In the United States, it is used to establish payment rates within health care in limited circumstances. For example, the states of New York and New Jersey use baseball-style arbitration to settle disputes about surprise medical bills between providers and payers at the individual claim level.

Germany provides the primary example of using arbitration to establish prices for new drugs and biologics at a national level. Beginning in 2011, Germany instituted a new system of establishing payment rates for drugs across insurers. Under that system, when new innovative products enter the market, the manufacturer and an organization representing health insurers have 6 months to negotiate a price, and if negotiations fail, they enter arbitration. The arbitration board includes five members, three neutral parties (including the chairman), one representative of insurers, and one representative of the manufacturer. When a product enters arbitration, the manufacturer and health insurers each offer a price, and the arbitration board chooses a price in the range between the two offers. (This differs from final offer (or "baseball") arbitration, where each side must present its single, best offer and the arbitrator selects one or the other.) In Germany, the arbitration price goes into effect the 13th month the product is on the market.

The Commission staff would be happy to assist your office with any additional questions you have about arbitration.