THE OBAMA ADMINISTRATION’S MEDICARE DRUG EXPERIMENT: THE PATIENT AND DOCTOR PERSPECTIVE

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED FOURTEENTH CONGRESS
SECOND SESSION
MAY 17, 2016
Serial No. 114–146

Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov
U.S. GOVERNMENT PUBLISHING OFFICE
WASHINGTON : 2017
COMMITTEE ON ENERGY AND COMMERCE

FRED UPTON, Michigan
Chairman

ED WHITFIELD, Kentucky
JOHN SHIMKUS, Illinois
JOSEPH R. PITTS, Pennsylvania
GREG WALDEN, Oregon
TIM MURPHY, Pennsylvania
MICHAEL C. BURGESS, Texas
MARSHA BLACKBURN, Tennessee

STEVE SCALISE, Louisiana
ROBERT E. LATTA, Ohio
CATHY McMorris Rodgers, Washington
GREGG HARPER, Mississippi
LEONARD LANCE, New Jersey
BRETT GUTHRIE, Kentucky
PETE OLSON, Texas
DAVID B. McKinley, West Virginia
MIKE POMPEO, Kansas
H. MORGAN GRIFFITH, Virginia
GUS M. BILIRAKIS, Florida
BILL JOHNSON, Ohio
BILLY LONG, Missouri
RENEE L. ELLMERS, North Carolina
LARRY BUCSHON, Indiana
BILL FLORES, Texas
SUSAN W. BROOKS, Indiana
MARKWAYNE MULLIN, Oklahoma
RICHARD HUDSON, North Carolina
CHRIS COLLINS, New York
KEVIN CRAMER, North Dakota

FRANK PALLONE, Jr., New Jersey
Bobby L. Rush, Illinois
Anna G. Eshoo, California
Eliot L. Engel, New York
Gene Green, Texas
Kathy Castor, Florida
JERRY McNerney, California
Peter Welch, Vermont
Paul Tonko, New York
John A. Yarmuth, Kentucky
Yvette D. Clarke, New York
John P. Sarris, Maryland
John J. Yarmuth, Kentucky
T. C. A. Veridiano, New Mexico
Doris O. Matsui, California
Frank Pallone, Jr., New Jersey (ex officio)

RANKING MEMBER

JOHN P. SARBANES, Maryland
Gene Green, Texas
G.K. Butterfield, North Carolina
Eliot L. Engel, New York
Anna G. Eshoo, California
Lois Capps, California
Janice D. Schakowsky, Illinois
John P. Sarris, Maryland
John J. Yarmuth, Kentucky
T. C. A. Veridiano, New Mexico
Doris O. Matsui, California
Frank Pallone, Jr., New Jersey (ex officio)

SUBCOMMITTEE ON HEALTH

JOSEPH R. PITTS, Pennsylvania
Chairman

BRETT GUTHRIE, Kentucky
JOHN SHIMKUS, Illinois
TIM MURPHY, Pennsylvania
MICHAEL C. BURGESS, Texas
MARSHA BLACKBURN, Tennessee
CATHY McMorris Rodgers, Washington
LEONARD LANCE, New Jersey
H. MORGAN GRIFFITH, Virginia
BILLY LONG, Missouri
RENEE L. ELLMERS, North Carolina
LARRY BUCSHON, Indiana
SUSAN W. BROOKS, Indiana
CHRIS COLLINS, New York
FRED UPTON, Michigan (ex officio)

GUS M. BILIRAKIS, Florida
SELASSIE DEGETTE, Colorado
DIANA DeGETTE, Colorado
DIANA DeGETTE, Colorado
DIANA DeGETTE, Colorado
DIANA DeGETTE, Colorado
DIANA DeGETTE, Colorado
DIANA DeGETTE, Colorado

RANKING MEMBER

LEONARD LANCE, New Jersey
H. MORGAN GRIFFITH, Virginia
BILLY LONG, Missouri
RENEE L. ELLMERS, North Carolina
LARRY BUCSHON, Indiana
SUSAN W. BROOKS, Indiana
CHRIS COLLINS, New York
FRED UPTON, Michigan (ex officio)

Gene Green, Texas
G.K. Butterfield, North Carolina
Eliot L. Engel, New York
Anna G. Eshoo, California
Lois Capps, California
Janice D. Schakowsky, Illinois
John P. Sarris, Maryland
John J. Yarmuth, Kentucky
T. C. A. Veridiano, New Mexico
Doris O. Matsui, California
Frank Pallone, Jr., New Jersey (ex officio)

TONY CARDENAS, California
Gene Green, Texas
G.K. Butterfield, North Carolina
Eliot L. Engel, New York
Anna G. Eshoo, California
Lois Capps, California
Janice D. Schakowsky, Illinois
John P. Sarris, Maryland
John J. Yarmuth, Kentucky
T. C. A. Veridiano, New Mexico
Doris O. Matsui, California
Frank Pallone, Jr., New Jersey (ex officio)
CONTENTS

Hon. Joseph R. Pitts, a Representative in Congress from the Commonwealth          of Pennsylvania, opening statement ....................................................... 1
    Prepared statement ..................................................................................... 3
Hon. Gene Green, a Representative in Congress from the State of Texas,         opening statement .......................................................................................... 4
Hon. Marsha Blackburn, a Representative in Congress from the State of         Tennessee, opening statement ........................................................................ 6
Hon. Frank Pallone, Jr., a Representative in Congress from the State of New   Jersey, opening statement ............................................................................ 7
    Prepared statement ..................................................................................... 7
Hon. Fred Upton, a Representative in Congress from the State of Michigan,     prepared statement ....................................................................................... 116

WITNESSES

Debra Patt, M.D., Medical Director, U.S. Oncology Network ................................ 9
    Prepared statement ..................................................................................... 12
Michael Schweitz, M.D., National Advocacy Chair, Coalition of State            Rheumatology Organizations ........................................................................... 28
    Prepared statement ..................................................................................... 30
Marcia Boyle, President and Founder, Immune Deficiency Foundation .............. 43
    Prepared statement ..................................................................................... 45
    Answers to submitted questions .................................................................. 269
Heather Block, Patient Advocate ....................................................................... 56
    Prepared statement ..................................................................................... 58
Joe Baker, President, Medicare Rights Center ................................................ 63
    Prepared statement ..................................................................................... 65

SUBMITTED MATERIAL

H.R. 5122, A Bill to prohibit further action on the proposed rule regarding testing of Medicare part B prescription drug models, submitted by Mr. Pitts ................................................................. 118
Letter of May 2, 2016, from Hon. Tom Price, et al., to Andy Slavitt, Acting      Administrator, Centers for Medicare & Medicaid Services, Department of Health and Human Services, submitted by Mr. Green ....................................................... 120
Letter of April 29, 2016, from Chuck Grassley, a United States Senator          from the State of Iowa, to Sylvia Burwell, Secretary, Department of Health and Human Services, submitted by Mrs. Blackburn ................................................. 141
Letter of May 2, 2016, from AARP, et al., to Sylvia Burwell, Secretary,        Department of Health and Human Services, and Andy Slavitt, Acting Administra-
    tor, Centers for Medicare & Medicaid Services, Department of Health and Human Services, submitted by Ms. Schakowsky ......................................................... 145
Statement of Ariel A. Gonzalez, Director, Federal Health & Family, AARP,      May 17, 2016, submitted by Ms. Schakowsky ................................................ 149
Statement of American Federation of Labor and Congress of Industrial Organi-
    zations, May 17, 2016, submitted by Ms. Schakowsky .................................. 151
Letter of May 16, 2016, from Robert Roach, Jr., President, Alliance for Retired Americans, et al., to Mr. Upton and Mr. Pallone, submitted by Ms. Schakowsky ......................................................... 152
Letter of May 16, 2016, from Scott Frey, Director of Federal Government Affairs, AFSCME, to Representatives in Congress, submitted by Ms. Schakowsky ......................................................... 154
Letter of May 16, 2016, from Judith Stein, Executive Director/Attorney, Center for Medicare Advocacy, to Mr. Upton and Mr. Pallone, submitted by Ms. Schakowsky .............................................................. 166
Letter of May 9, 2016, from Mary R. Grealy, President, Healthcare Leadership Council, to Mr. Pitts and Mr. Green, submitted by Mr. Pitts .................. 183
Letter of May 16, 2016, from Susan A. Cantrell, Chief Executive Officer, Academy of Managed Care Pharmacy, to Mr. Pitts and Mr. Green, submitted by Mr. Pitts ....................................................... 168
Letter of March 17, 2016, from 1 in 9: The Long Island Breast Cancer Action Coalition, et al., to House and Senate leadership, submitted by Mr. Pitts ................................................................. 170
Letter from the Alliance for the Adoption of Innovations in Medicine, et al., to House and Senate committee leadership, submitted by Mr. Pitts .......... 202
Letter of May 9, 2016, from Tony Coelho, Chairman, Partnership to Improve Patient Care, et al., to Andy Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, submitted by Mr. Pitts .......... 185
Letter of April 27, 2016, from Senate Finance Committee Democrats to Andy Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, submitted by Mr. Pitts ........................................... 180
Letter of April 28, 2016, from Senate Committee on Finance Republicans to Andy Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, submitted by Mr. Pitts ........................................... 214
Letter of May 9, 2016, from Scott H. Peters, a Representative in Congress from the State of California, to Andy Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, submitted by Mr. Pitts ................................. 217
Letter of May 13, 2016, from House Democrats to Andy Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, submitted by Mr. Pitts ........................................................................ 218
Letter of April 28, 2016, from Senate Committee on Finance Republicans to Andy Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, submitted by Mr. Pitts ........................................... 171
Statement of the International Union, United Automobile, Aerospace and Agricultural Implement Workers of America, May 17, 2016, submitted by Ms. Schakowsky .............................................................. 170
Statement of Wanda Filer, President, American Academy of Family Physicians, March 10, 2016, submitted by Ms. Schakowsky .............................................................. 171
Letter of May 16, 2016, from Holly R. Hart, Assistant to the International President, Legislative Director, United Steelworkers, to Ms. Schakowsky .............................................................. 166
Letter of May 9, 2016, from Ms. Schakowsky, et al., to Andy Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, Department of Health and Human Services, submitted by Ms. Schakowsky ........................................................................ 173
Letter of May 16, 2016, from Elizabeth Warren, a United States Senator from the Commonwealth of Massachusetts, et al., to Sylvia Burwell, Secretary, Department of Health and Human Services, et al., submitted by Ms. Schakowsky ........................................................................ 176
Letter of May 17, 2016, from Clyde Terry, Chairperson, National Council on Disability, to Andy Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, Department of Health and Human Services, submitted by Mr. Pitts .............................................................. 180
Letter of May 9, 2016, from Christopher W. Hansen, President, American Cancer Society Cancer Action Network, to Sylvia Burwell, Secretary, Department of Health and Human Services, submitted by Mr. Cárdenas ............ 225
Letter of May 9, 2016, from Sara Radcliffe, President and CEO, California Life Sciences Association, to Andy Slavitt, Acting Administrator, Centers for Medicare & Medicaid Services, submitted by Mr. Cárdenas .................................................. 253
Report by the Memorial Sloan Kettering Cancer Center, “Examining Congressional comments regarding Medicare’s Part B pilot proposal,” May 16, 2016, submitted by Mr. Welch ......................................................... 255
THE OBAMA ADMINISTRATION’S MEDICARE DRUG EXPERIMENT: THE PATIENT AND DOCTOR PERSPECTIVE

TUESDAY, MAY 17, 2016

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

The subcommittee met, pursuant to call, at 10:00 a.m., in room 2123 Rayburn House Office Building, Hon. Joseph R. Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Guthrie, Shimkus, Murphy, Blackburn, Lance, Griffith, Bilirakis, Long, Ellmers, Bucshon, Brooks, Collins, Green, Engel, Capps, Schakowsky, Butterfield, Castor, Sarbanes, Schrader, Kennedy, Cardenas, and Pallone (ex officio).

Also present: Representative Welch.

Staff present: Mike Bloomquist, Deputy Staff Director; Sean Bonyun, Communications Director; Rebecca Card, Assistant Press Secretary; Karen Christian, General Counsel; Paul Edattel, Chief Counsel, Health; Tim Pataki, Member Services Director; James Paluskiewicz, Professional Staff Member, Health; Graham Pittman, Legislative Clerk; Chris Sarley, Policy Coordinator, Environment and the Economy; Jennifer Sherman, Press Secretary; Adrianna Simonelli, Legislative Associate, Health; Heidi Stirrup, Policy Coordinator, Health; John Stone, Counsel, Health; Sophie Trainor, Policy Advisor, Health; Jeff Carroll, Democratic Staff Director; Tiffany Guarascio, Democratic Deputy Staff Director and Chief Health Advisor; Jessica Martinez, Democratic Outreach and Member Services Coordinator; Samantha Satchell, Democratic Policy Analyst; Andrew Souvall, Democratic Director of Communications, Outreach, and Member Services; and Arielle Woronoff, Democratic Health Counsel.

Mr. Pitts. I will ask all Members to take their seats. The time of 10:00 has arrived. The subcommittee will come to order. The Chair will recognize himself for an opening statement.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Today’s hearing will take a closer look at a recent proposed rule from the Centers for Medicare and Medicaid Services, CMS, on a
Part B drug payment model. This proposal represents the biggest change in Medicare drug reimbursement in years.

There are several aspects that are concerning to many, including the mandatory nature of this so-called demonstration project, the breadth of the experiment essentially across the Nation in virtually all primary care service areas and the timing.

These major changes would take place as early as July and on top of the current implementation of MACRA, the new payment structure for physicians that replace the SGR, the sustainable growth rate.

But perhaps the most concerning aspect of this proposal is that it came from unelected bureaucrats in this administration who made the decision behind closed doors affecting our seniors and their health care.

What happened to the transparency in regard to stakeholders that we expect when considering proposals of this magnitude? In fact, these concerns over provider reimbursement under the Medicare Part B program are so considerable that recently 242 bipartisan Members of Congress wrote to the administration and asked that the rule be withdrawn.

Several others letters from both the House and Senate have been sent detailing numerous and serious concerns. Moreover, our Health Subcommittee colleague, Dr. Larry Bucshon, recently introduced legislation that would stop this proposal from advancing.

So today, we’re going to hear from doctors and patient advocates about their views on this proposed rule. I want to make it clear at the outset that we are not opposed to demonstration programs and in fact have supported a number which tests certain models in limited areas to determine positive or negative outcomes and whether such demonstrations should be advanced in a larger context.

However, the health and well-being of seniors is nothing to be experimented with. This particular rule could result in grave consequences for our seniors. CMS is proposing to reduce reimbursement for physician-administered drugs with half of the country’s providers seeing dramatic cuts.

The other half will retain current reimbursement levels, but half of those will be used to test out vague value-based purchasing arrangements, and after a very long 5 years CMS will see what happened.

Keep in mind Medicare is the largest payer of provider-administered drugs. The Part B program covers provider-administered injectables and certain other drugs for physician offices and outpatient clinics the provider purchases and administers the product before submitting a claim to Medicare.

After purchasing a drug from a wholesaler or a specialty distributor, the provider will store the product at its location.

The provider then administers the drug to the patient and after the patient receives the drug and any other medical care, the provider then submits a claim for reimbursement, hence term buy and bill, because the medical claim is submitted after the provider has purchased and administered the drug.

The Medicare Prescription Drug Improvement and Modernization Act of 2003—MMA—requires Medicare to use a drug’s average sale
3

price—ASP+6 percent for reimbursing provider-administered injectable drugs.

ASP is based on the manufacturer’s actual selling price minus all price concessions. CMS asserts this system somehow gives incentives for physicians to prescribe more expensive drugs and therefore has proposed this nationwide two-phase experiment which would allow half of the providers to continue to be reimbursed at ASP+6 percent while the other half would receive the lower ASP+2.5 percent rate plus a fixed $16.80 payment.

However, with the impact of sequestration calculated in the reimbursement falls to nearly ASP+0 percent. This proposal is so far reaching and has caused so much concern it is difficult to imagine any meaningful conclusions can be drawn because marketplace realities will undermine the integrity of this massive and unprecedented experiment on patients and providers.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

The subcommittee will come to order. The chairman will recognize himself for an opening statement. Today’s hearing will take a closer look at a recent proposed rule from the Centers for Medicare and Medicaid Services (CMS) on a Part B Drug Payment Model. This proposal represents the biggest change in Medicare drug reimbursement in years. There are several aspects that are concerning to many, including: the mandatory nature of this so-called demonstration project; the breadth of the experiment—essentially across the Nation in virtually all primary care service areas; and the timing—these major changes would take place as early as July and on top of the current implementation of MACRA—the new payment structure for physicians that replaced SGR (Sustained Growth Rate).

But perhaps the most concerning aspect of this proposal is that it came from unelected bureaucrats in this administration who made decisions behind closed doors affecting our seniors and their health care. What happened to the transparency and regard for stakeholders that we expect when considering proposals of this magnitude?

In fact, these concerns over provider reimbursement under the Medicare Part B program are so considerable, that recently 242 bipartisan Members of Congress wrote to the administration and asked that the rule be withdrawn. Several other letters from both the House and Senate have been sent detailing numerous and serious concerns. Moreover, our Health Subcommittee colleague, Dr. Larry Bucshon, recently introduced legislation that would stop this proposal from advancing. So today we are going to hear from doctors and patient advocates about their views on this proposed rule.

I want to make clear at the outset that we are not opposed to demonstration programs and in fact have supported a number which test certain models in limited areas to determine positive (or negative) outcomes and whether such demonstrations should be advanced in larger contexts. However, the health and well-being of seniors is nothing to be experimented with.

This particular rule could result in grave consequences for our seniors. CMS is proposing to reduce reimbursement for physician administered drugs, with half of the country’s providers seeing dramatic cuts. The other half will retain current reimbursement levels but half of those will be used to test out vague value-based purchasing arrangements. And after a very long 5 years, CMS will see what happened. Keep in mind, Medicare is the largest payer of provider-administered drugs. The Part B program covers provider-administered injectables and certain other drugs. For physician offices and outpatient clinics, the provider purchases and administers the product before submitting a claim to Medicare.

After purchasing a drug from a wholesaler or specialty distributor, the provider will store the product at its location. The provider then administers the drug to the patient. After the patient receives the drug and any other medical care, the provider submits a claim for reimbursement. Hence the term, buy-and-bill, because the medical claim is submitted after the provider has purchased and administered the drug.
The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) requires Medicare to use a drug’s Average Sales Price (ASP) + 6% for reimbursing provider-administered injectable drugs. ASP is based on the manufacturer’s actual selling price, minus all price concessions. CMS asserts this system somehow gives incentives for physicians to prescribe more-expensive drugs and therefore has proposed this nationwide two-phase experiment which would allow half of the providers to continue to be reimbursed ASP + 6% while the other half would receive the lower ASP + 2.5% rate plus a fixed $16.80 payment. However, with the impact of sequestration calculated in, the reimbursement falls to nearly ASP + 0%.

This proposal is so far-reaching and has caused so much concern it is difficult to imagine any meaningful conclusions can be drawn because marketplace realities will undermine the integrity of this massive and unprecedented experiment on patients and providers.

Mr. Pitts. My time has expired, so I yield back the balance of my time and now recognize the ranking member of the subcommittee, Mr. Green, 5 minutes for his opening statement.

OPENING STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. Green. Thank you, Mr. Chairman. Good morning. I thank our panels for being here today.

As we know, CMS, through the Centers for Medicare and Medicaid Innovation, recently proposed to test value-driven payment models for prescription drugs under Medicare Part B. This proposal has garnered significant reaction and response from the provider, patient, and the pharmaceutical communities.

I appreciate the Chair for having this hearing today and hope this committee will take the opportunity to examine the proposals, merits and drawbacks.

While the loudest voices have been oppose to the model outright, it is important to thoroughly evaluate the issues CMS is attempting to address and look at the proposal with calm and reason, and I appreciate CMS’ consistent goal of strengthening the Medicare program. However, I have some concerns about the size and scope of the proposed demonstration and its potential impact on Medicare beneficiaries’ access to physician-administered drugs now and in the future.

I also question how the demonstration may affect physicians’ participation in existing and upcoming delivery and payment reform models.

Currently, Medicare Part B pays physicians and hospital outpatient departments the average sales price, or ASP, of a drug plus the 6 percent add-on on payment commonly referred to as ASP+6. Medicare pays ASP+6 for drugs regardless of the price paid to acquire the drug. MedPAC and others have raised concern that the 6 percent add-on may create incentives to use higher priced drugs when lower priced alternatives are available and appropriate for the patient.

It’s difficult to know the extent in which a percentage add-on to ASP influences drug-prescribing patterns because few studies have looked into this issue.

Prescription drug spending in the United States was about $457 billion in 2015 and roughly 17 percent of the overall health spending. In 2015, Medicare Part B spent $20 billion on outpatient drugs
administered by physicians and hospital outpatient departments, which has doubled the amount spent in 2007.

Beneficiary cost sharing under fee for service Medicare Part B is 20 percent with no out of pocket limit. According to the GAO, some seniors and people with disabilities have faced catastrophic expenses amounting to as much as $100,000. The median annual income for Medicare beneficiaries is less than $25,000 a year, and one in four have less than $12,000 in savings.

There’s a national conversation occurring about the cost of prescription drugs. I appreciate CMS for attempting to address this issue in part by proposing to test tools that reward value in Medicare Part B similar to the efforts in the private sector.

Congress should not ask seniors to pay 20 percent of increasingly expensive therapies without due consideration of whether their money is being well spent. Healthcare delivery systems are rightfully changing and Medicare should not be left behind.

I’m confident that providers will fulfill their calling and practice medicine, delivering the best care for their patients rather than pad their bottom lines.

Yet, on behalf of seniors and the sustainability of the healthcare system at large we cannot put our heads in the sand and ignore trends. This proposed model is far from perfect and I have serious concerns about the aspects of it.

Recently, I joined members of this committee in sending a letter to CMS outlining our concerns with the demonstration and urging the agency to address them.

I ask for unanimous consent, Mr. Chairman, to submit this letter for the record.

Mr. PITTS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. GREEN. I look forward to hearing from our witnesses about their perspective of the model and concerns we’ve outlined to the agency.

Taking a step back, I’m going to bring up a related issue that has become part of the conversation around the demonstration which is that of prompt pay.

I have long had an interest in preserving seniors’ access to quality care by ensuring Medicare pays at a rate that will retain a robust network of providers.

H.R. 696, also know and the Prompt Pay bill, is a piece of legislation I’ve introduced with my colleague on our committee, Mr. Whitfield, for several Congresses.

The bill excludes the prompt payment discounts offered by manufacturers to wholesalers from the average sales price for drugs and biologics covered under Medicare Part B.

This became an issue when the Medicare Modernization Act was enacted in 2003. It reduces the amount doctors are reimbursed for administrative treatments and as a result patients are pushed to more expensive settings for their care.

Reducing the number of options for patients, diminishing the access drives up the costs in both short and long term and is bad policy. The Prompt Pay discount has negatively affected patients for many years before sequestration and whether we adopt legislation
repealing, replacing or otherwise authoring the sequester without
adopting H.R. 696 the underlying issue will still exist.

Thank you, Mr. Chairman, and our witnesses here today and I
look forward to a robust discussion about the proposed demonstra-
tion and I yield back my time.

Mr. PITTS. The Chair thanks the gentleman and now recognizes
the vice chair of the full committee, Mrs. Blackburn, 5 minutes for
her opening statement.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REP-
RESENTATIVE IN CONGRESS FROM THE STATE OF TEN-
NESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman, and I do want to
say welcome to our witnesses. I think that you can tell from the
chairman’s statement and you’ll find out from the questions that
you hear we are all very concerned about a couple of things that
are happening with the demonstration project.

Number one, rural areas—they’re already challenged, and I have
19 counties in my district in Tennessee and some of the more rural
counties are quite concerned about this and healthcare providers
are very concerned about this and fear that this may be the type
component that pushes some of these providers to the brink and
out of the business in service areas.

So we are very concerned about that, especially when it comes
to things like cancer and getting the appropriate treatments. And
Mr. Chairman, I would like to include for the record a letter that
is dated April 29th from Senator Grassley to Secretary Burwell.

Senator Grassley has made specific inquiries of the secretary if
CMS—if this model is in fact a clinical trial but without the typical
patient safeguards.

And I understand that clinical trials are important. In my dis-
trict we have a lot of physicians and researchers who participate
in this when it comes to oncology treatment.

I have had the opportunity to visit with some of them, and they
are quite concerned about the way this is moving. So I ask permis-
sion to submit the letter.

Mr. PITTS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mrs. BLACKBURN. Thank you, Mr. Chairman, and to each of you
again, we’re going to look forward to digging a little deeper on this.
Access to the right type care at the right time is essential for posi-
tive outcomes and so we will be seeking your guidance and with
that I will yield to any other member of the committee seeking
time or will yield back.

Mr. PITTS. All right.

Mrs. BLACKBURN. Yield back.

Mr. PITTS. Without objection the lady yields back, and now the
Chair recognizes the ranking member of the full committee, Mr.
Pallone, 5 minutes for an opening statement.
OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman, and thanks to the witnesses who will be testifying today. I think we would all agree that it is critical we continue to transform our healthcare system into one that incentivizes value over volume.

That is the theme we heard time and again when we worked together to repeal the SGR and replace it with a payment system that rewards doctors for the quality of care they give to seniors and we were all in agreement that more care must be replaced with better care. The status quo, we said, was unsustainable.

The success of this kind of delivery system reform, however, is not possible if we do not give Medicare the tools to stay in business.

Medicare must be able to innovate just like the private sector is doing and that’s why I support the innovation center that was authorized in the Affordable Care Act because it allows Medicare to test new models that improve care and save money.

Now we’ve all heard loud and clear that there are concerns with the center’s most recent proposal to change the way we reimburse doctors for drugs administered in their offices under Part B. I look forward to hearing more from our witnesses today about the rule. I don’t think anyone here would claim this proposal is perfect. I’m particularly interested in hearing about how to ensure that seniors have access to necessary drugs. I’m also interested in better understanding how we can assure that the evaluation of this proposed model is robust and thorough before it’s expanded.

To date, there has been widespread engagement ranging from comments from stakeholders to letters from Members of Congress. This feedback is an important part of the process, and I believe the administration will take into account these concerns and make changes to address them in the final rule.

So I’d like to now yield the remainder of my time to Congresswoman Schakowsky.

[The prepared statement of Mr. Pallone follows:]
can ensure that the evaluation of this proposed model is robust and thorough before it is expanded. To date, there has been widespread engagement, ranging from comments from stakeholders to letters from Members of Congress. This feedback is an important part of the process, and I believe the administration will take into account these concerns and make changes to address them in the final rule.

I'd like to yield the remainder of my time to Congresswoman Schakowsky.

Ms. SCHAKOWSKY. I thank the gentleman for yielding. I strongly believe that lowering drug prices is imperative to the sustainability of our healthcare system, especially our public insurance programs like Medicare, and I support CMS' proposal to create a demonstration project for drugs paid under Part B.

Luckily, I'm not alone. Many organizations that represent beneficiaries, insurance companies and consumer organizations, including AARP, Aetna, the AFL–CIO, the Alliance for Retired Americans, AFSCME, the American Federation of Teachers, Center for American Progress, Center for Medicare Advocacy, Doctors for America, Consumers Union, Families USA, Justice in Aging, Kaiser Permanente, Medicare Rights Center, National Committee to Preserve Social Security and Medicare, the National Education Association, the National Partnership for Women & Families and the Boilermakers, among others, support this proposal, and I'd like, Mr. Chairman, to enter their letters of support for the Part B demonstration project into the record.

Mr. PITTS. Without objection, so ordered.

Ms. SCHAKOWSKY. I'd also like to enter into the record several additional statements of support from many of those same groups as well as the United Steelworkers, the Public Sector HealthCare Roundtable, United Auto Workers, and the Academy of Family Physicians supporting CMS' proposal.

Mr. PITTS. Without objection, so ordered.

Ms. SCHAKOWSKY. And I—thank you—and I'd also like enter into the record a letter signed by 20 Members of the House and a letter signed by 11 Senators supporting CMS' proposal.

Mr. PITTS. Without objection, so ordered.

[The information submitted by Ms. Schakowsky appears at the conclusion of the hearing.]

Ms. SCHAKOWSKY. Yet, every time we attempt to do anything to rein in drug costs we are met with fierce opposition. We are actively reforming every other aspect of our healthcare system to pay for value except pharmaceuticals.

In fact, drug manufacturers are the only one entity that can charge Medicare anything they want for their products. We would never accept that from any other entity in our healthcare system and we should no longer accept it from pharma.

The proposal from CMS is not final. They have committed themselves to working with stakeholders to address their concerns. In fact, CMS has indicated that they would be open to changes including the scope of the proposal and exceptions for small and rural providers.

But all we hear today is no. With no alternative ideas on how to realign incentives and reduce drug costs for beneficiaries and that is not good for anyone anymore.
We cannot continue on this unsustainable path where drug costs rise faster than overall health costs and patients are bankrupted in order to pay for the lifesaving drugs that they need.

You know, in some ways I would rather find out that there is no cure for a certain disease that I have than know that that cure is right there in front of me, but I simply cannot afford it. Because I don’t have the dollars to pay for it, I can’t get that cure. This is unconscionable. I think it’s also un-American, and I yield back.

Mr. Pitts. The gentleman's time has expired. As usual, all opening statements of the Members will be made a part of the record.

I have a UC request. as well. I’d like to submit the following documents for the record: statements from the National Council on Disability, Healthcare Leadership Council, American College of Rheumatology, Academy of Managed Care Pharmacy, letters from the ASP Coalition, two dozen members of the patient community, Partnership to Improve Patient Care, the American Association of People with Disabilities and over 80 other patient advocacy organizations, Senate Finance Democrats, Representative Scott Peters, 25 Democratic Members, Senate Finance Republicans and we also completed a review of 218 comments from State and national groups as well as over 800 individuals. The vast majority of comments express concern and urge withdrawal.

[The information appears at the conclusion of the hearing.]

Mr. Pitts. So at this point, I'll introduce the witnesses in the order that you will present testimony. First of all, we have Dr. Debra Patt, MD, MPH, MBA, Vice President, Texas Oncology Medical Director, the U.S. Oncology Network Chair, Clinical Practice Committee of the American Society of Clinical Oncology, Editor-in-Chief, Journal of Clinical Oncology, Clinical Cancer Informatics and Board Member of Community on Oncology Alliance. Welcome.

Then Dr. Michael Schweitz, MD, FACP, MACR, National Advocacy Chair, Coalition of State Rheumatology Organizations, CSRO; Ms. Marcia Boyle, President and Founder, Immune Deficiency Foundation; Ms. Heather Block, a patient advocate and Mr. Joe Baker, President, Medicare Rights Center.

Thank you for coming today. Your written testimony will be made a part of the record. We ask that you summarize. We'll give you each 5 minutes for your summary. So at this point the Chair recognizes Dr. Patt, 5 minutes for your opening statement.

STATEMENTS OF DEBRA PATT, M.D., MEDICAL DIRECTOR, U.S. ONCLOGY NETWORK; MICHAEL SCHWEITZ, M.D., NATIONAL ADVOCACY CHAIR, COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS; MARCIA BOYLE, PRESIDENT AND FOUNDER, IMMUNE DEFICIENCY FOUNDATION; HEATHER BLOCK, PATIENT ADVOCATE; JOE BAKER, PRESIDENT, MEDICARE RIGHTS CENTER

STATEMENT OF DEBRA PATT

Dr. Patt. Chairman Pitts and Ranking Member Green, thank you for the opportunity to testify today on behalf of Texas Oncology, the U.S. Oncology Network, the Community Oncology Alliance and the American Society of Clinical Oncology regarding the oncol-
ogy community's grave concerns with the proposed Medicare Part B drug payment model.

My written statement provides numerous arguments against the CMS-proposed model but with the limited time I have today as a physician I will tell you why this is bad medicine for patients.

I am Dr. Deborah Patt and for 13 years I have been providing care to cancer patients in Texas. As a physician, quality care and value are the standards by which I practice every day.

My patients often face life-and-death situations, and my responsibility is to help them choose and then deliver the personalized treatment for their disease. Increasingly, the time I have to spend with patients is consumed with overcoming a complex maze of administrative obstacles to provide treatment.

But the CMS-proposed model is not just another hurdle. It's an experiment that is simply unworkable in cancer care. Let me explain.

CMS has proposed an experiment that randomizes physicians by ZIP Codes into test and control groups. The study hypothesis is that financial disincentives for use of newer more expensive drugs will cause physicians to choose less expensive treatment alternatives.

In my world, this is clinical research. Unlike the CMS experiment, however, my patients have to volunteer their participation in a clinical trial. But there is no opting out of this mandatory national experiment.

There is no informed consent for patients, no monitoring for adverse events, and no ability to evaluate impact on quality and outcomes. These are central requirements of any ethical research.

In this experiment, Medicare beneficiaries in certain ZIP Codes won't have access to treatments that have a known survival advantage. This is simply unacceptable.

More fundamentally, the underlying hypothesis for this experiment that these incentives will result in reduced Medicare spending is simply unfounded. I will let my written testimony explain how UnitedHealthcare Project has already disproved the CMS hypothesis.

Today, I'd like to focus on how few opportunities there are to select therapeutic alternatives based solely on drug price. Ten years ago when I met my patient Karen, who has metastatic breast cancer, she couldn't walk. She couldn't stand without pain. Her bones were riddled with disease and she was told there was no hope. Within a year of meeting Karen she developed metastatic breast cancer to her brain. Ten years ago, we knew that patients with metastatic breast cancer to their brain lived an average of a few weeks. Karen had an option of a different treatment because the disease amplified a receptor called HER2, and she was given a novel and targeted therapy that we know would change her course dramatically.

In the last 10 years, Karen has had some disease progression in her brain. But she's lived to see her son get married and she danced at his wedding. She's lived to see her first grandchild be born and grown into school age and she continues to receive targeted treatment today and enjoys a good quality of life.
These targeted therapies are expensive but the alternative treatment to these expensive medications would lead to an early death. Premature death is not a treatment alternative.

When I started my fellowship at the MD Anderson Cancer Center in 2003, myeloma patients lived an average of 3 years. Usually they were 3 years of toxic therapy.

Today, an average myeloma patient lives greater than 7 years due to new novel therapies and they live better because myeloma has become a chronic disease where many patients have remission for many years.

The treatment is expensive, but the lower cost alternative would shave years off their life and diminish their quality of life as well. I remind the committee that Medicare covers 60 percent of cancer patients, and the number of Medicare beneficiaries are growing every day.

The CMS experiment has the potential to affect treatment options and outcomes for the most significant and vulnerable segment of the population fighting cancer. Interfering with the physician’s ability to act in the patient’s best interest is counter to our core values and certainly inconsistent with the good work Congress has done to advance high quality, high value care to every American.

It is not who we are. Like everyone here today, I am very concerned about the increase in cost of treating cancer, especially rising drug prices.

However, as I outlined in my written testimony, the CMS proposal will not only fail to reduce drug prices, but in fact it will likely increase costs.

In closing, I want to thank the members of the committee for their extraordinary support of community-based cancer care. Many on this panel and even more on the full committee have introduced legislation, authored amendments, and wrote letters to improve cancer care and access for our patients.

Most recently, thank you to Congressman Bucshon for introducing H.R. 5122. On behalf of oncologists nationwide, thank you for holding this hearing to highlight the serious concerns around the CMS proposal.

I know we share the common goal of providing high-quality medical care to Medicare beneficiaries and thank you for your work on their behalf. When it's appropriate I'm happy to answer any questions.

[The statement of Dr. Patt follows:]
Submitted Testimony of Dr. Debra Patt on
The Obama Administration’s Medicare Drug Experiment: The Patient and Doctor Perspective
Energy and Commerce Health Subcommittee Hearing
May 17, 2016

Chairman Pitts and Ranking Member Green, thank you for the opportunity to testify today on behalf of Texas Oncology, The US Oncology Network, the Community Oncology Alliance (COA) and the American Society of Clinical Oncology (ASCO) before the Energy and Commerce Subcommittee on Health on the proposed “Part B Drug Payment Model,” and H.R. 5122 sponsored by Congressman Larry Bucshon. The Members of the Health Subcommittee have been especially committed to the nation’s cancer patients and care providers over the years and many of the Members on this Committee can take credit for policies that have shaped our world-class cancer care delivery system. Thank you for your dedication and support for Americans and their families fighting cancer and for those of us who work to help patients live longer, happier, healthier lives.

I’m honored to appear before the Committee today. My name is Dr. Debra Patt, and for the last 13 years I have spent the majority of my time taking care of cancer patients as a practicing medical oncologist. On an average day I treat around 30 patients in a 12 hour day. I also donate my free time in different capacities including serving on multiple research, informatics and practice boards, acting as editor-in-chief of the Journal of Clinical Cancer Informatics and various leadership roles in my practice, The US Oncology Network, COA and ASCO. Slightly
more than 50 percent of my patients rely on Medicare. Another 5-10 percent are either covered by Medicaid or are uninsured. Throughout the country, over 60 percent of cancer patients rely on Medicare. Many of our seniors fighting cancer today have complex cases with other diseases and medical conditions, and face sometimes great difficulties navigating the health care system. Fortunately, community oncology clinics, such as the one where I practice, provide access to high-quality, state-of-the-art care close to home at a more affordable cost compared to large health systems.

I am proud to be a part of community oncology—the most effective and successful cancer care delivery system in the world. After nearly 100 years of increasing cancer death rates in the United States, we are turning the corner in this fight: cancer mortality has fallen by 20 percent from a 1991 peak and there are now nearly 14.5 million cancer survivors alive in the U.S. Cancer patients from around the world seek care here because Americans benefit from the best cancer survival rates in the world. Reasons for the increased survival rate are due in large part to earlier detection, breakthrough treatment options, such as immunotherapies, and the dedication of the nation’s oncology providers.

Despite significant progress in treatment and survival rates, we still have a long way to go in beating this terrible disease. The American Cancer Society estimates that in 2014 nearly 1.7 million Americans will be diagnosed with cancer and more than 595,000 will die of cancer, which is 1 out of every 4 deaths in America. These statistics underscore why the timing, scope, and fundamental structure of the “Part B Drug Payment Model” will be devastating to the advancements made in our continued fight against cancer.
I believe most oncologists share the Administration’s concern with the rising cost of cancer care and its impact on Medicare beneficiaries and the Medicare program’s sustainability. As community-based cancer care providers, we are well aware that cancer continues to be one of our nation’s most costly, serious, and prevalent chronic conditions. The National Cancer Institute states that the U.S. spent over $125 billion on cancer care in 2010 and projects that cancer care costs will increase to $156 billion by 2020.1 With Medicare beneficiaries making up 60 percent of the 14 million Americans living with cancer, and considering the elderly are 10 times more likely to have cancer than the younger population,2 Medicare must be heavily invested in ensuring access to beneficiaries for high-quality, innovative cancer treatment options close to home.

With all the media attention on the increasing costs of cancer care, especially the prices of new cancer drugs, it is very important for the Committee to understand a recently released study by the actuarial firm Milliman. It shows that from 2004 through 2014 Medicare’s cost of treating cancer patients rose at a rate that was no greater—I underscore the words “no greater”— than spending on all Medicare patients, regardless of disease or medical condition.3 And, in fact, if the site of cancer care had not shifted from physician-run community cancer clinics to outpatient hospital departments during this period the per-beneficiary cost of treating a cancer patient would have risen at a lower rate than for all Medicare beneficiaries.4 Results from this landmark study should be very important in guiding the Committee’s specific response to CMS’ proposed “Part B Drug Payment Model” and overall work on solutions to strengthening our nation’s cancer care delivery system.

---

1 The National Cancer Institute [http://www.cancer.gov/about-cancer/what-is-cancer/statistics
4 Id.
The “Part B Drug Payment Model,” which is aimed at reducing Medicare drug spending is ill-conceived and, most importantly, lacks a patient-centered focus. I am disappointed that CMS has masked their efforts to control rising drug costs by suggesting physicians are not providing their patients with the most appropriate, highest quality medical care but instead prescribe more expensive drugs for “profit.” CMS is absolutely incorrect in its assumptions that reducing reimbursements for Part B drugs will both lower Medicare costs and drug prices. In fact, looking at the oncology landscape documents that the reimbursement cuts proposed by CMS in Phase 1 of the “Part B Drug Payment Model” will actually increase Medicare costs and further fuel drug prices—the exact opposite of what CMS intends. More fundamentally, CMS’ proposal is an experiment on the care of seniors with cancer and other diseases that will hinder their access to life-saving/prolonging new treatment advances, such as the new immunotherapy that has former President Carter’s cancer in remission.

Today, 7 of the top 10 drugs that account for 48 percent of Part B drug spending are used to treat and cure cancer. Limiting an oncologist’s ability to provide current, cutting-edge treatments, as will occur if the “Part B Drug Payment Model” is implemented, will likely result in inferior outcomes for Medicare beneficiaries with cancer. As a provider caring for Medicare beneficiaries diagnosed with cancer, I believe the proposed “Part B Drug Payment Model” is unworkable and ask Congress to please stop this experiment on seniors with cancer and other serious diseases treated with Part B drugs.
I will use my time today to discuss why nationwide oncologists agree that the “Part B Drug Payment Model” will work counter to CMS’ goal of reducing costs and improving outcomes for cancer patients and will be detrimental to the medical care provided to the most vulnerable populations—seniors and disabled individuals covered by Medicare.

**Oncology Care Model versus “Part B Drug Payment Model”**

As a physician, I strive to demonstrate value, improve quality, strengthen patient outcomes, and hold down cancer care costs every day. Community oncologists appreciate programs and models that strive for those goals, as witnessed by the numerous oncology payment models already being implemented with payers such as Aetna, Cigna, Horizon, Humana, PriorityHealth, and UnitedHealthcare, as well as Medicare. In 2013, CMS reached out to the oncology community with the goal of developing an alternative payment model to manage the quality and costs of cancer treatment. My oncologist colleagues and I welcomed this opportunity and assisted the Center for Medicare and Medicaid Innovation (CMMI) in creating and developing the Oncology Care Model (OCM), an episode-based payment model aimed at improving coordination, appropriateness of treatment, and access to care for Medicare beneficiaries undergoing chemotherapy. It was a collaborative effort that involved outside experts, such as the MITRE Corporation and Brookings Institution, and considerable input from oncology providers, patients, and payers.

Unfortunately, CMS took the opposite approach in crafting and announcing the proposed “Part B Drug Payment Model.” The model was introduced to the oncology community for the first time when it was released on March 11, 2016. Oncologists, patients, and others had absolutely no input on the proposed model. While community oncology practices across the country were waiting to hear if they would be accepted into the OCM, CMS revealed the proposed “Part B Drug Payment Model.”
The contrast between the 3 years of collaborative, transparent effort in developing the OCM and the secretive, surprise introduction of the “Part B Drug Payment Model,” obviously developed entirely within CMS and CMMI, cannot be more stark.

Given the significant time, resources, and collaboration that went into developing the OCM, I question how CMS will effectively implement and manage these two separate payment models with two distinct and individual goals, not to mention the coming implementation of the new physician payment system under the Medicare Access and Chip Reauthorization Act (MACRA). I truly believe all these conflicting payment models will have natural consequences on the cancer care delivery system, complicating patient care and making it virtually impossible to measure the results of these payment initiatives.

An Experiment on Patient Care that is Bad Medicine and Unworkable in Cancer Care

Step back for a moment and consider what CMS is proposing in Phase 1 of the “Part B Drug Payment Model.” CMS believes that I, trained at MD Anderson Cancer Center and board-certified in medical oncology, am not treating my patients correctly. I am motivated to use the most expensive drugs, not the most appropriate, effective drugs for my patients. So, they propose to conduct a test to use financial disincentives to change my clinical decision making. Three-quarters of the country will be in a “test” arm and the remainder in the “control” arm. Primary care service areas, which are a collection of zip codes, will be randomized to these “test” and “control” arms. This experiment is clinical research, something I am very familiar with from daily practice. Yet, this is a mandatory experiment, where patients cannot opt out of and receive no “informed consent” on the research and their rights, as is mandatory in all ethical clinical research. As importantly, there is no real-time
monitoring of adverse events, outcomes, or quality. Phase 1 of the “Part B Drug Payment Model” is an experiment on the cancer care of seniors but without all the accepted patient safeguards.

More fundamentally, what CMS is proposing is unworkable in modern-day cancer care. There are few treatment situations where there are true clinical substitutes, with one costing less than the other. For example, multiple myeloma is a cancer of the bone marrow that without treatment has an average survival of 7 months. In the last 13 years the introduction of innovative therapies like bortezomib and lenalidomide has changed the average 3 year survival of myeloma patients from 50% to greater than 88%. It is now common to see patients living with multiple myeloma as a chronic disease for more than a decade. Avoiding these novel high cost therapies in myeloma would cost myeloma patients years of survival.

Phase 1 of the “Part B Drug Payment Model” places the oncologist in an impossible situation. CMS is using a substantial financial disincentive to block use of the most appropriate, often more expensive, standard-of-care treatment in favor of a less appropriate therapy, if one exists at all. This is simply bad medicine.

No Evidence for Phase 1 of the “Part B Drug Payment Model”

While the OCM seeks to incentivize improved care coordination for a six-month episode of chemotherapy, the “Part B Drug Payment Model” is only focused on reducing Medicare drug spending.

---


In the proposed rule, CMS recommends Phase I of the “Part B Drug Payment Model,” which is a reduction in the Part B drug reimbursement rate, because the agency believes that providers’ prescribing decisions are influenced by reimbursement incentives for higher priced drugs. Yet, CMS has yet to produce any evidence indicating that physician prescribing patterns show any correlation to that of choosing higher priced drugs as opposed to appropriate therapeutic treatment for patients. Additionally, there is no evidence that the payment changes contemplated by CMS’ model will improve the quality of care, or for that matter, ensure patients have access to the same level of care they are currently receiving.

In fact, data suggest that the current Part B drug payment system has been both cost effective and successful in ensuring patient access to their most appropriate treatment, as Part B expenditures remain relatively stable and Part B drugs account for just 3 percent of total program costs.7

Additionally, there is no evidence that the payment changes contemplated in the “Part B Drug Payment Model” will reduce spending. In fact, a recent UnitedHealthcare project, which eliminated any financial benefit from drugs for participating community oncology practices, proved the opposite. According to the study, “eliminating existing financial chemotherapy drug incentives paradoxically increased the use of chemotherapy.” The spending on drugs increased by 179 percent.8

It is critical to note that, although spending on drugs increased by a substantial amount, total cost of medical care decreased by more than 30 percent. This intervention focused on the entire system of

---

8 Journal of Oncology Practice: Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model. Available at: http://jop.aonc.org/content/10/5/322.full
care delivery and not solely on the cost of drugs. In another study that analyzed oncologists’
prescribing under the current Medicare Part B drug reimbursement system, researchers found
that, “[c]hanges in reimbursement after the passage of MMA appear to had less of an impact on
prescribing patterns in FFS [fee-for-service] settings than the introduction of new drugs and
clinical evidence as well as other factors driving adoption of new practice patterns.”⁸

Any government led initiative on significant payment reform must have the appropriate supporting
data before nationwide changes to the delivery system are employed. While CMMI has broad
authority, any initiatives should be developed and implemented in a more targeted, contained,
patient-centered, and transparent way that accounts for the unique needs of Medicare patients and
with input from affected stakeholders. Medicare beneficiaries with cancer must be assured the
appropriate patient safeguards are in place for any mandatory payment and delivery reform that has
the potential to impact their access to care and treatments.

Understanding of the Current Part B Reimbursement Model

Another important piece to note from the “Part B Drug Payment Model” is the incorrect assumption
CMS makes about the rate at which physicians are currently reimbursed for Part B drugs.
Specifically, in the proposed rule, CMS states that “we have chosen a 2.5 percent starting point
because we agree with MedPAC’s assessment that this value should be sufficient to cover markups
from wholesalers, such as prompt pay discounts that are not passed on to the purchaser.” While CMS
has included the 2.5 percent to address the prompt pay discount it has not accounted for the 2
additional factors that significantly diminish reimbursement under Part B. These are:

1) The 2 percent Medicare sequester cut that CMS decided to apply to the underlying cost of Part B drugs and;

2) The six-month lag that occurs between the time when drug prices change in the market place and when CMS updates ASPs.

CMS knew when it proposed the Phase I “Part B Drug Payment Model” experimental reimbursement rate of ASP plus 2.5 percent and a flat fee of $16.80 that the sequester cut alone reduces the real rate to ASP plus 0.86 percent and $16.53. The impact of the prompt pay discount and the ASP lag places the rate effectively “underwater”—that is, most treatment drugs will be reimbursed less than their acquisition cost. Hopefully, you can understand that this is an unsustainable situation where independent practices could simply not stay financially viable if they do not stop treating Medicare patients.

Additionally, it is important to note that smaller practices purchase many Part B drugs over ASP. These practices are not able to gain price advantages such as volume related discounts available to hospitals and large practices. It is often hospitals that receive Medicaid rebates, 340B discounts, and better prices on drugs, due to the volume of purchase. Many of community oncology practices are currently paying well above ASP for drugs, which is why in oncology we have experienced practice closings and mergers with hospitals over the past 10 years. Further impacting community-based practices are state taxes levied on prescription medicines, gross receipts, and provider services. Any further reductions to reimbursement will make it impossible for them to cover the acquisition cost of many, if not most, cancer treatments.

Site of Service Shift
This Committee is well aware of the recent trend in hospital acquisitions of physician practices and how this has resulted in access and cost issues for Medicare beneficiaries. I would like to commend the Committee for its efforts in understanding and exploring payment differentials and the incentives for hospitals to purchase physician practices. More specifically, I appreciate the work of Congressman Pompeo and others on the Committee for their efforts to ensure patient access to the community-based oncology setting by leveling the playing field in reimbursement for cancer care with the Medicare Patient Access to Treatment Act (H.R. 2895).

In an era of hospital acquisitions and consolidation in the oncology space, drastic changes in reimbursement, like those being proposed in the “Part B Drug Payment Model,” will most certainly further push oncology care into the hospital outpatient setting. I note that treating patients in community-based cancer clinics, as opposed to the outpatient hospital setting, results in significantly lower costs to both patients and the Medicare program.

Unfortunately, over the last decade there has been a marked shift in the site of cancer care from independent community cancer practices to more expensive outpatient hospital departments (HOPDs). In 2004, 84 percent of chemotherapy was administered in community cancer clinics but that has fallen to 54 percent by 2014.10 In 2014, Medicare spending on a per-beneficiary basis for patients receiving chemotherapy was 34 percent higher in HOPDs than independent community oncology practices.11

It is not just the Medicare program paying more for these services, patient out-of-pocket costs are approximately 10 percent lower in community clinics, equaling more than $650 in savings for each

10 See supra, n 4
11 See supra, n 4
Medicare beneficiary fighting cancer per year. Additionally, the average out-of-pocket patient cost for commonly used cancer drugs is $134 less per dose if received in an oncologist’s office.\textsuperscript{12}

These costs add up. Between 2009 and 2012, Medicare beneficiaries paid $4.05 million more in out-of-pocket costs because of the higher patient co-payment due to the HOPD for chemotherapy services that could have been performed at a community cancer practice for a fraction of the cost.\textsuperscript{13}

This February, a study released by the Health Care Cost Institute, confirmed that increased medical provider consolidation with hospitals and/or health systems results in increased spending on outpatient prescription drug-based cancer treatment. Specifically, that study found that “a one percent increase in the proportion of medical providers affiliated with hospitals and/or health systems is associated with a 34 percent increase in average annual spending per person and a 23 percent increase in the average per person price of treatment.”\textsuperscript{14}

The cost to Medicare of the shift in the site of cancer care is staggering. Looking at just chemotherapy costs alone, if the shift from independent community oncology practices to HOPDs from 2004 to 2014 had not occurred the costs to Medicare of chemotherapy alone would have been $2 billion less in just 2014.\textsuperscript{15}

CMS is well aware of this data and the shift of care, especially as it relates to cancer, as I was accompanied by several of my oncologist colleagues in reviewing it with officials from CMS and

\textsuperscript{12} Milliman, “Site of Service Cost Differences for Medicare Patients Receiving Chemotherapy,” October 2011.


\textsuperscript{14} Health Care Cost Institute, “The Impact of Provider Consolidation on Outpatient Prescription Drug-based Cancer Care Spending,” February 25, 2016.

\textsuperscript{15} See supra, n.4.
CMMI. It is unfortunate CMS does not seem to recognize this proposal would force some oncologists to close their community-based practices or consolidate with hospital systems that can negotiate much better rates on drugs and charge more for the same service, especially the 50 percent of hospitals with 340B discounts with upwards of 100 percent profit margins on cancer drugs. It is clear, based on empirical evidence and data that the “Part B Drug Payment Model” would end up costing Medicare and the entire health care system more than they hope to save with this proposal.

Value-Based Care

Oncologists have been leaders in the field of medicine when it comes to value-based care. We have worked hard to put systems, pathways, models, and treatment plans in place that provide high quality health care at a lower rate. We applaud CMMI and CMS for looking towards value-based care, and would welcome the opportunity to have a real discussion about what value-based care could look like in the oncology space. I have chaired the breast cancer pathways for The US Oncology Network for a decade and recognize this system as an effective way to deliver excellent cancer care. By using systems to incorporate efficacy, toxicity, and cost (in terms of comparative effectiveness), the pathways system facilitates compliance with evidence based guidelines and value based decision making.

As I continue to actively participate in crafting the scientific and policy agendas at the largest cancer organizations across this county, The US Oncology Network, COA and ASCO, we strive to find more value in cancer care every day. Our organizations have taken concrete steps to achieve this goal. The US Oncology Network has developed value-based pathways that serve to strengthen relationships with patients and payers by choosing regimens that demonstrate value and reduce non evidence-based variability in treatment. ASCO has put forward the Patient Centered Oncology
Payment (PCOP) model and—for more than a decade—has helped oncologists measure and improve performance through the Quality Oncology Practice Initiative (QOPI), and the QOPI Certification (QCP) program. As a board member for COA and in partnership with this Committee, we help craft a bipartisan congressional oncology payment reform bill, the Cancer Care Payment Reform Act (H.R. 1934), based on the Oncology Medical Home—a model actually successfully tested by CMMI in enhancing the quality of care and reducing costs. I want to thank Congresswoman Cathy McMorris Rodgers on her commitment to cancer care with this legislation.

There is no shortage of ideas from the oncology community on how we can drive value in cancer care. This Committee has been very open to those ideas and committed to preserving access to high-quality, affordable health care. As CMS and CMMI look to change those dynamics and dictate a top down approach with no input from stakeholders, it will become extremely hard for community oncologists to continue practicing appropriate medicine.

**Conclusion**

The National Cancer Institute estimated that there were approximately 13.7 million Americans living with cancer in the U.S. last year. About 8 million of those are over the age of 65 and approximately half of all cancer spending is associated with Medicare beneficiaries. As the baby boomers continue to age, this challenge will only become greater. Now is the time for Congress to ensure Medicare beneficiaries can continue to get the care they need—in the communities where they live and work—and that their providers have the tools and ability to choose the best treatment plan for their unique circumstances. The government should be

---

helping us deal with the expanding cancer population, not throw obstacles in our way, such as the “Part B Drug Payment Model.”

Please know that community oncology providers stand ready to partner with CMS and CMMI on value-based strategies for cancer care, including ways to address cost of drugs and services. We remain concerned with the increased cost of cancer care, especially as it relates to escalating drug prices, but any reform efforts must first do no harm—and must assure Medicare patients’ access to care that is vital to their quantity and quality of life. The proposed “Part B Drug Payment Model” does neither.

On behalf of oncologists nationwide, I appreciate the Committee’s leadership and dedication to our nation’s health care system in examining this issue. Thank you to those that have weighed in with CMS on your concerns with the proposed rule, and thank you to Congressman Bucshon for sponsoring H.R. 5122, which would prohibit the proposed “Part B Drug Payment Model” from advancing. It is important to look at the big picture: I believe there are serious flaws in the proposal that could affect our most vulnerable seniors in the middle of treatment. CMS should work with oncologists, and all affected stakeholders, especially patients, in crafting true value-based treatment going forward. When community cancer clinics close their doors, access to care is compromised for all cancer patients, but especially for our vulnerable seniors. The continued shift to hospital–based care doesn’t just reduce access to care for cancer patients, especially in rural areas, but it also increases costs to Medicare, taxpayers, and beneficiaries.
Finally, in addition to H.R. 2895 and H.R. 1934 mentioned above, I would like to highlight and thank several members of this Committee who have written legislation and signed letters that assist in preserving community cancer care. Specifically, H.R. 696, sponsored by Congressmen Whitfield, Green, and DeGette, which would result in a more accurately aligned Part B drug reimbursement by removing any discount between the manufacturer and distributor that is included in ASP but not passed on to the provider. H.R. 1416, introduced by Congresswoman Renee Ellmers, which would remove CMS’ decision to apply the 2 percent sequestration cut to the underlying cost of cancer drugs. On behalf of all the community cancer clinics struggling to keep their doors open, I urge the Committee and the Congress to enact these pieces of legislation to sustain community cancer care. Without your action, community cancer clinics will continue to close and care will continue to shift to the more expensive, less-accessible hospital outpatient setting. Americans fighting cancer will experience diminished access to care, and patients, payers, and taxpayers will pay more.

My oncology colleagues across the country and I are doing our very best to help patients fight cancer, and win. In order to continue to provide the world’s best cancer care in America, we need your help. Once again, thank you for the opportunity to address the Committee. I am happy to answer any questions the Committee has regarding my testimony.
Mr. PITTS. The Chair thanks the gentlelady and now recognizes Dr. Schweitz, 5 minutes for your opening statement.

STATEMENT OF MICHAEL SCHWEITZ

Dr. SCHWEITZ. Thank you, Chairman Pitts and Ranking Member Green, for inviting me to testify today on behalf of the Alliance of Specialty Medicine and the Coalition of State Rheumatology Organization.

The alliance is a coalition of national medical societies representing specialty physicians in the United States. The CSRO is a group of State and regional rheumatology societies primarily made up of community practitioners formed to ensure access to the highest quality care for rheumatologic disease.

I am a practicing physician and I spend the vast majority of my time taking care of patients. I am here today to discuss our concerns regarding the Part B demonstration project and to support Dr. Bucshon’s bill, H.R. 5122.

I note for the committee that our concerns track those expressed in the letter CSRO signed together with more than 300 stakeholders urging withdrawal of the demo.

We have expressed our procedural concerns in my written testimony. But today I will focus on our substantive concerns including prescriber behavior, patient access and sustainability.

First, clinical decision making is not influenced by the add-on cost. We take issue with the underlying premise of the rule which is the belief by CMS that clinical decision making is driven by the opportunity to maximize revenue.

Data supporting this premise is not existent. In fact, in a recent report by Magellan it looked at utilization of rheumatoid arthritis medications and found that physicians are not routinely prescribing the most expensive product.

In fact, in 2014 in the physician’s office the most expensive product was one of the least prescribed. Second, many rheumatology practices will be unable to absorb this reduction. The current 6 percent add-on already results in practices without volume purchasing power, being underwater on several products.

A reduction from 6 to 2.5 percent plus a nominal flat fee will result in unsustainable cuts, especially considering that CMS did not incorporate the impact of sequestration in its calculations.

Specifically, the current reimbursement level is actually ASP+4.4 percent. Accounting for sequestration, the new rate will be ASP+0.86 percent with a flat fee.

Rheumatology is a specialty of small practices. For example, in my State there are only a few practices with seven or more doctors. Many practices with one or two rheumatologists do not have the purchasing power to buy at ASP.

Third, and most importantly, is the impact on our patients. As a result of these unsustainable cuts, if the demo moves forward patients will lose access to office-based infusions.

CSRO surveyed its members to ascertain the behavioral response to the CMS proposal and 73.08 percent of respondents said that infusible Part B biologic options would no longer be available for Medicare patients in their offices—44.87 percent of respondents
noted that they would refer to hospitals or external infusion centers to continue therapy.

Hospital referrals will create challenges for patients with rheumatoid arthritis including the distance to an outpatient center and increased personal cost to beneficiaries, especially those in rural areas.

It also runs counter to the goals of the model as costs of the Medicare program will be higher when patients must receive therapy in the outpatient department instead of the physician’s office.

Fourth, value-based purchasing cannot be one size fits all and will require significant stakeholder input through pre-rulemaking engagement. One of the concepts in Phase II are interesting to explore while we believe they are not developed enough yet to even be in a proposed rule since they do not contain enough detail for comment meaningfully.

In addition, in rheumatology we don’t have comparative affecting this data to compare treatments. There are very few studies that do that. On average, it takes two or more drugs in sequence before finding the one that the patient responds to.

And finally, the cost of these drugs are closely grouped so there is little reason to apply tools such as reference pricing.

In conclusion, the alliance and CSRO appreciates CMS’ concern about high drug prices and would like to work with the Congress and the administration to find solutions.

However, we must oppose the Part B drug payment model as it suffers from serious procedural and substantial flaws that we believe render it unworkable and it does nothing to actually address the issue of drug costs.

As such, we have requested that CMS withdraw the model and we urge the committee to do the same. The alliance and CSRO thank the committee for its attention to this critical topic and for the opportunity to provide the views of practicing rheumatologists on the Part B model.

[The statement of Dr. Schweitz follows:]
STATEMENT OF MICHAEL SCHWEITZ, MD, FACP MACR

On behalf of the

COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS
and the

ALLIANCE OF SPECIALTY MEDICINE

before the

ENERGY AND COMMERCE COMMITTEE
HEALTH SUBCOMMITTEE

May 17, 2016

The Alliance of Specialty Medicine (the Alliance) is a coalition of national medical societies representing specialty physicians in the United States. This non-partisan group is dedicated to the development of sound federal health care policy that fosters patient access to the highest quality specialty care.

The Coalition of State Rheumatology Organizations, or CSRO, is a group of state and regional professional rheumatology societies formed in order to advocate for excellence in rheumatologic disease care and to ensure access to the highest quality care for the management of rheumatologic and musculoskeletal diseases. Our coalition serves the practicing rheumatologist in charge of patient care for these illnesses. CSRO is a member of the Alliance.

Appropriate Medicare coverage of and reimbursement for treatment are critical for our patients, which is why we are very concerned about the Part B Drug Payment Model (“the model”) proposed by CMS. I appreciate the opportunity to share the views of the many clinicians CSRO represents who see patients on a
daily basis. Specifically, my testimony will focus on the process and procedural concerns, as well as our substantive concerns including prescriber behavior, patient access, and sustainability.

THE MODEL

CMS proposes to modify the average sales price (ASP) add-on amount over the course of a two-phase demonstration. Under Phase I, CMS would create two study cohorts; one cohort would receive Part B drug payments under the current payment methodology (ASP+6 percent), whereas the other cohort would receive a reduced add-on payment (ASP+2.5 percent) plus a flat fee of $16.80. Under Phase II, CMS would create two additional study cohorts of the same but add value-based purchasing (VBP) tools currently employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization. CMS proposes that Phase I would begin in Summer 2016; Phase II would begin as soon as January 1, 2017. Specific to the VBP strategies, CMS proposes to allow 30 days for public comment and would provide a minimum of 45 days public notice before implementation.

As rheumatologists, we are on the frontlines treating actual patients with Part B drugs. We are keenly aware of the unsustainable rise in drug costs and the effects of those costs on our patients’ ability to adhere to their treatment regimens. While we appreciate CMS’s attention to the topic of drug costs, we feel that this proposal is misguided. As CMS acknowledges in the rule, the proposed approach “does not directly address the manufacturer’s ASP, which is a more
significant driver of drug expenditures than the add-on payment amount for Part B drugs.” Given that a slash to the ASP add-on is unlikely to actually lower costs for patients (and, as explained below, may increase it in some cases) and may jeopardize access, we have requested that CMS withdraw the model and we urge the Committee to do the same.

**PROCESS CONCERNS**

In early February 2016, CMS posted guidelines to contractors about the Medicare Part B Drug Payment Model, which proposed changes to the Average Sales Price (ASP) methodology for Part B drug reimbursement. This demonstration project would be mandatory for zip codes identified by CMS. The posting appeared to have happened erroneously, as the agency quickly removed the guidelines from its website. This posting and its subsequent hasty removal greatly worried us, as it indicated a major payment change was well underway, even though CMS had not engaged in any pre-rulemaking dialogue such as town halls or Requests for Information.

Rather than pause to address these concerns, CMS only seemed to accelerate its timeline for beginning this sweeping payment change. Within a month, CMS issued the proposed rule containing the model.

Executive Order 13563 (January 11, 2011) explains that, "Before issuing a notice of proposed rulemaking, each agency, where feasible and appropriate, shall seek the views of those who are likely to be affected, including those who are likely to
benefit from and those who are potentially subject to such rulemaking.” Apart from the erroneous posting for contractors described above, CMS did not engage affected stakeholders in an open, transparent manner to inform and improve the proposed regulation.

CMS has employed pre-rulemaking engagement strategies in developing the requirements associated with new physician payment programs established under the Medicare Access and CHIP Reauthorization Act (MACRA). It is unclear why CMS refused to utilize that process for the Part B Drug Model, particularly in light of the tremendous impact it will have on providers and patients. We see CMS’ process as a blatant overstep and abuse of its statutory authority.

PROCEDURAL CONCERNS

The Affordable Care Act authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing the quality of care furnished to beneficiaries. However, the scope of the Model far exceeds any reasonable definition of a “test” and is so expansive as to constitute a program change.

First, with very limited exceptions, the Model will include all Part B drugs. Second, CMS proposes to mandate participation by all providers who prescribe Part B drugs. The model can no longer be considered a “demonstration” when it is scaled nationwide (excluding Maryland) and will apply to all Part B medicines. Third, the length of the demo – five years – is an unusually long time period for a project that is intended to merely test a new
payment structure. Given that Congress statutorily defined the ASP methodology and add-on in section 303 of the Medicare Modernization Act of 2003, it is an inappropriate overreach of regulatory authority for CMS to force changes to this formula.

**SUBSTANTIVE CONCERNS**

*Clinical decision-making is not influenced by the add-on percentage.*

In the proposed rule, CMS notes that the "ASP methodology may encourage the use of more expensive drugs because the 6 percent add-on generates more revenue for more expensive drugs[.]" In other words, CMS implies that clinical decision-making by physicians is driven by the opportunity to maximize revenue. Yet, a recent report by Magellan studied utilization of rheumatoid arthritis medicines and found that physicians are not routinely prescribing the most expensive product. In fact, in 2014, in the physician’s office, Remicade was used 50% of the time. Rituxan was prescribed only 11% of the time, despite the fact that ‘Rituxan ($20,205) and Ocrevus ($15,892) costs were higher than Remicade ($15,312)[.]’¹ The entire graph is included below:

---

In the proposed rule, CMS cites MedPAC data in support of its assertion that clinical decisions are driven by revenue generation. However, MedPAC noted that, “it is difficult to know the extent to which the percentage add-on to ASP is influencing drug prescribing patterns because few studies have looked at this issue.” At a minimum, there are conflicting data on this point and, as such, these data should not drive a Medicare program overhaul as expansive as this one.

Many rheumatology practices will be unable to absorb this reduction.

The current six percent add-on already results in practices without volume purchasing power being “underwater” on several products. A reduction from 6% to 2.5% plus a $16.80 flat fee will result in unsustainable cuts, especially considering that CMS did not incorporate the impact of sequestration in its calculations. Specifically, the current reimbursement level is actually ASP plus 4.4% and, accounting for sequestration means the new rate will be ASP

---

plus 0.86% with a flat fee. We gathered some illustrative data from CSRO member practices:

<table>
<thead>
<tr>
<th>Practice Location</th>
<th>Practice Size</th>
<th>Drug</th>
<th>Purchase Price</th>
<th>Reimbursement Level (reflecting sequestration)</th>
<th>Differential</th>
<th>% +/-</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bethlehem, PA</td>
<td>2</td>
<td>Rituxan</td>
<td>$7,328.12</td>
<td>$7,567.10</td>
<td>$238.98</td>
<td>3.26%</td>
</tr>
<tr>
<td>Fremont, CA</td>
<td>2</td>
<td>Prolia</td>
<td>$904.41</td>
<td>$914.47</td>
<td>$10.06</td>
<td>1.11%</td>
</tr>
<tr>
<td>West Chester, PA</td>
<td>2</td>
<td>Benlysta</td>
<td>$3,715.20</td>
<td>$3,752.84</td>
<td>$37.64</td>
<td>1.01%</td>
</tr>
<tr>
<td>New Orleans, LA</td>
<td>4</td>
<td>Actemra</td>
<td>$2,408.96</td>
<td>$2,395.61</td>
<td>$-13.34</td>
<td>-0.55%</td>
</tr>
<tr>
<td>Riverview, FL</td>
<td>1</td>
<td>Euflexxa</td>
<td>$148.00</td>
<td>$146.71</td>
<td>$-1.29</td>
<td>-0.87</td>
</tr>
</tbody>
</table>

We hope that this data can help illustrate a few things. First, rheumatology practices are not getting wealthy off Part B drug purchases and, in fact, some practices are underwater on certain products. Second, there is no one factor that predicts whether a practice will be able to purchase at ASP. It depends on the volume of the purchase, the size of the practice, the ability to negotiate a rebate, and other factors. We have extended an offer to CMS to gather additional data from practices, should the agency wish to delve into these financial details, and
we extend that same offer to the Committee.

Additionally, the two-quarter delay in ASP uniquely affects small and rural practices, and this would only be exacerbated by a reimbursement reduction. The ASP at which a practice is reimbursed is two quarters behind the current prices. Given the fast and sharp increases in prices each and every quarter, this often puts a practice underwater for the medicines it is purchasing, even if it is able to purchase at ASP.

With regard to sustainability for the Medicare program, a far greater concern than the add-on percentage is the underlying ASP, and the steep, fast price increases that these medicines show each quarter. We included here a graph showing price increases for two representative rheumatology products from the first quarter of 2007 through the first quarter of 2016:

[Bar chart showing price increases for Remicade and Orencia from Q1 2007 to Q1 2016]
As noted above, these are only two representative products, but this trend is true across all Part B rheumatologic medicines. These ASP increases are unsustainable for both the Medicare program and its beneficiaries. However, the model does nothing to actually address the underlying prices.

**Patients will lose access to office-based infusions.**

Because the Model will include nearly all Part B drugs, rheumatologists may be forced to switch patients to alternative drug therapies, even if those patients are stable on their current medicines. This may be the case when the treating physician can no longer offer infusions, but there is no nearby hospital-based infusion center that the patient can travel to. Switching stable patients for non-clinical reasons violates the most basic teachings of rheumatology as it can result in loss of control over the disease – control that may not be regained even if the patient is switched back to the original product. This places patients at unnecessary risk and increases healthcare costs due to the potential for adverse reactions and loss of effectiveness.

As noted above, physicians may be forced to send patients to the closest hospital outpatient department to receive the needed medications. CSRO surveyed its members to better ascertain the behavioral response to the CMS proposal, and 73.08% of respondents said that infusible Part B biologic options would no longer be available for Medicare patients in their offices. 44.87% of respondents noted that they would refer to hospitals or external infusion centers
to continue therapy.

Hospital referrals will create financial challenges for patients who cannot afford the higher cost-sharing – for the exact same treatment. In Part B, most beneficiaries have wraparound coverage, so while the patients may not bear the increased financial costs directly, traveling to the hospital outpatient department is inconvenient and can be challenging for patients with rheumatoid arthritis, depending on the distance to the nearest hospital-based infusion center. It also runs counter to the goals of the model, as the cost to the Medicare program will be significantly higher when patients must receive therapy in the outpatient department instead of the physician’s office. Oddly, CMS states in the preamble of the proposed rule that growth in drug spending has largely been driven by spending on separately paid drugs in the hospital outpatient setting, which more than doubled between 2007 and 2015, from $3 billion to $8 billion, respectively.

The following graph illustrates the varying cost of medicines, depending on the setting, and supports the fact that the physician’s office is the cheapest setting to infuse rheumatologic medicines.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Cost per Unit</th>
<th>Cost per Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hospital Outpatient</td>
<td>Home Infusion/ Specialty Pharmacy</td>
</tr>
<tr>
<td>Botux</td>
<td>$5.89</td>
<td>$5.57</td>
</tr>
<tr>
<td>Gamagenpic Liquid</td>
<td>$42.83</td>
<td>$50.33</td>
</tr>
<tr>
<td>Garucix/OxGanmedic</td>
<td>$47.19</td>
<td>$42.80</td>
</tr>
<tr>
<td>Herceptin</td>
<td>$99.87</td>
<td>$80.62</td>
</tr>
<tr>
<td>Nevastax</td>
<td>$2,392</td>
<td>$2,691</td>
</tr>
<tr>
<td>Oncia</td>
<td>$189.79</td>
<td>$189.79</td>
</tr>
<tr>
<td>Remiclae</td>
<td>$563.40</td>
<td>$563.40</td>
</tr>
<tr>
<td>Zoins</td>
<td>$209.85</td>
<td>$189.44</td>
</tr>
<tr>
<td>Vigea/Hista</td>
<td>$57.69</td>
<td>$57.69</td>
</tr>
<tr>
<td>Verexy</td>
<td>$182.62</td>
<td>$127.62</td>
</tr>
</tbody>
</table>
Finally, not all patients have hospitals nearby that offer infusions. We have found that most of the hospitals still offering infusion centers are 340B hospitals. Non-340B hospitals have mostly closed down their infusion centers due to a lack of profitability. Since 340B hospitals are not present in every area of the country, this may force beneficiaries to travel long distances to receive treatment, should their physician be unable to continue infusing them.

Value-based purchasing cannot be one-size-fits-all and will require significant stakeholder input through pre-rulemaking engagement.

With regard to some of the value-based purchasing ideas proposed by CMS for Phase 2, we offer the following feedback.

- A cost-sharing reduction (or even elimination) for beneficiaries would relieve a lot of the financial pressure our patients feel when they enter Medicare. In the private insurance market, patients can often use coupons to offset the large coinsurances they are responsible for. When they enter Medicare Part D, this is no longer an option as the program prohibits such assistance. For Medicare Part B, however, beneficiaries often have supplemental insurance that covers some or all of the twenty percent coinsurance for their medicines. Thus, it is unclear what a reduction in cost-sharing for Part B medicines would accomplish other than allow supplemental insurers to pay less. This would do nothing to actually reduce costs for beneficiaries. A more effective proposal would look at
Medicare drug coverage in its entirety and explore lifting the ban on cost-sharing assistance for Part D medicines.

- The reference pricing concept did not have enough detail in the proposed rule to meaningfully comment on. Rheumatologic Part B medicines may be good candidates for reference pricing, since the ASPs are mostly clustered together. However, the challenge will be setting a reasonable reference price, figuring out how to make the manufacturer bear the risk in a purchasing system that currently puts the purchaser at risk, and, finally, figuring out how biosimilars will fit into such a reference pricing structure in a way that does not automatically drive all patients onto the biosimilar, even in cases when that is not clinically appropriate. We are concerned that CMS has not thought through any of these aspects.

- Indication-based pricing is a concept that is difficult to envision in rheumatology because there is no population-level data indicating what biologics work better than others for patients with rheumatoid arthritis. Indeed, there are robust rheumatology registries that have not yet yielded such data, likely because autoimmune disease may not lend itself to these types of studies. Additionally, it is unlikely that manufacturers would commit funds for head-to-head studies that may prove their product is inferior to another.

CONCLUSION

The Alliance and CSRO appreciate CMS’s concern about high drug prices and
would like to work with the Congress and the Administration to find solutions. However, we must oppose the Part B Drug Payment Model as it suffers from serious procedural and substantive flaws that we believe render it unworkable – and it does nothing to actually address drug prices. As such, we have requested that CMS withdraw the model and we urge the Committee to do the same.

In closing, the Alliance and CSRO thank the Committee for its attention to this critical topic and for the opportunity to provide the views of practicing specialists on the Part B model.
Mr. Pitts. Chair thanks the gentleman and now recognizes Ms. Boyle, 5 minutes for her opening statement.

STATEMENT OF MARCIA BOYLE

Ms. Boyle. Well, thank you, Chairman Pitts, Ranking Member Green and all members of the subcommittee for inviting me to testify today on behalf of the Immune Deficiency Foundation, or IDF.

IDF is the national patient organization founded in 1980 dedicated to improving the diagnosis, treatment and quality of life of people with primary immunodeficiency diseases through advocacy, education and research.

Primary immunodeficiency, or PI, represents a group of more than 250 rare chronic genetic diseases in which part of the body’s immune system is missing or functions improperly, resulting in decreased ability to fight infection.

Approximately 250,000 people are diagnosed with PI in the United States. Many require lifelong lifesaving treatment with immunoglobulin replacement therapy, or IG therapy, to replace antibodies needed to fight infection.

When patients cannot access IG, their lives are threatened and they experience more doctor visits, hospitalizations and time away from work and school.

I’m here today representing IDF and patients of PI, including my own son, who was diagnosed as an infant. We have serious issues with the Part B model and have asked CMS to withdraw it.

In addition, we signed a letter expressing these concerns led by the Arthritis Foundation and 24 groups representing millions across the country with wide ranging conditions such as lupus, mental illness, cancer and the healthcare needs our veterans face.

Our concerns are rooted in our experience with the previous Medicare reimbursement change that resulted in many of our Medicare patients losing access to their lifesaving treatment.

Starting in 2005, there was significant reductions in reimbursement for IG products as a result of the Medicare Modernization Act, which changed Part B drug reimbursement from the average wholesale price to ASP+6 percent.

In 2007, two studies by HHS reported on the difficulties physicians and specialty pharmacies had obtaining IG at the Medicare reimbursed price and the impact on patients’ ability to obtain their infusions.

One noted the 61 percent of responding physicians that they had sent patients to hospitals for IVIG treatment because of their inability to acquire adequate amounts of IVIG or problems with Medicare payment.

But the problems were even bigger than that. Many patients lost access to IG not only in the physician’s office but in the home as well. Thankfully, Congress responded by passing the Medicare IVIG Access Act with overwhelming support including support from every member of this subcommittee who was in Congress at that time.

This demonstration is currently underway and IDF anticipates it will lead to a permanent fix in the current Medicare home infusion benefit for IVIG.
We are not crying wolf. Patients with PI have personally experienced the unintended consequences of major payment changes, which is why we wish CMS had engaged in more pre-rulemaking dialogue with stakeholders before issuing such a sweeping proposal that will dramatically impact beneficiaries.

In addition, our fear is that the proposed Part B model which explicitly includes the ongoing Medicare IVIG access demonstration will undercut this demo. Some specialty pharmacies report that they are already close to underwater with ASP+6 and low payment for their items and services.

With regard to the so-called value-based purchasing tools contemplated by CMS for Phase II of the model there is insufficient detail on the concepts proposed to comment one way or the other and this is particularly troubling because we have never seen any definition around what value actually means particularly to patients.

Our patients have extensive experience with private insurers using the word value as a guise for implementing cost cutting tools that deny or delay access to needed treatments.

This experiment needs significant stakeholder input and requires true dialogue with those who will be affected, especially patients. We also have procedural concerns with the model. The innovation center is authorized to test innovative delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to beneficiaries.

However, the model is not a test. It contains a Medicare program change. In addition, we are concerned that this policy change does not preserve or enhance the quality of care for beneficiaries. In fact, we are convinced it will reduce quality and access for our patients.

In conclusion, IDF has urged CMS to withdraw the Part B drug payment model and request the Congress do everything in its power to stop this harmful experiment from moving forward. It jeopardizes beneficiary access to needed medications, is the result of an opaque and poorly thought out process and may actually increase costs to the Medicare program.

I thank the committee for its attempt to create accountability in the CMS process and for the opportunity to present the potential implications of the model for patients with PI.

[The statement of Ms. Boyle follows:]
The Immune Deficiency Foundation (IDF), founded in 1980, is the national patient organization dedicated to improving the diagnosis, treatment, and quality of life of persons with primary immunodeficiency diseases through advocacy, education, and research. On behalf of the thousands of patients we represent, we thank the Committee for its scrutiny of the Medicare Part B Drug Payment Model proposed by the Centers for Medicare and Medicaid Services (CMS) and for providing IDF the opportunity to present the patient perspective.

Primary immunodeficiency, or PI, represents a group of more than 250 rare, chronic genetic diseases in which part of the body's immune system is missing or functions improperly, resulting in a decreased ability to fight off infection. Throughout their lives, people with PI are more susceptible to infections, endure frequent health problems, including a number of other comorbidities, and can develop serious and debilitating illnesses.
Approximately 250,000 people are diagnosed with PI in the U.S. Depending upon the type of PI, treatments can include prophylactic antibiotic therapy, bone marrow transplantation, enzyme replacement, interferon gamma and antifungals. Patients with PI who have a lack of and/or impaired antibody function require lifelong, lifesaving treatment with immunoglobulin replacement therapy (Ig therapy), partly replacing what the body should be making and protecting them from infection. Today, with early diagnosis and appropriate therapies, such as Ig, many patients diagnosed with PI can live healthy, productive lives.

With that background, we provide the comments outlined below.

PROPOSED PART B DRUG PAYMENT MODEL

CMS proposes to modify the average sales price plus 6 percent (ASP+6%) add-on amount over the course of a two-phase demonstration. Under Phase I, CMS would create two study cohorts; each representing 50% of all providers administering Part B drugs. One cohort would receive Part B drug payments under the current payment methodology (ASP+6%), whereas the other cohort would receive a reduced add-on payment (ASP+2.5%) plus a flat fee of $16.80. Given that 2% of the add-on payments is already under sequester, the proposed reimbursement is effectively ASP+.5% plus $16.85.
Under Phase II, CMS would create two additional study cohorts using the same payment structures but add value-based purchasing (VBP) tools currently employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization. CMS proposes that Phase I would begin in Summer 2016; Phase II would begin as soon as January 1, 2017. Specific to the VBP strategies, CMS proposes to allow 30 days for public comment and would provide a minimum of 45 days public notice before implementation. Provider inclusion in the demo will be determined by randomly selected zip codes and, with very limited exceptions, all Part B drugs will be subject to the demo – including immunoglobulin (Ig).

IDF has serious concerns about the model and have asked CMS to withdraw it, for the reasons outlined below. We are not the only patient group with concerns: we joined 23 other patient groups representing millions of patients across the country to send a letter to Congress, expressing opposition to the demo. We hope the Committee will consider the serious concerns expressed by patients and prevent this harmful project moving forward.

**SUBSTANTIVE CONCERNS WITH THE MODEL**

**PHASE 1**

With regard to Phase 1, patients with PI are leery of reimbursement changes because our patient population has experienced severely compromised access to care in the past as a result of Medicare reimbursement changes. Specifically, starting in 2005,
patients with PI saw significant reductions in reimbursement as a result of the 2003 Medicare Modernization Act (MMA), which changed Part B drug reimbursement from the Average Wholesale Price (AWP) to ASP plus 6%. Two studies by the Health and Human Services Office of Inspector General (OIG) (http://oig.hhs.gov/oei/reports/oei-03-05-00404.pdf) and the Assistant Secretary for Planning and Evaluation (ASPE) (https://aspe.hhs.gov/sp/reports/2007/IGIV) reported in 2007 the difficulties physicians and specialty pharmacies had obtaining Ig products at the Medicare reimbursed price and the impact on patients' ability to obtain their infusions. The HHS OIG reported to Congress that, "Sixty-one percent of responding physicians indicated that they had sent patients to hospitals for IVIG treatment because of their inability to acquire adequate amounts of IVIG or problems with Medicare payment."

Many patients lost access to Ig in the physician’s office as well as in the home. As a result of the MMA cuts, intravenous immunoglobulin (IVIG) therapy (the only Ig therapy at the time) in the physician’s office was nearly eliminated because physicians could not afford to administer infusions. Even though Medicare covered home infusions, the reimbursement became so low that specialty pharmacies could not afford to provide the items and services necessary for IVIG in the home. Congress responded by passing the Medicare IVIG Access Act (P.L. 112-242) with overwhelming support (401-3 in the House; unanimously in the Senate). This demonstration is currently underway, and IDF anticipates it will lead to a permanent fix in the current Medicare home infusion benefit for IVIG. (See https://innovation.cms.gov/initiatives/IVIG/index.html ) Our fear is that the proposed Part B demonstration, which explicitly includes the current Medicare IVIG
Access demonstration, will undercut the IVIG demo. Specialty pharmacies already complain that they are close to underwater now with ASP+6 and low payment for the items and services needed for infusions in the home.

There have been comments by CMS officials intimating that the demonstration will not jeopardize patient access because patients could travel to a hospital or a practice in a zip code not affected by the demonstration. At best, this is poor stewardship of the Medicare program, given that the hospital is a more expensive setting than the physician’s office and the home, and a dangerous place to be for patients with malfunctioning immune systems. At worst, these comments indicate a disregard for the frustrating experiences that patients with PI face in trying to get the treatment necessary to save their lives. Most importantly, these comments have caused great consternation in the patient community, as it indicates an incredibly cavalier and patronizing attitude by the agency towards beneficiaries. No Medicare beneficiary should have to travel farther to a more expensive setting. In addition, there is no guarantee that patients will necessarily find a site of care that they will be able to access, particularly in rural areas. Physician offices and hospitals that administer Ig therapy are few and far between.

**PHASE 2**

Patients with PI have extensive – and usually negative – experience with the private payer tools that CMS proposes to utilize in Phase 2 of the demo. On a daily basis, IDF is called upon by patients to assist in overcoming insurance barriers associated with affording high out-of-pocket costs as a result of what CMS has termed “value-based”
policies used by commercial payers and pharmacy benefit managers. These are not the policies that should apply to Medicare beneficiaries.

The goals of value-based purchasing (VBP) – lowering health care costs and improving quality and outcomes – are laudable. The literature about VBP consistently discusses the need to look at the correlation between cost of care and patient outcomes. Patients, especially those with rare or chronic diseases, must be involved in every step of the value assessment process. Unfortunately, the extent of patient involvement in the proposed demo is nominal at best: CMS states that it expects “to base many of our analyses on secondary data sources such as Medicare FFS claims” but that it “may consider a survey of beneficiaries” and other stakeholders “to provide insight on beneficiaries’ experience under the model.” (Emphasis added.)

CMS’ endeavor to emulate the tactics used in the private sector to place barriers to care reflects the “one size fits all” mindset. For patients with PI, that approach is dangerous. One tactic in the private sector used against our patients is to limit Ig replacement therapy to just one Ig product. There are 13 Ig products in the market. Each product is different from the others; additionally, two patients may react differently to the same product. No two products are interchangeable. While each product is derived from donated pooled plasma, the formulation is different. For example, some have higher concentrations of salts or sugars and some lower. It would be medically dangerous to require a person with a heart condition to be forced to use a product with a high concentration of salt for their lifelong infusions. The same would occur with a product
with high concentration of sugars for a diabetic patient. A number of products are
developed for intravenous infusion (IVIG). Some are 5% and some are 10% solutions.
Some products are designed for subcutaneous infusion (SCIG), which is generally self-
infused after sufficient training. Some patients do well on IVIG, and other patients
cannot tolerate IVIG, and may have serious venous access issues and reactions. SCIG
can be a good choice for these patients but not for other patients who are unable to self-
administer.

Forcing a patient stabilized on a particular Ig product to switch to a different product is
also dangerous. IDF surveys and other studies indicate that upwards of 30% of patients,
when switched to a product they have never used before, will have adverse reactions
running from mild headaches to anaphylaxis shock, sepsis, thromboembolic events and
even death. Again, creating financial incentives to switch patients for non-medical
reasons is not a commercial payer tactic that should be emulated by CMS.

There is insufficient detail to even provide feedback on the proposals since it is unclear
how some of these could be implemented within Medicare Part B. For example, while
IDF has always supported any reduction in cost-sharing for beneficiaries, a large portion
of Medicare beneficiaries have supplemental coverage, so that a reduction in cost-
sharing would just be a reduction in what the supplemental insurer pays. This would do
nothing to actually reduce costs for beneficiaries.

Finally, what the proposal lacks – and what other CMMI demonstrations have included
very explicitly – is outcomes measures. For Ig, such measures are difficult in that the desired outcome is more holistic than that of some other products. For example, if a product treats hemophilia, a simple outcome measure will ask whether the drug is effective at stopping bleeds. For Ig products, a physician and patient will determine together whether the drug has reduced the number of pneumonias and other illnesses, but they must also determine how well the patient tolerates the product overall – and that will vary from person to person. Any VBP proposal must include outcomes measures, but they must be informed by patients and providers who actually experience the disease every day.

PROCEDURAL CONCERNS WITH THE MODEL

In early February 2016, CMS posted guidelines to contractors about the Medicare Part B Drug Payment Model, which proposed changes to the Average Sales Price (ASP) methodology for Part B drug reimbursement. This posting appeared to have happened erroneously, as the agency quickly removed the guidelines from its website. The posting and subsequent hasty removal greatly worried the provider, patient, and manufacturer communities, as it indicated a major payment change was well underway, even though CMS had not engaged in any pre-rulemaking dialogue such as town halls or Requests for Information.

Rather than pause to address these concerns, CMS only seemed to accelerate its timeline for beginning this sweeping payment demonstration. Within a month, CMS issued the proposed rule containing the Model. We believe that this retreat, followed by
the hasty rollout, indicates that the Agency knew how concerning the proposed change would be to the community.

Executive Order 13563 (January 11, 2011) explains that, “Before issuing a notice of proposed rulemaking, each agency, where feasible and appropriate, shall seek the views of those who are likely to be affected, including those who are likely to benefit from and those who are potentially subject to such rulemaking.” Apart from the erroneous posting for contractors described above, CMS did not engage affected stakeholders in an open, transparent manner to inform, and thus improve, the proposed regulation.

Given that CMS has employed pre-rulemaking engagement strategies in developing the requirements associated with new physician payment programs established under the Medicare Access and CHIP Reauthorization Act (MACRA), we do not understand why CMS failed to utilize this process for the Part B Drug Model, particularly in light of the tremendous impact it will have on patients.

The Affordable Care Act authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures, while preserving or enhancing the quality of care furnished to beneficiaries. However, the scope of the Model far exceeds any reasonable definition of a “test” and is so expansive as to constitute a program change. First, with very limited exceptions, the Model will include all Part B drugs. Second, CMS proposes to mandate participation by all providers who prescribe Part B drugs. The model can no longer be considered a “demonstration” when it is scaled nationwide (excluding Maryland) and will apply to all Part B medicines. Given
that Congress statutorily defined the ASP methodology and add-on in section 303 of the Medicare Modernization Act of 2003, it is an inappropriate overreach of regulatory authority for CMS to force changes to this formula, especially in a way that lacks any transparency or opportunity for meaningful input.

Finally, the ACA explicitly states that no ACA provision, including the provision creating the Innovation Center, can result in a reduction of guaranteed Medicare benefits. As outlined above, we believe that the model will jeopardize beneficiary access – and thus may be a potential violation of ACA section 3601, which provides, in relevant part, that nothing contained in the ACA "shall result in a reduction of guaranteed benefits under title XVIII of the Social Security Act."

CONCLUSION

IDF has urged CMS to withdraw the Part B Drug Payment Model and requests that Congress do everything in its power to stop this harmful experiment from moving forward. It jeopardizes beneficiary access to needed medications, is the result of an opaque and poorly thought out process, and fails to address the actual issue of drug pricing in any way. IDF proposes that CMS engage all stakeholders in a true dialogue to develop pilot projects to demonstrate the relative effectiveness of those pilots in reducing costs AND maintaining or improving outcomes of all beneficiaries.

IDF thanks the Committee for its attempt to create accountability in a CMS process that
has lacked any transparency or patient input whatsoever, and for the opportunity to present the potential implications of the model for patients with PI.

1 OIG, April 2007, OEI-03-05-00404, p. 13
Mr. PITTS. The Chair thanks the gentlelady and now recognizes Ms. Block, 5 minutes for your opening statement.

STATEMENT OF HEATHER BLOCK

Ms. BLOCK. Good morning. Thank you, Chairman Pitts, Ranking Member Green, and distinguished members of the Subcommittee on Health for inviting me to testify today.

I rarely share my cancer story as I find every cancer story is unique to the person and often frightening or boring to everyone else. But due to the importance of this hearing, I’d like to share my story.

I found a lump in my own breast while managing aid projects for the State Department and the U.N. in Afghanistan. I was mystified as no one in my family had ever had cancer before.

I returned to the U.S. for a diagnostic mammograms, and it was negative, so I returned to Afghanistan. My doctor suggested it might be a mastitis infection due to an injury. There was a chance I had bruised myself when I fled an attack that May. Running and jumping into a police truck will leave some bruises.

I ignored worsening symptoms as the mammogram had been conclusively negative. Within three months, I returned again to the U.S. for a second mammogram, and it was invasive breast cancer.

I continued to work through a mastectomy and six months of chemo, by then managing the monitoring and evaluation of aid projects in Iraq.

A year after my oncologist said I was cured, I learned that the cancer had returned. It was now in my liver. There was a chance to surgically remove the cancer from my liver but cancer cropped up in my lungs within days of a pretty brutal liver resection.

Stage IV, no cure—I was reeling with the news and my oncologist told me that 50 percent of women survived 2 years and only 20 percent approximately survive 5 years and that I would remain in treatment for the rest of my life.

At 4 ½ years, I’m living beyond most projections.

But this isn’t a feel-good story. My personal catch-22 is that while drugs are keeping me alive, I’m also going through my savings at an alarming rate.

I spend a ridiculous amount of time and energy trying to cut costs and drafting budgets based on living longer with less money and rising drug costs and trying to figure out how to move closer to my cancer center—I do live in a rural area—when I cannot sell my house.

It is the only asset that cannot be taken from me if I end up declaring medical bankruptcy.

I was so relieved when I found out that I qualified for Medicare, even though I’m well under 65. For those unaware, one can qualify for Medicare after 29 months on Social Security disability income if you’re unable to work.

My drugs are billed through Part B, as most cancer treatment drugs are, but my relief was short-lived when I realized that the drugs are exceedingly expensive, and I am always on the hook for the 20 percent copay.

Medicare right now pays about $2,000 a month for my monthly treatment. There’s no out-of-pocket maximum for Medicare Part B.
This means I’m responsible for paying 20 percent of ever cancer drug that I receive forever more.

This is why I was pleased to hear about the demo. The CMS demo proposes to address rising drug prices in a 5-year evaluation, not an overhaul of Medicare Part B. It’s a way for the Government to begin to shift pricing incrementally based on what they learn.

By evaluating payment models over a 5-year period CMS can determine best practices without forcing me to change doctors, hospitals or affecting my drug coverage.

How else can Medicare continue to ask me to pay for 20 percent of increasingly costly prescription drugs without any evaluation of whether my money is being well spent.

I want to know that the drugs that are being used to treat my cancer are the ones that will do the best job and not just make my doctor the most money.

Every patient deserves that. In all of the uproar over this proposal I have yet to hear anyone say that the current system is working. Where did the payment formula of +6 even come from and why would anyone push to keep a system where prescribing choices could be motivated by money?

It seems common sense to remove any possibility of financial incentive and instead create an appropriate handling or storage fee.

I also think it’s worth mentioning that my 20 percent co-pay is based on whatever Medicare pays. My provider may receive rebates or discounts. I’m still paying full freight.

I’m betting also that most patients don’t know that one component to be studies reduces or even waives the 20 percent co-pay and I’m hoping that my ZIP Code is selected for that part of the demo.

These proposals simply put new options on the table to evaluate tools that are already being used in the private sector.

As a taxpayer and a patient, this is exactly what I want our Government to be doing—getting the best value for our money. Frankly, we need to start somewhere. The price of drugs is not sustainable.

CMS needs to test ways to hold down prescription drug spending. Patients like me should not have to choose between getting lifesaving drugs or paying our mortgage. No one should have to fear bankruptcy as much as cancer.

Finally, I’d like to share America’s dirty little secret. We already have drug rationing. It’s called affordability. Drug innovation is meaningless without affordability.

Thank you for the opportunity to address the subcommittee, and I look forward to answering any questions that you might have.

[The statement of Ms. Block follows:]
Good morning and thank you Chairman Pitts, Ranking Member Green, and distinguished Members of the Committee for inviting me to testify today.

I rarely share my cancer story as I find every cancer story is unique to the person and boring or frightening to everyone else. But due to the importance of this hearing, I would like to share my story.

I found a lump in my own breast while managing aid projects for the State Department and the UN in Afghanistan. I was mystified, as no one in my family had ever had cancer. I returned to the US for a diagnostic mammogram and it was negative. So I returned to Afghanistan. My doctor suggested it might be a mastitis infection from an injury. There was a chance I had bruised myself when I fled an attack that May. Running and jumping into a police truck will leave some bruises. I ignored worsening symptoms, as the mammogram had been conclusively negative.

Within three months, I returned again to the US for a second mammogram and it was invasive breast cancer. I continued to work through a mastectomy and six months of chemo, by then managing the monitoring and evaluation of aid
projects in Iraq. A year after my oncologist said I was cured, I learned while in Baghdad, that the cancer had returned. It was now in my liver. There was a chance to surgically remove the cancer from my liver, as they saw no other organs compromised. But cancer cropped up in my lungs within days of a pretty brutal liver re-section.

Stage four, no cure. I was reeling with the news and my oncologist told me that 50% of women survive two years and only 20% survive five years. And I would remain in treatment for the remainder of my life. He even told me to start spending my savings, as he knew I was a big saver due to my unstable work environments.

At 4.5 years, I am living beyond most projections. But this isn’t a feel good story. My personal Catch-22 is that while drugs are keeping me alive, I am also going through my savings at an alarming rate. My oncologist jokes that he wouldn’t have told me to spend my savings if he’d known I’d stick around so long. I spend a ridiculous amount of time and energy trying to cut costs and drafting budgets based on living longer with less money and rising drug costs. And trying to figure out how to move closer to my cancer center when I cannot sell my house. It is the only asset that cannot be taken from me if I end up filing for medical bankruptcy.

I was so relieved when I found out that I qualified for Medicare, even though I was well under 65. For those unaware (as I was, pre-cancer), one can qualify for
Medicare after 29 months on Social Security Disability Income (SSDI) if you are unable to work. My drugs are billed through Part B, as most cancer treatment drugs are.

My relief was short lived when I realized that the drugs are exceedingly expensive, and I am always on the hook for the 20 percent co-pay. Medicare pays ~$2000 for my monthly treatment right now. There is no out-of-pocket-maximum for Medicare Part B. This means I am responsible for paying 20% of every cancer drug I receive forevermore.

This is why I was pleased to hear about the Demo. The CMS demo proposes to curb the tide of rising drug prices in a 5-year evaluation, not a complete overhaul of Medicare Part B. It is measured and fair, and it’s a way for the government to begin to shift pricing practices incrementally, based on what they learn. By evaluating payment models over a five year period, CMS can determine the best practices without forcing me to change doctors, hospitals or affecting my drug coverage.

We need to assess each model’s ability to lower program expenditures while maintaining the quality of care. How else can Medicare continue to ask me to pay for 20 percent of increasingly expensive prescription drugs without any evaluation of whether my money is being well spent? And who wants to wonder if their doctor is basing their prescribing decisions on how much they’re going to get paid rather than what’s the best course of treatment? I want to know that the
drugs that are being used to treat my cancer are the ones that will do the best job and not just make my doctor the most money. Every patient deserves that.

In all of the uproar over this proposal, I have yet to hear anyone say that the current system is working. Where did the payment formula even come from? And why would anyone push to keep a system where prescribing choices could be motivated by money? It seems common sense to remove any possibility of financial incentive and instead create an appropriate handling/storage fee.

I also think it's worth mentioning that my 20% coinsurance is based on whatever Medicare pays. Regardless of whatever rebates or discounts my provider might see, I'm still paying full freight. Why isn't anyone worried about what that means for me, especially if there's any question about whether I'm getting the best drugs for my condition?

I am betting that most patients don't know that one component to be studied reduces or even waives the 20% co-pay and I am hoping that my zip code is selected for that part of the demo. These proposals simply put new options on the table to evaluate value-based purchasing tools that are already being used in the private sector. As a taxpayer and a patient, this is exactly what I want our government to be doing – getting the best value for our money.

Frankly, we need to start somewhere. The price of drugs is not sustainable. CMS needs to test ways to hold down prescription drug spending. Patients like me
shouldn’t have to choose between getting access to life-saving drugs or paying our mortgage. No one should have to fear bankruptcy just as much as cancer.

Finally, I’d like to share America’s little secret, we already have drug rationing. It’s called affordability. Drug innovation is meaningless without affordability.

Thank you for the opportunity to address the Committee today and to support any efforts to stem the rising prices of drugs under Medicare Part B.

I look forward to answering any questions you might have.
Mr. PITTS. The Chair thanks the gentlelady and now recognizes Mr. Baker, 5 minutes for your opening statement.

STATEMENT OF JOE BAKER

Mr. BAKER. Thank you. Chairman Pitts, Ranking Member Green and distinguished members of the Subcommittee on Health, thank you for the opportunity to testify on the Part B drug payment model.

As president of the Medicare Rights Center, I lead a national nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs and public policy initiatives.

The Medicare Rights Center supports the proposed model. The model seeks to realign perverse payment incentives while ensuring that healthcare providers can continue to prescribe the medications best suited to the individual needs of patients.

The model also brings innovative value-based payment strategies being used in the private market to the Medicare program. Transitioning Medicare to a system that reimburses on the basis of value is an aim supported by diverse voices including patients and consumers, physicians, hospitals, health insurers and others.

This objective will not be realized if pursued only in silos, meaning the prescription drugs including Part B medications, must be part of these reforms.

Beyond improving the quality of care delivered to beneficiaries, the proposed model may help the Medicare program by promoting more efficient use of program funds. Last year, Medicare spent $22 billion on prescription drugs, double the amount spent in 2007.

The Medicare Rights Center answers nearly 17,000 questions on its national help line and provides educational resources to over 2 million individuals each year through medicareinteractive.org and other means.

Challenges affording needed health care are a common theme heard on our help line. Sky-high cost sharing for Part B drugs is a notable concern most often for cancer and immuno-suppressant medications.

Many of these cases involve beneficiaries with original Medicare who lack adequate supplemental coverage. Estimates suggest that between 10 to 14 of beneficiaries only have original Medicare, making them responsible for a 20 percent coinsurance on all Part B services with no out of pocket maximum. These beneficiaries can be exposed to catastrophic costs which can reach as high as over $100,000.

Calls to withdraw the Part B payment model fail to acknowledge the very real and unrelenting beneficiary access challenges that exist under the current payment system, not merely hypothetical ones.

We commend the Centers for Medicare and Medicaid Services for proposing to test solutions that have the potential to alleviate calamitous cost burdens which cause too many older adults and people with disabilities to forego care, and we urge Members of Congress to support and strengthen the proposal.
The Medicare Rights Center engage in this very process. Our comments on the model focus on the need for enhanced monitoring and oversight.

Among the topics we addressed were concerns raised about how the model might shift how care is provided such as from community practices to hospital settings. Though we note that such shifts are already occurring and that shifts predicted in the past were not as draconian or dramatic as projected.

We identified practical solutions that we believe can address this and similar concerns. Such is the creation of a dedicated ombudsman for this payment model.

We encourage CMS to carefully weigh comments submitted by diverse stakeholders and we urge Members of Congress to ensure that the proposal moves forward with refinements that reflect concerns identified through the comment process.

Prohibiting the payment model from moving forward would perpetuate a system that allows patients with less to go without needed care and halt progress in how—in transforming how Medicare pays for care and saddle taxpayers and saddle taxpayers with the unrestrained costs of prescription drugs. People with Medicare and taxpayers deserve a Medicare program that pays for high value innovative health care.

We believe the Part B drug payment drug model presents an important opportunity to ensure that Medicare meets this high bar.

Thank you.

[The statement of Mr. Baker follows:]
Testimony of Joe Baker
President, Medicare Rights Center

Prepared for the
United States House of Representatives
Energy & Commerce Committee, Subcommittee on Health

“The Obama Administration’s Medicare Drug Experiment:
The Patient and Doctor Perspective”

May 17, 2016
Introduction:

Chairman Pitts, Ranking Member Green, and distinguished members of the Subcommittee on Health, I am Joe Baker, President of the Medicare Rights Center (Medicare Rights). Medicare Rights is a national, non-profit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives.

Thank you for the opportunity to testify on the proposed Part B Drug Payment Model. Medicare Rights supports the proposed model. The model seeks to realign perverse payment incentives, while ensuring that health care providers can continue to prescribe the Part B medications best suited to the needs of individual patients. It also brings innovative, value-based payment strategies being used in the private market to the Medicare program.

Through the notice-and-comment rulemaking process, our organization submitted detailed comments on the proposal, including recommendations to strengthen the model through enhanced monitoring and oversight, well-planned outreach and education, and established processes for consumer and patient engagement.

We applaud the Centers for Medicare & Medicaid Services (CMS) for soliciting input on the payment model, and we encourage CMS to carefully weigh comments submitted by diverse stakeholders. Similarly, we urge members of Congress to ensure that the payment model moves forward with refinements that reflect reasonable concerns and recommendations identified through the comment process.

---

As defined in statute, Center for Medicare & Medicaid Innovation (CMMI) demonstrations are intended to address documented “...deficits in care leading to poor clinical outcomes or potentially avoidable expenditures.” Through over two decades of experience counseling people with Medicare and their families, we can attest that the proposed payment model has the potential to alleviate persistent “deficits in care.”

Medicare Rights answers nearly 17,000 questions on its national helpline and provides educational tools and resources to over two million beneficiaries, family caregivers, and professionals annually. Challenges affording needed health care are a common theme heard on our helpline, affecting nearly one in five callers. Sky-high cost sharing for Part B prescription drugs is a notable concern, most often for cancer and immunosuppressant medications.

Many of these cases involve beneficiaries with Original Medicare who lack adequate supplemental coverage. Estimates suggest that between 10 to 14 percent of beneficiaries have only Original Medicare, and are therefore responsible for a 20 percent coinsurance on all Part B services. This population includes a disproportionate share of people under age 65 with disabilities, those with annual incomes between $10,000 to $20,000, and African American beneficiaries. High coinsurance coupled with the absence of an out-of-pocket maximum on annual cost sharing expose these beneficiaries to catastrophic costs, which can range from as high as $1,900 to $107,000 for the most expensive Part B medications.

---

1 26 U.S.C. 1313(a)(4)(B)(vi)
3 Unpublished analysis of Medicare Rights Center national helpline calls from January 2015 through March 2016
In addition to our direct experiences serving people with Medicare, our support for the Part B Drug Payment Model is informed by our commitment to transforming how the Medicare program pays for care. The proposed model is aligned with ongoing efforts in delivery and payment system reform to shift payment away from a volume-based system to one that reimburses on the basis of health care quality and promotes innovation. The goals behind the payment model are entirely consistent with bipartisan reforms advanced through the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. MACRA was overwhelmingly supported by members of Congress and is now being implemented.

Transitioning Medicare to a system that reimburses on the basis of value is an aim supported by diverse voices throughout the health care system, including patients and consumers, physicians, hospitals, health insurers, and more. This objective will not be realized if pursued only in silos, meaning that prescription drugs—including Part B medications—must be a part of these reforms. The proposed payment model provides a platform to achieve this end, through the testing and evaluation of multiple strategies.

Beyond improving the quality of care delivered to beneficiaries, the proposed model may also help to support the Medicare program by promoting more efficient use of program funds. Last year, Medicare Part B spent $22 billion on prescription drugs—double the amount spent in 2007. This presents yet another reason why Congress should support CMS in moving the Part B Drug Payment Model forward.

Calls to withdraw the Part B Drug Payment Model fail to acknowledge the very real and unrelenting beneficiary access challenges that exist under the current payment system—not merely hypothetical ones. We applaud CMS for proposing to test solutions that have the

11 For example, see the Committed Partners of the Health Care Payment and Learning Action Network (HCP LAN): https://hcp-lan.org/about-us/committed-partners. Also, see the membership of the Health Care Transformation Taskforce: http://www.bhf.org/members. Medicate Rights Center is a member of the Consumer/Patient Affinity Group of the HCP LAN and the Advisory Group for Consumer Priorities for the Health Care Transformation Taskforce.
12 Part B Drug Payment Model, pg. 13231
potential to alleviate calamitous cost burdens, which cause too many older adults and people with disabilities to forgo necessary care. We urge members of Congress to support and strengthen the proposal by recommending improvements that put patients at the center of the payment model and all other CMMI programs.

**Current Reimbursement System for Part B Prescription Drugs:**

Under the current system, Part B medications are reimbursed at Average Sales Price (ASP) plus 6 percent. According to the Medicare Payment Advisory Commission (MedPAC), there is no clear historical basis for this percentage-based add-on, which is mandated through statute. This reimbursement scheme does not account for actual acquisition, storage, or dispensing costs, clinical effectiveness, or the cost of clinically comparable prescription drugs.

CMS expresses concern that the current reimbursement formula indiscriminately favors higher-priced medications, writing in the proposed rule, “Under this methodology, expensive drugs receive higher add-on payment amounts than inexpensive drugs while there are no clear incentives for providing high value care, including drug therapy.” Similarly, MedPAC states, “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.”

Some research is available to support the supposition that some providers may be more likely to prescribe a medication that will increase payment over an equally effective lower-cost medication, leading to increased costs for the Medicare program and higher cost sharing for
people with Medicare. Given this, Medicare Rights supports moving away from the perverse incentives inherent to a purely percentage-based payment formula. The model presents an opportunity to test multiple payment strategies to realign the incentives in the current system.

**Phase I:**

Under Phase I of the Part B Drug Payment Model, CMS proposes to reimburse some health care providers at ASP + 2.5 percent + a flat-fee (test group) and others at the current formula, ASP + 6 percent (control group) and then to evaluate and compare those groups. Decreasing the difference in the reimbursement rates between higher- and lower-cost prescription drugs among those in the test group is intended to neutralize the payment incentive favoring higher-cost medications, allowing health care providers to make clinically-driven—rather than economically-pressured—decisions.

Our organization supports the payment methodology proposed by CMS and informed by MedPAC analysis. With appropriate monitoring and oversight, Medicare Rights believes that beneficiaries will retain access to needed medications under the proposed model. The payment change in the Phase I test group simply redistributes the incentive to encourage prescribing of high-value medications where there is a choice.

The changes contemplated in Phase I could prove to both lower costs and improve care quality. Health care providers may be encouraged to prescribe lower-cost medications when appropriate, leading to improved affordability and access among people with Medicare. Additionally, a revised payment model may exert downward pressure on overall drug prices. That, in turn, will also help will lower costs for both the Medicare program and beneficiaries.

---


Phase II:

Medicare Rights is similarly encouraged by the value-based purchasing strategies incorporated in Phase II of the payment model. The concepts and goals reflected in Phase II are aligned with efforts to transition Medicare from a volume- to value-based payment system and to incentivize high-value clinical decision-making. By testing a variety of reimbursement methods and value-based purchasing innovations already in use in the private insurance market, Phase II will promote utilization of the most clinically effective medications—not the most costly.

Specifically, CMS proposes to test reference pricing, indication-specific pricing, outcomes-based risk-sharing agreements, and discounting or eliminating Part B coinsurance amounts. The model also incorporates clinical decision support tools that reflect up-to-date literature and consensus guidelines for use on a voluntary basis.

Medicare Rights appreciates that the payment model incorporates a transparent process for determining which prescription medications are appropriate for Phase II testing. For each of the value-based purchasing tools identified, it is critically important that CMS engage in—and Congress encourage—an open and deliberative dialogue for determining which medications are best suited to each of the specific tools. Our organization recommends the following options to strengthen the notice and comment process proposed to select medications for Phase II:

- Engage diverse stakeholders, especially clinicians, prior to notice and comment;
- Rely on the highest-quality evidence, including randomized trial designs where possible;
- Emphasize evidence from neutral and/or independent sources; and
- Release all evidence used as part of the notice and comment process.

In particular, Medicare Rights strongly supports lowering or eliminating Part B cost sharing for high-value medications through Phase II. Empirical literature on patient behavior makes clear that indiscriminate increases in cost sharing are shown to deter access to both necessary and unnecessary health care and that such increases have a disproportionate impact on lower-income,
vulnerable populations. Conversely, evidence demonstrates that decreases in cost sharing can improve adherence and may contribute to improved outcomes, such as through reduced hospitalizations and emergency room visits.

As discussed above, a transparent process for determining which Part B medications are “high-value” and therefore eligible for lowered or eliminated coinsurance is essential. Adequate beneficiary notice and provider education are also fundamentally important to promoting the successful use of this particular value-based tool.

Medicare Rights also strongly supports developing clinical decision support tools to assist health care providers in making the best treatment and prescription choices for their patients. This Phase II strategy appropriately reflects that health care providers—rather than patients—determine health care utilization trends. Our organization encourages CMS to develop complementary shared decision-making tools as a companion to the clinical decision support tools in order to further promote truly person-centered care.

Additionally, Medicare Rights commends CMS for including essential consumer protections specific to the value-based tools selected for Phase II. For example, with respect to reference pricing, our organization strongly supports the agency’s proposed prohibition on balance billing—a practice where a provider charges the beneficiary for the difference between the reimbursement rate and the cost of buying the prescription drug from the manufacturer. Balance billing would simply allow providers to shift higher costs to beneficiaries.

Importantly, Phase II also includes a Pre-Appeals Payment Exception Review Process (Pre-Appeals Process) for use by health care providers, suppliers, and beneficiaries who wish to challenge a particular payment rate under each of the proposed value-based purchasing tools. This is a crucial protection that will help prevent unintended access problems and other

---

beneficiary burdens. Yet, additional information is needed to ensure the Pre-Appeals Process is truly accessible to people with Medicare.

First and foremost, CMS should clarify how the Pre-Appeals Process will affect beneficiary cost sharing. Medicare Rights encourages CMS to allow beneficiaries and providers to use the Pre-Appeals Process to request lowered cost sharing in cases where an individual has a medical need for a prescription drug not identified as high-value, particularly among a grouping where lowered cost sharing is available for specific medications and not others. In addition, the agency should implement a “hold harmless” provision to shield beneficiaries from higher cost sharing when their provider or supplier successfully appeals for higher payment.

In addition, CMS must make explicit what information will be required for beneficiaries, providers, and suppliers to successfully request a pre-appeal, including any medical information or provider statements. For people with Medicare, information about how to access the Pre-Appeals Process should be made available in beneficiary-friendly formats and through multiple avenues, including 1-800-MEDICARE and all relevant contractors.

**Model Design:**

Throughout the notice-and-comment rulemaking process, CMS sought input on overarching design elements of the Part B Drug Payment Model, applicable to both Phase I and Phase II. Below our organization provides recommendations on several such elements:

**Demonstration size and scope:** As noted above, Medicare Rights believes that the Part B Payment Model is in line with CMMI’s statutory charge and authority. CMMI serves an important function, providing policymakers and regulators with unbiased evidence on the effectiveness and scalability of promising new payment and delivery models. Our organization appreciates that CMS designed the proposed payment model with this purpose in mind.

Full participation by Medicare providers will help ensure that the payment model does not suffer from selection bias inherent to voluntary participation and that observed outcomes are
generalizable. Medicare Rights recommends that CMS carry out a demonstration that allows for generalizable results and adequate comparisons among varying payment strategies, and we urge members of Congress to support CMS in carrying out this objective.

**Monitoring and oversight:** Medicare Rights anticipates that the proposed model will encourage trends in prescribing that ultimately benefit people with Medicare, such as by promoting enhanced access to Part B medications through lowered cost sharing where there is a choice among equally-effective but differently-priced alternatives. Recognizing that changes to payment may result in unintended consequences, CMS should be proactive in anticipating these and identifying mechanisms to guard against any beneficiary harms, such as diminished access. For this reason, our formal comments on the Part B Drug Payment Model detail extensive recommendations on monitoring and oversight policies that CMS should adopt in the final rule.

Specifically, Medicare Rights recommends that CMS create robust feedback loops to monitor beneficiaries’ and providers’ experiences throughout the proposed model and respond in real time to potential problems. To facilitate this process, CMS should:

- Establish a dedicated ombudsman program;
- Create formal processes to involve multiple, diverse stakeholders on an ongoing basis;
- Monitor for specific shifts in prescribing and dispensing; and
- Publicly release the agency’s plans for program monitoring and corrective action.

According to CMS, the agency will draw on its monitoring experience with the Durable Medical Equipment Prosthetic Orthotic and Supplies (DMEPOS) competitive bidding program for the Part B Drug Payment Model, namely through timely claims review. In our view, claims monitoring is not the only consumer protection that should be carried over from the DMEPOS

---

program. In 2008, Congress mandated the establishment of a dedicated ombudsman for the DMEPOS program through the Medicare Improvements for Patients and Providers Act.\(^{21}\)

Similar to this, our organization envisions a dedicated ombudsman for the Part B Drug Payment Model that would answer and track provider questions and complaints, resolve beneficiary problems, troubleshoot appeals, and report to Congress and CMS on its findings. This is only one example of a constructive recommendation that Congress can endorse to ensure the proposal incorporates adequate mechanisms to monitor the experiences of both beneficiaries and health care providers as the payment model is implemented.

In addition to developing adequate oversight tools, it is critical that CMS track potential shifts in Part B prescribing and dispensing identified through notice-and-comment rulemaking. Medicare Rights anticipates two such potential trends, including:

**Shifting from Part B to Part D:** CMS should monitor for how the proposed changes in payment may influence “brown bagging” and “white bagging” practices wherein a beneficiary must obtain their medication from a pharmacy or specialty pharmacy and bring it or have it delivered to their health care provider for administration. This practice shifts coverage from Part B to Part D and can significantly affect beneficiary cost sharing. Depending on the individual’s Medicare coverage, some see lower cost sharing as a result of this shift, while others pay more.

**Shifting from community-based to outpatient hospital settings:** Since the Part B drug payment model was initially proposed, our organization continues to hear concerns about the potential for the proposed changes in reimbursement to result in limited access to Part B medications among beneficiaries who see individual practitioners or who receive care in community-based settings, shifting those individuals to outpatient hospitals and hospital-affiliated clinics that can afford to supply the medications.

\(^{21}\) CMS, “Competitive Acquisition Ombudsman, Frequently Asked Questions (FAQ),” (March 2015), available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOS/CompetitiveBid/Competitive_Acquisition_Ombudsman_FAQ.html
Medicare Rights shares this concern, though we note that these shifts are already an observable trend among our helpline callers, where we hear from individuals who must pay facility fees in addition to standard cost sharing amounts for Part B services. Some experts attribute this trend to widespread consolidation in the health care market and notable increases in the acquisition of independent physician practices by hospital systems.32

CMS should monitor for these potential shifts in site of service—tracking prescription drug utilization according to provider type, geographic location, practice size, provider acquisition costs, and other characteristics. Where the agency uncovers notable shifts resulting from the model, supported by data, Medicare Rights will encourage CMS to adjust the demonstration.

It is noteworthy that CMS solicited specific comment on how the proposed model could affect rural health care providers. While the impact on such providers is expected to be minimal or even favorable, CMS should be responsive to the potential for site of service shifts in rural communities, while also ensuring that a demonstration can go forward that allows for adequate testing of the identified payment strategies.

Again, Medicare Rights believes concerns related to shifts in coverage or site of service would be best addressed through comprehensive monitoring and oversight systems, like those recommended above. Congress should embrace these tools to address the concerns raised by some in provider and insurer communities about potential shifts in prescribing practices, including from Part B to Part D coverage as well as from community-based to hospital settings.

**Outreach and education:** In addition to the monitoring and oversight mechanisms described above, Medicare Rights encourages CMS to carry out carefully designed outreach and educational initiatives. Specifically, our organization recommends that CMS:

• Leverage existing resources for beneficiary outreach and education;
• Conduct beneficiary focus groups to test language describing the model;
• Involve consumer advocates in content development; and
• Develop targeted beneficiary notices where necessary.

CMS should work closely with consumer advocates, utilize focus groups, consult readability experts, and promote language access as the agency designs communications related to the Part B Drug Payment Model. These are best practices that CMS should adhere to—and Congress should encourage—in the development of all beneficiary-facing notices and resources.

**Program evaluation:** Medicare Rights supports the agency’s plan to collect representative information from a wide and diverse array of health care providers, suppliers, and beneficiaries to evaluate the impact of the Part B Drug Payment Model on cost and quality. CMS proposes to use Part B claims data as the primary source of information for the program evaluation and suggests that the agency may also use surveys.

Medicare Rights strongly recommends that CMS incorporate surveys in the program evaluation, most importantly using patient-experience surveys to track the beneficiary experience under the model. The program evaluation should also directly address the potential shifts in prescribing and dispensing described above, specifically from Part B to Part D coverage as well as from community-based to hospital settings.

**Conclusion:**

As Congress evaluates the Part B Drug Payment Model, we encourage members to support the merits of the proposed adjustments to reimbursement incorporated in Phase I, the private market value-based payment strategies selected for Phase II, and the thoughtfully designed consumer protections outlined in the proposal. While improvements can and should be made—including those recommended above—Medicare Rights strongly believes the model should proceed.
Prohibiting the payment model from moving forward would perpetuate a system that allows those with less to go without needed care, halt progress in transforming how the Medicare program pays for care, and saddle taxpayers with the mounting and unrestrained cost of prescription drugs. People with Medicare and taxpayers deserve a Medicare program that pays for high-value, innovative health care. The Part B Drug Payment Model presents an important opportunity to ensure that the Medicare program meets this high bar.
Mr. PITTS. The Chair thanks the gentleman, thanks each of the witnesses for sharing your expertise with us. The Chair would like to note the presence of a former member of this subcommittee, a very valued member.

Dr. Phil Gingrey of Georgia is with us, sat for many years here with us on the dais. So welcome, Phil.

I’ll begin the questioning and recognize myself for 5 minutes for that purpose. There may be a misperception by some that the drugs we’re talking about being impacted in this proposal amounts to an issue of simple generic substitution—that patients can be easily switched to lower cost treatments without consequences.

However, I know that many of these drugs do not have alternatives that are clinically interchangeable—that even treatments that may appear similar can have different effects on individual patients. Many other patients only have one effective treatment option.

So, Dr. Patt, we’ll start with you and go to Dr. Schweitz. What have you seen in your own practical experience? What are some of the adverse effects that could occur if patients aren’t able to access their most appropriate prescribed treatment?

Dr. PATT. Thank you. I think there are many intended consequences of this policy. When Avalere did an analysis of the proposed Part B payment model, they demonstrated that for drugs that cost more than $480 that many practices would be underwater. We know that even in the ASP+6, which is not really ASP+6 model today, that 25 commonly used oncology drugs are in fact underwater.

So high cost drugs would commonly be underwater and this is a disproportionate burden on oncology practices because we have a higher percentage of more expensive drugs.

Unfortunately, many of the new innovative products that we have that are very effective don’t have generic treatment alternatives—don’t have interchangeable options that are a lower cost. And so by not allowing practices to use or not having practices be able to purchase drugs and give them to their patients it diminishes the Medicare beneficiary’s access to care.

An example of that is pembrolizumab, which is an immunotherapy in melanoma. So we all probably know about Jimmy Carter’s story with melanoma—that in August he was diagnosed with a metastatic melanoma to his brain.

Because of the advent of targeted therapy this immunotherapy pembrolizumab he informed his Bible school class in December that he was in remission. He would not have access to this treatment in Medicare under this new model.

Mr. PITTS. Dr. Schweitz?

Dr. SCHWEITZ. In rheumatology we have a limited number of agents, some with different mechanisms of action. Unfortunately, we have no way to predict response. It’s pretty much trial and error.

The average patient goes through at least two drugs before we find one that is effective for that patient and one of the tenets we like to follow is you don’t change a patient who’s doing well.
We have concerns about the Phase II that may dictate that we change medications into, quote, “higher value meds” and we don’t have a definition of that in rheumatology.

In the private world—in the commercial world—there are, quote, “value programs” which are really only directed at cost and don’t take into account the patient’s individual responses.

So it’s a difficult problem to try to change medications to a, quote, “more effective” or a, quote, “more value-based medicine” when it doesn’t exist.

Mr. Pitts. Ms. Boyle, did you want to add anything?

Ms. Boyle. Well, I agree with the sentiments because I’ve seen my own son, for instance, be on a 5 percent immunoglobulin product change to a 10 percent and collapse on the floor twice when they were trying to get used to it.

He is now in his late 30s and has been on a wonderful immunoglobulin product for years and he’s all of a sudden having reactions. He’s having high blood pressure and trying to control the reactions, and thankfully there’s a subcutaneous option out there that he’s able to take—a higher percent solution.

I have seen, again, private payers say well, we’re just going to use the least expensive. Their value is expense. It’s not patient reactions. If my son or other patients have to change to that least expensive option du jour they will have reactions. Their well-being will be compromised and it’s unconscionable.

Mr. Pitts. One more question. There’s a lot of speculation about what drives a doctor’s treatment of diseases using injectables. It appears that there’s speculation that decisions are made based of the ASP.

So Dr. Patt or Dr. Schweitz, would you please tell us what’s more important to you? Is it your patients’ need or preferences, your clinical evidence? Do you decide based on which drugs have a better reimbursement?

Dr. Patt. Obviously, as a physician I provide the care and prescribe the care for my patients that is a mutual shared decision in their best interest and that is solely what drives our decisions about patient care.

Mr. Pitts. Dr. Schweitz?

Dr. Schweitz. I concur 100 percent. The appropriate choice of medication is based on what’s best for the patient. I can tell you in our practice of seven rheumatologists if you ask any one of the doctors what the drugs actually cost or what the reimbursement is they will not know.

Mr. Pitts. Thank you. My time is expired.

The Chair recognizes the gentleman, Mr. Green, 5 minutes for questions.

Mr. Green. Thank you, Mr. Chairman.

Mr. Baker, the Medicare Rights Center is a trusted and respected organization that advocates on behalf of American seniors. The Medicare Rights Center has come out in support of the proposed demonstration.

Can you explain to the committee how your organization came to this conclusion?

Mr. Baker. Well, I think, once again, as I said in my spoken and my written testimony, we see in a daily way the consequences of
these high drug prices, which Ms. Block detailed I think so clearly as well in her own experience where folks just cannot afford the rising prices of these drugs.

The 20 percent co-insurance, if they don't have supplemental coverage—even those that do have supplemental coverage that might cover all or part of that 20 percent they are facing rising premiums for that supplemental coverage.

And then, of course, all people with Medicare see increases in the Part B premium based upon the rising cost of Part B medications as well as other services under Part B. And so we see the proposal as an attempt to, one, restrain those prices and provide relief to those individuals that are—cannot afford these drugs and cannot get access to them all at all.

You know, these are patients in effect that are under water, if you will, and cannot afford the care that they need. Secondly, we think it will help the program overall, once again get at high and rising——

Mr. GREEN. Let me ask another question.

Mr. BAKER. Of course. Of course.

Mr. GREEN. In both your comments of CMS in testimony before the committee the Medical Rights Center identified ways the organization believes the model could be improved to ensure access is maintained and care is not disrupted. Can you elaborate on these and did CMS adopt any of your suggestions on the model?

Mr. BAKER. Well, as you know, the comments were just recently submitted and now CMS has an opportunity to review all of the comments that they received. So we don't know yet whether they've adopted them.

But what they have done is said up front that there will be claims monitoring in real time so if there are dislocations they can be fixed, hopefully in real time. That's what they said they want to do.

We also have said that we think there should be an ombudsman as part of this program. So an ombudsman has been used in the DME purchasing project.

It has been very helpful in identifying problems quickly, helping individuals with those problems, also helping suppliers and others with those problems and also bringing systemic problems to the attention of not only CMS but to you all here in Congress.

I think the other thing that we're really looking for CMS to do is engage multiple stakeholders ongoingly and be very transparent with that monitoring that they're doing of claims with all stakeholders including Congress, not only transparent with that monitoring and what they're finding but also with any corrective action or corrective steps that we're taking.

So we really think that this has to be done transparently. It needs to be shown that there's clinical effectiveness here. I mean, if there aren't clinically equivalent drugs they won't move into this value-based purchasing kind of system that CMS wants to set up in Phase II of the program.

We think that certainly physicians and other providers with clinical knowledge, pharmaceutical manufacturers with clinical studies, need to come to the table, need to work with CMS to show that there is clinical equivalence.
If there is not there’s nothing in this proposal that would prevent coverage for a prescription drug for someone that needs it regardless of price. This is——

Mr. GREEN. The proposed demonstration project—I only have 5 minutes, and if you talk for 4 of them I can’t answer.

Mr. BAKER. I’m sorry about that.

Mr. GREEN. The proposed demonstration result in changes in Medicare payments is going to be all Part B medications over a 5-year period and require 75 percent of the providers to participate in either one or both of two phases.

Patients, providers and other stakeholders raised concern about the scope and size of this demonstration, recognizing the demonstration would affect care for our sickest seniors that’s being treated for serious illness I have concern—I have concerns and urge CMS to reexamine the size of the proposed model. Is that one that they share? Because this is a pretty large model——

Mr. BAKER. Right.

Mr. GREEN [continuing]. To do and I know that we need to have enough to get good information.

Mr. BAKER. Right.

Mr. GREEN. But it seems like they’re actually—the model is impacting the whole system.

Mr. BAKER. Well, we share that concern and many of the consumer organizations that we work with do share the concern and have questioned CMS about that.

I know that there is concern about rural providers has been mentioned and something that I think CMS needs to take a close look at as well as providers that are represented here at this table and the switch between facility type of—the types of facilities that are providing this care.

So I do agree that that size and scope needs to be examined and needs to be questioned. I also agree that the scope needs to be large enough to really test these models for payment.

Mr. GREEN. Thank you. My time is expired.

Mr. BAKER. Thank you.

Mr. PITTS. Chair thanks the gentleman. I now recognize the vice chair of the full committee, Mrs. Blackburn, 5 minutes for questions.

Mrs. BLACKBURN. Thank you, Mr. Chairman, and Dr. Patt and Dr. Schweitz, I want to come to you first. And I mentioned Senator Grassley’s letter to HHS and concerns with the—with this demonstration project and the fact that in the rule you have two different terms used, and I’ll just read from Senator Grassley’s letter. It’s more succinct. “I’m concerned that throughout this proposed rule two terms are repeatedly used—study and test. These terms seem to indicate there is a component of research going on in this proposal.”

So what I want to ask you—each of you to weigh in on because you’ve got oncology, rheumatology. When you have read this rule do you see this as being clinical research or do you just see it as being a test that they have thrown out there? And Dr. Patt, I’ll come to you first.

Dr. PATT. Representative Blackburn, thank you. I do see this as an experiment but we conduct clinical research in our cancer center
and patients have informed consent. They have to electively consent to clinical trials. They can opt out if necessary and we follow adverse events and outcomes of those patients.

In addition, clinical trials are to investigate potential enhancements. We know that this experiment would decrease the availability of some treatments that have a survival advantage.

So this is an experiment that would never pass an institutional review board. You know, as you mentioned your concerns about rural clinics, as you know, average sales price is an average. Some large groups like hospital systems and large practices are able——

Mrs. BLACKBURN. OK. Dr. Patt, let me just interrupt you there for the sake of time. So you say it wouldn't pass an IRB. So should they be forced to go in and get an IRB before they embark on this?

Dr. PATT. I think that's not a bad idea.

Mrs. BLACKBURN. OK. All right. Dr. Schweitz?

Dr. SCHWEITZ. You know, when you look at the goals of this plan, initially it appeared that it was to direct a way to save costs. But in meeting with CMMI, we were advised that this is budget neutral and if you look at the rule it's budget neutral.

So the goal of the program then is to collect information, which makes it a study—a test. So if the goal is to collect information and the patients are part of that process they should be signing informed consent. They should be notified this is going to impact their treatment. There may be changes in their treatment directed by Phase II, and they should be part of the process of consent.

Mrs. BLACKBURN. OK. Thank you for that.

Dr. Patt, I want to come back to you. As I mentioned in my opening, we are very concerned about access and the impact that this demo is going to have on access in the rural areas.

And I have talked with so many of my healthcare providers and I want you just to lay out what you see as being the impact on rural Medicare access for oncology services.

Dr. PATT. Thank you for that opportunity. I think that this will be a burden disproportionately hitting small practices in rural areas and the reason for that is because average sales price is by its very nature an average.

Some people will pay higher amounts for procurement than that average and some people will pay lower amounts. Larger hospital systems and larger practices have the ability to have contracting arrangements where they purchase at a lower price. What this means is that smaller practices disproportionately pay a higher amount.

You can imagine if in the new model, which is ASP+.86 percent, given Prompt Pay discounts, sequestration and the six-month delay in increasing prices that if you have a 1 percent difference in smaller practices they will lose money on all the drugs that they buy.

And so, you know, it will be impossible for smaller practices in rural areas to be open. What I think that you'll see is a natural unintended consequence of this policy is that you'll have a shift inside of service to hospital outpatient departments and you'll have decreased access where patients in rural areas will have to travel further distances to receive care.

I think that that's not in our best interest as we already have deficiencies in service in rural areas today.
Mrs. BLACKBURN. I thank you for that and I agree with you. I think what we’re going to see this type of disruption in the healthcare marketplace is going to lead some people to feel that they have to abandon a certain protocol or therapy or course of care and go to something that maybe is not as fitted to them.

So I yield back my time. Thank you, Mr. Chairman.

Mr. PITTS. Chair thanks the gentlelady. Now recognizes the ranking member of the full committee, Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman. My questions are of Mr. Baker. The Medicare Rights Center’s mission is to advocate for access to health care for Medicare beneficiaries.

In addition to public policy initiatives, Medicare Rights Center helps beneficiaries on the ground through educational programs and counseling including a national help line that provides direct assistance to Medicare beneficiaries and their friends, family and caregivers, and with beneficiary access as Medicare Rights Center’s sole focus, we in Congress should take seriously your recommendations to ensure the patient access is not disrupted by the proposed Part B drug payment demonstration project.

In your testimony you mentioned some monitoring and oversight ideas for the proposed demonstration that CMS should adopt in its final rule.

Could you just please discuss these proposals a little further and how they can help ensure that patients are getting the care they need and when have similar provisions worked or have they worked in other programs in Medicare?

Mr. BAKER. Of course. Thank you.

First of all, you know, in the proposal as written there is claims monitoring, and CMS is saying that they can fix problems that arise in real time with that claims monitoring.

The thing that we’re asking CMS to add to that protection for both providers and for patient is an ombudsman and an ombudsman, an ombudsman office was—should be created for this program, we believe.

The idea actually comes from one that Congress enacted with bipartisan support with the durable medical equipment competitive bidding program.

The ombudsman would serve both beneficiaries and providers, as I said, by tracking complaints, troubleshooting appeals, monitoring beneficiary and provider experiences and reporting to CMS and Congress on a regular basis.

We also, as I said earlier, think that CMS should regularly engage multiple stakeholders as part of the demonstration both in Phase I and then, of course, in Phase II they need to do that in order to find these clinically effective drugs and alternatives.

So that monitoring of claims about how care is received, where it is received and then publicly release the monitoring that they are doing and the corrective action that they may have taken or they will be taking.

So that can be, once again, commented on by all the stakeholders and, of course, by you in Congress.

Mr. PALLONE. Now, I was going to ask, unless you think you’ve already answered this, what should CMS do to evaluate the results
of the demonstration projects to ensure that if they move forward and expand it that Part B drug payment policy best suits the needs of Medicare beneficiaries?

Mr. BAKER. Yes, I think the claims data monitoring is something that is already in there that will help evaluate it. We also think there should be additions to that.

So we think that there should be patient experience surveys and focus groups of patients and providers as part of the evaluation to track the beneficiary experience with differing payment models.

I think they've also suggested that they might develop patient-reported outcome measures, particularly in Phase II of the model. And so we strongly support that and we actually think that should be part of the Phase II model.

And I think there should be multiple metrics that CMS uses. We don't have a patent on what those metrics are. It may be an iterative process as it moves forward.

But it should definitely be metrics that focus on patient access, access to particular sites as well as care quality and the access to particular medications.

Mr. PALLONE. All right. Thank you, Mr. Baker.

You did mention in your testimony I noticed a concern that has been expressed to me by some of the physicians in my district about shifting from community practices to hospital settings.

Did you want to talk a little bit more about why that might happen and whether that's a good or bad thing?

Mr. BAKER. Sure. First of all, I would say, you know, we certainly want to see Medicare beneficiaries have access to care in whatever setting is appropriate for them and the most convenient setting to them so, you know, that is important to us and I think that's why we urge CMS to monitor any unintended consequences vis-a-vis settings.

I think what we saw when we moved from AWP to ASP was a lot of concern about settings and moving to different settings and some of those concerns were proved not to be that significant.

That movement from physicians’ offices to hospital outpatient is happening regardless of this model and so it is something that we need to be concerned about and that has a larger causation from a consolidation that's happening across the healthcare market.

Mr. PALLONE. Thank you very much. Thank you, Mr. Chairman.

Mr. PITTS. The Chair thanks the gentleman. I now recognize the vice chair of the Health Subcommittee, Mr. Guthrie, 5 minutes for questions.

Mr. GUTHRIE. Thank you. Thank you all for being here to testify and thank you for your service overseas. I often talk about the experience I had in Yemen when I—not as a service person but in my role here and talk about the men and women in uniform over there serving and then I always point out—I said there are a lot of people in civilian clothes that are serving too from the Department of State and putting themselves in harm's way as well. So thanks for what you do in serving.

But I do have a couple of questions for the physicians here. I know a couple of you said you view this as a test. Some of us believe this is a way—the rule actually amends what we think is a statutorial set formula, which is the price plus 6 percent and sub-
ject to sequestration, so it’s really quite less—4.2 percent, I believe. But and so the concern is they’re using this process to amend the statute.

So wherever you are on what the policy should be I think all of us on this dais up here, both sides, should be concerned that our essential authority—our legislative authority is being, I think, infringed upon.

But one thing that we did all agree on was MACRA last year. We all wanted to put MACRA in place because we all realized that people are in situations like Ms. Block and we need to come up with a system that takes care of patients, that’s sustainable, that works.

And I’ve often said when I’m talking about MACRA if we don’t have everybody together—patients, providers—if it just comes from Washington it’s not going to—and goes out into the—where I think Mr. Baker was talking about, unintended consequences that could come needs to be monitored—you know the way that you eliminate those the most is that you have everybody involved going forward and because I don’t know what happens in rheumatology practice. I mean, people who practice it tell me but I think if we all sit down—fortunately, I haven’t had—been through an oncology practice as well.

But so I just want to look at the way this rule came about and we were troubled that unlike other CMMI initiatives it was negotiated behind closed doors, mysteriously placed on a Web site and then taken down, as far as I can tell without any input from providers, patients or other affected stakeholders and can the physicians here—can you speak to CMMI’s engagement with stakeholders prior to issuing this rule?

Dr. PATT. Thank you, Representative Guthrie.

So I’ll say that this proposal, unfortunately, did not have stakeholder input prior to it being air dropped and, to your point, was put out without stakeholder input during a time of tremendous system change.

So with the advent of MACRA we’ve had to infuse tremendous resources in infrastructure and systems changes. For me as an oncologist to do things like providing a standard treatment plan, standards survivorship counselling, patient navigation, ways to collect patient reported outcomes, ways in which to collect data for the merit-based incentive payment system, it’s been a tremendous infrastructure investment.

Not only has that been a tremendous infrastructure investment but my practice, which treats half of Texans, will participate in the oncology care model and that has been a tremendous infrastructure investment.

Mr. GUTHRIE. OK. I have a question. Now I’m going to get Dr. Schweitz next. But so my next question to you was how is the way this proposal has come forward different than the way that you worked on the oncology care model—how that came forth?

Dr. PATT. We worked in collaboration with 3 years. They got oncologists’ input. We were collaborating on how that model was formulated and many individuals from the U.S. oncology network and Texas oncology participated. This CMS-proposed drug proposal
had not input. It was put out there without any stakeholder input whatsoever.

Mr. Guthrie. The oncology care model was a collaborative effort to try to——

Dr. Patt. Yes.

Mr. Guthrie [continuing]. Look at costs to people in oncology care and try to lower the costs for people in oncology care.

Dr. Patt. Right. And for us in Texas oncology it brings in parts of that value because within the U.S. oncology network we have a system of value pathways where we take into account efficacy, toxicity and cost, looking at the incremental cost effectiveness in comparison to the next nearest comparator.

So when you have interchangeable drug opportunities we will always pick the lower cost alternative. And so that’s incorporated in this value-based system that we collaborated with CMS on.

Mr. Guthrie. There was a big effort legislatively to put forth last year.

Dr. Schweitz, I only have a minute left. I’d like for you to comment on.

Dr. Schweitz. We did have extensive involvement with MACRA pre-rule, pre-law. So we were not involved in the development of this policy.

In fact, I believe that there was guidance to the MACs even before the rule was released. So this was being developed without any knowledge or input of the stakeholders.

Mr. Guthrie. And I think that’s a frustration from our side who are involved along with all of you and patients and MACRA is that, you know, we put a lot of—that took a lot of time. The SGR finally went away.

We got MACRA in place and we’re looking at accountable care organizations value based. How do we have sustainable systems where people get caught in situations like Ms. Block and how do we avoid that and then all of a sudden this rule comes out when we’re in the middle of that process and that negotiation that we’ve all worked so hard on and it came from nowhere and we—or came from above without any input and we really appreciate your testimony. My time has expired.

Mr. Shimkus [presiding]. Gentleman’s time has expired.

The Chair now recognizes the gentleman from New York, Mr. Engel, for 5 minutes.

Mr. Engel. Thank you very much, Mr. Chairman.

I want to give a shout out to our colleague, Phil Gingrey, who served on this committee for many years. Good to see you, Phil.

Let me say to Ms. Block I was quite moved by your testimony and I would like to ask you to talk a bit more about why your personal experiences led you to support this demo even in the midst of so many voices saying that the demo that would be harmful to patients.

Ms. Block. Thank you.

I think, first of all, that we need to all remember why this demo was even put out. With all the talk about drugs being under water and doctors being under water, patients are already under water.

We’re already there, and I talk to patients all the time because that’s what I do. I end up sitting in chemo rooms talking to other
cancer patients and everyone is struggling. We're struggling to stay alive.

We're struggling to pay for our drugs. We're struggling to pay for our mortgage and take care of our kids and do everything else. We have to start somewhere.

You know, as many things as I'm hearing all of you say that you don't like about this demo, I say, OK, then let's work together and get a better finished product.

But you don't throw the baby out with the bathwater, as my mother would have said. We need to start somewhere, and this is a start.

I have read the regs through and through and I don't see any issue with access to drugs—my getting access to the drugs. So what I see is an attempt to figure out how to support patients. That's what I'm seeing. So thank you very much.

Mr. Engel. Well, thank you. I think your testimony was very, very——

Mr. Shimkus. Eliot, would you get a little bit closer to that mike so——

Mr. Engel. Yes. Sure.

Mr. Shimkus. We want to make sure we hear you.

Mr. Engel. Bring two microphones then. OK. Again, thank you, Ms. Block. You know, I also want to thank Ms. Boyle for talking a little bit about her son, and they're all so very courageous when we're asking people to come up and tell personal stories. It's really helpful to us and very, very courageous for the witnesses.

I have been a great supporter of infusion therapy and I'd like to talk about how the model that we've been discussing would impact patients who rely on such therapy.

Administering infusion therapies is very much more involved than administering oral medications.

Infusion therapy necessitates specialized equipment, supplies and professional services including sterile drug compounding, care coordination and patient education and monitoring.

And currently Medicare fully covers infusion therapy when it's administered in a hospital, a doctor's office or a nursing home. Medicare's coverage of infusion therapy in the home though is fractured and does not adequately cover the services needed to provide home infusions. That's the patient's home.

Not only does this coverage gap force patients into expensive institutional settings but it also puts patients at risk of developing additional infections in these environments and on top of that this coverage gap prevents patients from receiving the treatment they need in the most comfortable setting possible—their homes.

In 2003, Congress opted to exclude infusion drugs from the average sales price, or ASP pricing methodology, put in place for other Part B drugs, and as I mentioned Medicare does not reimburse for the services needed for home infusions and ASP pricing is insufficient to cover those necessary services. It just doesn't make sense. I want to highlight it because I think it's important.

Unfortunately, we still have not corrected this coverage gap and that's why Congressman Pat Tibiri and I have introduced H.R. 605, the Medicare Home Infusion Site of Care Act, which would ex-
pressly provide coverage for infusion-related services, equipment and supplies.

Given that this coverage is still not in place though I think we need to be cautious when considering changes to the reimbursement structure for infusion drugs.

While CMS has excluded DME infusion drugs from the Phase I of the Part B drug payment model, these drugs have not been excluded from Phase II.

So let me ask Mr. Baker, would you agree that more work is needed to ensure that Medicare beneficiaries can get the infusion therapy they need in the comfort of their homes?

Mr. Baker. Yes. I think that certainly Medicare doesn’t provide, as you said, adequate coverage right now for home infusion services and we would agree that this problem could be resolved outside of the demonstration.

It’s not necessarily affected one way or another by the demonstration, and certainly in part two this could be part of the resolution where there could be additional legislation that would bolster this benefit for beneficiaries and make it more available to them.

Mr. Engel. This is something that, obviously, is better for the patient but ultimately would involve a savings of money, it would seem to me. So it seems like a win-win.

Mr. Baker. If the setting is as safe as you’re saying and it’s at least a less expensive setting and more convenient to the patient and that would certainly be a win-win.

Mr. Engel. OK. Thank you. Thank you, Mr. Chairman.

Mr. Shimkus. Gentleman yields back his time.

The Chair now recognizes myself for 5 minutes for questions.

And first of all, before we start, I ask unanimous consent that the letter on May 2nd signed by 241 Republicans and one Democrat in opposition to this rule be placed into the record. Without objection, so ordered.

Mr. Shimkus. I want to go on, first, to Mr. Baker. Are you at all concerned that this proposal will force large numbers of Medicare beneficiaries into a mandatory test?

It was kind of talked about that this is not voluntarily. No one is signing consent forms. It’s a mandatory—so does that have some—are you concerned about that? I mean, that’s not really how tests are operated.

Mr. Baker. Well, we have a number of demonstrations that are going on throughout the country and, for example, ACOs——

Mr. Shimkus. Yes. But I mean we’re talking about size too. I mean, this is really not a test. This is in actions a rule, you know, promulgated because it dwarfs—the test dwarfs the remaining control group.

Mr. Baker. Right.

Mr. Shimkus. Significantly.

Mr. Baker. And we’ve done these kinds of, if you want to call them tests or——

Mr. Shimkus. Of this size, percentage wise?

Mr. Baker. We’ve changed reimbursement before. We were talking about a change in reimbursement. And so what I would posit is that we need to evaluate and monitor that change in reimburse-
ment very carefully because whenever we do that there can be unintended consequences.

Mr. SHIMKUS. OK. Let me ask another question. What’s a larger expense to the individual patient? Twenty percent of a doctor office oncology service rendered or 20 percent of an oncology services rendered in a hospital setting?

Mr. BAKER. Typically, the hospital settings can be more expensive than physicians.

Mr. SHIMKUS. Typically, like, if you find one that’s not please let us know. I just don’t think that’s possible, which is part of this debate, because especially in rural districts you’re changing really, in essence, a lifestyle in care of patients. We have great concerns.

I also, Ms. Block, want to—thank you for your service to the country. Brats—Army buy, I’m an Army guy so we’ve both done the deal.

But I don’t—so you got Medicare based upon disability. When you entered Medicare were you given a choice of supplemental or a Medicare Advantage?

Ms. BLOCK. Thank you for the question. I was not given the choice of a supplemental. Supplemental coverage for under 65 is a whole another issue. So I welcome a hearing on that.

Mr. SHIMKUS. Well, no. But were—so you could have?

Ms. BLOCK. I could not at that time, no.

Mr. SHIMKUS. And why?

Ms. BLOCK. They didn’t offer policies in my State. That’s a State-by-State issue on whether insurers have to offer policies for those under 65 that are disabled. Now, you could enter an Advantage plan but, unfortunately, I live in a rural area and the Advantage plan doesn’t cover any providers.

Mr. SHIMKUS. Right. OK. Thank you. I wanted to clear that up. Appreciate it.

Dr. Schweitz and Dr. Patt, CMS continues to reiterate that, and I quote, nothing in this proposal will prevent doctors or other clinicians from prescribing the treatment that a patient needs.

Do you believe this proposal will impact your ability to prescribe and administer the most appropriate treatments for your patients in your office? Dr. Patt first.

Dr. PATT. Thank you.

Mr. SHIMKUS. And pull that mike close.

Dr. PATT. So I don’t believe that this will change my opportunity to prescribe the appropriate therapy. It will alter my ability to deliver the appropriate therapy to my patients.

So I think that, you know, there are two alternatives. One, is that you either financially have a hazard for a practice that’s likely to have them closed by having them take money out of the practice to try to purchase a drug that they cannot afford or they’ll shift the patient’s care to a different site of service like the hospitals.

When we’ve seen the shift occur in the last decade, we know that the hospital outpatient department increased 30 percent of the chemotherapy infusions that they have in the last decade and the reason for the shift are the financial changes.

We know that during that time period of that 30 percent shift that the hospital cost is a higher site of service care—30 percent
higher—and the patient outpatient cost is higher in the hospital outpatient department as well.

Mr. Shimkus. Because the co-pay will have to pay that 30 percent additional cost?

Dr. Patt. In fact, we recently conducted a study with the Community Oncology Alliance and the Millman Group that looked at the 10-year shift from 2004 to 2014, and if you take the drug—if you take the costs in 2014 and attribute the cost only to site of service shift alone, it’s $2 billion in that 1 year.

Mr. Shimkus. Dr. Schweitz?

Dr. Schweitz. I agree with Dr. Patt. It won’t impact our ability to prescribe but our ability to deliver. If, as a business entity, we are unable to make ends meet we will not be able to provide the service.

That’s the central issue, and if we cannot provide the service in our office we’re going to have to move the patient to a different site of service, i.e. the hospital.

Mr. Shimkus. And I’ll just end on this. My time has expired. It doesn’t make sense to move people out of doctor-center oncology services and move them into a hospital setting where they—you have the chance of other infectious diseases that could occur and we all know of the risks that’s involved in that.

So with that, yield back my time and recognize the nurse, Ms. Capps, for 5 minutes.

Ms. Capps. Thank you, Mr. Chairman, and thank you all for being here today. I appreciate that this topic is brought up today and your expertise on it.

I believe we can all agree that the current system is not working. Providers have long noted that the ASP+6 drug reimbursement formula is inaccurate and some patients have struggled to come up with their 20 percent share of the cost of their share in these settings.

While the Part B program was intended to relieve our most vulnerable from catastrophic costs by providing access to important medications, for some—many individuals, I would say, it has fallen short.

While the problems with the current system are well known, how to move forward to address it is more controversial—complicated.

Through this—though this demonstration project is an opportunity to explore strategies that could help transition Medicare into a more value-based system, I remain concerned about some elements of the project.

Last week, my colleagues and I wrote a letter to CMS with concerns about certain components of the demonstration, particularly the nationwide scope of the project, the possible impact of it on small medical practices in under served areas and the potential shifting of patients of provider offices to expensive hospital settings.

As co-chair of the Cancer and Heart and Stroke Caucuses and as a nurse, my biggest concern is that CMS needs to find ways to address problems before they strike and have them place a strong mechanism or strong mechanisms to identify barriers to care that arise during the demonstration.
But and the very real fact that patients depend on drug therapies to extend and improve the quality of their lives is critical to this. But they and the system need to be able to afford it. In light of this, we must proceed thoughtfully and in the best interest of patients who will be most affected by this demonstration.

Ms. Block, you mentioned in your testimony the difficulties of paying the 20 percent co-insurance for vital drugs as a Medicare beneficiary.

And Mr. Baker, is Ms. Block's experience common for Medicare beneficiaries? Should Medicare have an out of pocket maximum like the one in the Affordable Care Act to address this?

Mr. Baker. There's about 10 to 14 percent of people with Medicare that do not have supplemental coverage, as Ms. Block does not, and they pay the full freight for that 20 percent.

As you note, there's no out of pocket maximum in the Medicare program so that means that, you know, you're paying that 20 percent up to infinity.

There's never a place where Medicare takes over that coverage and provides you with 100 percent of coverage regardless of how much you're spending out of pocket.

As you say, plans under the Affordable Care Act as well as plans available to employed individuals usually have some limit on out of pocket spending.

Ms. Capps. OK. As we look at the plans for this demonstration program, my primary concern is for the patients and the tools they will have to address any barriers to care on the front end rather than afterward.

I know some of my colleagues have touched on this but it is a great concern to me. So Mr. Baker, as someone who works to ensure access to affordable health care for Medicare beneficiaries, are there aspects of the demo that will help protect patients from disruptions in care?

Are there any other protections that you would like to see? This is demonstration. This is the time——

Mr. Baker. That's right.

Ms. Capps [continuing]. To look at it. Any other protections you would like to see to ensure that patient care is not disrupted?

Mr. Baker. Once again, I think that the ombudsman program that was used so successfully and the Congress mandated for the durable medical equipment program is an important protection, would be—would serve to protect consumers as well as this idea of getting shared decision-making tools out there for consumers and physicians to be able to work together and talk through clinical effectiveness as we move into Phase II.

But I think the ombudsman is why I haven't mentioned the pre-appeals process that would be used in the Phase II and that would basically allow providers and/or consumers to do an appeal and to get relief if they feel that something is unavailable to them or not reimbursed at the right rate in the value-based phase of the program.

Ms. Capps. Thank you.

You know, just in concluding, in our efforts to improve the Part B program we have to keep our eyes on the goal of ensuring that
patients have timely and affordable access to medications they need. That's got to be the bottom line.

As we move forward, I urge CMS to pay special attention to the impact the demonstration project will have on our Nation's most vulnerable and to continue to work with affected stakeholders to address issues and unintended consequences before any changes are implemented. This is the time to do that. So I yield back.

Mr. SHIMKUS. The gentlelady yields back the time.

The Chair now recognizes the gentleman from Pennsylvania, Dr. Murphy, for 5 minutes.

Mr. MURPHY. Thank you, Mr. Chairman, and I thank the panel for being here.

Before I start, Mr. Chairman, I just want to say I have a letter from the National Alliance on Mental Illness I'd like to submit for the record.

Mr. SHIMKUS. Without objection, so ordered.

I'd also like to correct the record. There were four Democrats on my letter, not one. So——

Mr. MURPHY. Thank you. That is recognized too.

Now, starting—Dr. Patt and Dr. Schweitz, you both deal with chronic illnesses of cancer and rheumatoid disorders. I want to just point a couple of things.

In the area of mental illness you may be aware that 75 percent of people with severe mental illness have at least one chronic illness. Among them are ones within the areas you practice.

Fifty percent of people with severe mental illness have at least two and a third have at least three or more other chronic illness and it is important we deal with those.

As a matter of act, Medicaid reports that they—about 5 percent of Medicaid recipients are responsible for about 55 percent of Medicaid spending and nearly all of them have a mental illness.

So in the context of this, I want to ask a couple questions here. Both of you discussed in detail some of the concerns about the proposed demonstration, the negative impact on patient access to treat cancer and arthritis.

Hopefully, you're aware that similar concerns are there also in the area of mental illness drugs, particularly long-acting injectables, anti-psychotic medications that treat schizophrenia and other psychotic disorders.

And, of course, when a person is more stable they are adhering to their other treatments for the diseases that you treat. When you're not stable they're not following through on this.

So with regard to this, I see that CMS' proposal is based on this idea that we should be paying for services based on the average patient under this Phase II CMS proposal to provide, quote, "equal payments for therapeutically similar drug products", unquote, and assuming the most clinically effective drug in a group can be identified.

But in practice—and I need you to answer this both in about 15 seconds—what impact will these one-size-fits-all value assessments have on patient access to individualized and personal medicine?

Can't have a dissertation. Real quick.

Dr. PATT. I think that they will have decreased access to higher cost appropriate therapies.
Mr. MURPHY. Thank you. Dr. Schweitz, would you so agree?
Dr. SCHWEITZ. I agree.
Mr. MURPHY. And so would you say with part of this is that, I
mean, certainly you would agree that different people respond differ-
ently to the same medication with regard to effect and side ef-
fects. Would you both agree with that?
Dr. SCHWEITZ. Right.
Mr. MURPHY. And also that you need to adjust your prescriptions
in order to decrease side effects and increase effectiveness and
therefore increase adherence. Is that correct too?
And now, the FDA said that medications not taken as prescribed
occurs about 50 percent of the time and the Center for Disease
Control tells that nonadherence causes 30 to 50 percent of chronic
diseases treatment failures and about 125,000 deaths per year.
So I look at this then that—an important safeguard in current
law that says CMS cannot use cost effectiveness as a threshold to
set Medicare average payments or payment policy.
However, in Phase II of the proposal CMS intends to use cost ef-
fectiveness in its analysis to inform value-based pricing.
Now, would it concern you if CMS said that in order to imple-
ment this proposal they would ignore or waive this safeguard? Dr.
Patt.
Dr. PATT. It would concern me.
Mr. MURPHY. Dr. Schweitz.
Dr. SCHWEITZ. Greatly. Greatly.
Mr. MURPHY. And with regard to this, it also seems to me that,
you know, obviously people more likely to take a medication that
they—that deal with the side effects—some may actually take a
certain medication because they find the side effects less objection-
able and another one will say I'll deal with the side effects but I've
got to have the treatment for this too.
But these are all tradeoffs. But it seems to me that the way this
proposal is coming through that it would limit the patient choice—
your choice—and when a patient is not adhering to those drugs we
saw from those statistics from FDA and CDC it may actually com-
plicate the diseases tremendously and increase the cost. Now, can
you elaborate on that, Dr. Patt and Dr. Schweitz?
Dr. PATT. So as I said before, I think that we would continue to
prescribe the drugs we think that are appropriate. But this pro-
posal would impact the patient’s ability to receive those drugs.
Mr. MURPHY. And with that, isn’t it—it’s best that—I understand
adherence works best if you actually have a conversation with a
patient with regard to the drugs.
Dr. PATT. Absolutely.
Mr. MURPHY. But if that—and I know you’re saying you would
prescribe it anyways—but if there’s a difference in reimbursement
or—
Dr. PATT. Well, I’m saying that I would prescribe the drug any-
way. But you can imagine a scenario if someone was in a rural
clinic and a drug is prescribed for them that they cannot receive
in that rural clinic and they have to travel a distance to a hospital
that may be two or 3 hours away to be able to receive that therapy.
That would likely diminish compliance with a therapeutic regimen.
Mr. MURPHY. Dr. Schweitz?
Dr. Schweitz. I would add to that. I'm in a relatively urban area, and there is no nearby hospital that I can send the patient to for an infusion.

Most of the hospitals are not treating our patients unless they're 340Bs. So there is decreased access in that way as well and our fear is that our patients are going to drop out—that compliance will drop and they won't get treated.

Mr. Murphy. And my fear is they're going to drop dead, according to statistics that CDC gives us and that's pretty frightening. And so we may save a little money in the front end by not prescribing the drug but the complications of the overall cost increases need to be taken in account. I thank you for your insights, and I yield back.

Mr. Shimkus. Gentleman yields back.

At this time the Chair now recognizes my colleague from the great State of Illinois, Ms. Schakowsky, for 5 minutes.

Ms. Schakowsky. Thank you, Mr. Chairman.

I want to make a couple of comments and then I want to get to Ms. Block and Mr. Baker with some questions.

But, you know, I just feel like if you are offended at all at the suggestions that physicians would prescribe higher cost drugs because you want to make more money then it seems to me that the suggestion of CMS, which is that there be a percentage plus, a lower percentage, plus a flat rate would be something that would not be objectionable.

Also, I wanted to mention that I found it very curious in testimony of Dr. Patt as well that there’s over two pages within your testimony that are exactly the same language—exactly the same language. Even the highlighted important parts are highlighted in the same—in the same way. I thought that odd.

But I also wanted to mention that there was a difference. Dr. Patt and Dr. Schweitz touched—both touched on something in their testimony.

Dr. Patt, you claimed that drug prices are not truly increasing faster than the rate of overall health costs. Yet, Dr. Schweitz, in your testimony you stated that you are keenly aware of unsustainable rise in drug costs and the effects of those costs on our patients' ability to adhere to treatment regimens. That's your quote.

And I have to say, Dr. Schweitz, that I agree with you that spending on prescription drugs has risen significantly in recent years, driven by high and rising drug prices and recent IMS health report found that list prices for brand name drugs increased by more than 12 percent in 2015, representing the second year of double-digit increases and on and on.

But I want to get to Ms. Block. Thank you so much for coming here today and telling your story. I know that there isn't a family including my own that hasn't gone through the issue of—related to cancer and treatments that are required and the issue of affording those treatments.

So you testified that your cancer treatment has been incredibly expensive. Can you detail some of the costs and how they've impacted your personal finances?
Ms. BLOCK. I guess I can begin—thank you, first of all—I think I can begin to say that when you enter cancer world it’s a different world and no one talks about cost at first.

So it’s very interesting when costs—when you start to ask questions and you have difficulty getting answers. I’ve had probably—I think I’ve had six surgeries by now, including one with a long stay in the hospital.

I’ve been through full ranges of chemo. This is the third type of drug that I’m on now. Having metastatic cancer, what that means is you’re constantly changing drugs to keep up with the cancer, so it’s always changing. And the future is stacking drugs, which means more than one drug at a time. So my expenses will only go up.

I make up budgets all the time. I think they’re probably meaningless because we don’t know how long I’m going to live. But you do the best you can to try and stay on top of it, and that’s what life is like living with cancer in a country like ours where the drug prices just continue to rise.

I’ve actually done my own studies on what my drug costs in other countries as opposed to the U.S. I did it on social media. It’s an amateur study.

But I was able to find out that I’m paying much more than every other country that I found, including Dubai, U.K., Denmark, you know, Norway, Sweden, on and on. Every other country that I have friends that were able to come back and tell me the monthly cost of their drug.

Again, it’s an informal amateur study, but I keep looking at am I going to have to move eventually—is that what my recourse is as the drug prices continue to rise and my savings dwindle?

Ms. SCHAKOWSKY. Thank you. I want to wish you the best, too. Mr. Baker, why is it important that we work to reduce or eliminate cost sharing for beneficiaries? What impact would this have on one’s ability to access care?

Mr. BAKER. I think, once again, certainly for the folks that go bare, as it were, on the 20 percent it will increase their ability to access these treatments.

They’re disproportionately folks with lower incomes, anywhere from $10,000 to $25,000 a year, disproportionately African American.

Ms. SCHAKOWSKY. I want to tell you, I have talked to—at my pharmacy. I said, “What happens when people are told it’s $1,000?” He says that often, not most, but often they just walk away.

Mr. BAKER. They walk away. Right. Or they find a way to pay for it with family friends mortgaging their home and other situations like that.

So they are, as we were saying, underwater and unable to access the care.

Mr. SHIMKUS. Gentelady yields back her time.

Chair now recognizes the gentleman from Missouri, Mr. Long, for 5 minutes.

Mr. LONG. Thank you, Mr. Chairman.

We are in the 114th Congress which each Congress, of course, runs for a 2-year period. During the 113th Congress, I did not miss a single vote in that 2-year period, which there was about a half
dozen of us that had that type of a voting record, and it's tough when you catch flights, you miss flights, there's connections, everything.

There's 2-minute votes. You have to be paying attention. And so voting is very important to me. In this Congress, the 114th Congress, I missed two solid weeks of votes.

Didn't go to the floor for two weeks because our 25-year-old daughter, youngest daughter, was diagnosed with non-Hodgkins lymphoma and so I kind of realized what it's like to go through that process. Thankfully, she's doing great, had her 12 rounds of chemotherapy, lost all her hair, got all her hair back, curls and all.

So we've been very, very fortunate with the—what's happened in oncology over this last 20-some years because I think that if it would have been 20 years ago we might not have had the same outcome.

So with that as a little background on my personal story with our daughter's battle, Dr. Patt, supporters say this proposal will remove incentives to use higher-priced medications that are no more effective than alternative therapies. Can you talk about therapeutic alternatives in oncology?

Dr. Patt. Yes, sir. First of all, I wish your daughter the very best.

Mr. Long. She's doing great.

Dr. Patt. I think most of us have a personal experience that we've been touched by at least someone with cancer. And so being able to deliver high-quality care close to one's home is critical to maintain quality cancer care for Americans.

With regards to therapeutic alternatives, I'll say that, you know, this proposal what it does is it disincentivizes utilization of high-cost options for treatment.

And so if there is a high cost alternative and a low cost alternative that's equivalent in terms of efficacy and toxicity obviously——

Mr. Long. And they were closing the door. I didn't hear—in terms of what?

Dr. Patt. In terms of efficacy and toxicity. Then, you know, we would want to facilitate utilization of the lower cost alternative.

In fact, the U.S. Oncology Network—my network, which treats over 12 percent of Americans with cancer—we use a pathway system in the network which brings in drugs if there are alternatives that we only have the option of using the lower cost alternative. The problem is is there are actually few instances where a therapeutic alternative that is equivalent actually exists.

And so, like, my patient in my testimony who receives Recepten, or a monoclonal antibody, against HER2 there is not a therapeutic equivalent for that drug and it's changed her survival from weeks to over a decade.

And so, you know, the therapeutic alternative would be to give no treatment because there's not a low cost alternative to that drug.

So it's either our sum scenarios—you know, I think that the stage two—stage IV second-line treatment colon cancer drugs are a commonly discussed alternative where there are drugs that are of equal efficacy and similar toxicity profile that have a difference
in costs. Non-small cell lung cancer is also another area that’s frequently talked about.

But the truth is oncology is a collection of many different diseases and many of them don’t have equivalent therapeutic alternatives.

And so a decision to provide a lower-cost drug may convey a diminished survival benefit for patients and that’s not an alternative. We want patients to live better.

We want patients to live, you know, on chronic therapy—to have even advanced cancer be a chronic disease where they can live a good quality of life and live a longer life.

Mr. Long. You sound like Michael Milken. That’s what he told me. He said he wanted to make cancer a chronic disease and they’ve done a lot of good work in that area.

Also, Dr. Patt, what impact will this proposal have on consolidation in the oncology space and the continued shift of care from the physician office to the hospital?

Dr. Patt. That’s a great question.

So as you know, in the last 11 years we’ve seen an over 30 percent shift from community clinics to the hospital outpatient department.

We recently conducted a study with Millman that demonstrated that community clinics gave about 84 percent of therapy in 2004 and only 54 percent in 2014.

We know that that site of service shift would be augmented with other financial pressures on community oncology practices and that the natural consequence of that action would be higher cost for payers and patients.

Mr. Long. OK. Thank you, and I’ll yield back my four seconds, Mr. Chairman.

Mr. Shimkus. We appreciate that. Thank you very much.

Chair now recognizes our veterinarian from Oregon, Dr. Schrader, for 5 minutes.

Mr. Schrader. Thank you very much, Mr. Chairman. Appreciate it.

I, like many others, have submitted a letter to CMS regarding the scope of this demonstration project and also sympathy particularly for the special need groups and the types of medications you administer.

You just can’t go to a generic. I mean, oftentimes even in my little world of veterinary medicine there were brand names drugs that would work and only be the drug that would work for certain patients of mine.

So I’m hoping and based on past track record that CMS will be responsive to a lot of the concerns you’re talking about as we go forward and the trick is, as everyone I think has alluded here tonight or today, is get it right. You know, make sure we get it right.

I don’t think the appropriate way though is to just stop the rule altogether. I think we’re losing a little bit of focus and this is a proposed rule. CMS hopefully will be listening to this testimony and come back with something that is better than what we have seen so far.
I’d be probably not smart to legislate before I actually see the proposed rule. And the goal is to get to a value-based, you know, outcome and value-based purchasing is part of that.

I think there’s some alternatives that are being discussed. The second phase I think is pretty interesting. But aside just dealing with this individual drug or that individual drug, different incentives are probably very, very appropriate and I guess I’m hoping that as we talk through this that this—we can—it continues to be very constructive as we go along.

Shifting gear a little bit, I guess, Dr. Baker, you talk a little bit about Phase II. We focused here pretty much on Phase I, but Phase II offers some options and I’d be curious your take on that.

Mr. Baker. There are many physicians on the panel, but I’m not one of them so——

Mr. Schrader. Mr. Baker, I do apologize.

Mr. Baker. So, first off, I think there are a number of value-based initiatives in phase two of this project, reference pricing, indication-based pricing, outcomes-based risk sharing agreements and others and, you know, for example, Express Scripts is looking at implementing a system—is implementing a system of indication specific pricing with some of its clients including with cancer drugs, several pharmaceutical companies and ensures health plans are partnering on outcomes risk—outcomes-based risk sharing Novartis with Anthem and Cigna on Entresto for treating heart failure, others with other drugs around moving cholesterol range, United Health with Gilead on Harvoni for hepatitis C.

CALPERS, the large California insurer for public sector employees and Safeway are using reference pricing.

First Safeway used it for colonoscopies because of the differences in prices in the markets across the country that they were seeing and within markets where they were—they had stores and now they’re expanding that to other aspects of health care.

So we see this in use in the private sector, these models being used—being heavily evaluated and monitored once again in the private sector and we do believe Medicare in phase two of this project can take advantage of that experience but also needs to be very transparent, needs to be very engaged with stakeholders because as we’ve heard there are instances where there are not clinically equivalent pharmaceutical products. And so we went to make sure that there is access to all of the products and that an individual determination will still be able to be made with a patient in a doctor.

That’s why the pre-appeals program is important that CMS has put in there with balance building protection to consumers which is very important as well to keep their access to all of the drugs that might be useful for their condition.

Mr. Schrader. Yes, and I do appreciate the tone of your response because the goal here is to treat the patient. I mean, we’ve heard everyone testify that is our goal and, you know, certainly, the—historically we’ve seen that through the prism of our own particular specialty or practice mode and I think one of the goals of healthcare treatment going forward, whether or not we like the ACA or not, is to treat the whole patient.
And that usually involves, frankly, getting together as groups of doctors and hospitals and organizations, not necessarily giving up their private practice but working with your colleagues and having a relationship so that Ms. Block or whoever can get the right referral.

You come in for one issue and you discover another one maybe much more serious—you want to make sure that that group takes care of you and I think the focus of this hearing has been on just a fee for service piece and the real goal, I think, is to get to bundle payments where different doctors with their patients get to make that particular choice of what type of treatment, what medication to get, if a medication is better than perhaps psychological behavioral treatment.

There’s a lot of what we’re talking about here focussing only on a fee for service and I think that’s an old way of treating things. We need to be moving forward and value-based bundle payments would, I think, a lot of the concerns that have been expressed here. And I yield back. Thank you, Mr. Chairman.

Mr. PITTS [presiding]. Chair thanks the gentleman.

Now I recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you, Mr. Chairman.

I’ve heard from ophthalmologists about the proposed demonstration’s potential impact on access to sight-saving treatments for numerous blinding conditions including age-related macular degeneration—AMD—which is the leading cause of blindness in the United States.

Currently, there are three treatment options for AMD and other ocular conditions. Two are name brand drugs approved for ocular use and one is a cancer drug, Avastin, that is repackaged for off-label use by ophthalmologists for the eye.

The demonstration seems to assume that lower cost alternatives are always available. However, many ophthalmologists are experiencing increasing difficulties accessing the lower cost drug, in this case Avastin, due to new Federal and State regulations on the compounding and repackaging of drugs.

Also, notwithstanding the fact this committee worked very hard to allay fears—the fears related to compounding drugs as a result of the New England Compounding Center scandal and tragedy has made many patients reluctant to receive a drug that is compounded and repackaged.

Both of these factors are leading to increased use of the more expensive brand drugs. Further, I am told that the continued access to Avastin for the treatment of AMD and other ocular decisions will effectively end if the FDA finalizes its pending February 2/15 draft guidance that calls for a maximum five day beyond use date for compounded or repackaged biologics.

So I know that it’s not directly on point with what you all have been testifying to this morning and you may not wish to comment on this.

But I’m just curious if you all would think that perhaps CMS ought to go back and take a look and instead of including all Part B drugs if the agency ought to give consideration to excluding certain classes and, obviously, the one that I just talked about are
classes of drugs that include compounded repackaged drugs or
drugs that are used off label for demonstration.

So do you think that—and I guess I'll ask you, Dr. Patt, although
I understand it's a little off your subject area.

Dr. PATT. Thank you, Mr. Griffith. So I'm not an ophthalmol-
ologist. But I will say that there have been discussions of carving out
the oncology care model, of carving out certain segments.

In my opinion, there's not a right way to do the wrong thing. We
need stakeholder engagement from the beginning to engage with
CMS and value-based ways in which we can move forward like we
did with the oncology care model. We want to participate.

In our oncology practices we have many value-based programs
and have demonstrated pilots that have saved tens of millions of
dollars. And so want to work with CMS on that kind of work. I
don't think that there's a way to exclude certain segments from
this pilot and make it make it better.

I think that we need to go back to the drawing board and look
to projects like the oncology care model that are collaborative and
value-based and have a better path forward. We would like very
much in the oncology community to participate in that.

Mr. GRIFFITH. Anyone else have a comment on that?

OK. Sticking with you, Dr. Patt, I noticed on Page 11 of your
written testimony—I didn't hear it in your oral testimony but in
your written testimony you did talk about the era of hospital acqui-
sitions and consolidation in the oncology space where doctors' prac-
tices are being taken over by the hospital and you think this exper-
iment by CMS will push more of that and then that makes it even
harder for rural districts like my own and earlier one of the folks
said they had a rural district—they had 19 counties. I have 29 geo-
political subdivisions, most of whom are rural counties.

Dr. PATT. Yes, sir. So as we mentioned, the current model which
is not really ASP+6, because you have to take out Prompt Pay se-
questation and the six-month lag, has to take into account not
only acquisition but also inventory storing of drugs, specialized
handling of drugs and then—and then disposal of drugs. So there's
a lot that has to go in there.

If you bring it down to ASP+.86 percent you have to know that
average sales prices by its very nature an average. There are peo-
ple that pay more than that average and people that pay less than
that average.

Hospital systems in large practices are going to get preferential
contracting to pay less than average on average and smaller prac-
tices are going to have less bargaining ability because of less vol-
ume-based purchasing and have to pay more.

So you can imagine if you're at ASP+6 percent it has to pay for
all of these other functions and you're paying 1 percent higher.
How will you be able to keep your doors open?

And so what we've seen with these financial pressures over the
last decade is the natural consequence of the shift from community
practices to the hospital outpatient department and we know that
that's a 30 percent shift in the last 11 years.

We also know that that conveys on average a higher cost of over
30 percent and a higher co-pay for patients. And again, if we look
at the cost of that shift in 1 year for cancer spending, just attributed to the distribution of site of service alone it's about $2 billion.

Mr. GRIFFITH. I do appreciate it. Thank you very much and I appreciate all of you being here today. Yield back.

Mr. PITTS. Chair thanks the gentleman and yields 5 minutes to the gentlelady, Ms. Castor, for questions.

Ms. CASTOR. Thank you, Mr. Chairman. Thank you to all of our witnesses for participating today.

Ms. Block, you've heard the testimony from the doctors on the panel that find the proposed model very problematic. They say that this will actually harm patient care, that oftentimes the doctors do not know the cost of drugs. They are focused on what is best for the patient. How does this—what's your response to that?

Ms. BLOCK. I guess I would start by saying in all of the work that I did in many countries around the world we were told that you could never even have the appearance of impropriety. So that we couldn't take a cup of coffee from someone because there could never even be an appearance of impropriety.

So I guess what I would say is that if there's a chance that there's financial incentives involved here then we remove them and come up with an appropriate storage and handling fee.

But as long as there is an appearance of financial impropriety I'm going to question that, number one. And the second thing is I am just still not reading where there's going to be a specific issue with access to any of the drugs.

I know my doctor is limited to what drugs I can get at this point too. But when I asked him he said he didn't see any issue with access after reading this demonstration project.

So I understand that maybe in some areas there's some drugs they're saying that maybe they can't afford to get. But is the 6 percent really making the difference?

So as a patient I really question some of this and just want to keep bringing the focus back to the patients are already under water. We already, you know, don't have enough money to pay for this.

So when everyone's talking about all these issues and obstacles in the way how do we get back to how to make the system work better for the patients.

Ms. CASTOR. And Dr. Schweitz, I mean, the cost of drugs now is astronomical for many families. You know, it just—it does oftentimes push care out of reach for them and then when we have anecdotes about how costs are so much lower in other countries a lot of my neighbours at home say why, why in America are drugs—why do they cost so much more.

So what advice can you provide about how we better control drug prices and Medicare spending?

Dr. SCHWEITZ. That's a very good question. Unfortunately, I don't have a clear answer. I do know that access to medications across all medications including generics is becoming problematic for our patients.

But it's not an easy problem. There is no easy answer. I think we all have to sit down at the table—patients, providers, payers and manufacturers—to see how we're going to work out that problem so that our patients have better access.
Ms. CASTOR. Dr. Patt, do you have any advice on how we address the high cost of drugs?

Dr. PATT. Ms. Castor, as you know, I’m very concerned and oncologists are very concerned about the increase in drug prices. I know you’ve heard from Dr. Diaz in your district with Florida cancer specialists and from others that this is a great problem.

Unfortunately, doctors don’t set the prices for cancer drugs, and when we look historically at what’s happened as a natural consequence of CMS decreasing reimbursement like the Prompt Pay discount and sequester, we see that during that time interval that costs went up tremendously.

And so what we see is that that’s not effective at controlling drug prices. What I’d like to see—what I think doctors can do and what we can partner with CMS to do within our realm is to change our system of care delivery to value-based systems and, again, like I’ve said before, we would like to be partners with CMS in that endeavor like we have been with the oncology care model and like we have done in our practice, the U.S. Oncology Network, that treats 12 percent of Americans with value-based pathways for a decade.

Ms. CASTOR. So Mr. Baker, you’ve heard what they’ve said. It’s—gosh, it’s very difficult, they don’t have all the answers on drug costs. Dr. Patt says we can look at value-based and indeed the second phase of the model proposed to examine the impact of certain value-based and you’ve mentioned that.

What I haven’t heard is how we link this to outcomes as well. When you’re talking about value is there no— is there no ling currently under Part B prescribing to outcomes? Do we not have the data and are you confident that this model is actually gathering that data?

Mr. BAKER. I think that right now we don’t have a lot of that data. I think we’re starting to get this data in part of the private sector value-based experiments that I talked about earlier.

I think those models can lead to further outcomes-based information that we can use in this space to this model. But I do think part of the challenge of getting to a good place on this Phase II is making sure we have the right metrics, that we have the right feedback loop on outcomes.

And so we recommended that that definitely be a part of Phase II.

Ms. CASTOR. Yield back.

Mr. PITTS. Gentlelady yields back. The Chair recognizes the gentleman, Mr. Bilirakis, 5 minutes for questions.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate it. I thank the panel for their testimony today as well.

Many conditions, especially within the rare disease community, lack treatment and those that have a treatment do not have multiple therapies to choose from.

Ms. Boyle and Dr. Patt, under the proposed rule it seems like it would encourage physicians to prescribe cheaper or generic alternatives to benefit from a flat fee in the reimbursement payment. Do many of the Part B drugs have interchangeable alternatives?

Ms. BOYLE. Well, representing the Immunodeficiency Foundation we have a number of conditions that only have drug. There is not an alternative.
Whether it's a generic or nongeneric, there's only one drug and, again, if this experiment reduces the ability of the physician to provide that drug, when you're talking rare diseases there are very few physicians or hospitals around that have the ability to treat the patients.

We experience this with intravenous immunoglobulin back in 2005, ’06 and ’07 with the change in the MMA and our patients were shifted from the physician office. Those that could find hospitals, and that was not always an easy thing to do to infuse immunoglobulin and where there are no generics but there are a number of products, we're lucky to find a site of care.

Very often they had to change their product and there were many who could not find a site of care and had to go without. There were—the OIG and the ASPE reports did report on adverse events for these patients—sickness, hospitalizations—and there just aren't alternatives for the rare disease community. It's not just our patients, it's many other patients with rare disorders. So this is very frightening.

Mr. BILIRAKIS. Thank you. Dr. Patt.

Dr. Patt. So I'll say in the oncology community there are a few examples of treatment alternatives with equal efficacy and toxicity that have differences in cost. And in those scenarios, you know, we think that utilization of the lower cost alternative would absolutely be appropriate.

The problem is is that these instances are few and far between. But in order to optimize the ability to give value-based prescribing, as I mentioned the U.S. Oncology Network had pioneered value pathways.

ASCO, the American Society of Clinical Oncology, has come out with a pathways policy statement. There are other pathway systems which utilize this and the community oncology alliance has come out with a patient-centered oncology medical home also trying to utilize a pathway system really to facilitate appropriate utilization because most of the time there are not alternatives that are equally efficacious and toxic that are of different costs where a lower cost alternative is truly therapeutically interchangeable.

Mr. BILIRAKIS. Thank you. The second part of the question—Ms. Boyle again and Dr. Patt—under the proposed rule one value-based tool is the use of reference pricing. This requires setting a standard payment rate for an entire group of drugs, usually using the most clinically effective drug in a group for therapeutically similar drugs.

Can you do reference pricing when there are no alternative drugs available?

Ms. Boyle. Well, for instance, in the immunoglobulin products there are 13 of them. There have never been any trials—head on trials comparing them. They all are approved by the FDA but they're all very different.

Some have high sugar content. Some have high salt content that would be bad for patients with heart conditions or diabetes. They all have different formulations and patients react differently.

Some are appropriate for subcutaneous infusion, which some patients need because they have poor venous access or they have other adverse events to IV.
Some patients cannot do subcutaneous. They are really not appropriate. So I don’t know how you would put these together. Patients react differently and when you look at the administration and talking precision medicine and let’s take best product for the individual patient this proposal runs counter to that.

Mr. BILIRAKIS. Dr. Patt, briefly, because I want to ask another question.

Dr. PATT. And I’ll say that we don’t today have a way to do reference and value-based pricing in oncology. But we would love to partner with CMS to do that instead of having a policy just drop down to us.

Mr. BILIRAKIS. Thank you very much. Mr. Chairman, I know I have seven seconds so more than likely I’ll yield back if you’ll give me a couple more. Can I have a few more seconds to ask another question? Yes? OK. Thank you.

Ms. Boyle and Dr. Patt again, under the proposed rule one of the value-based tools would have CMS pay more for effective treatments. Does CMS actually define what an effective treatment is? In the world of oncology or IG where treatment is more personalized, as you said, is it wise to have an unelected bureaucrat declare what is effective for all seniors, and I’ll start with Ms. Boyle.

Ms. BOYLE. No, it’s not. Essentially, we want our trained immunologists who are specialists in treating our patients to make these decisions. Again, this is important for any condition.

Let’s not take the decision away from the physician that works with the patient in what is the best treatment and the best outcome for that patient.

Mr. BILIRAKIS. Thank you very much. Dr. Patt?

Dr. PATT. I completely agree. I think that think that this is not something that we want outside of our specialty’s hands—outside of a physician’s hands and we would love to ask in partnership with CMS to think about a better path forward to try to institute value-based mechanisms for implementation of cancer care.

Mr. BILIRAKIS. Makes sense to me. Thank you very much. Mr. Chairman, I yield back.

Mr. PITTS. The Chair thanks the gentleman and now recognizes Mr. Cárdenas, 5 minutes for questions.

Mr. CÁRDENAS. Thank you very much, Mr. Chairman, and I appreciate all the panelists for sharing your expertise with us.

I’m not going to have enough time to ask all the questions that I’d like to ask. But at this time, Mr. Chairman, I request that I can submit two letters for the record. Request unanimous consent to submit the——

Mr. PITTS. Without objection, so ordered.

Mr. CÁRDENAS. One is by the American Cancer Society, Cancer Action Network, and the second is the California Life Sciences Association to the CMS on the proposed demonstration. Thank you, Mr. Chairman.

[The information appears at the conclusion of the hearing.] OK. With that, my first question is the proposed demonstration would be made so that three out of four Medicare Part B providers across the country would have to participate once we entered Phase II of the demonstration.
I have concerns about the nationwide scope of this demonstration. Mr. Baker, do you think it's possible for CMS to modify and narrow the scope of the model and yield efficiently reliable results to evaluate with respect to the goal of the model?

Mr. Baker. Our understanding is that the breadth of the model is in order to, you know, test the model and make the results generalizable or scalable. That said, I believe that they have been—they have said that they're open to suggestions about the scope and breadth of the model.

So I know folks have commented on that in this comment period and I hope and expect that CMS would take those comments into consideration in the comment period.

Mr. Cardenas. Dr. Patt, what do you think?

Dr. Patt. I think that, again, as I mentioned we need to do the right thing. There's not a right way to do the wrong thing.

I think this proposal needs to be pulled back completely. I think that we would really look forward to the opportunity to work with CMS on better value models. I sat with four of the leaders of CMS a month ago and gave them information on value pathways and how to work towards pathway systems or other alternative systems to reduce cost. I'll meet with CMS again tomorrow.

The oncology community would really look forward to the opportunity to focus on value in a collaborative way and not have a proposal that's bad medicine put down for patients that would decrease their access to care.

Mr. Cardenas. OK. Thank you.

This next question is to Mr. Baker and Dr. Patt and also Ms. Boyle. I'm going to give you a scenario. If I am a senior who is seeing my doctor for a medicine that's administered in his or her office and I disagree with the coverage or payment decision made by Medicare, it can seem daunting to file an appeal and many patients aren't aware that there is even an appeal process.

CMS is proposing that a new pre-appeals process would be most applicable to Phase II of this demonstration. Beneficiaries and/or providers can request a review of a claim before it's submitted for payment, giving the provider the opportunity to discuss why a particular drug or treatment would be best for a particular beneficiary.

Currently, appeals are handled by the Department of Health and Human Services Office of Medicine, Hearings and Appeals, otherwise known as OMHA. OMHA has a significant backlog in the processing cases.

Although beneficiary appeals generally can be expedited and the demonstration will establish a separate appeals process, apparently.

Mr. Baker, what's your experiences been with the Medicare appeals process and do you think that there should be an expedited appeals process for patients established in the demonstration?

Mr. Baker. I definitely think there should be an expedited appeals process for the demonstration not only in the pre-appeals process but we've also recommended to CMS, as I've said before, that there be an ombudsman both in Phase I and Phase II. And I might add that in Phase II a lot of the consultation that some of the other panel members are talking about will occur with regard to, you know, value-based payments.
So I do believe that consultation will ultimately occur before Phase II value-based ideas are implemented.

Mr. CÁRDENAS. Ms. Boyle or Dr. Patt, do you have any comments on that?

Dr. PATT. I would be concerned about an appeals processing causing inappropriate delays in patients receiving treatment.

Ms. BOYLE. I would agree on that sentiment because our experience with appeals through the years have been people making the decisions on the side of the insurers are not specialists, particularly when it comes to rare diseases, and we've just seen patients go through delays getting their lifesaving infusions.

Mr. CÁRDENAS. Thank you all very much. I yield back.

Mr. PITTS. The Chair thanks the gentleman. Now recognize the gentlelady from North Carolina, Ms. Ellmers, 5 minutes for questions.

Ms. ELLMERS. Thank you, Mr. Chairman, and thank you to the panel. This is a very important subcommittee hearing and I appreciate all of the testimony I am hearing, especially from the personal side, and I want to take my congressional hat off for a moment and put my nursing hat on, and I do want to ask Ms. Block—you have such a compelling story with your cancer treatments.

You know, I understand whether we're talking about oncology, whether we're talking about rheumatology or immunology, I know that the care that is provided is a multi-disciplinary education-based treatment where physicians and nurses, other healthcare providers are working with the patients and families to give the best care possible.

So I am—I am very concerned about some of the issues that you have brought as patient, especially in your unique situation with Medicare and the inability to have basically a secondary or Medicare Advantage availability.

So my question is where are you getting your care? Are you getting your care at a hospital or are you getting your care at a community-based oncology clinic or independent physician?

Ms. BLOCK. Sure. Thank you very much for the question. First of all, for the record, I now have a supplemental plan only because I drafted a bill and passed it in my own State legislature.

Ms. ELLMERS. Wonderful.

Ms. BLOCK. The only way that I could get it.

Ms. ELLMERS. Congratulations. That's great.

Ms. BLOCK. There's more problems coming in the weeds since Congress last year did away with some of the—selling some of the plans in the future. So I'm not going to be able to switch. But that's, again, it's trying to stay ahead of these bills.

Ms. ELLMERS. That's what we—unfortunately, what we do so many times is try to keep putting out those fires.

Ms. BLOCK. Right. So I've got problems that are going to be coming as my premiums rise to the point that I can no longer afford to pay them. I do—I get my treatment now at a hospital outpatient location.

Ms. ELLMERS. OK. So but it is a hospital-based facility?

Ms. BLOCK. Yes, and the irony is we don't have any private oncology practices in the State so that I had great difficulty at one
point because my co-pays would have been so much less expensive to go to a private practice but there wasn’t one.

Ms. ELLMERS. Right. Great. OK. Well, I do—I do think that it’s very important that we clarify that point because that gets back to the issue of cost based on site. The difference between the availability of having—being a patient at a primary care or a private practice versus a hospital-based, I mean, because we’re talking about kind of two different beasts there when we’re talking about Medicare. So that is a very important point to make. But thank you for that because that was part of my concern.

I guess the next issue I would—this last question for you as a patient have you had that conversation with your oncologist? Have you—have you actually asked is there a less expensive treatment because of this issue that I’m faced with financially? Is there something else that I could be receiving?

Ms. BLOCK. My oncologist is a rare bird and, when I was diagnosed with metastatic disease, he sat me down and talked to me about my finances and I found when——

Ms. ELLMERS. Wonderful.

Ms. BLOCK [continuing]. When I talked to other patients that that was unusual because he said, you know, things are going to be changing dramatically for you.

Ms. ELLMERS. It’s an issue. Yes. Definitely.

Ms. BLOCK. But that said, I ask—every single time that I go for treatment I ask the nurses giving me the treatment, I ask the doctors I talk to, do you know how much this costs.

Ms. ELLMERS. Uh-huh. And they don’t, do they? I mean, the answer is usually no, right?

Ms. BLOCK. For the most part. Especially the people the administering it.

Ms. ELLMERS. Yes.

Ms. BLOCK. No one, and they’re all amazed when I tell them.

Ms. ELLMERS. Yes. No, and that is typical because, you know, the healthcare provider is so concerned with providing for you the best possible care that you can receive that the issue of cost is not their focus.

It’s really the focus of us and for you and we want to do everything we can to make sure that you are getting that really good care and I just—there again, I’ve only got 50 seconds left.

Thank you, Ms. Block, for your testimony today, and I just want to thank the physicians who are here—Ms. Boyle and Mr. Baker as well.

I think we’re all in agreement here. Even though this is a possibility of moving forward, I think we really do need to put the brakes on this because there are other ways that we can achieve decreasing costs and I’m kind of a little amazed at some of my Democrat colleagues—not all, because I think we all care about patients—but I’m a little concerned because they seem to have a little bit of amnesia.

And there again, I’ll ask Ms. Block—are you aware of our 21st Century Cures Initiative that we passed here in the House?

Ms. BLOCK. No.

Ms. ELLMERS. This is actually an effort that we are putting forward. The Senate is working on their version right now and basi-
We have, you know, worked with other countries—how are you providing care that’s less expensive. We’ve worked with our universities, our patient advocacy groups, our hospitals, our high-end universities, NIH, CMS, FDA, so that we can get drugs through the process in a more efficient less expensive manner that takes care of our patients.

So I think we need to stay on that front and move forward and give the best possible care we can and keep those drugs costs down as well. So thank you all again. I apologize, Mr. Chairman. I went over.

Mr. PITTS. The Chair thanks the gentleman.

The Chair now recognizes Dr. Bucshon, 5 minutes for questions.

Mr. BUCSHON. Thank you very much and thank you to all the panellists for coming and, you know, I’m reading the legislation to restart this discussion and let me tell you why.

First of all, one thing I want to—I was a practising cardiovascular and thoracic surgeon for 15 years and to me discussing the and putting forth the premise of physicians out there basing therapy, whether it’s heart disease like I did or cancer therapy, based on how much they’re going to get reimbursed from Medicare is just—it’s almost an insult to the medical profession, from my perspective, because are there bad actors?

There are in all fields. But I can tell you the doctors that I know and myself never consider that—that we can make more money if we prescribe something else.

Now, that said, you also can’t have something like this that could force independent practitioners to lose so much money on these medications that it limits access and puts them out of business. So I think we have to address that. You know, but cutting provider reimbursement without addressing the ASP—the actual costs of the drug in the first place is just the wrong approach.

And, you know, for the last 30 years CMS has tried to control healthcare costs by cutting provider reimbursement almost exclusively and look where we are today. It hasn’t solved the problem.

This is a big problem. I empathize with everyone including myself and my own family. I’ve got—my father’s had all kinds of—have had four different cancers. My mother has had problems, and it is very expensive and costs are a real issue—no doubt about that.

But it seems CMS proposed this without any substantial stakeholder input other than MEDPac and threw mud at the wall, and they’re now trying to figure out what’s going to stick and what isn’t, and that’s just the wrong approach. This should be scrapped, and we should start from scratch.

We do need to address costs, no doubt about it, but we should get stakeholder input, and let’s all work together—patients, patient advocates, physicians, and CMS and Congress to address this issue.

You know, I’m going to ask a question of the physicians. First, say, for example, there are two practices within the proximity—in the same geographic area, and for whatever reason their ZIP Code isn’t picked.
How is that going to affect the local or regional care, potentially, of patients? Dr. Patt, do you want to—I mean, that could potentially happen, right? You have an urban area—half this town has this, half doesn’t and half the patients are at one place, half at the other. How is that—how might that affect this?

Dr. Patt. I think that if I was in a ZIP Code that was randomized to the experiment, having decreased reimbursement, that I would recommend my patient get the appropriate care not at my center.

Mr. Bucshon. So you can see—you have the Federal Government in Washington, DC, affecting the local marketplace and health care and picking winners and losers.

Dr. Schweitz. In rheumatology it’s a little more problematic. There aren’t many of us and there is usually a significant backlog to get in to see a rheumatologist.

So if I’m going to refer my patient to the ZIP Code across the county there’s going to be a delay in that patient being seen and a delay in that patient getting medication—his treatment.

Mr. Bucshon. You know, and this is Washington, DC, so I’ll say there very well could be politics involved in ZIP Code selection, believe it or not. I just want to put that out there, and for anyone to think that there won’t be is just—doesn’t know Washington, DC.

And people that have substantial political pull in this town will not be selected to have their reimbursement cut. I’m just here to tell you. That’s what’s going to happen, and it’s going to substantially affect practitioners’ ability in different communities to continue to treat their patients.

I mean, again, the other thing is as it relates to alternative payment models, Dr. Patt and Schweitz, do you see this affecting the development and resources going into implementing APMs, for example? Do you see this as an issue?

Dr. Patt. It does. I can say that as a network, the U.S. Oncology Network will put 10 percent of Medicare beneficiaries with cancer on the oncology care model and it’s been a tremendous infrastructure investment.

How do you then account for having to not have patients receive care in your practice because all of a sudden they’re in this experimental arm of this experiment as well? I can’t imagine a foreseeable situation where that will work.

And I’ll just say that, you know, we, as a large practice, have bought into a lot of infrastructure investment in procuring for these alternative payment models. I cannot imagine how a smaller practice will buffer that change.

Mr. Bucshon. Yes. My time has expired but I just want to say this at the end is that I would urge CMS to scrap this proposal and come to the table with stakeholders and look at other ways that we can address patient medication costs.

They are—it is an issue. We all know it. But cutting provider reimbursement, as I said in my opening, is not the solution to a very, very complicated problem that we all, I think, agree needs to be addressed.

I yield back.

Mr. Pitts. Chair thanks the gentleman. Now recognizes the gentleman from Massachusetts, Mr. Kennedy, 5 minutes for questions.
Mr. KENNEDY. Thank you, Mr. Chairman.

In recent years, the cost of prescription medication has risen sharply, raising concerns for patients and their families about how to access and pay for needed drugs.

The Boston Globe has reported that prescription drugs represent the fastest-growing component of health care, and spending on prescription drugs increased 13 percent from 2014 to 2015.

Given that, in 2016 alone Medicare is expected to cover about 57 million people. This hearing on Part B could not be timelier, especially as the entire healthcare system of the United States moves toward quality and value-based systems.

Delivery system reform are a key part to the future of medicine and finding ways to reduce costs and ensure patients have access to affordable effective medications while spurring innovation is absolutely critical.

Ms. Block, thank you for sharing your deeply personal story in your testimony earlier this morning. As we know, Medicare Part B beneficiaries pay 20 percent co-pays with no out of pocket money. Can you tell us more about how your doctor decides what course of treatment is right for you?

Ms. BLOCK. Thank you, sir.

Right now, I have limited options because I’ve already been through a range of drugs. So there are limits on what my doctor can offer me, though he is very cognizant of the co-pay and we spend a lot of time talking about the co-pay and what I can do to afford it and how to make that work in my life.

Mr. KENNEDY. Have you ever had to forego, Ms. Block, treatment because of those costs and if you have an idea of how this demo might affect you and patients like you?

Ms. BLOCK. OK. I have never foregone treatment under Part B. I still have a prescription under Part D sitting in CVS right now waiting for me to pick up since I can’t afford to get it. But under Part B I have not foregone treatment.

I believe this demo will enhance my life. I think that it’s going to reduce my co-pays. Number one, just off the bat, if they reduce that +6 percent after the—you know, with ASP that’s a reduction in my co-pay right there. So that’s number one.

Phase II, if I’m lucky enough to be in an area that reduces or waives the co-pays then again I get a win-win. So I see this as a very positive move.

Mr. KENNEDY. I appreciate that, Ms. Block.

Mr. Baker, in your testimony you highlight that Medicare paid $22 billion for prescription drugs last year, more than double the amount that was spent in 2007.

And as we all know, co-pays for beneficiaries aren’t decreasing either, which means that they already face access problems. As CMS moves forward with the demo, how can they ensure that the demo doesn’t hinder access?

Mr. BAKER. I think some of the key pieces are that real-time claims monitoring that I’ve been talking about. The other piece is the ombudsman program that we recommended and that was used in the durable medical equipment area I think to such great effect.

And once we’re moving into Phase II and the value based models that could be used in various specialities and with various drugs
the pre-appeals process would be a way of, once again, getting access where access is needed and ensuring that it occurs.

And then finally, those kinds of outcomes measures that we were talking about earlier would be a way not only of protecting patients but also of gathering research and data. And finally, we believe focus group testing, patient engagement surveys as well as provider engagement surveys to make sure that CMS has a full range of information about the effect of the model.

Mr. KENNEDY. And so I wanted you to clarify as well, sir, and I think you touched on it a little bit from your testimony earlier.

But can you clarify if this proposal would require to pick one drug over another or will doctors retain the ability to pick the most appropriate treatment for their patients?

Mr. BAKER. The proposal—the model as written would allow doctors to prescribe, you know, whatever drug. This isn't a formulary, a list of approved drugs or a limited group of drugs.

Doctors would be allowed to prescribe any drug that they felt was necessary for their particular patient and if there were some value-based program that indicated that maybe that drug wasn't the most clinically effective drug, once again, that doctor or that patient could use the pre-appeals process to or an ombudsman program, we would hope, to make the case that no, this is the most clinically effective drug for this particular individual because of their particular health profile or clinical needs.

Mr. KENNEDY. I appreciate that, and just before I run out of time I also want to echo some of the concerns raised by my colleagues that noted the similarities between testimonies today. I think that raises some important questions as well. I yield back.

Mr. PITTS. Chair thanks the gentleman.

Now, I recognize the gentleman from New York, Mr. Collins, 5 minutes for questions.

Mr. COLLINS. Thank you, Mr. Chairman. I want to thank all the witnesses. This has been very enlightening. And just to bring a couple of things up and Ms. Block, I know you said that you thought your co-pays would go down with this. Well, it doesn’t work that way.

I don’t want to be too contradictory but a $100 drug with a 20 percent co-pay is $20 whether it’s +6 or +2.5 because it’s—the ASP doesn’t change. So your co-pay doesn’t go down.

But Dr. Patt, in the big picture what I’ve heard is doctors don’t even know what the drugs cost, by and large. Maybe their office manager does.

They’re prescribing to treat their patients, as Dr. Bucshon indicated. So I kind of reject CMS’ whole premise that nuancing the +6, which we know is really 4.3, or the 2.5 which is really .86, that would only make an impact in prescribing drugs if these doctors, before they treated a patient, would be bringing out the spreadsheet to figure that out, which I don’t see happening.

Now, let me go through the math as well. Let’s say you’ve got a drug that’s $1,000 and you go to the 2.5 percent but under sequester it’s .86 and you’re one of the randomized, you’re going to get $8.60 as your markup. Then you get $16.80 flat fee. So you get $25.40 for that $1,000 drug.
Now, if there was a $500 version you get $4.30 instead of $8.60. You get the same $16.80. So now you have $21.10. So if somebody said that switching it from six to—you know, changing that would drive a physician to prescribe the lower cost, I guess I kind of reject that because under the higher cost you’re getting $25.40.

Under the lower one you’re getting $21.10. I don’t think either one is adequate. But I think a physician would rather have $25 than $21.

So the whole idea of driving someone to a lower cost drug you reject it categorically because the practice is still going to get more money with a higher priced drug.

The co-pay to the patient may switch with a lower cost. I don’t know that doctors are facing that. So I guess—I just don’t see in the big picture that any of this is going to impact the cost of drugs.

And I guess I’ll throw out there, because I’ve become the subject matter expert on 340B pricing, if there’s a problem in the cost of drugs and cancer drugs, it’s all the private oncology practices being purchased by hospital systems—DSH hospitals who then get a 50 percent break from the pharmaceutical companies on these expensive drugs and you’re seeing oncology practices bought up every single day so that the hospitals can cheat and get their 50 percent discount, which goes to their bottom line, which comes out of the hide of the pharmaceutical companies.

And at the end of the day, you want to talk about why prescription—why prices may be high? Every time one of these drugs is now getting a 50 percent discount, what do you think the pharmaceutical companies have to do?

I think the bigger savings is to stop the cheating on 340B pricing where fully covered patients the DSH hospitals are getting a 50 percent discount and yet the hospital is getting fully reimbursed by Blue Cross/Blue Shield. I’m just venting a little.

But, you know, Dr. Patt, as I’m sure you’ve seen these oncology practices bought out and I’m sure you’ve seen them go to DSH hospitals where under 340B now there’s this huge discount which has to impact you. Would you care——

Dr. Patt. Yes, sir, and also imagine a scenario that’s different than the one that you gave. Imagine that you’re in a rural clinic where you purchased 1 percent above ASP, because again, ASP is an average.

Mr. Collins. Well, that’s the other thing. People think ASP is the price. It’s not. Some smaller practices pay more than ASP.

Dr. Patt. Right. So imagine you’re in a scenario where you purchased a drug for 1 percent more and let’s say it’s a high cost drug. Let’s say it costs $10,000 per month to administer.

You can imagine that that would be a substantial loss to the practice—that if you transition that patient to the hospital outpatient department—let’s say it’s an hour away—where they may have the 340B preferred vendor program and the ability to purchase drugs at a 30 to 50 percent reduction in cost then you would, you know, transition that patient’s care. And I think that that trend is a trend we’ve seen over the last 11 years and we would see it continue to be propagated.

Mr. Collins. Well, and that’s—you know, I’m concerned about—I have a very rural area—access and it’s exactly what we’re seeing,
that the private practices are being bought up for one sole purpose and that’s so the DSH hospitals can cheat.

Get the 30 to 50 percent discount on the most expensive drugs—the $10,000 drugs—driving that to their bottom line and disadvantageing healthcare systems in total, pharmaceutical companies and ultimately patients.

I yield back.

Mr. Pitts. Chair thanks the gentleman. Without objection, we have a Member who’s not on the subcommittee present who would like to ask questions.

The Chair now recognizes Mr. Welch, 5 minutes for questions.

Mr. Welch. Thank you very much, Mr. Chair, and I thank my colleagues for allowing me to sit in.

I have some sympathy with the point that Dr. Bucshon made and Mr. Collins made about the cost and the complexities that are involved. But this is not a case of cutting provider reimbursement as much as it is about linking physician reimbursement to the cost of drugs they prescribe.

I share the concern about cutting to the bone the providers but there is no transparency whatsoever in what medical care costs are.

Nobody knows, and it’s really true with respect to prescription drugs. And I have to say—I’ve been in and out but I am very alarmed at the lack of sense of urgency about something that is absolutely intolerable—prescription drug prices.

First of all, prescription drugs save lives. They alleviate pain. But the market is broken and the cost that the pharmaceutical companies are charging is starting to kill patients they’re trying to save, and no one’s in charge. The doctor, Mr. Collins says, doesn’t know how much the drug is. I think they should, like Ms. Boyle said.

That’s relevant to the everyday lives of people. And what I’ve heard Dr. Patt, from you, and Ms. Boyle is sort of the situation normal. It’s all complicated. We want to collaborate.

We have value pathways. But I don’t know what that means if I’m a patient. I literally don’t know what it means. What it sounds like to me is that let’s keep rolling.

The problem I have with the prescription drugs is that it’s not a value proposition. It’s a broken market. So the price is set by the pharmaceutical companies and it’s whatever the traffic will bear, and they’re protected by patent protection and they’re entitled to that because it’s intellectual property.

But should they be charging $1,000 a day to a patient or to the taxpayers that have no recourse whatsoever but have a desperate need for the medication? And where you have—what we’re talking about here is not the global mess of pricing and health care.

We’re talking about this system where the prescriber makes more money when he or she prescribes a more expensive drug. Dr. Patt, is that true or not?

Dr. Patt. So I’ll say that in my practice that is not true because our physician compensation model is not in any way dependent upon the drugs that I write.

Mr. Welch. All right. But the—
Dr. PATT. But there is variability between practices. But I'll say in my practice.

Mr. WELCH. Right. So just—if I am—work at a car store—you've rented a car and you've seen how much people try to upsell what it is you're trying to rent, and there's an incentive for that salesperson, right? Now, if a doctor's going to prescribe something, let's say a regular—anybody who's got—and they've got their challenges, like Dr. Bucshon said.

They've got to pay their assistants and they want to do the right thing. But the model by which they're paid is affected by whether they prescribe the $50,000 drug or a $3,000 drug.

So just isn't that an incentive that would make one question whether that affected their decision?

Dr. PATT. Mr. Welch, I think you make some very good points. But I'll say again that my personal income from my practice that treats half of Texans is not dependent upon the drugs that I write.

Mr. WELCH. You know, that's great, and I'm talking just about the pricing model here.

Dr. PATT. Right. So I think there are limitations because when we talk about value pathways and when you have opportunities to exchange therapeutic alternatives, to use those opportunities for better value choices, that that's really important.

But the issue of drug pricing—

Mr. WELCH. But I mean, I don't have much time so let me interrupt. But thank you.

In this proposal the medical provider is going to be in control of the final decision about what's the most efficacious drug. That is agreed, because the patient's entitled to that.

Mr. BUCSHON. Will the gentleman yield real quickly? That depends, I would say, Peter, on whether or not the pricing results in a massive loss to the practice, and then they may not be able to absorb that without closing their practice.

Mr. WELCH. Thank you. Reclaiming my time.

Then that gets us to the heart of another problem. If we create this Rube Goldberg situation where you've got to do all of these maneuvers to try to get your practice to be solvent instead of paying fair value for the procedure you do but then not linking your bottom line to whether the prescriptions are the most expensive drugs then we're going to get a chance to deal with this.

But I just want to say this is—this is a disaster looming. The taxpayer can't afford it, employers can't afford it and patients like—my first wife had cancer 9 years. We had a fantastic oncologist.

Drugs extended her life. They alleviated her pain. They made our family much stronger. But you know what? That's out of reach for more and more Americans and this economy can't support it.

I really was upset about the lack of urgency on the part of some of the witnesses here to what I think is a very urgent problem.

Thank you, Mr. Chairman.

Mr. PITTS. Chair thanks the gentleman and recognizes Dr. Bucshon for UC request.

Mr. BUCSHON. Yes, I just want to ask unanimous consent to introduce an article from the New York Times from an oncologist
from New York describing how this type of thing may limit their ability to properly treat cancer patients.

Mr. PITTS. Without objection, so ordered.

Mr. Welch.

Mr. WELCH. I'd like to introduce into the record an article examining congressional comments regarding Medicare's Part B pilot proposal.

Mr. PITTS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. PITTS. That concludes the questions of the Members present. We will have some follow-up questions. We'll send those to you in writing. We ask that you please respond.

Thank you very much. This is a very important hearing, very timely, lots of good information. Members have 10 business days to submit questions for the record. So they should submit their questions by the close of business on Tuesday, May 31st.

Without objection, this hearing is adjourned.

[Whereupon, at 12:42 p.m., the committee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Today's hearing is an important exercise in Congressional oversight on a recently proposed rule from the Centers of Medicare and Medicaid Services (CMS) on Part B drugs. There is bipartisan concern that this proposed Medicare drug experiment will threaten the care of our most vulnerable seniors in Michigan and throughout the country, and reduce access and availability of lifesaving drugs.

There are several characteristics that make this proposal unique when taken together. The new model is mandatory. CMS proposes to waive entire sections of statute and carefully negotiated Medicare reimbursement policy, effectively rewriting at least seven payment provisions established by Congress over the years.

Currently, Medicare pays for Part B drugs by reimbursing providers the Average Sales Price (ASP) plus 6 percent. In the first phase of the new model, providers in half the country would be reimbursed ASP plus 2.5 percent and an additional flat fee of $16.80 per drug per day. Application of sequestration would effectively bring this payment to 0 percent. Translation: reimbursement will fall short in covering the costs of acquisition, storage, and administration of many drugs that seniors with serious medical conditions need—quite a dangerous policy change.

CMS has also suggested value based purchasing arrangements be applied in half of the country under Phase II, including reference pricing and Indication Based Pricing. CMS would set payment rates for drugs they believe are therapeutically similar, despite which drug a patient needs and vary payments for drugs based on what the Federal Government determined is their clinical effectiveness. These tools are dramatic departures from how we approach prescription drugs access in this Nation and give the Federal Government far too much control over decisions that should be left between a doctor and their patient. Another dangerous policy change.

I do support efforts to test models that seek to improve quality of care, lower cost, and increase access. These themes are the backbone of our SGR reform legislation, MACRA. In the past, patient rights and access to care have always been given serious attention and weight but they are disturbingly lacking in this proposal. There was no input from patients or providers. In fact, this proposal threatens to disrupt many important Medicare models from Accountable Care Organizations to the CMMI sponsored Oncology Care demonstration. This is unnecessary and disruptive as providers prepare for MACRA.

Fundamentally though, there is a serious separation of powers issue that cannot be overlooked. This model represents a dangerous precedent where future administrations could change the statutory reimbursement for any provider or service, anywhere or everywhere in the country, under the guise of a demonstration, without any input from patients, providers, or Congress.

Each reason by itself should cause us pause. Taken together, there is no question that the policy must be withdrawn. And today, we will examine thoughtful legislation by Dr. Bucshon to do that and protect seniors.
The potential for harm from the administration's alarming proposal for seniors in Michigan and across the country is real. Doctors, patient advocates, and patients are standing up and vocally declaring the threat this model could have on their care. We are talking about our moms and dads, grandparents, friends, neighbors, and our Greatest Generation—and the Government wants to experiment with their care. Seniors deserve our respect. They deserve to be treated with nothing but dignity.
114TH CONGRESS  2d SESSION  H.R. 5122

To prohibit further action on the proposed rule regarding testing of Medicare part B prescription drug models.

IN THE HOUSE OF REPRESENTATIVES

APRIL 29, 2016

Mr. BUCHON (for himself, Mr. DOLD, Mr. BOUSTANY, Mr. TOM PRICE of Georgia, and Mr. SHIMkus) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

A BILL

To prohibit further action on the proposed rule regarding testing of Medicare part B prescription drug models.

1  Be it enacted by the Senate and House of Representa-
2  tives of the United States of America in Congress assembled,
3  
4  SECTION 1. PROHIBITION OF FURTHER ACTION ON PRO-
5  POSED RULE REGARDING TESTING OF MEDI-
6  CARE PART B PRESCRIPTION DRUG MODELS.

The Secretary of Health and Human Services may not take any action to finalize, implement, or enforce the
2 proposed rule entitled “Medicare Program; Part B Drug Payment Model” (81 Fed. Reg. 13230 (March 11, 2016)).
May 2nd, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Acting Administrator Slavitt:

We write to express our deep concerns regarding the Centers for Medicare & Medicaid Services (CMS) “Part B Drug Payment Model” proposed rule, published in the Federal Register on March 11, 2016. CMS’s proposed Medicare drug experiment would unnecessarily disrupt care for the sickest seniors who depend on Medicare, including those with cancer, macular degeneration, rheumatoid arthritis, neurological disorders, rare diseases and primary immunodeficiency diseases. Given these concerns outlined here, we ask that CMS withdraw this proposed rule that could endanger access to care for America’s most vulnerable seniors.

CMS’s proposed Medicare experiment would impose cuts in Phase I that will severely harm patient access to needed drugs. Under CMS’s Medicare drug experiment, numerous physicians would face acquisition costs that exceed the Medicare payment amount for certain drugs. This policy will make it harder for patients to receive the drugs they need and especially hurt seniors who depend on doctors in smaller practices or those who live in rural areas.

The scope of the proposed experiment on drugs for seniors is also deeply troubling. CMS proposes forcing nearly 75% of the country to participate in the Medicare drug experiment. The impact on patients will be sweeping and affect seniors across the country.

CMS’s proposed Medicare drug experiment would also lead physicians to refer patients to a hospital outpatient department (HOPD). Driving more care to an often less convenient, more costly setting makes it more challenging for beneficiaries to access needed care and increases overall Medicare costs. This will lead to further consolidation and less choice for seniors.

The policies in the proposed Part B model were developed with no input from outside experts and those with real-world experience. CMS should have consulted with affected stakeholders considering the proposal’s broad scope and risk for beneficiaries.
We are concerned that the proposed model will hinder physician efforts to participate in delivery and payment reforms, including the Oncology Care Model (OCM) and the various alternative payment models (APMs) incentivized by the bipartisan Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). OCM practices have voluntarily engaged to make changes aimed at bringing more value through a model that CMS established in close consultation with stakeholders. Layering cuts on top of sweeping systematic changes will hurt efforts at payment reform in Medicare.

We are also concerned that the proposal fails to state how CMS will assess the impact on the quality of care beneficiaries receive. The proposal states an expectation that the model will reduce Part B drug spending while maintaining the quality of care beneficiaries receive, yet it does not provide the specifics of how access and quality will be assessed throughout the duration of the model or in the evaluation phase. Understanding the quality metrics used to determine whether there are acute problems or what constitutes the ultimate success of the model is critically important. Yet CMS failed to address this in their proposed rule.

This experiment affects all our constituents, Democrat or Republican, and we believe that Congress, whose responsibility is to the electorate, is best tasked with making these decisions, not an unaccountable entity. Every American should have their voices heard rather than be silenced by Washington politics.

Given the numerous concerns regarding this rule and the impact it will have on Medicare seniors’ access to lifesaving drugs, we again urge CMS to withdraw this proposed regulation.

Sincerely,

TOM PRICE, M.D.  PATRICK SHRECKES  CHARLES Boustany, M.D.

KEVIN BRADY  FRED UPTON  STEVE SCALISE
Jeff Johnson  Cord Taylor
Zach CPS  Jordan Eise
Anne  Jeff Henry
Terrance Miller  Michelle  Jo Johnson
Lyle Jenkins  Lynn Ewenz  Esther
Sally Jong Lauritzen  Robin
Paul  Dutch Ruppersberger  Bill Posey
The Honorable Tom Price, M.D.
The Honorable John Shimkus
The Honorable Charles Boustany Jr., M.D.
The Honorable Kevin Brady
The Honorable Fred Upton
The Honorable Steve Scalise
The Honorable Mac Thornberry
The Honorable Candice Miller
The Honorable Steve Chabot
The Honorable Bill Shuster
The Honorable Charles W. Dent
The Honorable Michael T. McCaul
The Honorable Luke Messer
The Honorable Patrick McHenry
The Honorable Cathy McMorris-Rodgers
The Honorable Lamar Smith
The Honorable John Kline
The Honorable Jeb Hensarling
The Honorable Robert W. Bishop
The Honorable Harold Rogers
The Honorable Pete Sessions
The Honorable Michael Conaway
The Honorable Bob Goodlatte
The Honorable Edward R. Royce
The Honorable Jason Chaffetz
The Honorable Jeff Miller
The Honorable Robert Dold
The Honorable Larry Bucshon, M.D.
The Honorable Michael C. Burgess, M.D.
The Honorable Randy Hultgren
The Honorable Michael G. Fitzpatrick
The Honorable Brett Guthrie
The Honorable Tom Cole
The Honorable Rodney Davis
The Honorable Tom Reed
The Honorable Tim Walberg
The Honorable David W. Jolly
The Honorable Frank Lucas
The Honorable Doug Lamborn
The Honorable Bob Latta
The Honorable Robert J. Wittman
The Honorable Stephen Fincher
The Honorable Kristi Noem
The Honorable Daniel M. Donovan, Jr.
The Honorable Richard Nugent
The Honorable F. James Sensenbrenner, Jr.
The Honorable Darren LaHood
The Honorable Christopher H. Smith
The Honorable Tom Graves
The Honorable Jeff Denham
The Honorable Mike Coffman
The Honorable Cynthia M. Lummis
The Honorable Virginia Foxx
The Honorable Walter B. Jones
The Honorable Frank A. LoBiondo
The Honorable Steve Pearce
The Honorable Ted Poe
The Honorable Blaine Luetkemeyer
The Honorable John L. Mica
The Honorable Tom McClintock
The Honorable Collin C. Peterson
The Honorable Mick Mulvaney
The Honorable Duncan Hunter
The Honorable John R. Carter
The Honorable Michael Simpson
The Honorable David A. Vitter
The Honorable Austin Scott
The Honorable Trent Franks
The Honorable John Culberson
The Honorable Patrick Meehan
The Honorable Rod Blum
The Honorable Ryan A. Costello
The Honorable Barbara Comstock
The Honorable Gregg Harper
The Honorable George Holding
The Honorable Mimi Walters
The Honorable Mike Rogers
The Honorable Paul A. Gosar, D.D.S.
The Honorable Scott DesJarlais, M.D.
The Honorable Brad Ashford
The Honorable Tom Marino
The Honorable Doug LaMalfa
The Honorable Scott Tipton
The Honorable Ann Wagner
The Honorable Erik Paulsen
The Honorable Joseph R. Pitts
The Honorable Bradley Byrne
The Honorable Bruce Westerman
The Honorable David Rouzer
The Honorable Rick Allen
The Honorable David P. Roe, M.D.
The Honorable Mike Pompeo
The Honorable Bob Gibbs
The Honorable Robert Pittenger
The Honorable David Young
The Honorable Earl L. "Buddy" Carter
The Honorable Robert B. Aderholt
The Honorable Steve Russell
The Honorable James B. Renacci
The Honorable Richard Hudson
The Honorable Dan Benishek, M.D.
The Honorable John R. Moolenaar
The Honorable Mike Bishop
The Honorable Chris Stewart
The Honorable Dennis A. Ross
The Honorable Lou Barletta
The Honorable Ron DeSantis
The Honorable David B. McKinley
The Honorable Martha Roby
The Honorable Jackie Walorski
The Honorable Glenn "GT" Thompson
The Honorable Jim Bridenstine
The Honorable Mia Love
The Honorable Crescent Hardy
The Honorable Ralph E. Abraham Jr., M.D.
The Honorable Mark E. Amodei
The Honorable Charles J. Fleischmann
The Honorable Brian Babin, D.D.S.
The Honorable Frank C. Guinta
The Honorable Evan Jenkins
The Honorable Mario Díaz-Balart
The Honorable Glenn Grothman
The Honorable Tom Rice
The Honorable Kevin Yoder
The Honorable Scott E. Rigell
The Honorable Joe Heck, D.O.
The Honorable Tom Emmer
The Honorable Dave Brat
The Honorable John Ratcliffe
The Honorable Garret Graves
The Honorable Barry Loudermilk
The Honorable Thomas Massie
The Honorable Jason Smith
The Honorable Andy Barr
The Honorable Bill Flores
The Honorable Steve Womack
The Honorable Kevin Cramer
The Honorable Diane Black
The Honorable Devin Nunes
The Honorable French Hill
The Honorable Morgan H. Griffith
The Honorable David G. Valadao
The Honorable Adam Kinzinger
The Honorable Patrick J. Tiberi
The Honorable Mike Bost
The Honorable Markwayne Mullin
The Honorable Carlos Curbelo
The Honorable Chris Collins
The Honorable Susan Brooks
The Honorable Steve Knight
The Honorable Keith Rothfus
The Honorable Renee Ellmers
The Honorable Bill Huizenga
The Honorable David B. Reichert
The Honorable David P. Joyce
The Honorable Steve Stivers
The Honorable Todd Young
The Honorable Doug Collins
The Honorable Daniel Webster
The Honorable Scott Perry
The Honorable Martha McSally
The Honorable Brad R. Wenstrup, D.P.M.
The Honorable Sean P. Duffy
The Honorable Sam Graves
The Honorable John Katko
The Honorable Alex Mooney
The Honorable Blake Farenthold
The Honorable Randy Neugebauer
The Honorable Roger Williams
The Honorable Mark Meadows
The Honorable Jaime Herrera Beutler
The Honorable Kay Granger
The Honorable Reid J. Ribble
The Honorable Trey Gowdy
The Honorable Vern Buchanan
The Honorable Greg Walden
The Honorable Leonard Lance
The Honorable Marsha Blackburn
The Honorable Tim Murphy, M.D.
The Honorable Thomas J. Rooney
The Honorable Ed Whitfield
The Honorable Gus M. Bilirakis
The Honorable Joe Barton
The Honorable Adrian Smith
The Honorable Pete Olson
The Honorable Peter J. Roskam
The Honorable Kenny Marchant
The Honorable Lynn Westmoreland
The Honorable Scott Garrett
The Honorable Sam Johnson
The Honorable Rodney P. Frelinghuysen
The Honorable Vicky Hartzler
The Honorable Matt Salmon
The Honorable Ken Calvert
The Honorable Don Young
The Honorable John Fleming, M.D.
The Honorable Louie Gohmert
The Honorable John J. Duncan Jr.
The Honorable Ileana Ros-Lehtinen
The Honorable Darrell E. Issa
The Honorable Michael R. Turner
The Honorable Joe Wilson
The Honorable Randy J. Forbes
The Honorable Steve King
The Honorable Ander Crenshaw
The Honorable Mike Kelly
The Honorable Billy Long
The Honorable Lynn Jenkins
The Honorable Bill Johnson
The Honorable Jeff Fortenberry
The Honorable Andy Harris, M.D.
The Honorable Lee Zeldin
The Honorable Todd Rokita
The Honorable Eric A. Crawford
The Honorable Jody Hice
The Honorable Dan Newhouse
The Honorable Ken Buck
The Honorable Peter T. King
The Honorable Steven Palazzo
The Honorable Krysten Sinema
The Honorable Ted S. Yoho
The Honorable Mark Walker
The Honorable Jeff Duncan
The Honorable Jim Jordan
The Honorable Bill Posey
The Honorable Elise Stefanik
The Honorable Randy Weber
The Honorable Will Hurd
The Honorable Bruce Poliquin
The Honorable Robert Hurt
The Honorable David Schweikert
The Honorable Ryan Zinke
The Honorable Trent Kelly
The Honorable Chris Gibson
The Honorable Paul Cook
The Honorable Richard L. Hanna
The Honorable Curt Clawson
The Honorable C.A. Dutch Ruppersberger
The Honorable Gary Palmer
The Honorable Mo Brooks
The Honorable Tom MacArthur
The Honorable Raúl Labrador
VIA ELECTRONIC TRANSMISSION

The Honorable Sylvia Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: 42 CFR Part 511 Medicare Program; Part B Drug Payment Model; Proposed Rule

Dear Secretary Burwell:

On March 11, 2016 the Centers for Medicare Medicaid Services (CMS) issued a proposed rule for comment. The proposed rule puts forward for consideration a new Medicare payment model under section 1115A of the Social Security Act (SSA). The proposal is a two-phase model that would test whether an alternative drug payment system will lead to a reduction in Medicare Part B expenditures. The first phase would involve reducing the 6 percent add-on to the Average Sales Price (ASP) that is currently used to a 2.5 percent add-on plus a flat fee. The second phase would test the use of value-based purchasing tools1.

I am concerned that throughout this proposed rule two terms are repeatedly used - "study" and "test." These terms seem to indicate there is a component of research going on in this proposal. I am writing you today to see if that is true and if that is true, are adequate protections in place for the Medicare beneficiaries who will be research participants.

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral research wrote the Belmont Report5. This landmark document was the foundation for U.S. federal policy for the protection of human subjects in research. This policy was published as the "Common Rule" in 1991 and then codified through regulation (45 CFR part 46, subpart A) to apply to all of the departments and agencies listed below:

Agency for International Development

3 Ibid
4 Ibid
5 Ibid
Consumer Product Safety Commission
Department of Agriculture
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Housing and Urban Development
Department of Justice
Department of Transportation
Department of Veterans Affairs
Environmental Protection Agency
National Aeronautics and Space Administration
National Institute of Standards and Technology
National Science Foundation

In addition, the following departments and agencies must also comply with 45 CFR part 46:

Central Intelligence Agency
Department of Homeland Security
Social Security Administration

Among other protections, the Common Rule requires any researcher to obtain “legally effective informed consent”\(^1\). Furthermore, the law says a person participating in research should do so of his or her own free will. Undue influence or coercion to participate in a study is prohibited.

It is my understanding that there are certain exceptions that allow government agencies to perform research without the informed consent of an individual. One exception is “research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;
(ii) procedures for obtaining benefits or services under these programs;
(iii) possible changes in or alternatives to these programs or procedures;
(iv) possible changes in methods or levels of payment for benefits or services under those programs\(^2\).

\(^1\)https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model
\(^2\)http://www.hhs.gov/ohrp/human-subjects-guidance/belmont.html
\(^3\)http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subparta
\(^4\)ibid
\(^5\)ibid
However, it is my understanding that the proposed study for Part B of Medicare will be testing the hypothesis that a change in payment methodology will change a doctor's prescribing habits resulting in a Medicare beneficiary receiving a different medication. To me, that seems to be going beyond the intention of the exception in the Common Rule. By randomizing people to different payment methodologies, it seems possible that patients might receive a drug that is less effective for them. And, that seems to be a clinical trial. Therefore, please answer the following:

1. Is the Medicare Part B proposal research? If not, why not?
2. If this is research, how do you intend to obtain legally effective informed consent?
3. If this is research, how does HHS intend to collect and report adverse events?
4. If this is research, does HHS need to report findings at ClinicalTrials.gov?
5. If the results of this study are negative, that is it fails to show savings in Part B, will the results be made public?
6. Does HHS have any responsibility to inform physicians that they are participating in research? If not, why not?
7. Have other study designs to evaluate payment change been considered?

Please contact my staff, Karen Summar, with questions and with your answers.

Klaus.Summar@Grassley.Senate.Gov

Sincerely,

Chuck Grassley
Charles E. Grassley
U.S. Senator

2 http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
4 Ibid
5 Ibid
Cc: Andrew Slavitt, Acting Administrator, Centers for Medicare and Medicaid Services
    Patrick Conway, M.D., MSc, Deputy Administrator for Innovation and Quality & CMS
    Chief Medical Officer
    Jerry Menikoff, M.D., Director of the Office for Human Research Protections (OHRP), HHS

2 http://www.hhs.gov/ohrp/humanobjects/guidance/beinprob.html
4 Ibid
5 Ibid
May 2, 2016

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health & Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Burwell and Acting Administrator Slavitt:

As national organizations, including those representing consumers, purchasers, health care professionals, and insurers, we are writing in support of the Centers Medicare and Medicaid Services’ (CMS) proposed rule to test value-driven payment and delivery system models for prescription drugs covered under Medicare Part B. We believe that CMS' proposal has the potential to improve care quality and value for Medicare beneficiaries and support Medicare providers in delivering the right care at the right time. Importantly, the proposal appropriately focuses on changing prescriber behavior while ensuring that Medicare beneficiaries can maintain access to the medications that they need.

Beneficiary cost-sharing under fee-for-service (FFS) Medicare Part B is 20 percent with no out-of-pocket limit, leading some older adults and people with disabilities to face catastrophic expenses, amounting to as much as $100,000 per year.[^1] Meanwhile, the median annual income for people with Medicare is less than $25,000 and one in four have less than $12,000 in savings.[^2] We do not believe that it is reasonable or acceptable to expect beneficiaries to continue to pay for increasingly expensive prescription drugs without any consideration of whether their money is being well spent.

We share CMS' concern that Medicare Part B reimbursement for prescription drugs may inadvertently encourage the use of more expensive drugs. While we know that providers weigh a number of important factors in making treatment decisions, we cannot ignore research that the program’s current financial incentives may encourage providers to select higher-priced treatments even if they are no more effective than lower-priced alternatives.

We agree that CMS should explore these challenges and adapt accordingly as the health care system continues to move towards value-driven care.

We do not believe that the model’s proposed changes to Medicare Part B prescription drug payment will adversely impact beneficiary access to needed care or a provider’s ability to make care decisions in the best interest of their patient. Under the proposal, health care providers maintain the ability to choose the treatment that best meets the needs of individual patients—CMS’ proposal merely takes steps to help ensure that treatments are chosen based on how well they work and not their price tag.

We also support CMS’ proposal to test the feasibility of value-based pricing strategies that have shown promise in the private insurance market, including reference pricing, indication-specific pricing, outcomes-based risk-sharing agreements, and discounting or eliminating beneficiary coinsurance amounts. CMS also plans to develop a voluntary evidence-based clinical decision support tool for prescribers that will provide information that reflects up-to-date literature and consensus guidelines. Importantly, these strategies will only be used for prescription drugs with a strong clinical evidence base to support their use.

Recognizing the unique characteristics and needs of Medicare beneficiaries, we believe that the proposed model will ensure that these value-based pricing strategies are tested in a way that safeguards access, while encouraging providers to deliver effective, high-value care. For example, CMS’ proposal establishes that beneficiary cost-sharing responsibilities will either remain unchanged or decrease, prohibits balance billing, and adds a pre-payment exceptions review for prescription drugs subject to value-based purchasing that will allow providers and beneficiaries to explain why an exception is warranted. We strongly encourage CMS to monitor beneficiary access and ensure that beneficiaries are well-informed about any impact this model will have on their benefits or care experience, as well as their rights to appeals processes.

Beyond improving the quality of care furnished to Medicare beneficiaries, the proposed model may also help to support the long-term sustainability of the Medicare program by promoting more efficient use of program funds. Last year, Medicare Part B spent $22 billion on prescription drugs—double the amount spent in 2007. This spending escalation is simply unsustainable. By removing incentives to use higher-priced medications that are no more effective than alternatives, the model creates value for both the beneficiary and the program. Further, private purchasers can use any insights gained from the model to help refine their own payment arrangements. Given Medicare Advantage plans are not subject to the demonstration, we recommend CMS work with health insurance issuers participating in Medicare Advantage (MA) to ensure that beneficiaries in both FFS and MA are treated comparably, and that CMS’ Part B drug payment model demonstration does not inadvertently encourage or discourage beneficiaries from enrolling in either option.

It is also important that CMS intends to implement the demonstration in a measured and thoughtful manner. CMS notes that implementation could take several years, with the goal of making the program fully operational in two years. We believe that this timeline will provide more than enough time for CMS to obtain feedback and ensure that the proposal is implemented appropriately.
We also believe that the Part B proposal is in line with the Center for Medicare and Medicaid Innovation’s (CMMI) statutory charge and authority. The ability of CMMI to independently test the effectiveness and scalability of promising new payment and delivery models to improve patient care and outcomes is critical to ensuring that policy makers and regulators have the unbiased evidence necessary to determine how to best deliver care to millions of Americans covered by public programs.

We commend CMS for requesting input on a number of important and salient questions within this proposed rule and are optimistic that the public comment process will ensure that concerns and comments raised by a variety of stakeholders are appropriately considered and addressed. We expect that the final rule issued by CMS will reflect the diversity of information gathered in the rulemaking process including public comment as well as expert opinion and scientific data. The final rule should draw on this feedback to ensure the final model is designed to drive enhanced value, and to ensure tested programs do not adversely affect beneficiary access or quality of care. We urge CMS to move forward with this demonstration, and we look forward to continuing to work with the agency to ensure that Medicare delivers the highest quality care to all beneficiaries.

Sincerely,

AARP
Aetna
AFL–CIO
Alliance for Retired Americans
American Federation of State, County and Municipal Employees
American Federation of Teachers
Blue Shield of California
California Health Advocates
Center for American Progress
Center for Elder Care and Advanced Illness, Altarum Institute
Center for Medicare Advocacy
Community Catalyst
Consumers Union
Doctors for America
Families USA
Justice in Aging
Kaiser Permanente
Lutheran Services in America
Medicare Rights Center
National Committee to Preserve Social Security and Medicare
National Education Association
National Partnership for Women & Families
National Physicians Alliance
Pacific Business Group on Health
The International Brotherhood of Boilermakers
cc: Dr. Patrick Conway
Acting Principal Deputy Administrator, Deputy Administrator for Innovation & Quality,
CMS Chief Medical Officer
Centers for Medicare & Medicaid Services

Tim Gronni Ter
Director of Delivery System Reform
Centers for Medicare & Medicaid Services

The Honorable Orrin Hatch
Chairman
Committee on Finance
U. S. Senate

The Honorable Ron Wyden
Ranking Member
Committee on Finance
U. S. Senate

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U. S. House of Representatives

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
U. S. House of Representatives

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U. S. House of Representatives

The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
U. S. House of Representatives
STATEMENT FOR THE RECORD
SUBMITTED TO THE HOUSE ENERGY & COMMERCE HEALTH
 SUBCOMMITTEE

By
Ariel A. Gonzalez, Director, Federal Health & Family
AARP

May 17, 2016

AARP Reiterates Its Support for CMS' Medicare Part B Drug Payment Model as the House Committee on Energy and Commerce Considers a Measure to Block It

AARP supports the Centers for Medicare & Medicaid Services' (CMS) demonstration project that modifies how Medicare pays for certain prescription drugs administered by physicians and other clinicians. The proposed model aligns with ongoing bipartisan efforts to shift U.S. health care away from a volume-based system to one that reimburses based on health care quality and innovation. This project is a thoughtful, measured approach to modernizing the way that Medicare pays for what are often incredibly expensive drugs. Many of the changes that CMS is considering in this demonstration project are already being used in the private sector.

Given current prescription drug price and spending trends, it is imperative that policymakers find ways to ensure that treatments are chosen based on how well they work and not their price tag. Thoughtful efforts to move towards higher value and improved quality of care in the Medicare Part B program are far preferable to the unsustainable escalations in beneficiary and taxpayer spending that would accompany maintaining the status quo.

Last year, Medicare Part B spent $22 billion on prescription drugs, double the amount spent in 2007. Beneficiary cost sharing is 20 percent with no out-of-pocket limits, leaving some older adults and people with disabilities with out-of-pocket costs that can reach as much as $100,000 per year or more. Like all Americans, Medicare beneficiaries cannot continue to absorb the costs associated with skyrocketing prescription drug prices indefinitely; the median annual income for Medicare beneficiaries is less than $25,000 and one in four have less than $12,000 in savings.
AARP applauds CMS for its commitment to improving the quality of care for Medicare beneficiaries. Contrary to how it has been portrayed by various entities that benefit financially from the current Medicare Part B payment system, there is longstanding and widespread support for the ideas underpinning this proposal. Indeed, given the outlook for the U.S. health care system, taxpayers, and beneficiaries, it is critical that CMS be able to evaluate ways to more effectively hold down prescription drug spending.

We encourage CMS to respond as appropriate to concerns raised by some stakeholders and to make improvements that we have suggested in our formal comments, including enhanced monitoring and oversight. Similarly, we urge Members of Congress to focus their efforts on constructive refinements to the proposed model instead of ill-advised legislative efforts that would block this worthwhile initiative from moving forward.

# # #
151

Statement of American Federation of Labor and Congress of Industrial Organizations 815 Sixteenth Street, NW Washington DC 20006

House Energy and Commerce Committee Subcommittee on Health  “The Patient and Doctor Perspective” and H.R. 5122, to prohibit further action on the proposed rule regarding testing of Medicare Part B prescription drug models

May 17, 2016

The AFL-CIO submits this statement on behalf of its 56 affiliate unions, which collectively represent 12.5 million working men and women, and our community affiliate, Working America.

Many seniors rely on prescription drugs for their health and well-being, but much of their limited retirement income is dedicated to paying for those drugs. Last year, Medicare part B spent $22 billion on prescription drugs, and many seniors cannot afford the 20 percent they are required to pay.

That is why the AFL-CIO supports the Centers for Medicare and Medicaid Services (CMS) rulemaking regarding physician reimbursement for Medicare Part B prescription drugs.

No one would argue against a program that improves health outcomes without unnecessary costs, yet the bill that is the subject of this hearing would torpedo a Medicare pilot proposal intended to do just that, long before it is finalized. While those who stand to lose financially have objected strenuously to the proposal, we have not seen any compelling evidence that the proposal will have an adverse effect on patient health because of impaired access to needed medications or that any legitimate concerns raised through the rulemaking process will not or cannot be addressed by CMS in the final rule or during the proposal’s implementation.

Aligning how doctors get paid by Medicare with the patient’s best interest is the right thing to do. The current system creates a clear and significant financial incentive to prescribe a medication because it has a higher price tag than an alternative drug, regardless of whether that higher-priced drug will provide the best treatment for the patient. Perverse systemic incentives like this are at the root of the quality and cost problems facing our nation’s health care system, and they must be addressed.
Dear Chairman Upton and Ranking Member Pallone,

The Alliance for Retired Americans, representing more than 4.3 million older Americans, supports the Centers for Medicare and Medicaid Services’ (CMS) Part B demonstration project. This proposed rule will test new payment models for prescription drugs covered under Part B, which are drugs administered in a doctor’s office or in an outpatient setting.

Drug costs, particularly under the Part B program, continue to outpace inflation. Prescription medications administered under Part B are specialty drugs, including biologics, and are some of the most expensive drugs on the market. In 2013, the average widely used specialty drug cost $53,184. Last year, Medicare spent $22 billion on Part B drugs. This is a two-fold increase over the $11 billion spent in 2007. The increased costs are passed on to taxpayers, as well as to Medicare beneficiaries in the form of Part B premiums and out-of-pocket costs.

CMS’ current reimbursement policy incentivizes doctors to choose more expensive drugs, without considering less expensive alternatives which are often more effective. The pilot payment model will allow physicians to administer medications based on drug efficacy rather than monetary considerations. The proposed rule would enhance care for Medicare beneficiaries without adversely impacting access to needed drug therapies or affecting a provider’s ability to make treatment decisions that best meet the patient’s needs. The proposed rule will also allow CMS to develop evidence-based clinical practice guidelines that will be a useful tool for providers.

We welcome CMS’ efforts to explore payment alternatives and advance value-driven care, as is now done in the private sector. The rise in use of specialty drugs, including biologics, is putting pressure on the Medicare program, threatening to drive up costs. Every effort must be made to ensure that Medicare dollars are used wisely while putting patients’ health first.

The Honorable Fred Upton
Chairman
House Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone
Ranking Member
House Energy and Commerce Committee
2322A Rayburn House Office Building
Washington, DC 20515
The proposed Part B demonstration project makes good sense. It will help reduce costs for beneficiaries and taxpayers without compromising care and help extend the solvency of the Medicare trust fund. We urge Congress to allow CMS to move forward on the demonstration project.

Sincerely,

Robert Roach, Jr.
President

Joseph Peters, Jr.
Secretary-Treasurer

Richard A. Fiesta
Executive Director
Dear Representative:

On behalf of the 1.6 million members of the American Federation of State, County and Municipal Employees (AFSCME), I am writing to express our support for the Centers on Medicare and Medicaid Services’ (CMS) proposed Part B Drug Payment Model proposal and our opposition to H.R. 5122, which would block CMS from finalizing and implementing this important demonstration project.

The CMS proposal is designed to test payment models in order to determine whether alternative models would promote better quality and higher value. Currently, CMS reimburses for drugs administered in a doctor’s office or hospital outpatient setting by paying the average sales price plus 6%. As a consequence, the payment methodology creates a bias for the use of more expensive drugs and may encourage drug makers to continually inflate their prices. Under the current payment system, providers who prescribe equally effective but less expensive drugs are disadvantaged financially.

Because beneficiaries are responsible for 20% of the cost of Part B drugs, a payment methodology that encourages the use of more expensive drugs creates a substantial and even unaffordable burden for many Medicare beneficiaries, especially the six million beneficiaries who do not have supplemental coverage. A study by the Government Accountability Office found that out-of-pocket costs for new Medicare Part B drugs ranged up to $107,000 per drug in 2013. Higher than necessary costs for Medicare Part B drugs also drive up costs for employers who provide their retirees with supplemental coverage. In 2013, CMS and Medicare beneficiaries spent $20.9 billion on the administration of Medicare Part B drugs. With this level of spending, it is incumbent upon CMS to seek to ensure that its payment methodology is aligned with quality and value.

We do not believe that the CMS proposal will limit the ability of providers to make decisions that are in the best interest of their patients. Nor do we believe that the proposal will adversely impact beneficiary access to needed care. In fact, the proposal minimizes payment as a factor in treatment decisions.

The CMS proposal is a thoughtful approach to testing reforms that will deliver the best value for taxpayers and beneficiaries. We believe that it is in the best interest of taxpayers and beneficiaries that this demonstration project be allowed to go forward.

Sincerely,

Scott Frey
Director of Federal Government Affairs

American Federation of State, County and Municipal Employees, AFL-CIO

SC: BC: rf

American Federation of State, County and Municipal Employees, AFL-CIO

T: (202) 419-3000 F: (202) 419-2991 D: (202) 639-0941 WEB: www.afscme.org

1451 1 St NW, Washington, DC 20036-5407
May 16, 2016

Honorable Fred Upton  
Chairman  
House Committee on Energy and Commerce  
United States House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515

Honorable Frank Pallone, Jr.  
Ranking Member  
House Committee on Energy and Commerce  
United States House of Representatives  
2322A Rayburn House Office Building  
Washington, DC 20515

Re: Support for Medicare Part B Payment Model

Dear Chairman Upton and Ranking Member Pallone:

The Center for Medicare Advocacy (the Center) writes to express our support for the Centers for Medicare & Medicaid Services’ (CMS) Part B Payment Model as outlined in the Notice of Proposed Rule Making (NPRM) CMS–1670–P published in the Federal Register on March 11, 2016 (81 Fed. Reg. 13230). The Center, founded in 1986, is a national, non-partisan education and advocacy organization that works to ensure fair access to Medicare and quality health care.

The proposed Medicare Part B Payment Model is aimed at both reducing costs and increasing access to effective prescription drugs. At a time when prescription drug costs are growing at a significant pace, many Medicare beneficiaries cannot afford cost-sharing for high-cost medications, while others struggle to find a pharmacy or supplier that will provide lower-cost drugs. CMS’ Part B Payment Model seeks to address affordability, in part, by testing a range of value-based pricing tools for a limited number of Part B medications. The goals of the Model are aligned with broader payment reform efforts to transition Medicare from volume-based to value-based payment system and to encourage high-value, evidence-based clinical decision-making. We see no reason that prescription drug pricing should be excluded from such efforts.

Moreover, the Part B Payment Model would simply remove a purely monetary incentive for prescribing more expensive medications. It would not limit providers from prescribing the medications they believe are best suited for each individual patient. The proposed Model, as outlined, proceeds with caution, and includes appropriate safeguards that improve transparency for identifying high value services and decrease discrimination based on health status-related factors.
The Center for Medicare Advocacy’s complete comments to the proposed rule are available on our website at: http://www.medicareadvocacy.org/center-comments-on-proposed-part-b-payment-model/. For additional information, please contact our Senior Policy Attorney David Lipschutz at dlipschutz@medicareadvocacy.org. Thank you.

Sincerely,

Judith Stein
Executive Director/Attorney
Statement from Doctors for America in Support of CMS part B demo

As physicians and medical students advocating for an affordable and sustainable system of drug pricing for our patients, we support the proposal by the CMS to test a sensible set of models aimed at changing how CMS pays for medications under Medicare Part B. We need to ensure that essential treatments are available for all of our patients. The unwillingness to sensibly limit the prices of specialty drugs threatens access and affordability to the majority of patients. It is heartbreaking to see our patients struggle to choose between medications and rent as their out of pocket costs grow.

Reforms are vital to align the prices of prescription drugs with their efficacy and the value that they provide for patients. We believe that the CMS proposals aim to place quality and value at the center of the shared decisions we make in partnership with our patients and ultimately have the potential to safeguard affordability of the medications delivered under Medicare Part B. Testing a variety of reforms and initiatives as pilot projects will enable us to obtain vital information on which types of reforms will best achieve these goals.

We believe that all of the six alternative models proposed by CMS to address drug prices under Medicare Part B are worthy of consideration. Full testing of these alternative payment models, including the systematic comparison of their effects on patients as well as physicians, will enable us - physicians, medical students, advocates, policy experts, and the patients for whom we care - to make an educated choice for the best path forward toward making our healthcare system work better for all.

There may be multiple ways to improve these proposed models to further align incentives and ensure that physicians who rely on reimbursement under Part B are treated fairly. As an example, slight modifications have been proposed (during Public Comment and elsewhere) to the CMS phase one payment model. This model tests reallocating, not cutting, payments to physicians through the change from ASP + 6% to ASP + 2.5% + flat fee payment of $16.80 per drug per day, which we believe is a rational approach to limit incentives for prescribing highly-priced drugs when less expensive options may be available. However, it is an unfortunate reality that the financial well-being of many specialty physicians - community oncologists, rheumatologists, orthopedists, and those of other similar specialties - are too often dependent on the reimbursements they receive for

Doctors for America is a 501(c)(3) national movement of physicians and medical students working together to improve the health of the nation and to ensure that everyone has access to affordable, high-quality health care.
prescribing drugs. We want to ensure that these specialists do not bear an undue burden for cost savings and can remain financially solvent for the sake of these physicians and their patients, and thus this may be an area where a modification ought to be considered. In particular, we point to the analysis done by Peter Bach MD, Director of Memorial Sloan Kettering’s Center for Health Policy and Outcomes, which calls for raising the flat rate to $24.43 per treatment without sequestration, or $23.74 per treatment under sequestration.

With the needs for conversation, flexibility, foresight, and potential modifications in mind, we are confident that the pilot testing of these models can be successful and will yield important information on how we can best achieve a system of affordable prescription drugs moving forward. We believe the proposed CMS part B demos should move forward, and should be improved with input from all stakeholders and then implemented and tracked for outcomes throughout the process. However, these demos do not negate the responsibility of Congress to address pharmaceutical companies pricing policies. Addressing prescription prices should be a priority to maintain patient access to affordable treatments.

About the Doctors for America Drug Pricing & Value Campaign

Through the Drug Pricing and Value Campaign and other initiatives, Doctors for America is committed to speaking on behalf of our membership of more than 18,000 physicians and medical trainees and to advocating for our patients in discussions surrounding prescription drug pricing, value, affordability, and sustainability of the healthcare system.
May 17, 2016

The Honorable Joseph Pitts, Chairman
The Honorable Gene Green, Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Pitts and Ranking Member Green:

Consumers Union, the public policy and advocacy division of Consumer Reports, appreciates the attention the Subcommittee is bringing to the issue of how prescription drugs are priced and paid for under the Medicare Part B benefit. We support the Center for Medicare Services (CMS) proposed rule regarding the Medicare Part B Drug Payment Model Program.

We are deeply concerned about the affordability of drugs for consumers and the growth of health system costs, both due, in part, to rising drug costs. In 2015 Medicare spending on Part B drugs reached $22 billion, representing an average annual increase of 8.6% in Part B spending since 2007. It is imperative that we get these costs under control; they threaten our healthcare system, as well as household, federal and state budgets.

Medicare beneficiaries bear these high costs through direct cost-sharing and the premiums they pay for supplemental insurance. Under Medicare Part B, beneficiary cost-sharing represents 20% of Part B drug costs with no annual cap on these out-of-pocket expenses. The median income for Medicare beneficiaries is $25,000 and one in four beneficiaries has less than $12,000 in savings. Many Medicare beneficiaries are financially unprepared to afford extremely expensive and potentially life-saving medicines when they are very sick.

We share the concern of many experts and other consumer advocates that the current Part B payment methodology incentivizes the use of more expensive drugs. The add-on of 6% of the drug’s Average Sales Price (ASP) for drugs that are administered in a physician’s office or

---

1Consumers Union is the policy and advocacy division of Consumer Reports. Consumer Reports is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. Founded in 1936, Consumer Reports has over 8 million subscribers to its magazine, website, and other publications. In addition to our policy work, Consumer Reports is the world’s largest independent product-testing organization. Using its more than 50 labs, auto test center, and survey research center, the nonprofit organization rates thousands of products and services annually.


hospital outpatient department means that providers make more money when they use more expensive treatments. While we believe that providers have their patients’ best interests in mind, studies show that financial incentives influence providers’ treatment decisions; providers are more likely to choose a more expensive treatment option over an equally effective lower-cost option. The non-partisan MedPAC issued a report showing that, in general, Part B overpays for drugs and that the current payment methodology may incentivize the use of higher cost drugs.

We believe that to truly make progress on the pressing issue of rising health care costs and to ensure that high drug prices do not threaten Medicare beneficiary access to potentially life-saving treatments, we must pilot a new way to pay for Part B drugs focused on affordability and value. We also strongly support the thoughtful manner in which CMS designed the project, the use of randomized assignments and a control group, and the solicitation of feedback from diverse stakeholders. We believe that the evidence gathered from this project will greatly move our system towards a system that rewards value and quality. For these reasons, Consumers Union strongly supports this demonstration project.

We would be happy to provide a complete copy of our comments to CMS addressing the specifics of the proposed rule and providing additional suggestions for tracking and safeguarding the experiences of beneficiaries involved in the pilot.

We respectfully request that this letter be included in the official record of the hearing.

Sincerely,

Lynn Quincy
Associate Director, Health Policy
Consumers Union

Victoria Burack,
Policy Analyst,
Consumers Union

---

JUSTICE IN AGING
FIGHTING SENIOR POVERTY THROUGH LAW

Statement for the Record
Submitted to
U.S. House of Representatives Committee on Energy and Commerce
Subcommittee on Health

Hearing on The Obama Administration’s Medicare Drug Experiment:
The Doctor and Patient Perspective

May 17, 2016

Justice in Aging appreciates the opportunity to submit this statement in support of the Center for Medicare & Medicaid Services (CMS) Medicare Part B Drug Payment Model.

Justice in Aging, formerly the National Senior Citizens Law Center, is a national advocacy organization that uses the power of law to fight senior poverty by securing access to affordable health care, economic security, and the courts for older adults with limited resources. We support the Part B drug payment model because the proposal has the potential to improve quality and value for Medicare beneficiaries.

As a national organization advocating on behalf of the 6.4 million seniors who live in poverty, we are particularly attuned to the needs of Medicare beneficiaries to have a high value health care system that increases quality while reducing costs. This proposal appropriately focuses on changing incentives for prescribers that currently favor high-cost drugs, even when lower-cost alternatives are available, while ensuring that Medicare beneficiaries can maintain access to the medications that they need.

Changing the trajectory of prescription drugs costs in Medicare is particularly important for lower income Medicare beneficiaries. Low income Medicare beneficiaries who cannot afford supplemental insurance and, due to the strict income and asset requirements for Medicare Savings Programs, do not receive any assistance with Medicare cost sharing are particularly vulnerable when faced with high cost Part B prescription drugs. The median income for Medicare beneficiaries is less than $25,000, and one in four beneficiaries have less than $12,000 in income. Since there is no out-of-pocket limit for cost-sharing for Medicare beneficiaries, costs can soar, reaching as high as $100,000 or more.

We do not believe that the model’s proposed changes to reimbursement will adversely impact beneficiary access. In contrast, they may increase beneficiary access, as studies demonstrate that very

high coinsurance can dissuade beneficiaries from receiving even needed care. When drug prices go down, access can increase as more people can afford their copayments, and do not go without care.

We support the size and scope of this demonstration. As consumer advocates, we are aware that many beneficiaries cannot afford the 20 percent coinsurance on high-cost medications, while others struggle to find a pharmacy or supplier who will provide very low-cost prescription drugs. The Part B Drug Payment Model aims will help resolve both of these challenges.

We have shared our comments with CMS. As we state in our comments, we support Phase I and Phase II, with recommendations for monitoring, transparency and beneficiary outreach. With these protections, we expect that beneficiaries will retain access to needed medication under both models. Phase I has the potential to minimize unaffordable cost sharing and increase access to medication where there are less costly alternatives. In 2010, 14 percent of beneficiaries had Original Medicare without supplemental coverage. This population includes a disproportionate share of people under age 65 with disabilities, those with annual incomes between $10,000 to $20,000, and African American beneficiaries. This demonstration may prove particularly valuable to this group.

We also support Phase II, and the proposal to test different value based purchasing strategies for a limited number of Part B Drugs. We support testing these strategies and emphasize the importance of real time monitoring and feedback to assess beneficiary experience. In our comments to CMS, we urged the agency to develop strong opportunities for stakeholder engagement and a robust feedback loop to monitor the beneficiary experience, as the agency implements Phase II. We suggested that CMS create stakeholder advisory groups to solicit input from a wide range of stakeholders. We also recommended the agency create an ombudsman program to assist beneficiaries, monitor beneficiary access, and help CMS implement any course corrections that may be needed to ensure access is advanced and not harmed during implementation.

Thank you for the opportunity to comment on this important and innovative model. Our comments to CMS in support of the model are available here: http://www.justiceinaging.org/wp-content/uploads/2016/05/Justice-in-Aging-Part-B-Drug-Payment-Model-comments.pdf. For further information, please contact Jennifer Goldberg, Directing Attorney, at jgoldberg@justiceinaging.org.

---


---

JUSTICE IN AGING
Statement on the Proposed Part B Drug Payment Model

Statement of Max Richtman
President and CEO
National Committee to Preserve Social Security and Medicare

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

Hearing on "The Obama Administration's Medicare Drug Experiment: The Patient and Doctor Perspective"
Washington, DC

May 17, 2016

Chairman Pitts and Ranking Member Green:

I am Max Richtman, President and Chief Executive Officer of the National Committee to Preserve Social Security and Medicare, and I appreciate the opportunity to submit this statement for the record. With millions of members and supporters across America, the National Committee is a grassroots advocacy and education organization dedicated to preserving and strengthening safety net programs, including Social Security, Medicare and Medicaid. These programs are the foundation of financial and health security for older Americans, but improvements are needed to ensure that beneficiaries receive the care they need and that they are protected from unaffordable out-of-pocket costs.

The Medicare Part B payment model proposed by the Centers for Medicare & Medicaid Services’ (CMS) provides an opportunity for improving the incentives for prescribing drugs by creating an evidenced-based approach to payment. The model will test the suitability for the Medicare program of value-based insurance design tools used in the private sector. The National Committee supports transitioning Medicare to a program that rewards value not volume in order to improve health outcomes and reduce wasteful spending. The proposed drug payment model is an important step toward that goal.

Establishing an Evidence-Based Approach to Payment
It is critically important that CMS calibrate payment for drugs to guard against inappropriate prescribing of higher-cost drugs where similarly effective lower-cost alternatives exist. Payment policy should promote appropriate use of drugs to ensure the best patient outcomes and careful stewardship of limited resources.

Under the current Average Sales Price (ASP) +6% payment methodology, physicians get paid more for more expensive drugs than for less expensive drugs. There is some evidence showing that ASP +6 creates incentives for physicians to steer patients to more expensive drugs and that it may create access problems to less expensive drugs. But the actual impact of this method on prescribing patterns has not been comprehensively evaluated by CMS. We applaud the agency for proposing an evidence-based framework for testing an alternative payment system that neutralizes reimbursement as a consideration for physicians when prescribing drugs. We appreciate CMS’ responsiveness to the Medicare Payment Advisory Commission’s (MedPAC) suggestion that CMS consider a blended flat fee plus percentage payment in order to eliminate a payment bias toward higher cost drugs that exists under ASP +6.

It should be noted that the current ASP +6 has not been similarly evaluated to ensure that access and quality are not negatively affected by current practice. Any alternative payment structure that ultimately emerges from the proposal’s Phase I and Phase II results will be more empirically informed than the current physician payment model.

Monitoring

The National Committee believes that while the scope of the proposed model is comprehensive—requiring participation of all providers and suppliers within selected regions in either the trial or control arm—it includes appropriate safeguards to ensure that access and quality of care are not adversely affected during the course of the demonstration. Also, CMS has raised reasonable concerns about selection bias that may occur in a voluntary model or one that is limited by various characteristics of either physicians or drug type. The National Committee believes that CMS has built in adequate safeguards into the model to detect unintended negative responses to changes in its comprehensive model that should mitigate concerns about the expansive scope of the model. The National Committee believes that any changes to the model must not compromise the adequacy of the sample size, which must be sufficiently large to generate unbiased, generalizable results.

The key safeguard under the proposal is its ongoing evaluation of prescribing patterns. This ongoing evaluation of data should allow CMS to detect problems and make mid-course corrections in the event that problems with access to medications and/or quality of care emerge. Specifically, CMS indicates it has the capacity to review claims data in near real time to assess for access and outcomes, a process it has used effectively to monitor the durable medical equipment competitive bidding demonstration.

Test of Value-Based Insurance Designs

The National Committee further supports the payment model’s Phase II efforts to improve the evidence base around value-based design tools. This careful approach will allow Medicare to
learn from innovations in the private sector while tailoring these approaches to the needs of beneficiaries.

The National Committee is encouraged by CMS' intent to better align payment with outcomes through an evaluation of payment methods such as outcomes-based pricing, indication-based pricing, and lower cost sharing for high-value care. A great deal of transparency around how high-value therapies will be identified will be required. The National Committee is particularly supportive of efforts to look at eliminating cost sharing for high-value services and the prohibition on balance billing in the evaluation of reference pricing. Half of beneficiaries have annual incomes at or below approximately $24,000. Value-based payment methods should positively encourage the use of appropriate services without placing onerous financial burdens on beneficiaries.

The National Committee has urged CMS to engage in regular public reporting of results and to solicit input from a broad range of stakeholders, including consumer groups, in order to inform both the development of the model and also to identify potential areas of concern as they emerge. Given the scope of the test, the National Committee has urged CMS to develop formal opportunities for stakeholder engagement such as holding regular stakeholder meetings and creating an advisory committee.

We look forward to working with members of the Energy and Commerce Committee on ways to improve the Medicare program for beneficiaries.

Sincerely,

Max Richtman
President and CEO
May 16, 2016

Congresswoman Jan Schakowsky
2367 Rayburn House Office Building
Washington, DC 20515

Dear Congresswoman Schakowsky:

On the occasion of tomorrow’s Energy & Commerce Health Subcommittee hearing, I write to you today on behalf of the 1.2 million active and retired members of the United Steelworkers (USW) in support of the rule proposed by the Centers for Medicare & Medicaid Services (CMS) that would implement pilot programs to test new Medicare Part B drug payment models.

The USW is the largest industrial union in North America and represents workers in a range of industries including metals, mining, rubber, paper and forestry, oil, health care, security, hotels, municipal governments and agencies. The vast majority of the USW retirees receiving health care coverage are enrolled in Medicare, which is the primary payer. Retiree health care plans negotiated with employers and Voluntary Employees’ Benefit Association (VEBAs) provide secondary coverage. The USW provides coverage to its Medicare-eligible members through a variety of Medicare Advantage plans and through plans that “wrap” original Medicare.

Overall, the high and rising cost of prescription drugs is a concern for USW members and retirees. Our union supports innovative solutions to bring down costs including the proposed pilot programs to test value-based payment models for prescription drugs covered under Medicare Part B. As indicated in the proposed rule, many of these payment models already are being successfully used by entities in the private sector.

Unfortunately, the current Part B drug payment formula creates an economic incentive for providers to administer high cost drugs, even where there is a lower cost alternative that would be equally or more effective. The proposed pilot programs would eliminate this unfortunate incentive and would not restrict the ability of providers to prescribe whatever medications they believe are necessary and proper for their patients.
Based on our own experience and the experiences of other private sector entities, we believe that the value-based purchasing models have the potential to reduce expenditures for prescription drugs, while maintaining or enhancing the quality of care for patients. Thus, we believe the proposed pilot programs will be able to show reductions in Medicare expenditures for Part B drugs. And, significantly, it will help to reduce out-of-pocket expenses for many individual beneficiaries for prescription drugs covered by Part B.

The proposal for the pilot program is just that—a proposal for a pilot. Therefore, while we offer support for the pilot, USW believes it is important for CMS to put in place mechanisms to monitor the impact of the pilot programs on the access of beneficiaries to providers. Specifically, we urge CMS to do periodic analyses and make prompt changes should analyses reveal problems in access.

In conclusion, USW applauds CMS for issuing the proposed rule on Medicare Part B drug payment models. In our judgment, these models have the potential to provide significant benefits, both to Medicare and to private retiree health care plans, as well as to beneficiaries.

Sincerely,

Holly R. Hart
Assistant to the International President
Legislative Director

---

United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union
Legislative Department, 1155 Connecticut Ave., Suite 500, N.W., Washington, D.C. 20036 • 202-778-4384 • 202-419-1488 (Fax)
www.usw.org
May 6, 2016

Sylvia Matthews Burwell  
Secretary  
U.S. Department of Health and Human Service  
200 Independence Avenue, SW  
Washington, DC 20201

Andrew Slavitt  
Acting Administrator  
Centers for Medicare and Medicaid Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Burwell and Acting Administrator Slavitt:

On behalf of the Public Sector HealthCare Roundtable, as well as those public sector health care purchasers listed below, we would like to express our support for the recent CMS proposal to test new Medicare Part B prescription drug models to improve quality of care and deliver better value for Medicare beneficiaries. This proposal represents an important step in encouraging high-value care and smarter spending and will provide much needed financial relief for millions of Medicare beneficiaries.

The Public Sector HealthCare Roundtable is a non-profit, non-partisan coalition of public sector purchasers from across the U.S. including states, counties, and municipalities that collectively spend over $14 billion annually on health care benefits to provide coverage for millions of employees, retirees, and their dependents. We are squarely focused on ensuring that seniors and especially those who rely on critical prescription medications to manage their health conditions receive care that is of the highest-quality, well-coordinated and affordable. CMS’ proposed Part B prescription drug model aligns with this focus, and we support the forward progression of this proposal.

Recognizing that retirees have cost-sharing associated with Part B administered drugs, this proposal will address and ameliorate perverse incentives under the current payment formula that encourage providers to prescribe higher priced drugs under Medicare. While plans work to minimize cost-sharing for prescription drugs for their retirees, even a minimal coinsurance can still amount to a significant sum when considering some of the higher priced drugs that may be prescribed. Further, we support testing the implementation of the value-based purchasing tools that CMS has outlined as potentially successful pricing strategies in the context of payment for Part B drugs. While we strongly urge CMS to move forward with value-based purchasing initiatives, we do not support proposals that would lead to increased costs for our members and the public sector employees and their dependents we serve.

The Roundtable, together with the plans listed below, appreciates the opportunity to provide comments on this proposed rule based on the experience of our members and our desire to support proposals that expand innovative models of
Secretary Sylvia Matthews Burwell  
Acting Administrator Andrew Slavitt  
May 6, 2016  
Page two

care delivery while constraining health care cost growth. We strongly encourage  
CMS to move forward with new payment models for prescription drugs and we  
look forward to working with you and the broader stakeholder community to this  
end.

Please do not hesitate to contact the Public Sector HealthCare Roundtable Senior  
Policy Advisor, Andrew MacPherson, at andrew@healthperx.com should you  
have any questions or would like further information.

Sincerely,

GARY HARBIN, President  
Public Sector HealthCare Roundtable

Health Plans:

California Public Employees Retirement System  
Colorado Public Employees Retirement Association  
Kentucky Teachers Retirement System  
Missoula County, Montana  
Ohio Public Employees Retirement System  
School Employees Retirement System of Ohio  
State of Montana
United Auto Workers Leadership Statement in Support of Medicare Part B Prescription Drug Project
Statement from UAW President Dennis Williams

The International Union, United Automobile, Aerospace and Agricultural Implement Workers of America, UAW strongly supports the proposed Part B drug pilot programs and commends the Obama Administration for taking this important step to reign in out of control prescription drug costs. The value-based purchasing models reduce the cost of prescription drugs. In addition to reducing costs for Medicare, it could reduce out-of-pocket costs for many seniors and save taxpayers’ money. This includes some of the most vulnerable seniors, such as cancer patients.

At the same time, the pilots could improve the quality of care received by patients. This is because the pilot programs will enable providers to focus on what medication are most effective and provide the greatest value to their patients, not the ones that pay the most. Quality of care may also be enhanced through policies that include evidence based clinical decision support tools that help providers determine the best course of treatment. Similarly, discounting or eliminating patient cost sharing can result in patients getting the treatment they need.

For the foregoing reasons, the UAW supports the proposed Part B drug pilot programs. We urge Congress to back the implementation of these pilot programs and oppose efforts to prevent them from moving forward.
Proposed Part B Medication Payment Model Promises
Improved Patient Access and Efficiency

FOR IMMEDIATE RELEASE
Thursday, March 10, 2016

Statement attributable to:
Wanda Filer, MD, President
American Academy of Family Physicians

“Family physicians welcome the opportunity to improve methods by which the Centers for Medicare & Medicaid Services pays for Medicare Part B medications that patients receive in physician offices or hospital outpatient departments.

“The transformation of our health care system requires a fresh perspective and new ideas on how we deliver and pay for health care services. The AAFP applauds CMS’s efforts to apply common-sense, value-based payment principles to the delivery of physician-administered pharmaceutical and biologic treatments. Physicians, hospitals and other Medicare providers are aggressively pursuing value-based payment models, and it only makes sense that we would explore the applicability of these same ideas to the pharmaceutical industry.

“By seeking public comment on how to test new payment models for physician-administered medications, CMS is taking a step toward ensuring that Medicare patients get the most appropriate drugs while simultaneously minimizing costs for patients and thus the U.S. health care system.

“The proposed rule, if finalized, would test the impact of paying for medications administered in a physician’s office based on average sales price, plus a flat fee and 2.5 percent add-on. Equally important, the CMS proposal would test making these medications more accessible to patients by decreasing or eliminating cost-sharing.

“The AAFP believes that all physicians should be paid accurately for the clinical services they provide and that delivery systems should not favor certain drugs or medical devices over others. This proposed rule offers the opportunity to test program changes that may be an important step in this direction and the AAFP looks forward to providing CMS with a full reaction prior to the comment deadline.”

Editor’s Note: To arrange an interview with Dr. Filer, contact Leslie Champlin, (900) 274-2237, Ext. 5224, or lchampl@afp.org.
About the American Academy of Family Physicians
Founded in 1947, the AAFP represents 120,900 physicians and medical students nationwide. It is the only medical society devoted solely to primary care.

Family physicians conduct approximately one in five office visits -- that's 214 million visits annually or 48 percent more than the next most visited medical specialty. Today, family physicians provide more care for America's underserved and rural populations than any other medical specialty. Family medicine's cornerstone is an ongoing, personal patient-physician relationship focused on integrated care.

To learn more about the specialty of family medicine, the AAFP's positions on issues and clinical care, and for downloadable multi-media highlighting family medicine, visit www.aafp.org/media. For information about health care, health conditions and wellness, please visit the AAFP's award-winning consumer website, www.FamilyDoctor.org (www.familydoctor.org).
May 9, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Acting Administrator Slavitt:

We are writing today to express our support for the Centers for Medicare and Medicaid Services (CMS) proposed rule to test new payment models for Part B prescription drugs. It is essential to test methods to ensure that senior citizens and people with disabilities on Medicare receive the most cost-effective, appropriate drugs; and we support using authorities provided to the Center for Medicare and Medicaid Innovation (CMMI) to develop better models to meet that goal. We believe this proposal will not only help to fix the flawed status quo but will also help combat the increasingly unaffordable prices that drug companies are charging for their products.

We share our constituents’ concern about the high cost of prescription drugs, and we are eager to work with you on a broad range of proposals to lower those costs in ways that do not inhibit access. Determining the best payment mechanism for Part B drugs must be part of that solution. High Part B drug costs affect individuals who face 20 percent cost-sharing requirements with no out-of-pocket limits, contribute to increases in Part B premium costs to beneficiaries and taxpayers, and can impact the long-term solvency of the Medicare Part B Trust fund. We share CMS’s concern that current payment mechanisms—which peg provider payments to a percentage of the cost of the drug—could affect prescribing behavior and believe it is essential to investigate alternatives.

In addition, we do not believe that the model’s proposed changes to Medicare Part B prescription drug payment will adversely impact beneficiary access to needed care or a provider’s ability to make care decisions in the best interest of their patient. On the contrary, this important step will reduce the role of money in the equation, keeping the focus on the needs of the patient. Moreover, this does not limit a doctor’s ability to prescribe what they believe to be the most appropriate therapy. Instead, CMS’ proposal takes steps to help ensure that treatments are chosen based on how well they work and not just their price tag.

The second phase of the proposed model, which will test value-based purchasing models for Part B drug payment, also holds great promise. By adopting reforms that are currently being
explored in the private sector, these tests will drive innovation to both reduce costs and improve the quality of care, and help to strengthen and improve Medicare.

We are pleased that CMS has requested input on a number of important questions and are confident CMS will take into account the comments received from various stakeholders to ensure the final rule is as effective as possible. We understand that achieving the balance between cost and access is complicated, which is exactly why CMMI should use its authority to proceed with rigorous demonstrations that will test different approaches. Only by doing so will we be able to answer the questions that have been raised and obtain the data we need to select the best value-based payment model to meet the needs of beneficiaries and taxpayers.

Sincerely,

[Signatures of Congress members]
May 16, 2016

Sylvia Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Andy Slavitt
Acting Administrator
Center for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Patrick Conway, MD, MSc,
Acting Principal Deputy Administrator
Deputy Administrator for Innovation and Quality
Chief Medical Officer
Center for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Burwell, Acting Administrator Slavitt, and Acting Principal Deputy Administrator Conway:

We write to offer our support for, and comments regarding, the Centers for Medicare & Medicaid Services' (CMS) proposed Medicare Part B drug payment demonstration (the Demonstration) announced on March 11, 2016.1 We commend the administration’s efforts to address the burden of high drug costs on Medicare beneficiaries and taxpayers and to align drug purchasing with value. As you move forward with finalizing and implementing the Demonstration, we urge you to consider changes proposed by stakeholders, including patients and providers. It is important that Medicare Part B program drug payments ensure access to necessary medications, build on existing payment reform models, enhance private sector payment innovations, and promote value.

Spending on prescription drugs has risen significantly in recent years, driven in part by high and rising drug prices. This affects patients and taxpayers alike. A recent IMS Health report found that list prices for brand-name drugs increased by more than 12% in 2015, representing the

second year of double-digit increases. In the Medicare Part B program, spending increased by an average annual rate of 7.7% between 2005 and 2014, with just 20 drugs accounting for 57% of the costs. Given that seniors enrolled in Medicare Part B are required to pay 20% of costs with no limit on cost sharing in the standard benefit, the amount beneficiaries have to pay for these drugs can be significant, ranging from $1,900 up to $107,000 per beneficiary, according to the Government Accountability Office. Now is the time for CMS to act to help these beneficiaries, especially those who struggle to financially absorb these high costs.

The Demonstration advances the conversation about how the Medicare payment system can incentivize value and outcomes, rather than simply volume. Phase I of the Demonstration project aims to improve financial incentives that currently reward physicians and hospitals for choosing more expensive treatments, rather than the ones that are the most effective. Phase II of the Demonstration will test new value-based payment models.

As you work on finalizing the Demonstration, we ask that CMS consider the following:

- **The Demonstration should be finalized after taking into consideration, and addressing, information submitted by healthcare and beneficiary communities.**
  
  Some stakeholders have cautioned that the Demonstration may limit beneficiary access to important medications, especially in community-based settings, shift the site of service to hospitals, or that it may adversely impact rural providers and small, independent physician practices, especially given the short implementation timeline. Other stakeholders have expressed strong support for the Demonstration, including many organizations that represent beneficiaries, such as AARP, Medicare Rights Center, and Families USA. Any change to reimbursement will result in changes to the delivery system, and CMS should take all steps necessary to carefully assess and monitor feedback from patients and physicians, and preserve beneficiary access to medically necessary medications.

- **The Demonstration advances CMS, Congressional, and private-sector efforts to pay for value in the health care system.**
  
  Drugs paid for by Medicare Part B represent some of the greatest advancements in medical treatment. These products are helping seniors and people with disabilities live longer, healthier lives. As new products are developed, Medicare should continue to advance the way it pays for these products, building on existing efforts that reward health outcomes and value.

Paying for value is a strong theme in the health care system, as payments to hospitals, post-acute care providers, and physicians from both public and private payers have been transitioning from fee for service to alternative payment models. Congress has consistently signaled its support for transitioning away from fee-for-service payments, most recently with the passage of the Medicare Access and CHIP Reauthorization Act of

---


3 [https://aspe.hhs.gov/sites/default/files/pdf/187581/PartBDrug.pdf](https://aspe.hhs.gov/sites/default/files/pdf/187581/PartBDrug.pdf)

2015 (MACRA), CMS is engaged in several hospital and physician payment demonstrations, including the recently implemented Comprehensive Care for Joint Replacement model, which provides a single bundled payment for all care required for hip and knee replacement surgeries, and several Accountable Care models.

Commercial insurers and drug companies are likewise engaged in numerous payment initiatives to promote value and patient outcomes. For example, Express Scripts is moving forward with its Oncology Care Value Program, an indication-based pricing framework specifically for cancer care that pays for a drug based on how much evidence supports its use for a given type of cancer. And Harvard Pilgrim Health Care and Cigna have both launched outcomes-based pricing arrangements for certain new cholesterol drugs that pay for a drug based on how well patients fare on the treatment. These are just two of the value-based pricing strategies that the Demonstration will test, alongside others that include discounted or eliminated cost-sharing for high value drugs, increased feedback on prescribing patterns, and reference pricing.

We ask that CMS continue to work with stakeholders to refine these value-based pricing models, and other tools proposed by CMS, to ensure that they build on, or are complimentary to, other public and private efforts that reward innovation, reduce costs, and improve care.

Medicare beneficiaries deserve high-quality, affordable health care. We appreciate your efforts to test new ways of delivering this care so that it is available now and in the future. Prescription drug spending, especially in the Medicare Part B program, is rising rapidly, and we believe that the Demonstration offers an important opportunity to provide better value to beneficiaries. As you move toward finalizing the Demonstration, we ask that CMS consider the breadth of issues raised by stakeholders and patients to inform the final design. We believe that with refinements, the Demonstration can be an integral part of the administration’s commitment to lowering health care costs and improving quality for our nation’s Medicare beneficiaries.

Sincerely,

Elizabeth Warren
United States Senator

Al Franken
United States Senator

1 https://innovation.cms.gov/initiatives/cjr
5 http://www.wsj.com/articles/health-insurers-push-to-better-drug-prices-to-outcomes-1462957052
An independent federal agency making recommendations to the President and Congress to enhance the quality of life for all Americans with disabilities and their families.

May 17, 2016

Administrator Andrew Slavitt
Centers for Medicare and Medicaid Services (CMS)
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Slavitt:

I write on behalf of the National Council on Disability (NCD) -- an independent, nonpartisan federal agency charged with providing advice to Congress, the President, and other federal agencies on matters affecting the lives of people with disabilities -- to urge you to withdraw CMS’s March 11 proposed rule regarding changes to Medicare’s Part B drug payment model due to its likelihood of disproportionately negatively affecting people with chronic health conditions, and to utilize NCD as a convenor to more fully engage patient stakeholders who stand to be most impacted by the effects of the rule.

CMS’s stated purpose of this proposed rule is to “improve outcomes and reduce expenditures for Part B drugs.” While we appreciate the challenge of proposing policies that reduce prescription drug expenditures while at the same time doing no harm to patient self-direction, to the doctor-patient relationship, and/or to patient outcomes, we believe that the proposed rule does not succeed in doing no harm. CMS noted that the proposed rule was aligned with the Administration’s strategy of encouraging “better care” and “healthier people,” however overwhelmingly, it is patient groups and their specialty care providers who have voiced concern that this rule would have the opposite effect of such pursuits, which shows at a minimum that the process CMS undertook to involve stakeholders in the development of the NPRM may not have been adequate to address concerns.

For several years now, NCD has traveled the country to host stakeholder forums regarding states’ transitions to Medicaid managed care to promote greater dialogue and contact between key CMS regional office staff and the disability community regarding managed care waiver applications and dual eligible demonstration proposals. Each forum involved seven stakeholder groups comprising consumers/self-advocates, families, other advocates, providers, informal family caregivers, state government agency workers, managed care organizations (MCO), researchers, and various professionals in academia. On the basis of this extensive stakeholder engagement, NCD was able to confidently advance recommendations to CMS regarding transitions in the service delivery system.

Indeed, NCD has extensive experience with stakeholder engagement as a means to inform and confirm its own policy recommendations. In fact, in 2012, in our Guiding Principles: Successfully Enrolling People with Disabilities in Medicaid Managed Care Plans publication, NCD identified key stakeholder involvement as a guiding principle and stated the
importance of "fully engag[ing] [stakeholders] in designing, implementing, and monitoring the outcomes and effectiveness."\(^1\) of the proposed systems change (emphasis added). Of the importance of this step, we wrote:

Active, open and continuous dialogue with all affected parties offers the best prospects for creating and maintaining a service delivery system that meets the needs of people with disabilities. All participants must be confident that the transition to a managed care system will yield better outcomes for people with disabilities. The involvement of disability stakeholders should not end with approval of a state’s managed care plan. Instead, stakeholders should participate in monitoring the implementation of the plan and provide feedback on system performance and needed plan modifications on an ongoing basis.\(^2\)

We reference NCD’s work in this different healthcare topic area because of its relation in process to what seems lacking in CMS’s approach to this NPRM – namely, a thoughtful and robust process of stakeholder engagement in the development of the proposal itself, the five-year plan to implement the proposal, and in the monitoring of its outcomes and effectiveness in achieving its aims. We believe that CMS has received the amount of negative reaction to its NPRM in large part due to the absence of meaningful stakeholder engagement, and as the federal voice for the more than 50 million Americans with disabilities, including chronic health conditions, we are willing to assist CMS in its stakeholder engagement should they choose to withdraw their rule and desire to begin anew with stakeholders assisting in informing the proposed rule’s development.

In addition to CMS’s inadequate stakeholder engagement, NCD is also concerned that the outcomes CMS wishes to improve through this rule may not be as all-encompassing in their focus as they should be; that this proposed rule could act as a deterrent to the use of new medications that could radically improve the quality of one’s life; and that some of the proposed value-based pricing models may utilize assessments of value that are diametrically out of sync with core tenets of disability civil rights.

A bedrock philosophy of disability civil rights is “independent living,” as embraced and reflected in many federal disability civil rights laws. The U.S. Commission on Civil Rights has observed that a key element of independent living is self-determination for people with disabilities: “Independent living programs insist on client self-choice rather than incorporation of the client into a set of goals established by program managers, service professionals, or funding mechanisms”\(^3\) (emphasis added). This “client self-choice” is consistent with the theme of ‘patient-centeredness’ that permeates the Affordable Care Act, with which so many disability organizations related during the development and passage of the law.

In NCD’s Guiding Principles document previously mentioned, another core principle regarding quality management stated, “Monitoring strategies must be developed to ensure

---


2 Ibid.

that: (a) assessments... are person-centered; ...(c) services are tailored to achieve outcomes desired by the individual, meet the individual's needs, and are modified as his or her needs change..."\(^4\)

Clinical effectiveness should not singularly determine the way in which the government values and therefore prices a medication. For example, two drugs may be very similar in clinical effectiveness but vary considerably in the manner in which a particular individual experiences side effects – some side effects being quite extreme or even debilitating. Therefore, treating them as clinically equal and thus favoring the less expensive of the two in pricing policies may well result in that individual experiencing worsened outcomes, whereas because of the formulation of the assessment, the Government may view the cost savings for clinically similar drugs as an “improved outcome.” The definition of what an “improved outcome” entails, then, is quite different among stakeholders, and CMS’s pursued policies must reflect the importance of both. People with chronic health conditions, many of whose current medications are at the heart of this proposed rule, have been on an array of medication prior to the expensive ones on which they currently rely and thus have valuable firsthand knowledge of relative “value” as well as their own practical definitions of what constitutes “improved outcomes” when living with a chronic disease. CMS should seek to glean this variety of stakeholder experiences to inform their policy development. While it is true that many new medications carry a great expense with their use, some radically improve the quality of one's life in ways that may enable fuller participation in society, including employment. The improvement in the quality of one's life must also be considered when seeking to define “improve outcomes,” lest the absence of its consideration act as a deterrent to new medications' coverage and use.

For the aforementioned reasons, NCD urges CMS to withdraw its proposed rulemaking and pursue meaningful stakeholder engagement to inform revisions or wholesale changes to the proposed rule. As exemplified in states' experiences with Medicaid managed care rollout, foregoing this critical step will result in a proposed national policy that the disability community will view with determined opposition.

NCD stands ready to assist CMS with its stakeholder engagement. Please do not hesitate to contact us to discuss this offer further. Please contact NCD staff member Anne Sommers, Director of Legislative Affairs and Outreach, at asomers@ncd.gov to follow-up on this correspondence.

Very Respectfully,

Clyde Terry
Chairperson

Cc: House Energy and Commerce Committee
Susan Janeczko, Jasmine McKenzie

STATEMENT FOR THE RECORD

House Energy and Commerce Committee
Subcommittee on Health:

The Obama Administration’s Medicare Drug Experiment: The Patient and Doctor Perspective

May 17, 2016

Dear Chairman Pitts and Ranking Member Green:

The Healthcare Leadership Council (HLC) appreciates the opportunity to submit a statement for the record regarding the hearing entitled, “The Obama Administration’s Medicare Drug Experiment: The Patient and Doctor Perspective.” We applaud the subcommittee for focusing on the implementation of the Center for Medicare and Medicaid Innovation’s (CMMI) Part B Drug Payment Model demonstration and the impact on patient access and the quality of care for beneficiaries.

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation’s healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century health system that makes affordable, high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, biotech firms, health product distributors, pharmacies, post acute care providers, and information technology companies – advocate measures to increase the quality and efficiency of healthcare through a patient-centered approach (attached is a list of our members).

Please find attached comments that HLC provided to Acting CMS Administrator Slavitt in response to the proposed rule. In our comments, we emphasize that CMMI was created under the Affordable Care Act (ACA) to selectively test new payment and delivery models in the Medicare and Medicaid programs. In order to protect beneficiaries and avoid treatment disruptions, the ACA requires CMMI to perform extensive analysis in the selection and expansion of its demonstrations. The statute ensures that a demonstration may only be expanded on a nationwide basis after CMMI
can establish that the demonstration (1) improves or maintains the quality of care while (2) reducing spending. We feel that it is critically important for CMMI to adhere to this process before expanding any demonstration to ensure that improved patient access and quality of care are the defining characteristics of any demonstration being advanced.

On behalf of HLC, I applaud you for your bipartisan work to support meaningful healthcare reforms and ensure that they are implemented effectively. As you know, HLC has been supportive of the concept of testing a variety of healthcare delivery strategies to determine best approaches to possible systemic reform, but has some concerns related to the scope of CMMI’s operations and statutory authority.

We stand ready to assist and support your efforts.

Sincerely,

[Handwritten Signature]

Mary R. Grealy
President

Attachments
May 9, 2016

Mr. Andrew Slavitt  
Acting Administrator  
Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, D.C. 20201  


Dear Acting Administrator Slavitt:

The Healthcare Leadership Council (HLC), a coalition of chief executives from all sectors of the healthcare industry, appreciates the opportunity to comment on the Center for Medicare and Medicaid Innovation’s (CMMI) demonstration and the impact on patient access and the quality of care for beneficiaries. CMMI was created under the Affordable Care Act (ACA) to selectively test new payment and delivery models in the Medicare and Medicaid programs. Since its inception, CMMI has administered new, innovative models that aim to enhance beneficiary care, improve health outcomes, and provide assistance to populations with special health needs. In order to protect beneficiaries and avoid treatment disruptions, the ACA requires CMMI to perform extensive analysis in the selection and expansion of its demonstrations. The statute ensures that a demonstration may only be expanded on a nationwide basis after CMMI can establish that the demonstration (1) improves or maintains the quality of care while (2) reducing spending. We feel that it is critically important for CMMI to adhere to this process before expanding any demonstration to ensure that improved patient access and quality of care are the defining characteristics of any demonstration being advanced.

Transparency

As you know, HLC has been supportive of the concept of testing a variety of healthcare delivery strategies to determine best approaches to possible systemic reform, and to allow a mechanism for faster nationwide adoption of those approaches that improve value. We believe that efforts to move all health care stakeholders—including payers, manufacturers, and providers—towards a system grounded in value over volume will ultimately improve patient outcomes and reduce costs, and thus appreciate the work
CMMI has taken on to achieve these goals. We do, however, believe that some of these efforts by CMMI have moved beyond the intended scope established by Congress, and have done so in a way that could impede patient access to and the delivery of quality care. Furthermore, as CMMI contemplates additional payment and delivery system reforms, there is a critical need for transparent, comprehensive collaboration with stakeholders throughout the demonstration process.

Effective communication is particularly important in that all healthcare stakeholders are already adjusting to rapidly evolving payment and coverage rules under the ACA, and soon, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). CMMI, however, has generally provided a limited opportunity for stakeholder input before launching new payment demonstrations. For example, with the recently announced Medicare Part B Payment Model, stakeholders did not have the opportunity to discuss potential opportunities and challenges with the Agency’s proposed construct, including potential impact that the demonstration’s reimbursement changes could have on patient access or the spillover effect on the Medicare program.

We would also recommend enhanced efforts to share the lessons learned and best practices from completed demonstration projects and to do so in a timely manner. Especially during this critical time of innovation in healthcare delivery, more information about both successful and unsuccessful CMMI pilots could help to inform private sector efforts to improve value and enhance the patient experience.

*Burden Some or Misaligned Incentives*

We also suggest that CMS consider the challenges involved in participating in many of the demonstrations and whether there are properly aligned incentives for participation. We have heard from many of our members that they choose not to participate in demonstration projects because the participation requirements are onerous, incentives are not appropriately aligned, or data from CMS is insufficient to make educated decisions about participation. CMMI pilots should allow participants the flexibility to determine the tools that will promote innovation while ensuring regulatory consistency and a level playing field between federal programs such as fee-for-service and Medicare Advantage.

For example, the proposed rule on Revised Benchmark Rebasinng Methodology did not allow enough lead time for providers to adjust their strategies for assuming risk. As a result, providers were locked into a term which precluded assuming risk in the timeframe necessary to qualify as an alternative payment model (APM) under the MACRA rule. In another example, the Comprehensive Primary Care Plus (CPC+) payment model does not provide adequate incentives or flexibility for payer participation. Thus, participation in the first round (Comprehensive Primary Care Initiative) has been tepid, and it is unclear with the CPC+ whether this will change because the model remains largely unaltered.

*Scope*
In addition to potential patient access and treatment disruption concerns, several recent CMMI demonstrations also raise questions about the large scope and required participation of these demonstrations. Under the ACA, CMMI was charged with implementing payment and delivery demonstrations in a targeted, patient-centered, and transparent way that accounts for the unique needs of beneficiaries. CMMI is statutorily required to ensure that its initiatives target "deficits in care," and can only expand the scope and duration of a demonstration after careful assessment of its impact on quality of care, patient access, and spending. We are, therefore, concerned that the scope of the Part B Payment Model appears to conflict with the narrow, targeted "demonstrations" that CMMI is required to administer under the ACA. Of particular concern is the lack of data to verify that patients will not lose access to life-saving drugs for diseases like cancer.

HLC appreciates the opportunity to provide input on issues related to the scope of CMMI’s operations and statutory authority. If you have any questions, please feel free to contact Tina Grande at 202-449-3443.

Sincerely,

Mary R. Grealy
President
May 16, 2016

Rep. Joe Pitts (R-PA)
Chairman
Subcommittee on Health
Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Rep. Gene Green (D-TX)
Ranking Member
Subcommittee on Health
Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

Re: “The Obama Administration’s Medicare Drug Experiment: The Patient and Doctor Perspective”

Dear Chairman Pitts and Ranking Member Green:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to submit comments for the record on the hearing titled “The Obama Administration’s Medicare Drug Experiment: The Patient and Doctor Perspective” scheduled for May 17, 2016. AMCP submitted detailed comments1 to the Centers for Medicare and Medicaid Services (CMS) in response to the proposed rule titled “Medicare Program; Part B Drug Payment Model (CMS-1676-P)” published in the Federal Register on March 11, 2016.

AMCP is a professional association of pharmacists and other practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy’s 8,000 members develop and provide a diversified range of clinical, educational, medication and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

While AMCP was pleased to see a commitment by CMS to evaluate methods to move from quantity and process-oriented payments for drugs under Medicare Part B to payment policies focused on rewarding higher quality and improved patient outcomes, AMCP expressed concern that the proposal, as written, did not fully consider the unintended consequences to beneficiaries that may result from the scope and design of the model. AMCP offered comments on several elements that we believe were either missing from the proposed rule, could be improved upon, or required clarification. AMCP urged CMS to carefully consider comments received and release a revised proposed rule with an opportunity for additional stakeholder feedback prior to finalization and adoption to ensure that the perspectives of managed care pharmacy and other stakeholders are considered. AMCP recommended that after consideration of comments, CMS reissue the proposal focused on areas that could successfully achieve the objectives of improving outcomes and quality and lowering costs without jeopardizing beneficiary access to medications.

Specifically, AMCP commented that:

- **The Scope and Breadth of the Model Should be Narrowed** - The proposed rule would require significant and complex changes and could ultimately result in a mandatory nationwide pilot that would impact up to 75 percent of providers. CMS should narrow the scope in consultation with providers and health plans and pharmacy benefit management companies (PBMs) that have implemented value-based purchasing initiatives in the commercial market to determine the potential for success under Medicare Part B.

- **The Model Should Include Pharmacists as Key Members of the Health Care Team** - Pharmacists play a critical role as members of the health care team by serving as the medication management experts to help patients achieve clinical goals, reduce overall health care costs, and improve patient satisfaction. CMS should include pharmacists as key members of the health care team for phase II of the model to achieve enhanced benefits to Medicare beneficiaries through a collaborative approach to medication management.

- **The Model Should Create an Allowance for Formularies and Utilization Management Tools** - The proposed rule does not accommodate the use of pharmacy and therapeutics (P&T) committees established by health plans and PBMs to develop formularies for Medicare Part B or allow for the use of utilization management tools, which are elements that have been key to the success in decreasing costs, improving quality, and increasing value in Medicare Part D and the commercial market. CMS should consider the inclusion of a requirement to establish a Part B formulary with appropriate utilization management tools facilitated by health care providers, health plans, and PBMs under phase II of the model.

- **The Model Should Detail How VBP Tools Will be Monitored & Evaluated** - CMS should release detailed plans for how it will evaluate the model's success, including specific clinical end points (such as quality of life, patient-reported outcomes, and survival rates).

- **The Model Should Focus on Targeted Disease States** - AMCP is concerned that the proposed rule is overly ambitious in including Part B drugs for all disease states in the model. CMS should reevaluate the scope of the model and focus on specific disease states that are prevalent in the Medicare population that have multiple therapies available with non-significant differences in clinical benefit but significant differences in cost of therapy, such as the treatment of age-related macular degeneration. In addition, CMS should also consider disease states and drug categories where biosimilars are entering the marketplace such as psoriasis, rheumatoid arthritis, and white blood stimulants.

- **The Model Should Require Documentation of Part B Drug Claims Using NDC Numbers** - A barrier to evaluating the success of VBP tools in Part B is the current method of documenting drugs under Part B using Healthcare Common Procedure Coding System (HCPCS) codes and not National Drug Code (NDC) numbers. The ability to track the drug administered to the specific NDC number is critical to truly implement VBP tools as they are used today in Medicare Part D in the commercial market. CMS should require documentation of NDCs on all Medicare Part B claims.

- **The Model Should Evaluate the Impact on Specialty Care Providers** - Primary Care Service Areas (PCSAs) may not be the most appropriate geographic unit for specialty care providers, as
specialty care providers are typically located in very different geographical areas and practice settings than a traditional primary care provider, and often entail networks that may span across multiple PCSAs. CMS should evaluate the impact of using PCSAs on specialty care providers and whether there is sufficient correlation between the two or whether consideration of an alternate geographic unit for specialty care providers is warranted.

- **The Model Should Use a Comprehensive Approach to Develop Evidence-Based Clinical Practice Guidelines** - CMS should support medication product selection by P&T Committees and providers using the totality of the evidence. Therefore, CMS should be comprehensive in the type of information that is used to develop VBP frameworks, and to avoid relying on a single source.

- **The Model Should Monitor for Unintended Consequences to Beneficiaries** - CMS should amend the proposed rule to include a mechanism for monitoring unintended consequences to beneficiaries and a strategy for suspending the model, in part or in its entirety, if beneficiary harms are identified.

- **The Model Should Evaluate the Impact of Competing CMMI Initiatives** - AMCP is concerned about the impact and potential overlap of the proposed Part B payment model with other CMMI initiatives, such as the Oncology Care Model, and alternative payment models under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). CMS should consider the potential overlap in test models and ensure a mechanism is in place to encourage active participation in ongoing and future test models to allow for meaningful assessment for improving value in the United States health care system.

- **The Model Should Evaluate the Impact on Medicare Advantage Benchmarks** - The proposed rule does not reference Medicare Advantage, which covers approximately one-third of Medicare beneficiaries. CMS should clarify how Medicare Advantage plans are accounted for in the proposed rule and whether Medicare Advantage plans will have access to the same VBP tools to help offset reductions in benchmarks.

- **The Model Should Evaluate Potential Market Shifts** - CMS should consider how the proposed rule may result in a market shift of costs from Medicare Part B to other payment areas and care settings with greater costs.

AMCP appreciates your concern with the proposed rule and the opportunity for stakeholders to be heard. If you have any questions regarding AMCP’s comments or would like further information, please contact me at 703-683-8416 or sean@amcp.org.

Sincerely,

[Signature]

Susan A. Cantrell, RPh, CAE
Chief Executive Officer
March 17, 2016

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
Washington, D.C. 20510

The Honorable Harry Reid
Minority Leader
U.S. Senate
Washington, D.C. 20510

The Honorable Paul Ryan
Speaker of the House of Representatives
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
Washington, D.C. 20515

Dear Leader McConnell, Leader Reid, Speaker Ryan and Leader Pelosi:

We, the 316 organizations listed below, are writing to express our strong concern with the Centers for Medicare & Medicaid Services’ (CMS) March 8, 2016 proposed rule that would implement a new “Medicare Part B Payment Model.” We believe that this type of initiative, implemented without sufficient stakeholder input, will adversely affect the care and treatment of Medicare patients with complex conditions, such as cancer, macular degeneration, hypertension, rheumatoid arthritis, Crohn’s disease and ulcerative colitis, and primary immunodeficiency diseases. We previously sent a letter to Department of Health and Human Services (HHS) Secretary Sylvia Burwell asking her not to move forward with this type of initiative, and we now respectfully request that you ask CMS to withdraw the proposed rule.

Medicare beneficiaries – representing some of the nation’s oldest and sickest patients – must often try multiple prescription drugs and/or biologics before finding the appropriate treatment for their complex conditions. These patients need immediate access to the right medication, which is already complicated by the fact that treatment decisions may change on a frequent basis. These vulnerable Medicare patients and the providers who care for them already face significant complexities in their care and treatment options, and they should not face mandatory participation in an initiative that may force them to switch from their most appropriate treatment.

A Center for Medicare & Medicaid Innovation (CMMI) initiative that focuses on costs rather than patients and health care quality, implemented based on primary care service areas, rather than the unique challenges of patients, is misguided and ill-considered. Medicare beneficiaries with life-threatening and/or disabling conditions would be forced to navigate a CMS initiative that could potentially lead to an abrupt halt in their treatment. This is not the right way to manage the Medicare program for its beneficiaries.

As CMS contemplates payment and delivery system reforms, there is a critical need for transparent, comprehensive communications with stakeholders throughout the process. We were deeply disappointed that CMS only provided a limited opportunity for stakeholder input before announcing sweeping proposed changes to Medicare Part B drug payments. In doing so, the agency largely failed to consider stakeholder concerns that the initiative could adversely impact patients’ access to life-saving and life-changing Medicare Part B covered drugs.
We believe these types of initiatives should be initially implemented in a targeted, patient-centered and transparent way that accounts for the unique needs of Medicare beneficiaries. In fact, CMMI is statutorily required to ensure that its initiatives target “deficits in care,” and can only expand the scope and duration of a model after careful assessment of the model’s impact on quality of care, patient access, and spending. We are very deeply concerned, therefore, that CMS’ proposed Part B Model would be applied on a nationwide basis – to all states except Maryland, due to its all-payer model – and would include the “majority” of Part B drugs. Furthermore, given the success of the current Part B reimbursement methodology in ensuring patient access to the most appropriate treatments, it is unclear what “deficits in care” CMS is attempting to address in this incredibly wide-ranging initiative.

In the proposed rule, CMS expresses concern that the 6% ASP add-on payment “may encourage the use of more expensive drugs because the 6 percent add-on generates more revenue for more expensive drugs.” This assumption fails to take into account the fact that providers’ prescribing decisions depend on a variety of factors, including clinical characteristics and the complex needs of the Medicare population. Most importantly, there is no evidence indicating that the payment changes contemplatd by the model will improve quality of care, and may adversely impact those patients that lose access to their most appropriate treatments. In fact, data suggests that the current Part B drug payment system has been both cost effective and successful in ensuring patient access to their most appropriate treatment, as Part B expenditures remain relatively stable¹ and Part B drugs account for just 3% of total program costs.²

Finally, it is important to understand that with the Budget Control Act, CMS has already cut Medicare reimbursement for physician-administered drugs by 2%, further impacting some providers’ ability to administer essential drugs at the current reimbursement rate. It is imperative CMS acknowledges and evaluates the impact of the current, real payment rate and engages multiple stakeholders, starting with patients and providers, before implementing a new, severe reimbursement cut that is effectively ASP + 6.86% (plus a small flat fee). In closing, we urge you to ensure that our nation’s oldest and sickest patients continue to be able to access their most appropriate drugs and services. We therefore request that you ask CMS to permanently withdraw the Part B Drug Payment Model from consideration.

Sincerely,

1 in 9: The Long Island Breast Cancer Action Coalition
Action CF
ADAP Advocacy Association (aaa+)
Advocates for Responsible Care (ARxC)
Aimed Alliance
Alabama Academy of Ophthalmology

¹ 2015 Medicare Trustees Report.
Alabama Cancer Congress
Alabama Gastroenterological Society
Alaska Society of Eye Physicians and Surgeons
Alliance for Patient Access (APPA)
Alliance of Specialty Medicine
Alzheimer's and Dementia Alliance of Wisconsin
American Academy of Allergy Asthma and Immunology (AAAAI)
American Academy of Ophthalmology
American Association of Diabetes Educators
American Bechet's Disease Association
American College of Mohs Surgery
American College of Rheumatology
American Gastroenterological Association
American Liver Foundation, Upper Midwest Division
American Society of Clinical Oncology (ASCO)
American Urological Association
AmerisourceBergen
Anticoagulation Forum
Arizona BioIndustry Association (AZBio)
Arizona United Rheumatology Alliance
Arkansas State Rheumatology Association
Arthritis Foundation
Asian Americans for Community Involvement
Association of Black Cardiologists
Association of Community Cancer Centers (ACCC)
Association of Idaho Rheumatologists
Association of Indian Physicians of Ohio
Association of Northern California Oncologists (ANCO)
Association of Women in Rheumatology (AWIR)
Asthma & Allergy Foundation of America, New England Chapter
Axis Advocacy
Biocon
BioFlorida, Inc.
Bioforward
BioHouston
BioKansas
BioNJ
BioNorth TX
Bioscience Association of West Virginia
Biotechnology Innovation Organization (FKA Biotechnology Industry Organization)
BioUtah
Brain Injury Association of Georgia
California Academy of Eye Physicians and Surgeons
California Hepatitis C Task Force
California Life Sciences Association (CLSA)
California Rheumatology Alliance (CRA)
Cancer Support Community
Cancer Support Community Central Ohio
Cancer Support Community North Texas
CancerCare
Cardinal Health
Caregiver Action Network
Caring Ambassadors
Cascade AIDS Project
Center for Healthcare Innovation
Central Texas Rheumatology Society
Chicago Life Sciences Consortium (CLSC)
COA Patient Advocacy Network (CPAN)
Coalition of Hematology Oncology Practices (CHOP)
Coalition of State Rheumatology Organizations (CSRO)
Coalition of Texans with Disabilities (CTD)
Colon Cancer Alliance
Colorado BioScience Association
Colorado Gerontological Society
Colorado Rheumatology Association
Colorado Society of Eye Physicians and Surgeons (CSEPS)
Colorado State Grange
Community Access National Network (CANN)
Community Liver Alliance
Community Oncology Alliance (COA)
Connecticut Oncology Association (COA)
Connecticut Rheumatology Association
Cutaneous Lymphoma Foundation
Delaware Academy of Ophthalmology
Delaware BioScience Association
Día de la Mujer Latina
Digestive Disease National Coalition (DDNC)
Digestive Health Physicians Association (DHPA)
Easter Seals Massachusetts
Eastern Pennsylvania Chapter, National Hemophilia Foundation
EDSers United Foundation
Elder Care Advocacy of Florida
Epilepsy Foundation of Greater Chicago
Epilepsy Foundation of Western Wisconsin
Fabry Support and Information Group
Florida Allergy, Asthma & Immunology Society (FAAIS)
Florida Gastroenterologic Society
Florida Psychiatric Society
Florida Society of Clinical Oncology (FLASCO)
Florida Society of Neurology
Florida Society of Ophthalmology
Florida Society of Rheumatology
Florida State Hispanic Chamber of Commerce
GBSCIDP Foundation International
Georgia Bio
Georgia Chapter of the American College of Cardiology
Georgia Mental Health Consumer Network
Georgia Society of Clinical Oncology (GASCO)
Georgia Society of Rheumatology
Global Colon Cancer Association
Global Healthy Living Foundation
H.E.A.L.S of the South
Hawaii Society of Clinical Oncology
Health Coalition, Inc.
Healthcare Distribution Management Association
Healthcare Institute of New Jersey (HINJ)
Healthcare Leadership Council
HealthHIV
Hematology-Oncology Managers of New York (HOMNY)
Hepatitis Foundation International
iBio - Illinois Biotechnology Industry Organization
Idaho Society of Clinical Oncology
Idaho Society of Ophthalmology
Illinois Medical Oncology Society
Illinois Society of Eye Physicians & Surgeons (ISEPS)
Immune Deficiency Foundation (IDF)
Indiana Academy of Ophthalmology (IAO)
Indiana Health Industry Forum (IHIF)
Indiana Oncology Society
INduniv Research Consortium
International Cancer Advocacy Network (ICAN)
International Foundation for Autoimmune Arthritis (IFAA)
International Institute For Human Empowerment, Inc.
ION Solutions
Iowa Academy of Ophthalmology (IAO)
Iowa Biotechnology Association
Iowa Oncology Society
Iowa State Grange
Kansas City Area Life Sciences Institute, Inc.
Kansas Rheumatology Alliance
Kansas Society of Clinical Oncology
Kansas Society of Eye Physicians & Surgeons (KSEPS)
Kentuckiana Rheumatology Alliance
Kentucky Association of Medical Oncology (KAMO)
Kentucky Life Sciences Council
Large Urology Group Practice Association (LUGPA)
Life Science Washington
Louisiana Oncology Society
Lung Cancer Alliance
LUNGevity
Lupus Foundation of America (LFA), Indiana Chapter
Lupus Foundation of Colorado
Maryland DC Society of Clinical Oncology
Maryland Society for the Rheumatic Diseases (MSRD)
Massachusetts Association for Mental Health
Massachusetts Society of Eye Physicians and Surgeons (MSEPS)
Massachusetts, Maine and New Hampshire Rheumatology Association
MassBio
Mayors Committee on Life Sciences
McKesson
Medical Oncology Association of Southern California (MOASC)
Medical Partnership of MS
Medical Society of the State of New York
Men's Health Network
Mental Health Systems, Inc.
Metropolitan Atlanta Rheumatology Society (MARS)
MichBio - Michigan Biosciences Industry Association
Michigan Lupus Foundation
Michigan Osteopathic Association
Michigan Rheumatism Society
Michigan Society of Eye Physicians and Surgeons (MISEPS)
Michigan Society of Hematology and Oncology (MSHO)
Midwest Oncology Practice Society (MOPS)
Minnesota Academy of Ophthalmology
Minnesota Society of Clinical Oncology
Mississippi Academy of Eye Physicians and Surgeons
Mississippi Arthritis and Rheumatology Society
Mississippi Oncology Society
Missouri Biotechnology Association (MOBIO)
Missouri Oncology Society
Missouri Society of Eye Physicians & Surgeons (MoSEPS)
Montana BioScience Alliance
Montana State Oncology Society
NASW-NC (National Association of Social Workers)
National Alliance on Mental Illness (NAMI)
National Alliance on Mental Illness Greater Des Moines (NAMI)
National Alliance on Mental Illness Iowa (NAMI)
National Alliance on Mental Illness Kentucky (NAMI)
National Alliance on Mental Illness Texas (NAMI)
National Association for Rural Mental Health
National Association of County Behavioral Health & Developmental Disability Directors (NACBHDD)
National Association of Hepatitis Task Forces
National Blood Clot Alliance (NBCA)
National Cancer Care Alliance
National Hispanic Medical Association
National Infusion Center Association (NICA)
National Medical Association (NMA)
National Minority Quality Forum
National MPS Society
National Patient Advocate Foundation
Nebraska Academy of Eye Physicians and Surgeons
Nebraska Medical Association (NMA)
Nebraska Oncology Society
Neurofibromatosis Mid-Atlantic
Nevada Oncology Society
New England Biotech Association (NEBA)
New Jersey Academy of Ophthalmology
New Jersey Association of Mental Health and Addiction Agencies, Inc. (NJAMHAA)
New Jersey Rheumatology Association
New Jersey Society for Oncology Managers (NJSOM)
New York State Ophthalmological Society
New York State Rheumatology Society
NewYorkBIO
NMBio
NORM - National Organization of Rheumatology Managers
North American Thrombosis Forum
North Carolina Biosciences Organization (NCBIO)
North Carolina Oncology Association
North Carolina Psychiatric Association
North Carolina Psychological Association
North Carolina Rheumatology Association (NCRA)
North Carolina Society of Eye Physicians and Surgeons (NCSEPS)
Northern New England Clinical Oncology Society
Ohio Association of Rheumatology
Ohio Foot and Ankle Medical Association
Ohio Gastroenterology Society
Ohio Hematology Oncology Society
Ohio Ophthalmological Society (OOS)
Oklahoma Academy of Ophthalmology
Oklahoma Society of Clinical Oncology
Oncology Managers of Florida
Oncology Nursing Society
Oregon Bioscience Association
Oregon Rheumatology Alliance
Oregon Society of Medical Oncology (OSMO)
Oregon State Grange
Oregon Urological Society
Patients Rising
PCa Blue Inc.
Pennsylvania Academy of Ophthalmology
Pennsylvania Bio
Pennsylvania Rheumatology Society
Pennsylvania State Grange
Pharmaceutical Research and Manufacturers of America (PhRMA)
Philadelphia Rheumatism Society
Phoenix Rheumatology Association
Physicians Advocacy Institute (PAI)
Premier Oncology Hematology Management Society (POHMS)
Prevent Blindness
Prevent Blindness, Ohio Affiliate
Prevent Cancer Foundation
Prostate Conditions Education Council (PCEC)
Puerto Rico Society of Ophthalmology
Pulmonary Hypertension Association
Quality Cancer Care Alliance (QCCA)
RetireSafe
Rheumatism Society of the District of Columbia
Rheumatology Alliance of Louisiana
Rheumatology Association of Iowa (RAI)
Rocky Mountain Oncology Society
Rush To Live
Saltus USA
SCBIO
Society for Women's Health Research
Society of Utah Medical Oncologists
South Carolina Gastroenterology Association
South Carolina Oncology Society
South Carolina Rheumatism Society
South Carolina Society of Ophthalmology
South Dakota Biotech
South Florida Cancer Association
Southern California Rheumatology Society (SCRS)
Spina Bifida Association of Kentucky
State of Texas Association of Rheumatologists (STAR)
State of Texas Kidney Foundation
StopAfib.org
Taking Control Of Your Diabetes (TCOYD)
Tech Council of Maryland
Tennessee Oncology Practice Society (TOPS)
Tennessee Rheumatology Society
Texas Association of Business
Texas Association of Manufacturers
Texas BioAlliance
Texas Healthcare and Bioscience Institute (THBI)
Texas Life Sciences Collaboration Center
Texas Nurse Practitioners
Texas Ophthalmological Association
Texas Society of Clinical Oncology
Texas State Grange
The American College of Surgeons/Commission on Cancer
The Arizona Clinical Oncology Society
The Crohn's Colitis Effect
The Medical Alley Association
The Mended Hearts, Inc.
The Retina Society
The US Oncology Network
The Vasculitis Foundation
U.S. Hereditary Angioedema Association
United States Cutaneous Lymphoma Consortium
Utah Ophthalmology Society
Veterans Health Council
Vietnam Veterans of America
Virginia Association of Hematologists & Oncologists
Virginia Biotechnology Association
Virginia Hematology Oncology Association (VAHO)
Virginia Society of Eye Physicians and Surgeons
Washington Academy of Eye Physicians and Surgeons
Washington Rheumatology Alliance
Washington State Medical Oncology Society
Washington State Prostate Cancer Coalition
Washington State Urology Society
Wellness and Education Community Action Health Network
West Virginia Oncology Society
West Virginia Rheumatology State Society
Wisconsin Academy of Ophthalmology
Wisconsin Association of Hematology & Oncology
Wisconsin Association of Osteopathic Physicians & Surgeons
Wisconsin Rheumatology Association
Wyoming Epilepsy Association
Wyoming Ophthalmological Society

c: The Honorable Orrin Hatch
Chairman
Committee on Finance
U.S. Senate

The Honorable Ron Wyden
Ranking Member
Committee on Finance
U.S. Senate

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
U.S. House of Representatives

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
U.S. House of Representatives
Dear Chairman Hatch, Ranking Member Wyden, Chairman Upton, Ranking Member Pallone, Chairman Brady, and Ranking Member Levin:

Our organizations, which represent millions of patients across the country, write to express our opposition to the Centers for Medicare and Medicaid Services’ (CMS) Center for Medicare and Medicaid Innovation (CMMI) March 8, 2016 proposed rule that would implement substantial changes to the Medicare Part B Payment program. In its current form, we believe that implementation of this Proposed Rule is misguided and would negatively impact the quality and accessibility of care that patients with complex conditions currently receive. We also remain deeply concerned with the lack of stakeholder engagement by CMMI throughout the development of this proposal. We believe that it is in the best interest of patients and providers that CMS withdraw this rule and, moving forward, implement a process that allows for those who will be most significantly impacted by a payment or delivery system change – patients and providers – to engage with CMMI and offer input throughout the development of any future proposed reforms.

Our organizations represent some of the sickest patients with the most complex conditions, such as arthritis, cancer, and primary immunodeficiency diseases. Many of these patients have complex conditions and a diagnosis of several chronic diseases. It can often take people with chronic diseases years to find the most appropriate medical services and drug that works best for them. It is critically important that these patients have access to the drugs that they need, and are not subjected to random programs that could threaten that access. Patients and providers already face considerable hurdles securing timely care; they should not also be faced with a mandate to participate in an initiative that could force a physician to alter his or her clinical decision making authority based solely on an economic model and not what is in the best interest of the patient.

We agree that the current system is unsustainable, but we fear that the proposal as written would result in major unintended consequences that would hinder patient access to care. For example, if
physicians stop offering infusions in their offices as a result of this policy, it could force patients into the hospital setting for their infusions, which would ultimately be more costly to the patient and to Medicare. Some of the value based models may also pose access challenges to patients. For example, we fear that the “least costly alternative” model could result in a patient who is stable on a more expensive drug potentially losing access to that drug. The “indications based pricing” model also raises concerns, since the criteria that would determine clinical effectiveness have not been defined nor has the process by which it will be defined. Further, the pre-appeals and notification requirements are not adequate and do not provide patient safeguards. From this proposal, it is unclear how patients would even be notified about the demonstration project, let alone submit a pre-appeal from the demonstration project.

Additionally, any time CMS considers payment and delivery system reforms, it is imperative that the agency communicate with stakeholders through a transparent process that allows for engagement in the development of such a reform. Our organizations appreciated the process by which CMMI solicited stakeholder input during the development of the Oncology Care Model it released in 2015. It is disappointing that CMS provided only a very narrow opportunity for stakeholder input prior to announcing such drastic changes to the payment of drugs under Medicare Part B. In our view, this action failed to consider the consequences raised by the patient and physician communities about the negative impact this proposal will have on patients’ access to and physicians’ ability to prescribe drugs covered under Medicare Part B.

CMS has indicated they have no intention of denying patients access to the drugs they need, but the concerns outlined above make it clear that patient access is a real threat under the current proposal. As such, we respectfully request that you ask CMS to permanently withdraw the Proposed Rule from consideration. We stand able and willing to work with Congress and CMS to ensure that our nation’s sickest patients are able to access the treatments that work best for them.

Should you require additional information, please contact Sandie Preiss, the National VP of Advocacy and Access at the Arthritis Foundation spreiss@arthritis.org 202 887 2910.

Sincerely,

Alliance for the Adoption of Innovations in Medicine (Aimed Alliance)
American Academy of Ophthalmology
American Autoimmune Related Diseases Association
American College of Rheumatology
American Sexual Health Association
Arthritis Foundation
Asthma and Allergy Association of America
CancerCare
Coalition of State Rheumatology Association
Epilepsy Foundation
Global Colon Cancer Association
Immune Deficiency Foundation
Lupus and Allied Diseases Association, Inc
Lupus Foundation of America
National Alliance on Mental Illness
National Cervical Cancer Coalition
National Fabry Disease Foundation
National Fibromyalgia & Chronic Pain Association
RetireSafe
San Francisco AIDS Foundation
The AIDS Institute
The Veterans Health Council
US Pain Foundation
Vietnam Veterans of America

cc: Majority Leader Mitch McConnell
Ministry Leader Harry Reid
Members, Senate Committee on Finance
Speaker of the House Paul Ryan
Minority Leader Nancy Pelosi
Members, House Committee on Energy and Commerce
Members, House Committee on Ways and Means
May 9, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services 200 Independence Avenue, S.W.
Washington, DC 20201

Dear Acting Administrator Slavitt:

The Partnership to Improve Patient Care (PIPC) and the undersigned organizations appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed Part B Drug Payment Model.1 Since its inception, PIPC, including patients, physicians, caregivers and people with disabilities, has been a leading proponent of patient-centered comparative effectiveness research. We also have strongly opposed misuse of comparative effectiveness research (CER) and cost effectiveness in one-size-fits-all government policies.2 Our comments will focus on concerns over the agency’s proposed use of CER and cost effectiveness as national Medicare standards in Phase 2 of the proposal.

The U.S. has made significant progress in advancing patient-centeredness in clinical and health systems research over the last several years. At the same time, much work remains to be done. The progress we have made is the fruit of a movement that spans several decades, and we are proud to have lent our voices to this effort.

The approach CMS has taken in the proposed rule would represent a major step back for patients and people with disabilities. We urge CMS not to move forward with its proposal. Instead, we hope to continue working with the agency and other stakeholders to ensure that, as it seeks to advance value-based health care, it is supporting care valued by patients and people with disabilities. The Patient-Centered Outcomes Research Institute (PCORI), the Food and Drug Administration (FDA) and others have advanced patient engagement strategies to identify and achieve outcomes that matter to patients and people with disabilities that should be modeled by CMS before advancing policies with such far-reaching consequences. Otherwise, the agency should defer to Congress on such a fundamental policy change.

OVERVIEW OF PIPC CONCERNS

We highlight the following significant implications for patients related to Phase 2 of the proposed Part B Drug Payment Model:

---

1 81 FR 13229
2 see http://www.pipcpatients.org/about.php
• Reliance on Centralized Value Assessments That Are Based on Average Results and Ignore Patient Differences
• Use of Payer-Centered Assessment Standards and Methods Including Those from the Institute for Clinical and Economic Review
• Focus on One-Size-Fits-All Policy Standards and National Protocols Will Set Back the Drive for Patient-Centeredness and Disadvantage People with Disabilities
• Undermines ACA Protections Against Misuse of CER and CEA in Medicare
• Excluded Patients and People with Disabilities from a Seat at the Table in the Development of a Major Shift in Public Policy

We urge CMS not to move forward with its proposal. While no doubt a well-intentioned effort to advance value-driven health care, the approach it takes would represent a major step back for patients and people with disabilities. Instead, we hope to continue working with CMS to ensure that, as it seeks to advance value-based health care, it is supporting care valued by patients and people with disabilities.

**Centralized Value Assessments Rel y on Average Results, Ignore Patient Differences**

The agency proposes to provide “equal payment for therapeutically similar drug products,” assuming that the “most clinically effective drug” in the group can be identified as the basis for a price benchmark. While we appreciate the agency’s proposal not to allow for “balance billing” of beneficiaries, patients who are not “average” will be disadvantaged by a clear financial incentive to the provider to drive care to the benchmark treatment or a less expensive treatment that may be less effective based on that particular patient’s needs, outcomes and preferences.

Average assessments routinely fail to consider differences in patient outcomes, needs and preferences and do not recognize the unique nature and value of targeted therapies that benefit specific groups of patients and people with disabilities, particularly those with rare and orphan diseases. Even when average study results suggest treatments are “clinically similar,” different treatments are valued differently from patient-to-patient and among patient subgroups based on subtle, but real, differences. No patient is average.

**Use of Payer-Centered Assessment Standards, Including Those from ICER**

CMS’ proposal to set national policy based on assessments such as those generated by the Institute for Clinical and Economic Review (ICER) contradicts our mission to support patient-centered approaches to CER and payment/delivery reform. ICER’s Governing Board consists mainly of payers, with no representation from patients or people with disabilities. Yet, as discussed below, their reports hold significant implications for the communities we serve.

---

1 B1 PR 33243
2 If
Reliance on average value assessments is not a policy that drives “value for the patient” – it is a policy intended to contain short-term costs for payers. Yet, the result is a less effective and efficient system of care. A truly cost-effective system of care would include tools to inform patients and people with disabilities about their treatment options, and their impacts on outcomes that matter to them – because patients and people with disabilities will adhere to treatment protocols when they are actively engaged and are less likely to encounter significant (and expensive) adverse events as a result. The idea of clinical decision support tools discussed in the proposed rule holds potential for supporting shared decision-making, but the approach described by CMS is focused on informing clinicians to help them control costs, not informing and engaging patients and people with disabilities.8 Real shared decision-making requires that patients, people with disabilities and providers have access to the information they need to ensure care is tailored to the individual with transparency of financial incentives potentially driving their care decisions.7

**ONE-SIZE-FITS-ALL POLICIES SET BACK THE DRIVE FOR PATIENT-CENTEREDNESS**

The agency proposes to set prices for treatments based on a judgment of comparative effectiveness, and notes that it would use reports developed by the Institute for Clinical and Economic Review, which evaluate comparative and cost-effectiveness of treatments as the basis for setting prices. We are very concerned that CMS would propose reliance on ICER reports, because they are developed through a method that provides little or no input from patients and people with disabilities, lack transparency in our patient-focused outcomes are considered, and utilize methods tailored to the needs of payers and not patients. For example, ICER relies on quality-adjusted-life-years or QALYs in determining the “value” of treatments, a policy long opposed by patients and people with disabilities.8 Professor Peter Singer, in a 2009 article calling for health care rationing, explained clearly his view that QALYs necessarily (and in his view, appropriately) place less value on the lives of people with disabilities.8 It is unimaginable that we would allow public programs to incorporate the use of QALYs as is being proposed.

As a long-time advocate for people with disabilities, I have been open and vocal about my opposition to the use of QALYs and value assessments that look at average impacts. I have seen patients and people with disabilities judged and “valued” by a health care system via the sort of “one-size-fits-all” standards that are often praised by academics. Most recently, people with disabilities in the United Kingdom have been on the receiving end of benefit cuts.9 I have pointed to the use of cost and QALY thresholds in England, for example, where the standards are so controversial that public pressure forced the country to create a separate fund to ensure patient access to cancer treatments that otherwise would have been rejected.10 In the real world, QALYs are supremely unpopular. By contrast, the United States is at the forefront of the patient-

---

6 Federal Register 13244-13246
10 The Guardian at http://www.theguardian.com/politics/2016/nov/19/piisee-rather-than-piisee-push-piisee-duncan-smith-over-the-edge
11 Huffington Post at http://www.huffingtonpost.co.uk/simon-hawkins/cancer-drugs-fund_b_6733754.html

1720 Eye Street, NW | Suite 400 | Washington, DC 20006 | PIPCpatients.org
centeredness movement, a position we will lose if we advance models that take a paternalistic approach.

Nowhere in this "value" discussion do we see an honest consideration of the real-world impact these proposals would have on the individual patient or the person with a disability for whom an innovation may have significant value. No academically pristine algorithm is going to capture value to the patient because no patient is average. Even the American Society for Clinical Oncology (ASCO) recognized the shortcomings of QALYs as a measure of value. In developing its own value framework, ASCO decided against using QALYs, stating:

"There are significant limitations to the application of QALYs, because individuals with the same illness may have different preferences for a health state. For example, one individual with advanced cancer may prefer length of overall survival (OS) above all else, whereas another might view minimization of symptoms as the highest priority." 12

Even those advocating for use of QALYs would not call such a policy "patient-centered." In fact, Congress explicitly pointed to QALYs as an example of a policy that is inconsistent with patient-centered principles when it created the Patient-Centered Outcomes Research Institute (PCORI):

"[PCORI] shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended... The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs." 13

Congress spoke to the centrality of patient-centeredness when it established PCORI to advance a new model of research that centers on the needs of patients and respects patient differences. We should be building upon this foundation and extending it more broadly into health care delivery and decision-making.

**Undermines ACA Protections**

This is not the first time that policymakers have sought to impose average value assessments within Medicare. The agency has encountered significant opposition from stakeholders to all proposals to include cost effectiveness to national coverage determinations since first proposed in 1989. 14 Thankfully, in creating PCORI, the Congress recognized that the evidence base is not sufficient to assess clinical equivalency between therapies or to reconcile a cost effectiveness standard with the emerging field of personalized medicine and patient-centered care. 15 Understanding the

---

12 American Society of Clinical Oncology Statement: A Conceptual Framework to Assess the Value of Cancer Treatment Options at http://jco.ascopubs.org/content/early/2015/06/22/JCO.2015.61.8786.full
13 42 U.S.C. 1320a–1 (c)
15 42 U.S.C. 1320a–1 (c)
consequences for patients and people with disabilities, PIPC and others fought hard for patient protections in the ACA that ensure CMS does not misuse clinical CER to impose "one-size-fits-all" coverage or payment policies.

The ACA sought to empower patients with information on the clinical effectiveness of treatments on the outcomes that matter to patients and people with disabilities and to improve health decision-making by supporting the translation of patient-centered outcomes research to shared decision-making tools accessible to patients, people with disabilities and their providers. Ultimately, these patient-centered policies will make the health system more efficient and effective. This proposal disregards those protections, and ignores the considerable work that PCORI and other organizations have been doing to advance patient-centered decision-support and shared decision-making, by embracing paternalistic policies that leave patients with fewer choices.

**Patients Deserve a Seat at the Table in the Development of a Major Shift in Public Policy**

Despite our strong advocacy to engage patients and people with disabilities in the development of alternative payment models (APMs), this proposal appears to have been rushed forward with little or no input from our communities. The phase involving centralized use of CER and cost-effectiveness begins early in 2017, eventually covering 50% of providers and beneficiaries, leaving little time for meaningful engagement of patients and people with disabilities.

While we understand the agency has stated its intention to engage stakeholders in the implementation of its proposal, there is no explicit pathway for our communities to be engaged, or to trust that our engagement makes a difference. Meaningful engagement must occur earlier in the process – prior to release of a specific proposal. We are deeply concerned that CMS did not consult the patient and disability communities prior to release of the proposed rule.

After announcing the Better Smarter Healthier initiative and the Health Care Payment and Learning Action Network (LAN), almost 80 patients, people with disabilities and their representative organizations sent a letter to HHS asking to be engaged in this work. We noted that we have learned through implementation of PCORI that the goal of patient-centeredness can only be achieved with a meaningful voice for patients and people with disabilities. When patients and people with disabilities feel heard, they feel valued. When they feel valued, they have more confidence, contributing to a greater sense of well-being, which any physician will tell you can only help them in their treatment path.

PIPC and several organizations representing patients and people with disabilities reiterated this message in a meeting with Dr. Patrick Conway and his staff on October 16, 2015, and again in a

15 80 FR 13232

1720 Eye Street, NW | Suite 400 | Washington, DC 20006 | Pipcpatients.org
follow-up letter to Dr. Conway, and again in our comments to the agency on MACRA.  

PIPC specifically proposed a pathway for patient engagement in CMMI’s work by creating a Patient Advisory Panel that would help to ensure new payment models are aligned with care that patients value. PIPC proposed the Patient Advisory Panel be positioned to provide guidance to CMMI in identifying the key areas that would benefit from patient input, including APM development, model design features that will promote effective patient engagement, and metrics (e.g., patient-centered quality measures and other tools) on which to assess the success of these efforts. In addition, we advocated that the Patient Advisory Panel develop and apply patient-centered criteria to APMs as called for in Section 1115A of the ACA. The panel could also serve as an invaluable conduit connecting CMMI staff with the broader patient community, including a simple and streamlined process for soliciting patient participants in advisory roles.

Despite our continuous efforts, this proposal reflects precisely what we most feared. Instead of our voices being heard and valued, we are faced with the reality that our voices are not as valuable as those of other stakeholders despite that we are the stakeholders that these policies are supposed to be serving. In meetings, in letters, and in public comments, patients and people with disabilities have stated their unequivocal opposition to “one-size-fits-all” policies grounded in cost effectiveness and average value assessments. We are at a loss for why our concerns were so explicitly dismissed.

While there are models for patient engagement that are used to identify outcomes that matter to patients (FCORI, FDA, etc), these have yet to be translated into CMS policy-making. After this proposal is withdrawn, we would propose that CMS prioritize building an effective patient engagement strategy that appropriately connects the dots between its policies and achieving outcomes that matter to individual patients and people with disabilities. Without that infrastructure, there is no way to evaluate the impact on “quality of care, access to care, timeliness of care, and the patient experience of care” as proposed. Although a Pre-Appeals Payment Exceptions Review process to dispute payments is an interesting idea to consider more broadly, it is not sufficient to mitigate the consequences of the policies being proposed nor are there sufficient details provided in the proposed rule about it.

CONCLUSION

Instead of policies that reinforce the old paternalistic system of health care, policymakers should focus on delivery reforms that activate and engage patients and people with disabilities and support shared decision-making between patients, people with disabilities and their providers. We

210

25 if
26 81 FR 13250
believe that solutions that center on patients and people with disabilities are the best approach to improving overall health care efficiency and quality. We also know that meaningful engagement requires that patients and people with disabilities trust in the system and their care providers, embrace the principles of shared decision-making, and recognize the benefits of being activated. We should be embracing the ACA’s provisions to translate patient-centered outcomes research into shared decision-making tools that improve health decision-making, not taking a leap backward to reconsider policies that were determined by Congress to undermine the very core of the ACA’s goals for advancing a patient-centered health system.

We strongly urge CMS not to move forward with this flawed policy. Instead, CMS should work to engage patients, people with disabilities and their families, providers and other stakeholders in the identification of models that put patients and people with disabilities at the center, as well as in the development of thoughtful policies that balance progress toward a patient-centered health system and overall health costs. We continue to stand ready to convene our members and other organizations representing patients and people with disabilities in the development of APMs. Let’s work together toward patient-centered solutions.

Sincerely,

Tony Coelho, Chairman, Partnership to Improve Patient Care and the undersigned organizations:

Academy of Spinal Cord Injury Professionals
Advocacy Group
ACISSE - (formerly American Congress of Community Supports and Employment Services)
Alliance for Patient Access (APF/A)
American Association of Neurological Surgeons (AANS)
American Association of People with Disabilities (AAPD)
American Association on Health and Disability
American Association on Intellectual and Developmental Disabilities (AAIDD)
American Congress of Rehabilitation Medicine (ACRM)
American Foundation for the Blind (AFB)
American Gastroenterological Association (AGA)
American Network of Community Options and Resources (ANCOR)
American Therapeutic Recreation Association
Association of University Centers on Disabilities
Autistic Self Advocacy Network
The Bazelon Center
Brain Injury Association of America
California Chronic Care Coalition
Cancer Support Community (CSC)
CancerCare

1720 Eye Street, NW | Suite 400 | Washington, DC 20006 | PIPCPatients.org
Caring Ambassadors Program, Inc.
Center for Independence of the Disabled, NY
Center for Medicare Advocacy
Christopher and Dana Reeve Foundation
Cutaneous Lymphoma Foundation
Disability Rights Education and Defense Fund (DREDF)
Easter Seals
Epilepsy Foundation
Epilepsy Foundation Central and South Texas
Epilepsy Foundation of Arizona
Epilepsy Foundation of California
Epilepsy Foundation of the Chesapeake Region
Epilepsy Foundation of Georgia
Epilepsy Foundation of Greater Cincinnati and Columbus
Epilepsy Foundation Heart of Wisconsin
Epilepsy Foundation of Indiana
Epilepsy Foundation of Long Island, a Division of EPIC Long Island
Epilepsy Foundation of Metropolitan New York
Epilepsy Foundation of Michigan
Epilepsy Foundation of Minnesota
Epilepsy Foundation of Missouri & Kansas
Epilepsy Foundation of Nevada
Epilepsy Foundation of New England
Epilepsy Foundation of North/Central IL, IA, NE
Epilepsy Foundation of Northeastern New York
Epilepsy Foundation Northwest
Epilepsy Foundation Texas-Houston/Dallas-Fort Worth/West Texas
Epilepsy Foundation of Utah
Epilepsy Foundation of Vermont
Epilepsy Foundation of Virginia
Epilepsy Foundation Western/Central Pennsylvania
Epilepsy-Pralid, Inc.
FH (Familial Hypercholesterolemia) Foundation
Fight Colorectal Cancer
Global Liver Institute (GLI)
Help4Hep
Hepatitis C Association
Hepatitis Foundation International (HFI)
Institute for Educational Leadership, Disability Power & Pride
International Myeloma Foundation
Kidney Cancer Association
Lakeshore Foundation
Lung Cancer Alliance
National Alliance on Mental Illness (NAMI)
National Association of Councils on Developmental Disabilities (NACDD)
National Association of State Directors of Developmental Disability Services (NASDDDS)
National Association of State Head Injury Administrators
National Association for the Advancement of Orthotics and Prosthetics
National Council on Independent Living (NCIL)
National Disability Rights Network
National Infusion Center Association
National Organization of Nurses with Disabilities (NOND)
National Patient Advocate Foundation
National Viral Hepatitis Roundtable
Not Dead Yet
Parent to Parent USA
Patient Services, Inc. (PSI)
Pediatric Congenital Heart Association
RetireSafe
The Arc of the United States
The Hepatitis C Mentor and Support Group (HCMSG)
United Cerebral Palsy
United Spinal Association
U.S. Pain Foundation
April 27, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Slavitt:

As members of the Senate Finance Committee, we write to express our concerns regarding the Part B Drug Payment Model (the Model), recently proposed by the Centers for Medicare & Medicaid Services (CMS) through the Center for Medicare and Medicaid Innovation (CMMI).

We appreciate CMS's interest in testing strategies to improve value in all aspects of our health care system. However, we have heard numerous concerns from patients, providers and other stakeholders about the Model's potential to have unintended consequences on Medicare beneficiaries' access to care and physician-administered drugs. Any proposed changes to the Part B program must be carefully considered to prevent any disruptions in care for Medicare beneficiaries, particularly those with serious and complex conditions.

CMMI plays an important role in driving the health care system toward the delivery of high-value, integrated care. As a general principle, CMMI should initially implement focused demonstrations, which, if successful, can be adopted by the Medicare program. However, the changes that CMS has put forward in the Model are significant and complex. As proposed, the Model tests the impact of mandatory changes to Medicare payments for nearly all Part B medications, with up to 75 percent of providers required to participate in the Phase I change to the statutory Average Sales Price (ASP)-based payment methodology and/or the Phase II value-based purchasing tools.

Given the broad scope, CMS should resolve the following issues before moving forward with the Model:

Beneficiaries' access to Part B medications and quality of care. We have heard concerns from numerous stakeholders that the combined effect of sequestration and the proposed changes to the ASP-based payment methodology may result in some physicians facing acquisition costs that exceed the Medicare payment for certain Part B prescription drugs, potentially limiting beneficiary access to these medications. This is of particular concern for physicians in small, independent practices and those practicing in rural and/or underserved areas, and the patients they serve.
Letter to Mr. Slavitt
Page 2

CMS should ensure that adequate real-time monitoring systems are in place to rapidly detect and respond to any negative impact on beneficiaries' access to medications or quality of care. CMS should also establish a formal mechanism that allows for direct patient input throughout the duration of the Model. In addition, we urge CMS to ensure that the scope of each phase of the Model is no larger than necessary to allow for meaningful assessment, paying special attention to the potential impact on Medicare beneficiaries receiving care from physicians in small, independent practices and rural and/or underserved areas.

Potential impact on site of service. We are concerned that the Model may not adequately account for the differentials between care settings. In the event that their acquisition costs exceed the Medicare payment available under the Model, community-based physicians may refer their patients to hospital outpatient departments (HOPDs) to receive Part B medications. Community-based care is an essential part of our health care system, and a shift in site of service from community-based practices to HOPDs would result in higher overall costs for both beneficiaries and the Medicare program. We therefore urge CMS to prevent incentives to shift site of service from community-based practices to HOPDs and take action to ensure appropriate access is maintained.

Interaction with existing delivery and payment reform models. We have also heard concerns about the impact of the Model on physicians' ability to participate in existing delivery and payment reform models, such as the Oncology Care Model (OCM) and alternative payment models incentivized by the bipartisan Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). We urge CMS to ensure that the Model does not unintentionally discourage participation in existing and future initiatives designed to improve value in our health care system.

In addition, greater engagement with the impacted community is needed, and we urge CMS to engage in a meaningful dialogue with stakeholders. As an example, we believe value-based purchasing strategies have the potential to result in both lower costs and improved quality of care for Medicare beneficiaries. However, stakeholder involvement, including direct patient input, is essential to the successful development and application of value-based purchasing tools.

In closing, given the broad scope of the Model and the concerns raised by patients, providers and other stakeholders, it is critical that CMS resolve each of the above-described issues before proceeding.

Sincerely,

[Signatures]

Senator Ron Wyden
Senator Charles E. Schumer
Letter to Mr. Starvitt  
Page 2

Senator Debbie Stabenow  
Senator Maria Cantwell

Senator Bill Nelson  
Senator Robert Menendez

Senator Thomas R. Carper  
Senator Benjamin L. Cardin

Senator Sherrod Brown  
Senator Michael F. Bennet

Senator Robert P. Casey Jr.  
Senator Mark R. Warner
Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue SW
Washington, DC 20201

Dear Acting Administrator Slavitt,

Last week I joined my colleague, Rep. Richard Neal in raising concerns about the new proposed Part B Drug Payment model through the Center for Medicare and Medicaid Innovation (CMMI). Like many of my colleagues, I support CMMI’s mission to test innovative payment and service delivery models to reduce healthcare costs without compromising quality of care.

The letter I co-authored raised concerns and asked for clarification in eleven areas including beneficiary impact, physician impact, and model scope. I want to reiterate the importance of addressing the concerns raised in that correspondence. Absent substantial modifications to the proposal, I urge you to withdraw the proposed rule and engage physician groups, patient groups, and life-sciences organizations to craft a new proposal that ensures patient access to the medicines they need.

Sincerely,

Scott Peters
Member of Congress
May 13, 2016

Mr. Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

Dear Acting Administrator Slavitt:

We write to express our deep concerns with your agency’s “Part B Drug Payment Model” proposed rule, published in the Federal Register on March 11, 2016. As Members who represent constituencies with diverse healthcare needs in some of the most underfunded systems in the country, we stand with more than 300 health advocacy organizations in our belief that this proposed demonstration would threaten the solvency of our nation’s health care delivery system, particularly through entities that serve a disproportionate share of aging, low-income, and rural communities. After hearing from many patient advocacy groups, beneficiaries, and providers in our respective districts, we urge CMS not to move forward with this proposed rule due to the possible disruption it will cause our constituents and the providers who care for them.

Particularly, the demonstration’s proposed Average Sales Price (ASP)-based payment methodology may cause providers with less purchasing power to face Part B prescription payment amounts that exceed their acquisition costs. Small, independent, and rural providers will be left with the following options: send their sickest patients greater distances to larger specialty providers and health systems, buy and administer the drug at a loss to their practice, or prescribe cheaper, less effective, and often toxic medications. All of these potential outcomes put the healthcare needs of some of our most vulnerable seniors in serious jeopardy.

We are opposed to any demonstration that would result in underserved patients having to travel farther to more expensive infusion centers to access needed care. Transportation barriers and expenses not only add significant burdens to vulnerable, sick patients, and exacerbate health disparities but can also negatively impact outcomes, quality of life, and adherence to prescribed treatment regimens. The proposed demonstration neglects the transportation barriers and challenges faced by senior patients in accessing vital specialized care and its impact on treatment adherence and outcomes.

According to the proposal, the purpose of the model is to determine whether altering reimbursement for Part B covered drugs can reduce costs and increase quality for both beneficiaries and the system. We believe the reimbursement cuts for more expensive drugs will
have the opposite effect. The proposed rule includes no metrics to measure access or patient outcomes, both important determinants to monitor in areas with significant health disparities.

Most importantly, we believe these reimbursement cuts must be considered along with other factors that have contributed to our nation’s hospital and facility closure crisis, including sequestration, Disproportionate Share Hospital (DSH) cuts, and bad debt reductions. Current reimbursement rates, particularly those that do not adjust for socio-economic factors, create substantial challenges for Medicare providers, some of which already operate in negative margins. The inability of many small, independent, and rural providers in our districts to absorb additional reductions, without negatively impacting our most vulnerable populations, is without question. We urge CMS to resolve deficiencies and inequities in current reimbursement rates before implementing the new cuts proposed in this demonstration.

Our strong support for the Affordable Care Act (ACA) demonstrates that we all share the goal of reducing health care costs. Further, we appreciate the hard work CMS continues to do to tackle many of the critical issues pertaining to the delivery of health care services to our constituents. With deep concern that the proposed demonstration threatens these achievements, we request that your agency not move forward with the proposed rule. We stand ready and willing to work with you to craft a solution that better suits the needs of our seniors without negatively impacting their access to critical lifesaving drugs.

Sincerely,

Robin Kelly
Member of Congress

Terri Sewell
Member of Congress

Hakeem Jeffries
Member of Congress

Hank Johnson
Member of Congress

Bennie Thompson
Member of Congress

Donald M. Payne Jr.
Member of Congress
Ann Kirkpatrick  
Member of Congress

Filemon Vela  
Member of Congress

Pete Aguilar  
Member of Congress

Mare Vanasse  
Member of Congress

Joyce Beatty  
Member of Congress

Norma Torres  
Member of Congress

David Scott  
Member of Congress

Alma Adams  
Member of Congress

Stacey Plaskett  
Member of Congress

Bobby Rush  
Member of Congress
April 28, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Slavitt:

We write to express our strong concern with the policies in the Centers for Medicare & Medicaid Services (CMS) “Part B Drug Payment Model” proposed rule, published in the Federal Register on March 11, 2016. We urge you to withdraw the proposed rule immediately as it would severely disrupt care for vulnerable beneficiaries with cancer, macular degeneration, rheumatoid arthritis, neurological disorders, primary immunodeficiency diseases, rare diseases, and other serious medical conditions.

We are perplexed by the scope of the proposed experiment as it would require providers in the vast majority of the country to participate in at least one dramatic payment change. The unprecedented scope is especially troubling considering the policies could decrease the quality of beneficiary care and increase Medicare costs.

We are concerned that the proposed Phase I Average Sales Price (ASP) payment reduction would harm beneficiary access to vital drugs as many providers would face acquisition costs that exceed the Medicare payment amount. This problem would likely be especially acute for small physician practices and practices in rural areas. Physicians who have trouble accessing drugs at the reduced ASP payment would likely refer patients to the hospital outpatient department (HOPD). Driving care to a less-convenient, more costly setting would reduce beneficiary choice, increase costs, and likely further hospital-physician practice consolidation.

We are even more concerned that the Phase II policy ideas are numerous, complex, and not sufficiently vetted. The proposal provides little detail on the ideas and overstates the extent to which they have been tried while asserting that they could all be implemented on January 1, 2017. Stakeholders need to understand these ideas and their implications, which could include denying beneficiaries the drug that best meets their clinical needs.

We are dismayed that the proposal fails to indicate how CMS will assess the impact on the quality of beneficiary care. The proposal states an expectation that Part B drug spending will decrease without harming quality, yet it does not provide the specifics of how access and quality will be assessed during the experiment nor in the evaluation of it. This glaring omission deprives
stakeholders from commenting on how CMS would identify acute problems and determine what constitutes overall success.

We find the process by which CMS developed the proposals as concerning as the policies themselves. CMS failed to consult with outside experts and those with real-world experience. It decided to override the Part B drug payment methodology in statute in nearly all areas of the country on the hunch that it will decrease spending without harming patients. These decisions deeply call into question the ability of CMS to use the Center for Medicare & Medicaid Innovation (CMMI) authority prudently.

In 2014, bipartisan efforts helped prevent CMS from implementing the ill-conceived proposed Part D program changes that would have harmed beneficiaries, especially our seniors. While we were unable to find common ground with our colleagues on the Democratic side of the aisle to join us in this letter, we continue to hold out hope for future bipartisanship since ensuring continued access to life-saving drugs is a shared interest.

Further, we caution against invoking a similar unilateral effort to make changes to the successful Part D program through a flawed and overreaching read of the CMMI’s authority. The Senate has already resoundingly rejected in a bipartisan manner many of the policies that the Administration may entertain through the above mentioned 2014 rebuke of the Part D proposed rule. We sincerely hope that you will withdraw this proposed rule and work with Congress on a bipartisan approach.

Sincerely,

Orrin G. Hatch
Chairman
Chuck Grassley
United States Senator
Mike Crapo
United States Senator
Pat Roberts
United States Senator
Michael B. Enzi
United States Senator
John Cornyn
United States Senator
May 9, 2016

The Honorable Sylvia Burwell
Secretary
Department of Health and Human Services
Attention: CMS-1670-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Re: CMS-1670-P – Medicare Program; Part B Drug Payment Model; Proposed Rule
81 Fed. Reg. 13230 (March 11, 2016)

Dear Secretary Burwell:

The American Cancer Society Cancer Action Network (ACS CAN), appreciates the opportunity to comment on the Medicare Part B Drug Payment Model proposed rule. ACS CAN, the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation’s leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

In 2016, nearly 1.7 million new cases of cancer will be diagnosed in the United States.1 Because the incidence of cancer increases with age – 86 percent of cancers in the U.S. are diagnosed in people 50 years of age or older2 – cancer and the therapies used to fight the disease have an enormous impact on the Medicare program. Cancer patients and survivors rely on drug therapies for life-saving treatments; thus, it is paramount that any new payment model must ensure that beneficiaries have access to medically necessary treatments in the setting that is best for them.

ACS CAN is deeply troubled by the proposed Part B Drug Payment Model in its current form. We are concerned that, as currently proposed, the demonstration does not protect cancer patients’ access to the life-saving drugs needed to treat their disease. We are also concerned that system capacity needed by cancer patients may be negatively impacted as well.

We are particularly concerned that the project’s breadth and scope go well beyond the standard size of a demonstration project and could directly impact a cancer patient’s access to care. Cancer patients already face access problems. The number of small oncology practices has declined – from 64 percent in 2014 to 41 percent in 20153 – and this provider consolidation makes it harder for beneficiaries to access

---

2 Id.
cancer care, particularly in rural areas where only 5.6 percent of oncologists provide service.\(^4\) We are worried that the demonstration, as designed, could result in more oncologists leaving their practices, further exacerbating beneficiary access to needed cancer care. The stated goal of the demonstration project is to improve patient quality and lower spending but, as outlined in the proposed rule, the Part B Drug Payment Model could actually result in cancer patients getting care in higher-cost, less desirable settings like hospital outpatient departments. For these reasons we strongly urge CMS to reconsider implementing the Part B Drug Payment Model on a national scope. We also strongly suggest CMS outline how it intends to monitor in real time the effect of any new model on cancer patients’ access to the medications and what safeguards it will put in place to ensure that if cancer patients’ access is compromised immediate steps can take place to address any access problems.

Beyond these major issues we also have other concerns and questions highlighted below including:

- **Timing:** ACS CAN is extremely concerned that the implementation timeline is unrealistic given the magnitude and scope of the proposed Part B Drug Payment Model. Effective education and outreach about the Part B Drug Payment Model cannot begin until the model has been re-scaled into a viable final form and we do not believe the proposed timeframe provides adequate time to effectively educate beneficiaries, physicians, and suppliers about the proposed changes. As discussed in more detail below, ACS CAN has serious concerns with some of the proposed policies contained in the Part B Drug Payment Model and we urge CMS to address these concerns before it even considers implementing any new payment model.

- **Impact on Cancer Care:** The budget neutrality of Phase I will result in significant reductions in reimbursement to oncologists for some cancer drugs. According to one analysis, more than 50 percent of the payment reductions are expected to come from 30 drugs, seven of which are used to treat cancer.\(^5\) We are concerned that this proposal, absent changes, has the potential to result in beneficiaries being unable to access their cancer medications in their preferred setting of care. The payment reductions combined with the Value Based Purchasing Tools in Phase II will accentuate this concern about beneficiaries obtaining necessary care. CMS must establish specific beneficiary protections and evaluation measures as discussed in more detail in our comments below.

- **Shifting to Higher Cost Settings of Care:** One unintended consequence of the Part B Drug Payment Model will likely be a shift in some care to higher-cost settings. Unfortunately, if providers are unable or unwilling to dispense a medically necessary Part B drug due to the reimbursement rate, beneficiaries who need that treatment may have no choice but to seek care in a higher-cost setting of care. This result would be particularly problematic for beneficiaries who reside in rural areas who have fewer treatment options and who may be forced to travel further distances to receive care. We urge CMS to outline the specific proposals it intends to utilize to ensure that beneficiaries have access to their preferred treatment location.

\(^4\) Id.

• **Stakeholder Input**: ACS CAN is concerned that because many of the policies outlined in the Part B Drug Payment Model require input from stakeholders, the timeline proposed is unattainable. In fact, as discussed in more detail below, ACS CAN urges CMS to consider additional stakeholder input to ensure beneficiary access is not compromised.

• **Need for Extensive Beneficiary Education and Outreach**: Given the size and scope of the proposed Part B Drug Payment Model, we strongly urge CMS to conduct extensive education and outreach activities specifically intended for Medicare beneficiaries. The information beneficiaries need is different— but no less important— than the information that physicians and suppliers may need to understand the changes that result from the use of the value-based pricing tools — and indeed, the overall changes contemplated by the Part B Drug Payment Model. We recommend that any communication to beneficiaries be field tested — both with beneficiaries as well as beneficiary advocate groups — to determine the most appropriate way to communicate information to beneficiaries.

• **Value-Based Pricing (VBP) Tools**: CMS proposes value-based pricing strategies that include one or more of the following specific tools: reference pricing, indications-based pricing, outcomes-based risk-sharing agreements, and discounting or eliminating patient coinsurance amounts. As CMS considers implementing the VBP tools, we urge the agency to balance the impact of the tools with advancements in treatments based on personalized medicine, including treatments based on genetic information, and issues related to side effects and drug-to-drug interactions.

• **Clinical Decision Support (CDS) Tools**: ACS CAN appreciates CMS’ recognition that clinical decision support tools can help providers choose the best treatment for the beneficiary. We urge CMS to use existing evidence-based standards, rather than creating new standards. CDS tools should be developed and utilized with both patients and providers in mind. We are disappointed that CMS missed the opportunity to clarify that the CDS tool should be developed and utilized as a treatment decision counseling tool so that a patient and his/her provider can work together to determine the best course of treatment based on the individual preferences of the patient.

• **Pre-Appeals Payment Exceptions Review Process**: While we support the addition of this new appeals process as part of the Part B Drug Payment Model, we note that beneficiaries typically do not take advantage of their appeals rights and often are only informed of their rights by their provider. We appreciate CMS’ acknowledgement that the Pre-Appeals Payment Exceptions Review process cannot be used by a provider or supplier as a back-door way to impose higher cost-sharing on the beneficiary than would otherwise be required. We urge CMS to clarify that if a provider/supplier successfully appeals for a higher reimbursement amount, the beneficiary should be held harmless to the original cost-sharing amount to which she/he was otherwise required to pay.

• **Use of Contractors**: It is unclear the extent to which CMS intends to utilize contractors to administer parts or all of the Part B Drug Payment Model. Many policies raised in the proposed rule (e.g., development of the VBP tools, administration of the Pre-Appeals Payment Exceptions Review Process, beneficiary and provider education and outreach, etc.) are important functions and should not be contracted to an outside entity.

• **Evaluation**: We note that CMS intends to conduct an evaluation of the Part B Drug Payment Model. We urge CMS in its evaluation to conduct specific analysis regarding beneficiary access to oncology care. Included in this analysis should be a determination of the extent to which the
Part B Drug Payment Model has resulted in disruptions in beneficiary care and beneficiaries having to get care in higher-cost sites. We believe it is critically important for CMS to provide additional information regarding the specific quality measures it intends to use to evaluate this model and encourage the adoption of outcomes measures over process measures.

In addition, we note that CMS recently released a proposed rule implementing key parts of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), which will impose a new Medicare physician payment system. We are concerned that the simultaneous implementation of the Part B Drug Payment Model and the changes imposed as a result of MACRA will create an added administrative complexity on providers and may result in the unintended consequence of exacerbating beneficiary access issues.

I. Executive Summary

B. Summary of Major Provisions

CMS proposes to implement the Part B Drug Payment Model in two phases. Phase I is intended to test the extent to which an alternative approach to the ASP add-on payment would create a financial incentive for physicians to prescribe higher value drugs. CMS proposes to assign all providers within a given geographic unit into two arms. One arm would constitute the control group whereby providers and suppliers would continue to receive the ASP + 6 percent add-on payment. Providers and suppliers in the second arm would receive a reimbursement of ASP + 2.5 percent add-on + a flat fee. Under Phase II, providers and suppliers would be further divided into two arms which would permit the use of value-based purchasing tools.

The preamble includes a helpful chart depicting the proposal:

<table>
<thead>
<tr>
<th>TABLE 1: Summary of the Proposed Model</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Phase 1 - ASP+X</strong></td>
</tr>
<tr>
<td>(no earlier than 60 days after display of final rule, Fall 2016)</td>
</tr>
<tr>
<td>ASP+6% (control)</td>
</tr>
<tr>
<td>ASP+2.5% and Flat Fee Drug Payment</td>
</tr>
<tr>
<td><strong>Phase 2 - VBP</strong></td>
</tr>
<tr>
<td>(no earlier than January 2017)</td>
</tr>
<tr>
<td>ASP+6% (control)</td>
</tr>
<tr>
<td>ASP+6% with VBP Tools</td>
</tr>
<tr>
<td>ASP+2.5% and Flat Fee Drug Payment</td>
</tr>
<tr>
<td>ASP+2.5% with Flat Fee Drug Payment</td>
</tr>
</tbody>
</table>

**Note:** Primary Care Service Areas (which are clusters of ZIP codes that reflect primary care service delivery) would be randomly assigned to each model test arm and the control group. The assigned PCSAs would not include ZIP codes in the state of Maryland where hospital outpatient departments operate under an all-payer model.

---

1. **Model Overview**

The proposed rule states that “[i]mplementation of the Part B Drug Payment Model will be on or after August 1, 2016.” According to the preamble CMS “propose[s] to implement this first phase of the overall model no earlier than 60 days following display of the final rule.” The proposed rule states that “Phase II will be implemented on or after January 1, 2017.”

Proposed timeline: ACS CAN is extremely concerned that this entire plan and implementation timeline is unrealistic given the magnitude and scope of the proposed Part B Drug Payment Model and should not be implemented as outlined under the proposed rule. As discussed in more detail below, ACS CAN has serious concerns with some of the proposed policies contained in the Part B Drug Payment Model and we urge CMS to address these concerns before it even considers implementation of any new payment model.

If Phase I begins on August 1, 2016 (as stated in the proposed rule) and the first phase of the model begins 60 days after display of the final rule (as stated in the preamble) it suggests that CMS considers it possible to release a final rule (if only for display purposes) by May 31, 2016. In order to accomplish this goal, CMS only would have three weeks (between May 10th and May 31st) to review and synthesize all of the stakeholder comments, make modifications to the proposed rule based on stakeholder recommendations, and acquire the necessary administrative clearance in order to release a final rule before June 1st, which is 60 days before the earliest implementation date for Phase I. Given the size and scope of the Part B Drug Payment Model, it is anticipated that CMS will receive numerous detailed comments, which will further impede CMS’ ability to meet the proposed timeframe.

In addition, we are concerned with CMS’ proposal to begin Phase II of the Part B Drug Payment Model as early as January 1, 2017 (less than seven months after the close of the proposed rule’s comment period). Phase I represents the most significant change in Part B drug payment policy in over a decade. Given the magnitude of the proposed rule and the need for significant beneficiary, provider, and supplier education and outreach about the policy change, we strongly urge CMS to consider delaying implementation of Phase II until the agency has an opportunity to fully implement and conduct at least some initial evaluation of the first phase of the proposal. We believe it prudent to allow additional time for Phase II to be implemented in order to allow CMS the opportunity to more fully develop the details of the VBPP tool that could be used as well as to provide a more robust opportunity for public comment.

The scope and breadth of this particular model requires CMS to establish a more realistic timeframe for implementation. This would ensure that the model is well designed such that it avoids—or at the very least minimizes—unintended consequences for cancer patients.

---

7 § 511.205(d)(1).
9 § 511.205(d)(2).
10 We note that it can often take days—if not weeks—for a display copy of a rule to be published in the Federal Register. For example, the MACRA proposed rule was released by CMS twelve days before publication in the Federal Register. At the very least, any deadlines should be imposed based on the date of publication in the Federal Register and not the availability of the display of the rule.
Potential for increased beneficiary cost-sharing: According to an analysis by Avalere, under the Part B Drug Payment Model, Part B products that cost less than $480 would receive higher payments relative to the current reimbursement structure. Beneficiaries without supplemental coverage pay 20 percent cost-sharing for Part B services, and thus their cost-sharing would increase for lower cost drugs. Even beneficiaries with supplemental coverage may not necessarily be immune from increased cost-sharing. For example, beneficiaries with Medicare supplemental coverage could see these premiums increase. Thus, as the CMS model seeks to incentivize physicians to prescribe higher-value Part B drugs by providing a higher reimbursement, it could create a disincentive for beneficiaries to take higher-value drugs because they would have higher cost-sharing compared to a lower-value drug. We urge CMS to examine additional ways to ensure that while physicians are incentivized toward higher value drugs, similar incentives are provided for beneficiaries as well.

Need for beneficiary education and outreach: In recent years, there have been significant improvements to the Medicare program including the creation of the Medicare Prescription Drug Benefit and the important changes included in the Affordable Care Act (including the closure of the Medicare Part D donut hole, coverage of additional preventive services, and policies that have extended the solvency of the Medicare Part A Trust Fund). While these policies have significantly improved the quality of life and care for Medicare beneficiaries, we have also learned that beneficiaries are vulnerable to misinformation absent extensive education and outreach specifically geared to that demographic.

Effective education and outreach about the Part B Drug Payment Model cannot begin until the policy has been finalized. We do not believe that 60 days will provide sufficient opportunity for CMS—or any stakeholder—to develop, test, and implement an extensive and well-designed beneficiary education and outreach program, particularly given the complexity of the issue. We urge CMS to engage in significant education and outreach specifically targeted to beneficiaries, providers, and suppliers before implementing the Part B Drug Payment Model. This education and outreach may identify additional guidance that would be needed before proceeding with the implementation of the model.

Stakeholder involvement: We note that the Center for Medicare and Medicaid Innovation (CMMI) has successfully developed new models of care— including the Oncology Care Model (OCM) and the Medicare Care Choices Model (MCCM) which are both at various stages of implementation. We have very much appreciated CMMI’s extensive outreach to the stakeholder community for both of these models as well as other models being tested.

Given that CMS is using the demonstration authority granted to CMMI to conduct the Part B Drug Payment Model, we are deeply disappointed that the agency failed to provide significant stakeholder input prior to the release of the proposed rule. Stakeholder input prior to the formal rulemaking process allows CMMI the opportunity for open discussion and dialogue which we believe results in models that are more defined and targeted to achieve the Triple Aim. By not engaging in an extensive stakeholder outreach process prior to the introduction of the proposed rule, we believe CMS missed out on an opportunity to solicit feedback and address concerns that could have resulted in a better proposal.

2. Model Scope

CMS proposes that the Part B Drug Payment Model run for five years. The preamble states CMS' expectation that Phase I could take several years to fully implement, though at the same time CMS' goal is to have both phases of the model in full operation during the last three years of the proposed five-year duration to fully evaluate changes and collect sufficient data. ACS CAN recognizes that CMS' proposed five-year duration is consistent with other CMMI models. While we appreciate CMS' intention to gain sufficient data in order to fully evaluate the model, we urge CMS to consider allowing additional time to implement the first phase of the Part B Drug Payment Model before proceeding to the second phase. As discussed in more detail below, ACS CAN has concerns with several of the policies contained in both Phase I and Phase II. It will take time for beneficiaries, providers, and suppliers to adjust to any new payment model. Also, as discussed above, ACS CAN believes the scope of the Part B Drug Payment Model must be dramatically reduced.

II. Participation

B. Proposed Drugs Paid Under Part B To Be Included in the Model

With limited exceptions, CMS proposes to include all Part B drugs in the Part B Drug Payment Model. One notable exception includes Part B covered vaccines. With respect to drugs that have been reported by the FDA to be in short supply, CMS proposes to pay for those drugs using the current ASP + 6 percent payment methodology and seeks comment on alternate approaches.

ACS CAN supports CMS' proposal to exclude influenza, pneumococcal pneumonia and hepatitis B vaccines from the Part B Drug Payment Model. ACS CAN is supportive of the recognition of the value of preventive services such as these vaccines which, when used properly, help to keep beneficiaries healthier and improve their quality of life. We note, however, that the text of the proposed rule appears to contain a misprint in that it refers to section 1862(s)(10) rather than section 1861(s)(10). We urge CMS to correct this error when promulgating the final rule.

Drugs in short supply: CMS proposes that for drugs determined to be in short supply, CMS would continue paying for those drugs using the existing statutory methodology (e.g., ASP + 6 percent). ACS CAN is pleased that CMS expressed concern about how to address drugs that are in short supply and recognized the need to provide a safeguard to preserve access to these drugs. We note, however, that there are many different factors that cause drugs to be in short supply. It is unclear whether the proposed policy will ensure whether either payment methodology will affect the primary factors leading to drug shortages, but we encourage CMS and FDA to closely monitor any potential effects of the demonstration project on drug supplies. We encourage CMS to work with the FDA and other stakeholders to develop a policy to address any potential supply shortages.

12 § 511.205(d)(1).
14 § 511.200(e)(3).
C. Proposed Participants, Selected Geographic Areas, and Sampling

CMS proposes to require all providers and suppliers who furnish Part B drugs within a select geographic area to participate in the Part B Drug Payment Model. CMS contemplated using several different geographic units and ultimately proposed to use the Primary Care Service Area (PCSAs) as the most appropriate geographic unit. Exempting providers in Maryland due to its unique waiver system, CMS estimates where would be potentially 7,048 PCSAs used in the Part B Drug Payment Model. When both Phase I and Phase II of the Part B Drug Payment Model are implemented CMS expects approximately 1,700 PCSAs in each of the control and three test arms.

ACS CAN agrees with CMS’ concern that using states as the appropriate geographic unit would be problematic given that there is significant variation in size and numbers of beneficiaries among the states. Some states are so large as to make evaluation and monitoring too cumbersome a process.

Unlike most other CMMI demonstrations, CMS proposes that the Part B Drug Payment Model be mandatory and national in scope. Given the various stakeholder concerns expressed regarding the potential impact of the Part B Drug Payment Model, we urge CMS to reconsider implementing this model on a national scope. Rather, CMS could identify a number of targeted geographic areas in which to test a new payment model.

In addition, it is unclear from the proposed rule the extent to which contiguous PCSAs would be assigned to the same arm of the Part B Drug Payment Model. If contiguous PCSAs are randomly assigned to different payment models, it seemingly would be possible for a large group practice that operates in different PCSAs to direct a Medicare beneficiary to the practice location that offers the greater financial incentive to the provider. This diversionary practice could result in higher cost-sharing for the beneficiary depending on the reimbursement model being used within the PCSA. The beneficiary could also face transportation issues accessing the alternate site of care. We note that some providers operate in multiple states and thus this potential diversionary practice could occur regardless of geographic area chosen.

While similar diversionary practices could occur regardless of the geographic unit, we urge CMS to establish safeguards to ensure that beneficiaries are not directed to a particular site of care depending on the more advantageous reimbursement structure provided under the Part B Drug Payment Model. For example, CMS could monitor the extent to which a beneficiary receives care at more than one PCSA. This evaluation may be challenging given that CMS proposes to assign providers to the PCSA using their National Provider Identifier (NPI). While all solo physicians are required to have their own NPI, physicians who are part of a large group practice are not required to have their NPI and may use the NPI of the large group practice.

However, to the extent that multiple beneficiaries are receiving care from the same provider (identified by the billing NPI) at two or more PCSAs (particularly if these claims are for the same drug), CMS should examine the extent to which beneficiaries are being diverted to different sites of care to be more financially advantageous to the provider. In such instances, CMS should make clear to the provider that diversionary tactics are not permitted.
III. Payment Methodology

A. Phase I: Proposed Modifications to the ASP Add-On Percentage for Drugs Paid Under Part B

In Phase I of the Part B Drug Payment Model, CMS proposes to assign providers and suppliers into two arms: the first would be the control group who would continue to receive ASP + 6 percent and the second group would receive ASP + 2.5 percent add-on payment + a flat fee (which under the CMS proposal would be $16.80 per drug per day). While the flat fee would be updated annually based on the Consumer Price Index – Medical Care (CPI-MC), CMS proposes to keep the 2.5 percent add-on constant over the duration of the Part B Drug Payment Model. Phase I is intended to be budget neutral across all Part B drugs.15

ACS CAN understands CMS’ attempt to address rising cost of prescription drugs. However, we are concerned the implementation of Phase I of the Part B Drug Payment Model could negatively impact cancer patients’ ability to access their Part B drugs in their preferred setting of care. According to CMS’ analysis, some providers (like primary care) will see an increase in their Part B reimbursement and some providers (like those providing specialized services such as oncology) will see a decrease in their reimbursement. While overall these changes in reimbursement may be budget neutral in Phase I, we are concerned that the shift in reimbursement – from specialists like oncologist to primary care – may fundamentally shift the administration of health care services.

We want to ensure that any payment model incentivizes beneficiaries to receive the right care, at the right time, and in the right setting. While we are supportive of primary care, a cancer patient will rely on her/his oncologist for most – if not all – of her/his health care needs during active treatment. Given a variety of factors – including the frequency with which patients in active cancer treatment interacts with their oncologists, the potential side effects of the medication, etc. – the oncologist often serves as the care coordinator for an individual in active treatment before the beneficiary transitions back into primary care.

ACS CAN is concerned that while CMS’ proposal may be budget neutral in the aggregate, the proposal’s impact has the potential to negatively impact oncology services. The preamble acknowledges that Phase 1 “has the overall effect of modestly shifting money from hospitals and specialties that use higher cost drugs ... to specialties that use lower cost drugs.”16 According to one analysis, more than half of the payment reductions provided for under the proposed rule would come from 10 drugs (7 of which are used to treat cancer).17 In fact, CMS’ impact analysis estimates that hematology/oncology will see a 0.4 percent reduction in their Medicare reimbursements while medical oncology will see a 0.5 percent reduction in their Medicare reimbursements.18 CMS notes that these estimated reductions do not take into account reductions applied to Medicare payment under sequestration. According to another

16 Id.
18 CMS, Table 2 – Impact of Part B Drug Payment Model on Hospitals, Practitioners, and Pharmacies by Specialty, 81 Fed. Reg. at 13255.
analysis, oncologists could see payment reductions of 14 percent. We are concerned that depending on the generosity and size of the reimbursement reduction, beneficiaries may experience problems accessing oncology care. We note that in its June 2015 report, the Medicare Payment Advisory Commission (MedPAC) presented a similar proposal to revise the Part B payment methodology as outlined in Phase I, but even the Commission noted the uncertain effects of these payment changes on physician behavior and beneficiary access.

ACS CAN highly values the role of primary care providers, however, the services they provide are not interchangeable with the specialized services provided by oncologists. As previously noted, that while a beneficiary is undergoing cancer treatment, the oncologist is most likely to be that beneficiary’s primary care provider until the oncology services are finished and the individual transitions back to primary care.

Higher-cost settings of care: While the Part B Drug Payment Model seeks to reduce overall Part B costs, ACS CAN is concerned the model as proposed could result in the unintended consequence of shifting care to higher-cost settings, thus resulting in increased—not decreased—Part B costs. To the extent that a provider’s cost for acquiring a Part B drug exceeds the reimbursement provided for that drug (e.g., the provider is “underwater” with respect to the drug), the provider will be unable, or unwilling, to administer the drug in the physician office setting. In such instances, the provider could send the beneficiary to the hospital outpatient department to obtain treatment.

Shifting the site of care to the hospital setting results in an undue burden on the beneficiary. First, the beneficiary’s cost-sharing will be higher in the hospital setting relative to the physician’s office setting. When services are provided in a physician’s office, Medicare makes a single payment for the service, but when services are provided in a hospital Medicare makes two payments: one to the facility and one to the provider. Not only would the beneficiary’s cost-sharing be higher, but moving the site of care for the hospital setting increases costs for the overall Medicare program—the antithesis of one of the stated goals of the Part B Drug Payment Model.

In addition, many beneficiaries prefer to receive treatment in the community setting and not the hospital setting. Often it can be challenging for the beneficiary to obtain access to a hospital. Depending on the geographic area, beneficiaries may have to travel a far distance in order to obtain care in the hospital setting. For a cancer patient in active treatment, this creates an additional burden. Cancer patients are told not to drive following treatment because chemotherapy leaves patients fatigued, and some of the medications administered along with chemotherapy tend to make patients drowsy and unable to drive themselves or use public transportation. In addition, many cancer patients—particularly those with low or limited incomes—may not own a vehicle, be unable to afford public


18 In its June 2015 report, MedPAC explored two policy options: (1) 100 percent of ASP + $24 per drug per administration day, and (2) 102.5 percent of ASP + $14 per drug per day. The MedPAC reported noted that “It is difficult to know the extent to which the percentage add-on to ASP has the potential to affect drug prescribing patterns and the resulting spending levels.” MedPAC, Report to the Congress: Medicare and the Health Care Delivery System, June 2015, Ch. 3 at 69.
transportation, or do not live in an area where public transportation is readily accessible. Often patients do not have a family member or friend who is available to provide regular assistance with transportation. Individuals with cancer need regular access to care and cancer treatment services and when that access is disrupted the effectiveness of the treatment could be jeopardized and the individual’s chance of survival could be significantly reduced.

Potential for “brown bagging”: ACS CAN is concerned the proposed Part B Drug Payment Model creates an incentive for providers to encourage the practice of beneficiaries obtaining their Part B drugs at the pharmacy and then carrying the medication to the physician’s office for administration (so-called “brown bagging”). In essence, brown bagging shifts coverage from Part B to Part D, thus exposing some beneficiaries to additional cost-sharing depending on his/her Medicare Part D plan.

Brown bagging poses a number of challenges for Medicare beneficiaries. It requires beneficiaries to make a separate trip to the pharmacy to obtain their drugs. As discussed above, beneficiaries in active cancer treatment may be too sick to drive to the pharmacy to obtain the drug. While many cancer patients have a caregiver who may be able to obtain the medication at the pharmacy, not all cancer patients have this level of support.

In some cases, the beneficiary may be able to obtain the medication through mail order pharmacy, though this too creates challenges for the beneficiary. While mail order can be a viable option for the administration of medications used for chronic conditions, it is not necessarily an appropriate option for physician administered drugs. A drug shipped through the mail may get lost in transit, may not be received on time, or may be inadvertently damaged during shipment. In some instances, the dosing amount of the drug may need to be slightly changed before the drug is administered to the patient. Moreover, some Part B medications may require special handling (such as refrigeration) which may make mail order an unwise alternative.

We urge CMS to make clear in its final rule that brown bagging is prohibited. We also urge CMS to engage in extensive monitoring to determine the extent to which “brown bagging” occurs. Further, as part of its evaluation of the Part B Drug Payment Model – discussed in more detail below – we urge CMS to identify specific evaluation tools it will implement to determine the extent to which this practice is being utilized.

B. Phase II: Applying Value-Based Purchasing Tools

1. Introduction

In Phase II, CMS proposes to implement Value-Based Purchasing (VBP) tools for Part B drugs using value-based pricing and clinical decision support tools. The preamble notes that the application of VBP tools “to drugs that are typically paid for under a medical benefit, such as physician administered drugs, has the potential to result in significant savings.” 21 CMS notes that it intends to implement the VBP tools through a contractor.

Potential for cost-shifting: When properly utilized to ensure beneficiary access, some VBP tools can improve quality while lowering health care costs. Some of the VBP tools referenced in the Managed Care article cited in the preamble may be worthy of consideration. However, we are concerned that the article cited by CMS suggests that one way to reduce prescription drug costs under the medical benefit would be to “move[ ] specialty medications from the medical benefit to the pharmacy benefit where appropriate.” While this policy could result in savings for commercial plans, in the Medicare context this would result in shifting prescription drugs from Part B coverage to Part D coverage. Part B spending would decrease, but there would be a corollary increase in Part D spending.

This policy could negatively impact cancer patients, depending on the coverage provided by their Medicare Part D plan. Whereas Medicare Part B provides coverage for all physician-administered prescription drugs that are approved by the FDA, the Medicare Part D program is operated exclusively through private plans—all of which provide coverage through the use of a drug formulary. To the extent that drug coverage is moved from Part B to Part D, beneficiaries may experience higher cost-sharing depending on the Part D plan coverage or could encounter access problems if their Part D plan does not provide coverage for the specific drug. While we recognize that Medicare beneficiaries could file an exception to obtain coverage under their Part D plan, this does not guarantee that coverage will be granted.

Use of a contractor: The proposed rule states that “[o]ne or more contractors will be utilized to implement CMS approved VBP tools.” While we recognize that CMS uses contractors for a variety of purposes, we urge CMS to provide additional information regarding how it intends to use contractors for the Part B Drug Payment Model.

While the proposed rule states that contractors would be used to implement VBP tools, it is unclear the extent to which CMS would utilize contractors to develop the VBP tools. We urge CMS to conduct the development of the VBP tools (with public input as discussed below) and to not contract out this important function to an outside entity.

To the extent CMS intends to contract with multiple entities it is not clear whether the contracts would be awarded based on each arm of the Part B Drug Payment Model (e.g., CMS would initially contract with two entities for Phase I and then conceivably at least two additional entities for Phase II). The concern with this approach is that there could be significant variation between the contractors with respect to the use of VBP tools. Thus, beneficiaries in one geographic unit (e.g., the proposed PCSA) could be subject to a different interpretation of a given VBP tool than a similarly situated beneficiary in another geographic unit.

Alternatively, CMS could award contracts based on specific VBP tools (e.g., implementing the use of value-based pricing based on the clinical effectiveness of a drug). While this approach would better ensure consistency across all Part B providers, it could prove operationally challenging to ensure that the combination of one or more VBP tools do not create unintended access problems for beneficiaries.

23 § 511.205(e).
It also is unclear whether CMS intends for the contractor(s) to be responsible for evaluating and monitoring any potential access problems a beneficiary may encounter as a result of the Part B Drug Payment Model. If that is CMS’ intent, we urge greater clarification regarding the specific methods the contractor(s) will utilize to ensure that beneficiaries have access to their Part B covered drugs.

Given that the VBP tools will be implemented via contractor(s), we question whether it is CMS’ intent that these entities bear responsibility for collecting and addressing any beneficiary complaints or concerns that may arise as a result of the use of the tools. While CMS intends to provide a Pre-Appeals Payment Exception Review Process – discussed in more detail below – beneficiaries may have questions or concerns about the use of the VBP tools outside the limited scope of the Pre-Appeals Payment Exception Review Process (e.g., beneficiaries may have questions or concerns raised after the submission of a claim subject to a VBP tool). If it is CMS’ intention to use contractor(s) for the appeals process, it is unclear how a beneficiary will be made aware of how to contact the contractor(s) – which may prove challenging if CMS intends for multiple contractors to operate within the same geographic area.

While CMS recognizes in the proposal the need to conduct education and outreach regarding the changes implemented under the Part B Drug Payment Model, it is unclear whether the contractor(s) responsible for implementing the VBP tools also will be responsible for providing this necessary education and outreach. Presumably the contractor(s) will conduct education and outreach to physicians and suppliers who are impacted by the VBP tool. However, we strongly urge CMS to provide education and outreach to beneficiaries as well. The information beneficiaries need is different – but no less important – than the information that physicians and suppliers may need to understand the changes that result from the use of the VBP tool – and indeed, the overall changes contemplated by the Part B Drug Payment Model.

The preamble also is silent with respect to what happens if a given contract is terminated (either due to cause or because the contractor is unable or unwilling to perform specified contract functions). We are concerned that if a contract is terminated within the demonstration period, it could create a gap in vital functions of the Part B Drug Payment Model particularly if, as discussed above, the contractor is responsible for beneficiary education and outreach and/or implementation of the Pre-Appeals Payment Exception Review Process. The final rule should specify the action CMS would take in the case of contract termination.

Finally, given the proposed timeframe, we question whether CMS will have sufficient time to be able to finalize the rule, draft a detailed scope of work, create an open contractor bidding process, and select one or more contractors before the beginning of Phase II, which according to the proposed rule could be as early as January 1, 2017. Thus, we reiterate our concern with the proposed timeframe and urge CMS to provide additional time before implementing Phase II.
2. Value-Based Pricing Strategies

CMS proposes value-based pricing strategies that include one or more of the following specific tools: reference pricing, indications-based pricing, outcomes-based risk-sharing agreements, and discounting or eliminating patient coinsurance amounts. As CMS considers implementing the VBP tools, we urge the agency to balance the impact of the tools with advancements in treatments based on personalized medicine, including treatments based on genetic information, and issues related to side-effects and drug-to-drug interactions.

Opportunity for public comment on the proposed VBP tools: CMS intends to finalize the implementation of specific tools for specific HCPCS codes after soliciting public input on each proposal which it will post on the CMS website. CMS notes that it will allow 30 days for public comment and will provide a minimum of 45-days public notice before implementation.

ACS CAN is concerned that the proposed public comment period for feedback on the VBP tools is insufficient for a number of reasons. First, depending on how CMS proposes to apply a specific VBP tool to a particular drug, the use of the VBP tool can raise clinical and other concerns. Thus, a longer comment period may be necessary in order to provide the public with sufficient opportunity to review the proposal and provide meaningful comment. Moreover, it is unclear from the preamble whether the 30-day comment period would consist of 30 business days, or 30 calendar days—the former would provide for a greater opportunity to review and submit more robust comments.

Similarly, we are concerned with CMS’ proposal to provide a minimum of 45 days “notice” before implementation of a VBP tool. We do not believe this timeframe is adequate to allow CMS to properly educate beneficiaries, providers, and suppliers about the proposed VBP tool. In addition, we question whether the 45-day notice period would be sufficient to permit contractors, manufacturers, suppliers, physicians, and other stakeholder the opportunity to update their IT systems and/or make other necessary changes.

We are concerned with CMS’ intent to implement the use of VBP tools through sub-regulatory guidance. Given the potential impact of a given tool on a beneficiary’s access to a medically necessary Part B drug, we do not believe that simply posting the proposed VBP tools on the CMS website provides a sufficient opportunity for public comment. It is unclear from the preamble whether comments will be submitted via an open process (like regulations.gov) whereby comments submitted are made public, or whether CMS will receive comments similar to its collection of comments through other sub-regulatory guidance (like comments on the Medicare Advantage-Prescription Drug Plan (MA-PDP) call letter) where comments received are not made publicly available. We strongly urge CMS to make publicly available any comments it receives through this process. This will allow stakeholders the opportunity to review others’ comments so that a more robust dialogue can exist among all interested parties.

Use of VBP tool by HCPCS code: The preamble notes that CMS does “not intend to apply the [VBP] tools to all Part B Drugs; we plan to implement the use of the tools in a limited manner for certain drug HCPCS codes after considering these tools’ appropriateness to specific Part B drugs within those codes.”

ACS CAN appreciates CMS’ clarification that not all Part B drugs will be subject to VBP tools. For example, unlike some Part B drugs, oncology care can be very specific and only one drug may exist to treat an individual’s specific cancer. Thus, reference-based pricing or other tools may not be appropriate in those instances.

When determining which VBP tool(s) should be implemented, we urge CMS to begin with drug categories for which there are many different drug options within one category or class and for which there exists extensive research regarding the comparable efficacy of the drugs within the class.

**Use of pharmacy utilization management tools:** The preamble suggests that CMS could consider allowing the use of certain formulary tools that are commonly used by plans to steer utilization management of particular drugs.

We are pleased with a number of policies that exist in the Medicare Part D program that protect beneficiary access to medically necessary drugs. Beneficiaries in Medicare Part D are permitted to appeal the formulary tier and apply to move a drug to a lower-cost tier when access to the higher-tiered drug is medically necessary. Medicare Part D also has requirements in place regarding which drugs can be placed in the highest formulary tier. Medicare Part D plans are also limited in their ability to switch their formularies mid-year. Part D also has adopted a policy of classes of clinical concern (e.g., the six protected classes) whereby beneficiaries must have access to all or substantially all drugs within these six classes of drugs.

To the extent that CMS will allow the use of VBP tools that create a formulary or mirror the utilization management tools commonly utilized in the Part D benefit, we urge CMS also to adopt appropriate beneficiary protections as provided in Part D.

**Potential for a discriminatory benefit design:** We are concerned that some of the VBP tools that may be considered could result in a potential discriminatory benefit design. For example, to the extent that CMS would permit the creation of a formulary for Part B drugs and that formulary placed all drugs to treat a specific disease or condition on the highest formulary tier, such a design could constitute a discriminatory benefit design.25

We strongly urge CMS to ensure that the design and utilization of any VBP tool – either the tool itself or in combination with one or more VBP tools – does not result in a discriminatory benefit design. In fact, in reviewing any VBP tool, we urge CMS to make a specific determination that the use of the tool would not constitute a discriminatory benefit design prior to allowing the use of the specific VBP tool.

While HHS has yet to publish the final rule implementing section 1557 of the Affordable Care Act (ACA), we are concerned that the proposed rule would not apply to physicians who receive Medicare Part B payments but no other funding.26 If this provision is included in the final rule implementing ACA section 1557, we urge CMS to specifically note in the final regulation implementing this model that the nondiscrimination protections provided under ACA section 1557 would apply to any and all VBP tools utilized under this model.

---

25 See Letter from Christopher W. Hansen, President, American Cancer Society Cancer Action Network, to Sylvia Burwell, Secretary, Department of Health and Human Services (Nov. 3, 2015).

Use of reference-based pricing: One VBP tool CMS proposes to implement is providing equal payment for therapeutically similar drug products (e.g., reference pricing). CMS explained its vision of this policy in the preamble:

A benchmark is set based on the payment rate for the average price for drugs in a group of therapeutically similar drug products, the most clinically effective drug in the group, or another threshold that is specifically developed for such drug products, like a specific percentile of the current price distribution; and all drugs from the group are then paid based on this amount. Individual characteristics of each group of drugs considered for reference pricing, such as relative effectiveness demonstrated in competent and reliable scientific evidence, would be taken into account before selecting a benchmark rate.27

ACS CAN believes the use of reference-based pricing as proposed by CMS would not be suitable for all Part B drugs. We have concerns about the implementation of this policy with respect to oncology drugs—most notably those medications that are developed through precision medicine or personalized medicine. By better understanding the molecular alterations that cause a given cancer, researchers are able to develop targeted therapies aimed at specific genetic mutations that drive that cancer.28 For example, the broad category of tyrosine kinase inhibitors has been developed to treat cancer, but each drug within this category may target a different mutation that is relevant to a small subcategory of patients with a given disease. This targeting means that any comparators within a reference pricing scheme would have to be for the same molecular target, and in many cases there are only one or two drugs for each target, making reference pricing unsuitable.

Even where there may be multiple therapies for a given type of mutation, (e.g., ALK or EGFR) there are important differences between their performance characteristics, especially when considering first and second generation drugs from these classes. Any attempts to implement reference pricing on cancer therapeutics must therefore overcome the small category sizes and account for important differences between drugs within a category. Thus, we urge CMS to ensure the Part B Drug Payment Model does not impede access to drugs that are designed to treat beneficiaries who possess specific genetic markers.

Prohibition of balance billing for reference pricing: CMS proposes that any version of reference pricing implemented under this model would prohibit balance billing of the beneficiary for any difference in pricing.29

27 81 Fed. Reg. at 13243.
28 While targeted cancer therapies are a relatively new field, more and more promising research is being conducted in this area and new treatments are currently in the pipeline. According to some research up to fifty percent of drugs currently in the clinical pipeline are estimated to involve the use of genetic or molecular markers. American Cancer Society Cancer Action Network, Fulfilling the Promise of Personalized Medicine for Patients: Background and Overview Paper #1: Patient Expectations and Access Barriers, available at http://www.cancer.org/content/wc-content/uploads/2014/04/Patient-Expectations-and-Access-Barriers.pdf.
29 “Medicare providers and suppliers may not bill the beneficiary for any difference in pricing between the benchmark rate and the statutory payment rate or the provider or supplier’s charge for the drug prescribed.” § 511.305(1)(i).
ACS CAN supports CMS’ inclusion of this important beneficiary protection. If the intent of reference-based pricing is to encourage the use of high-value services, beneficiaries should not be asked to pay more for a lower-value drug. The decision of which drug a beneficiary should use is largely driven by the physician prescriber. Medicare beneficiaries should not be asked to pay more in the event that their prescriber chooses a drug that is above the reference price.

**Indications-based pricing:** CMS proposes to vary prices for a given Part B drug based on the varying clinical effectiveness for different indications. The preamble uses the example of a drug used to treat two different cancers.\(^{30}\) If clinical trial data demonstrated that the drug’s effectiveness was no better than an existing treatment for one type of cancer, but better than the existing treatments for another type of cancer, the indications-based pricing tool would result in lower payments when the drug is used to treat the first type of cancer and higher payments when the drug is used to treat the second cancer. The preamble notes that the Institute for Clinical and Economic Review (ICER) is in the process of producing reports on high-impact drugs.

ACS CAN believes that indications-based pricing, if used appropriately, may be suitable in oncology care. Beneficiaries should be prescribed the drug that is expected to result in the best health outcomes for the beneficiary. This determination can vary depending on the beneficiary’s overall health status (e.g., her/his disease or condition, comorbidities, allergies, etc.) as well as non-health factors (e.g., availability of a caregiver, transportation issues to and from treatment, financial considerations, etc.). Such determinations are particularly important in oncology care given that potential side-effects of medication can be challenging to manage and few treatment options may exist. This is why it is imperative that any treatment decision be made through informed decision making so the beneficiary – in consultation with her/his oncologist – can choose the treatment path that best meets her/his needs.

In addition, we urge CMS not to rely solely on ICER for its determination of what constitutes clinical effectiveness. We are concerned that some of ICER’s evaluations have focused too much on the cost of a given treatment and fail to accurately incorporate the long-term health outcome benefits and quality associated with the treatment. We strongly urge CMS to rely on multiple sources for the determination of clinical effectiveness.

**Linking health outcomes with payment:** Another tool under consideration in the Part B Drug Payment Model would be to allow CMS to enter into voluntary contracts with manufacturers to link health care outcomes with payment. Any outcomes-based risk-sharing agreements would require clearly defined outcomes goals.

ACS CAN sees some value in this proposed VBP tool insofar as it could reward innovation that leads to the defined health outcome. Unfortunately, cancer care lacks a robust field of outcomes measures. According to Avalere, there are 305 cancer measures currently in use, but 85 percent of them are process not outcomes measures.\(^{31}\) We are pleased there is a recognition of cancer as a national priority for quality improvement\(^ {27} \) and as such there needs to be more attention paid to the gaps in oncology measures so a tool like linking outcomes to payment is possible.

---

30 81 Fed. Reg. at 13243.
32  Id.
Waiving beneficiary cost-sharing: CMS proposes implementing a VBP strategy “that involves discounting or eliminating patient coinsurance amounts for services that are determined to be high in value in an attempt to tailor incentives.” Under this proposed policy, CMS would have the authority to waive beneficiary cost-sharing from the current 20 percent to a value that is less than 20 percent and could be waived completely.

ACS CAN supports this policy which is intended to ensure that beneficiaries are financially incentivized to utilize higher-value drugs when available and medically appropriate.

We urge CMS to provide specific details regarding what constitutes a “high-value” drug. It is not clear whether a drug is determined to be “high-value” relative to other drugs available in the marketplace or whether the value of the drug is determined relative to other Medicare-covered products and services. For example, a cancer drug that has been clinically shown to be effective at treating a specific cancer, thus eliminating the need for additional surgery and/or radiation services could be considered high in value. In making the determination of what constitutes a “high-value” drug, we urge CMS to examine all factors, including the availability of similar Part B drugs, costs for other Medicare-covered services, and value to the beneficiary.

Beneficiary cost-sharing: Similarly, the preamble notes that CMS will not exceed the 20 percent cost-sharing for low-value drugs. We appreciate and support CMS’ clarification that the policy does not intend to increase cost-sharing for beneficiaries who receive lower-value drugs. However, as a practical matter given that beneficiaries’ cost-sharing is represented as a percentage of the cost of the Part B drug, as CMS increases provider reimbursement beneficiaries will pay a higher cost-sharing.

Educational activities: The preamble notes that CMS “would also engage in educational activities to support implementation and testing of the value-based pricing strategies.”

ACS CAN urges CMS not only focus these activities on providers and suppliers, but also to develop an educational plan specifically designed and targeted to Medicare beneficiaries. We recommend that any communication to beneficiaries be field tested – both with beneficiaries as well as beneficiary advocate groups – to determine the most appropriate way to communicate information to beneficiaries.

Potential safeguards: CMS recognizes that “the value-based pricing tools discussed here could pose a risk of abuse if not properly structured and operated.” CMS therefore seeks comment on potential safeguards that could be implemented to ensure the intent of the policy is not undermined.

ACS CAN appreciates CMS’ recognition of the need for additional safeguards to ensure that beneficiary access is protected. As discussed in more detail below, we strongly urge CMS to provide additional beneficiary safeguards. We strongly urge CMS to include quality measures as a component of the Part B Drug Payment Model. Dr. Conway has indicated that CMS is inclined to adopt specific quality measures – including patient-reported outcomes measures and measures that have yet to be developed – and we urge CMS to provide additional information regarding the measures CMS intends.

33 81 Fed. Reg. at 13244.
34 Id., § 511.305(1)(i)(v).
35 81 Fed. Reg. at 13244.
36 Id.
37 Remarks from Dr. Patrick Conway, Acting Principal Deputy Administrator, Deputy Administrator for Innovation and Quality, and Chief Medical Officer, Centers for Medicare and Medicaid Services, Public Forum on the Medicare
to use. We also urge CMS to clarify the extent to which CMS intends to develop its own measures, or whether it will rely on a multi-stakeholder consensus-building entity like the National Quality Forum (NQF) to develop new measures.

Similarly, as discussed above, the role of the contractor(s) has not yet been clearly defined and it is unclear the extent to which a contractor(s) will be tasked with developing one or more quality measures. Given the rigor required to develop and implement high-quality measures, ACS CAN urges CMS to utilize measures developed from a multi-stakeholder consensus entity like the NQF.

Moreover, we urge CMS to establish a clear, standard quality measure set — based on outcomes, not process measures — that will be used across all arms of the Part B Drug Payment Model. This measure set should be designed to ensure that beneficiary access is not compromised by initiatives utilized in the model. In addition, CMS should develop standard quality measures to be used in each arm of the model as well as quality measures for each of the VBP tools utilized. Some of the measures may be overlapping.

ACS CAN urges CMS to identify the measures used through an open, public, and transparent process. Such measures should be developed through a multi-stakeholder entity like the NQF. Given the technical nature of quality measure development, we urge CMS to provide at least a 60-day comment period in which to respond and provide feedback to CMS’ proposed quality measures. All comments received should be made publicly available so that stakeholders have an opportunity to review any and all comments and determine the extent to which consensus exists. Further, we strongly urge CMS to delay implementation of the Part B Drug Payment Model until it has finalized at least a preliminary set of quality measures that will be used to safeguard beneficiary access to Part B drugs.

**Timeframe:** ACS CAN is concerned the proposed implementation timeframe for Phase II fails to provide adequate opportunity for public comment before implementing the VBP tools proposed by CMS. We strongly urge CMS to delay any implementation of Phase II until it has had an opportunity to fully implement and conduct an initial evaluation of the first phase of the Part B Drug Payment Model to ensure that any beneficiary access problems and/or unintended consequences are addressed before moving to the next phase of the model.

**Variation in the use of VBP tools:** It is unclear from the preamble the extent to which CMS envisions the implementation of the VBP tools. While CMS has stated that a VBP tool will be applied to a specific HCPC code, it is unclear whether each geographic unit (i.e., PCSA as proposed in the rule) would be subject to all of the approved VBP tools or whether the contractor(s) responsible for implementing the VBP tools would be permitted to determine which VBP tool (if any) would be appropriate for a given geographic area.

Assuming CMS finalizes its policy of defining the geographic unit as a PCSA, there would presumably be approximately 3500 geographic units where VBP tools could be imposed. If CMS determines that a specific drug is appropriate for a specific VBP tool, it is unclear whether that tool will be uniformly applied to all geographic units implementing VBP tools (e.g., 3500 PCSAs) or whether each of the geographic units would have the opportunity to develop their own version of the specific VBP tool. We would caution against multiple versions of the same VBP tool being implemented in each geographic area.

---

area. Such a policy would prove too onerous for adequate stakeholder involvement. Moreover, evaluation of the VBP tool would prove challenging if CMS were to attempt to evaluate similar versions of the same tool in different geographic areas.

Adherence: As CMS drafts its VBP tools, we urge CMS to clarify whether a provider who utilizes VBP tools must maintain a 100 percent adherence to these tools or whether the provider is permitted to prescribe outside the tools. Particularly in cancer care, it may be medically appropriate – depending upon the evidence and individual needs of the beneficiary – for the provider to deviate from the standard of care. It is for this reason that the American Society of Clinical Oncology recommends that clinical pathways do not seek a 100 percent adherence rate, but rather establish a more realistic adherence rate of 80 percent in order to allow providers the opportunity to prescribe according to the individual needs of the patient.

3. Development of a Clinical Decision Support Tool

One component of value-based purchasing proposed by CMS is the development and use of clinical decision support (CDS) tools, for accurate clinical decision-making based on up-to-date scientific and medical evidence. In the preamble, CMS references specific examples of CDS tools including standardized drug and test orders that are developed from evidence-based medical guidelines when prescribing for a particular condition or type of patient; preventive care reminders; and alerts about potentially dangerous situations such as adverse drug events. CMS proposes a two component CDS tool that consists of an online tool that supports clinical decisions through education and provides feedback based on drug utilization of Medicare claims.

CDS design: It is unclear from the preamble whether the CDS tools are intended to be text-based logic trees or whether CMS intends to incorporate specific software to be used by providers. If the latter, it is unclear whether CMS intends for the software to be a stand-alone system or whether CMS envisions the software to be based off the provider’s existing claims and/or administrative software, as well as the extent to which the CDS tool will be integrated into electronic medical records. In order to be effectively utilized by providers, the CDS tools should be embedded into the electronic medical records. To the extent that CMS intends for this outcome, we encourage the agency to work with the National Institute of Standards and Technology (NIST) to develop pilot testing to ensure that the integration of the CDS tools work with the electronic medical records.

Process for developing the CDS: We appreciate CMS’ recognition that clinical decision support tools can help providers choose the best treatment for the beneficiary. As noted in the preamble, the National Comprehensive Cancer Network (NCCN) publishes evidence-based clinical practice guidelines to assist oncologists in determining the most appropriate cancer treatment.

We urge CMS to use existing evidence-based standards rather than creating new standards. We note that the Institute of Medicine has created requirements for the creation of high-quality guidelines and

40 More information on the NCCN guideline process is available at www.nccn.org.
we urge CMS to adhere to these standards. Given that in the oncology arena the NCCN guidelines are well-regarded and utilized — in large part because they are developed through an evidence-based multi-stakeholder process — we urge CMS not to circumvent the NCCN process and create a separate clinical decision support tool to be used in oncology care. Rather, we urge CMS to incorporate the NCCN process into its clinical decision support tool with respect to oncology care.

**CDS development feedback:** The preamble notes that the CDS tool will be developed by CMS with support from the VBP contractor\(^{41}\) and notes that CMS would consider feedback from the public on the evidence base for 30 days before finalizing a CDS tool for a specific indication.\(^{43}\)

ACS CAN appreciates CMS’ intention to “consider” feedback on the evidence that serves as the basis for the CDS prior to finalizing the CDS tool. However, we urge CMS to provide additional information regarding what constitutes consideration of feedback. We urge CMS to create an open and transparent process for solicitation of feedback both for the evidence being utilized in the development of the CDS, but also in the final CDS product. This process should include extensive opportunity for public feedback and public comments should be posted on the CMS website. Finally, we urge CMS to clarify its intent to test the CDS tool with providers prior to implementation to ensure the usefulness of the tool.

**Treatment decision counseling:** CDS tools should be developed and utilized with both patients and providers in mind. We are disappointed that CMS missed the opportunity to clarify that the CDS tool should be developed as a treatment decision counseling tool. While education of providers is an important aspect to improving the quality of health care, we caution that CDS tools should not be developed solely for the provider. Beneficiaries need to be informed of their treatment options and then be allowed to have meaningful conversations with their provider to discuss the benefits and risks of each treatment option. CMS should also consider developing CDS-like tools to educate the beneficiary (as the NCCN has done with its development of materials specifically geared toward patients and meant to facilitate informed provider-patient discussions). As CMS finalizes the rule we urge the agency to develop the CDS so that the patient is represented in the equation.

C. **Comment Solicitation**

1. **Episode-Based or Bundled Pricing Approach: Solicitation of Public Comments**

CMS is soliciting comments and suggestions to consider in future rulemaking related to an episode-based or bundled pricing approach for Part B drugs in both physician offices and hospital outpatient settings.

ACS CAN is supportive of the Oncology Care Model (OCM) currently being implemented by CMS. However, we note that the OCM begins at the point of administration of chemotherapy. While chemotherapy is often a major component of cancer treatment it is by no means the only form of treatment — surgery and radiation are other types of cancer treatment options. We would urge CMMI to consider the development of a future oncology model in which eligibility begins closer to the point of diagnosis and includes transitions back into primary care following the end of cancer treatment as appropriate. This will allow CMS the opportunity to evaluate all the factors that affect the course of cancer treatment to determine the extent to which the quality of cancer care can be improved through informed decision making.

\(^{41}\) 81 Fed. Reg. at 13245.

\(^{43}\) 81 Fed. Reg. at 13246.
D. Interactions With Other Payment Models

2. Most Shared Savings Programs and Models

CMS proposes not to exclude from the Part B Drug Payment Model beneficiaries assigned to an Accountable Care Organization (ACO) in the Medicare Shared Savings Program or otherwise accounted for in the shared savings model.

ASC CAN notes that the National Association of Quality Assurance (NCQA) is in the process of evaluating a patient-centered oncology care model, which has been shown to improve quality for beneficiaries and reduce health care expenditures.44 This program is currently being expanded to be tested in additional sites across the country. Given the initial indications of the success of these programs, we urge CMS to consider exempting providers participating in the oncology Patient-Centered Medical Home (PCMH) from the Part B Drug Payment Model.

3. Oncology Care Model

CMS notes the overlap between the Part B Drug Payment Model and the Oncology Care Model (OCM) currently being tested by CMMI. However, CMS intends to include OCM practices in all arms of the Part B Drug Payment Model.

ASC CAN supports CMMI’s Oncology Care Model which we believe has the potential to improve the quality of care for cancer patients actively undergoing chemotherapy treatments. We strongly urge CMS to exclude participants in the OCM from the Part B Drug Payment Model. We note that since the release of the proposed rule, representatives from CMS have been reported as being favorably inclined to this change.45

The OCM represents an opportunity to test a new delivery payment model for the administration of chemotherapy and supportive care for Medicare beneficiaries in active cancer treatment. In its original Request for Applications, CMS indicated that it expected to receive approximately 100 applications from providers to participate in this model,46 which it believes would provide sufficient participation in which to effectively evaluate the model. We note that participation in the OCM model is voluntary for providers whereas participation in the Part B Drug Payment Model is not. Both models will result in varying degrees of change for a provider’s practice. We are concerned that providers who may have intended to participate in the OCM model may withdraw from the OCM due to concern that participation in two unique payment models may prove too onerous for the provider’s practice. As such, CMMI ultimately may not receive the minimum participation necessary in order to test and evaluate the OCM.

Thus, we strongly urge CMS to exempt from the Part B Drug Payment Model those practices who participate in the OCM. We believe this exemption will ensure a more accurate evaluation of the OCM model, and may result in additional provider interest in the OCM.

---

IV. Provider, Supplier, and Beneficiary Protections

A. Pre-Appeals Payment Exceptions Review Process

CMS proposes to establish a Pre-Appeals Payment Exceptions Review process for pricing established under the value-based pricing section of Phase II in order to allow an opportunity to dispute payments made under Phase II. The proposed rule notes this new process would be in addition to—and not in lieu of—the current appeals process. This process only would be available to providers, suppliers, or beneficiaries receiving services in areas assigned to one or more of the VBP arms and would not include any modifications to the ASP add-on. The Pre-Appeals Payment Exceptions Review process would allow the provider, supplier, or beneficiary to contact the contractor prior to submitting a claim, and explain why the exception to the Medicare pricing policy is warranted. The contractor would provide a written decision within 5 business days of receipt of the exception. The Pre-Appeals Payment Exceptions Review process would not confer any appeals rights, though claimants would be permitted to file an appeal after the submission of a claim.

Beneficiary awareness: ACS CAN supports CMS’ proposal to establish a new pre-appeals mechanism. We appreciate the proposed rule’s clarification that this Pre-Appeals Payment Exceptions Review process will be in addition to—and not in lieu of—the existing Medicare appeals processes. However, we are concerned that as a practical matter, Medicare beneficiaries may not be made fully aware of these new pre-appeals rights. Historically very few Medicare appeals are filed by beneficiaries. In addition, the Pre-Appeals Payment Exceptions Review process only would be available prior to the submission of a claim subject to VBP tools. Medicare beneficiaries often are unaware of the timing of a submission of a Medicare claim on their behalf and thus may miss out on the ability to take advantage of this additional pre-appeals process.

Beneficiaries who utilize their Medicare appeals rights are often told of their rights by their health care provider. To the extent that the provider has a financial incentive to utilize one treatment over another (e.g., due to reference pricing) then the provider would be less inclined to inform the beneficiary of her/his new pre-appeals rights. Therefore, we are concerned that appropriate pre-appeals will not be filed and some patients will not receive access to the treatments that are right for them.

Beneficiary cost-sharing: The preamble notes that “[t]hroughout this process, providers and suppliers would be prohibited from charging a beneficiary more than the applicable cost sharing [provided under the VBP tool] even if a payment exceptions request is not approved by the contractor or the payment amount determined by the contractor remains unchanged as a result of the appeals process.” We appreciate CMS’ acknowledgement that the Pre-Appeals Payment Exceptions Review process cannot be used by a provider or supplier as a back-door way to impose higher cost-sharing on the beneficiary than would otherwise be required. We urge CMS to codify this important beneficiary protection into the final rule.

In addition, it is not clear whether the Pre-Appeals Payment Exceptions Review process could result in a beneficiary incurring higher cost-sharing. Under the proposal, a supplier or physician could utilize the Pre-Appeals Payment Exceptions Review process to obtain a higher reimbursement. Beneficiaries without supplemental coverage pay 20 percent cost sharing for Part B services. Thus, if a supplier’s or physician’s successful appeal resulted in a higher reimbursement, beneficiary cost-sharing would also increase.

This creates a number of potential problems. A beneficiary would likely be confused upon receiving a supplemental bill from her/his provider – presumably months after the service was provided – to account for the additional cost-sharing she/he would be required to pay as a result of the provider’s successful appeal. In addition, the assessment of the additional cost-sharing would be conducted after the submission of the claim (and after the provider’s successful appeal) and thus by definition the beneficiary would be unable to utilize the Pre-Appeals Payment Exceptions Review process. The beneficiary’s only recourse would be the current review process, which could take significantly longer to adjudicate.

We strongly urge CMS to clarify that in cases where the provider’s or supplier’s appeal results in a higher reimbursement, the beneficiary should be held harmless to the original cost-sharing amount to which she/he was otherwise required to pay.

Expedited timeframe: The proposed rule requires the Payment Exceptions decision to be issued, in writing, within five business days of receipt of the request. ACS CAN supports CMS’ policy that requires prompt review of Payment Exceptions. We urge CMS also to require an expedited appeals process in cases where the beneficiary or her/his physician believes that waiting for a decision under the standard time frame could place the beneficiary’s life, health, or ability to regain maximum function in serious jeopardy.

Data collection: Given historically low beneficiary utilization of the Medicare appeals process, we strongly urge CMS to establish a process to use real-time data to actively monitor how beneficiaries utilize the Pre-Appeals Payment Exceptions Review process. This real-time information will help CMS identify the extent to which the use of the VBP tools in general and/or the use of a particular VBP tool may be hindering beneficiaries’ access to Part B drugs. In the event that such access problems occur, it could be helpful to know whether the access problems are occurring in specific geographic areas, or with specific contractors, or whether the use of specific VBP tools are hindering access.

As discussed in more detail below, we urge CMS to make clear that it intends to use real-time data on the use of beneficiary appeals under the Pre-Appeals Payment Exceptions Review process as one of many tools to evaluate the Part B Drug Payment Model. When promulgating the final rule, CMS should codify its ability to be able to halt the use of one or more VBP tools – on a temporary or permanent basis and regionally or nationally – if it is determined in part through the real-time monitoring of beneficiaries’ use of the Pre-Appeals Payment Exceptions Review process that beneficiary access is hindered by the use of the tool(s).
VI. Evaluation

CMS proposes to evaluate the Part B Drug Payment Model similar to other models developed and tested under CMMI’s authority. The preamble notes that CMS “will compare historic patterns of Part B drug use and Medicare program costs for providers and suppliers, and health outcomes for beneficiaries in response to the alternative interventions proposed in the [Part B Drug Payment Model].”

ACS CAN is deeply concerned that the proposed rule focuses more on the potential for cost savings and provides little specific information (other than a few notable exceptions discussed in greater detail below) regarding how CMS intends to ensure the quality of care for Medicare beneficiaries is preserved or enhanced. Improving quality should be one of the basic outcomes of a CMMI demonstration. In fact, the CMMI was created to “test innovative payment and service delivery models to reduce program expenditures ... while preserving or enhancing the quality of care furnished to individuals” who receive Medicare, Medicaid, or Children’s Health Insurance benefits. We believe improved quality for the patient is as important as program savings. Therefore, we urge CMS to clarify how it will ensure that the quality of care provided to beneficiaries is maintained or improved under the Part B Drug Payment Model.

Beneficiary evaluation: ACS CAN is pleased with CMS’ intent to include beneficiaries in its evaluation of the Part B Drug Payment Model. As discussed in more detail above, we are concerned that some of the proposed policies could hinder beneficiary access to medically necessary treatments and thus urge CMS to develop a specific set of evaluation tools that would allow access to real-time data to ensure that beneficiaries do not experience access problems. We understand that CMS has access to claims data on an almost real-time basis – with as little as two- or three-day lag time. We urge CMS to utilize this real-time data to ensure beneficiary access is protected.

The preamble states that CMS “may consider a survey of beneficiaries, suppliers, and providers to provide insights on beneficiaries’ experience under the model and additional information on any strategies undertaken by those providing drugs included under this model.” We strongly urge CMS to conduct this beneficiary survey – including focus groups from beneficiaries who are taking one or more of the top 10 drugs where 50 percent of the payment reductions are expected to result. In 2014, more than 1 million Medicare beneficiaries were treated with one of these 10 drugs. We agree with CMS that it is important to include providers and suppliers in its evaluation of the impact of the model on beneficiaries. However, we caution CMS that these stakeholders’ views should not be used as a surrogate for the views of actual beneficiaries who have participated in the Part B Drug Payment Model.

49 81 Fed. Reg. at 13252.
52 81 Fed. Reg. at 13252 (emphasis added).
Specific oncology evaluation: Oncology drugs represent 42 percent of Part B spending, and according to one analysis more than 50 percent of the payment reductions that would result from the proposed methodology change come from 10 drugs, seven of which are oncology drugs. As discussed in more detail above, we are concerned about the potential impact of the Part B Drug Payment Model on beneficiaries with cancer. Thus, we urge CMS in its evaluation to conduct specific analysis regarding beneficiary access to oncology care. Included in this analysis must be a determination of the extent to which the Part B Drug Payment Model has resulted in disruptions in beneficiary care and beneficiaries having to get care in higher-cost sites.

Additional beneficiary safeguards: As discussed in more detail above, ACS CAN is deeply concerned that the proposed Part B Drug Payment Model could hinder beneficiary access to medically necessary cancer treatments. We note that CMS has indicated it has the ability to be able to access in real time claims data to evaluate a new payment model. We strongly urge CMS to engage this evaluation tool to ensure that beneficiaries’ access to oncology medications is not hindered — including monitoring the extent to which beneficiaries are accessing oncology services through a higher cost site of care. Prior to the launch of any new payment model CMS should develop a contingency plan to be triggered in the event that the real-time evaluation reveals beneficiary access problems. Such a plan must clearly identify the action steps CMS will implement in the event that access problems are identified. We strongly urge CMS to develop this plan and solicit stakeholder comments through an open and transparent comment process.

Periodic evaluations: As part of its evaluation process, we urge CMS to conduct evaluations of the Part B Drug Payment Model on a yearly basis. The results of these evaluations should be made publicly available shortly after their completion so that interested parties can obtain a better understanding of any concerns or problems that may arise. Releasing an evaluation at the conclusion of the Model – particularly given the Model’s five-year scope – would be too long of a delay.

Quality measures: We are pleased the preamble references the fact that CMS intends to evaluate the quality of care provided under the Part B Drug Payment Model. However, the preamble is silent with respect to which specific quality measures CMS is considering as requirements in the model. As discussed in more detail above, we urge CMS to adopt quality measures that have been accredited by a multi-stakeholder entity through an evidence-based process and should include patient experience measures.

In order to be effective, any quality measures must be identified and available for at least a 45-day public comment period before CMS finalizes the use of the measures. This process will allow for sufficient time for stakeholders to provide input on the number and specific measures being proposed by CMS.

In addition, given that the Part B Drug Payment Model is intended to be five years in scope, we urge CMS to include some quality measures that are intended to remain in place throughout the duration of the model. However, we also anticipate that CMS will add new quality measures to the model as well.

CMS intimated that some of the quality measures that will be included in the Part B Drug Payment Model will be patient-reported outcome measures (PROMs). ACS CAN is pleased that CMS is considering adding PROMs to the quality measures that will be used to evaluate this new model. We note that in cancer care, beneficiaries may choose a treatment option based on a variety of factors – the drug’s toxicity, side-effects, interaction with other drugs, etc. Many of these factors differ among patients. As CMS begins the process of developing PROMs, we urge the agency to specifically develop PROMs for cancer patients.

Simultaneous MACRA implementation: CMS proposes simultaneous implementation of physician reimbursement changes imposed under MACRA and the Part B Drug Payment Model. We are concerned that the simultaneous implementation of two major changes to Part B reimbursement for physicians may make it harder for CMS to evaluate the Part B Drug Payment Model. Thus, as discussed in more detail above, we strongly urge CMS to reconsider implementing the model on a national scope, and rather identify a number of smaller, targeted geographic areas in which to test the model.

Conclusion

On behalf of the American Cancer Society Cancer Action Network we thank you for the opportunity to comment on the Medicare Part B Drug Payment Model proposed rule. As discussed in more detail above, ACS CAN is deeply concerned with the Medicare Part B Drug Payment Model as proposed by CMS, and we urge CMS to address these concerns before implementing any new Part B payment policies. ACS CAN is concerned the proposal has the potential to result in beneficiaries being unable to access their cancer medications in the setting of care that is right for them. We note that one unintended consequence of the Part B Drug Payment Model will likely be a shift in some care to higher-cost settings. Unfortunately, if providers are unable or unwilling to dispense a medically necessary Part B drug due to the reimbursement rate, beneficiaries who need that treatment may have no choice but to seek care in a higher-cost setting. This result would be particularly problematic for beneficiaries who reside in rural areas who have fewer treatment options and who may be forced to travel further distances to receive care. As CMS considers implementing the VBP tools, we urge the agency to balance the impact of the tools with advancements in treatments based on personalized medicine, including treatments based on genetic information, and issues related to side-effects and drug-to-drug interactions.

57 Id.
ACS CAN is pleased the proposed rule recognizes that clinical decision support tools can help providers choose the best treatment for the beneficiary. CDS tools should be developed and utilized with both patients and providers in mind. We are disappointed that CMS missed the opportunity to clarify that the CDS tool should be developed as a treatment decision counseling tool so that a patient and his/her provider can work together to determine the best course of treatment based on the individual preferences of the patient. Similarly, while we are pleased that CMS established the Pre-Appeals Payment Exceptions Review Process as part of the Part B Drug Payment Model, we note that beneficiaries typically do not take advantage of their appeals rights and often are only informed of their rights by their provider. We strongly urge CMS to clarify policies to ensure that this process will not result in beneficiaries being charged higher cost-sharing.

Finally, we urge CMS in its evaluation to conduct specific analyses regarding beneficiary access to oncology care. Included in this analysis should be a determination of the extent to which the Part B Drug Payment Model has resulted in disruptions in beneficiary care and beneficiaries having to get care in higher cost sites of care. We urge CMS to provide additional information regarding the specific quality measures it intends to use to evaluate this model and encourage the adoption of outcomes measures over process measures.

Ultimately, this proposed rule is a long way from where it needs to be and could well create significant harm as currently drafted. If you have any questions, please feel free to contact me or have your staff contact Anna Schwanlein Howard, Policy Principal, Access and Quality of Care at Anna.Howard@cancer.org or 202-985-3261.

Sincerely,

Christopher W. Hansen
President
American Cancer Society Cancer Action Network
May 9, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Part B Drug Payment Model [Docket Number CMS-1670-P]

Dear Acting Administrator Slavitt:

As life sciences associations representing biotechnology, pharmaceutical, medical device and diagnostic companies, universities and research institutions, and venture capital firms across California, we are writing to express our serious concerns with the Centers for Medicare & Medicaid Services’ (CMS) proposed rule that would implement a new “Medicare Part B Payment Model.” This proposal, offered with only limited opportunity for input from stakeholders, would make sweeping changes to payment mechanisms for Medicare Part B covered drugs and directly and negatively impact California’s most vulnerable seniors’ access to life-saving therapies. Given the breadth of our concerns detailed herein and the adverse effects that will be directly felt by Medicare beneficiaries if these cuts were to be implemented, we respectfully request that CMS withdraw the proposed rule.

California is home to a thriving life sciences community with more than 2,800 companies and research institutions clustered throughout the state, whose efforts have led to groundbreaking therapies and technologies to diagnose, treat and prevent conditions such as cancer, cardiovascular disease, diabetes, HIV/AIDS, chronic pain, Alzheimer’s, Parkinson’s Disease, rare diseases, and others. In 2015, the most recent date for which full-year data is available, California companies advanced research and development into 1,235 new therapies – at least 366 of those medicines are to treat cancer. These companies share one core mission: the desire to improve the health and well-being of patients in need. Most life sciences companies are initially supported by the venture capital (VC) community, which helps provide the significant level of funding necessary to innovate and develop new cures and treatments for serious diseases. Without appropriate and predictable coverage and payment mechanisms, VC firms will be less willing to invest in expensive and high-risk biotechnology projects, cutting off the funding necessary to bring a new medicine or treatment to market. Imperative to the continued success of California's innovation ecosystem and its ultimate goal of providing patients with access to new, life-saving medical treatments and therapies is protecting coverage and access programs that are working—like Medicare Part B.

With enactment of the Affordable Care Act, Congress established and empowered the Centers for Medicare and Medicaid Innovation (CMMI) to test new methods of payment and service delivery models in healthcare to reduce spending – without sacrificing Medicare and Medicaid patients’ access to treatment and services. Unfortunately, the Medicare Part B Payment Model unveiled by CMS on March 8, 2016 focuses solely on cost, rather than on quality and access to therapies for...
Medicare patients. The draft rule proposes to implement a Medicare Part B drug reimbursement demonstration that would represent a substantial reduction to the current reimbursement scheme of Average Sales Price (ASP) + 6%, down to ASP + 2.5% with a flat $16.80 payment. Factoring in sequestration, reimbursement for Part B drugs under the demonstration would amount to ASP + 0.86% plus $16.80—a dramatic cut in coverage and payment for these therapies. The proposal therefore not only undermines a key tenet of the mission of CMMI, but will undoubtedly lead to disruption in access to care for Californians who depend on Medicare services to treat complex conditions like cancer, rheumatoid arthritis, Crohn’s disease, and rare diseases.

As reported in a recent Avalere study, CMS’ proposed demonstration would disproportionately affect doctors who utilize more expensive drugs in their treatment of patients, including specialties like ophthalmologists, oncologists, and rheumatologists. In the proposed rule, CMS indicates their belief that the ASP + 6% reimbursement model may encourage the use of more expensive drugs to generate more revenue for providers. This assumption fails on the account that the specialties most impacted by this proposed demonstration often do not have a more affordable alternative to the drugs they administer to their patients.

Without adequate coverage and payment of these therapies, community physician practices will be forced to refer patients to hospital outpatient departments (HOPD), where the cost of care under Medicare is increased to the beneficiary. Patients will face reduced options for treatment and may be forced to travel long distances to receive care, posing a considerable barrier to treatment for the most vulnerable population of ailing Californians. Furthermore, researchers have routinely found that improved medication adherence—that is, getting people to take medicines prescribed for them—is associated with greatly reduced total health care use and costs. Imposing additional hurdles on patients to obtain care—such as forcing them to travel long distances for care, or pay higher out-of-pocket costs for treatment—will undoubtedly increase medicine non-adherence, thus decreasing health outcomes and driving up health care costs when a patient incurs hospitalizations and emergency department visits.

As representatives of California’s innovative life sciences research and development community, we believe this misguided policy will put at risk the promise of existing and future therapies and gravely impede California’s seniors’ access to life-saving drugs. We therefore again respectfully request that CMS permanently withdraw the proposed Part B Drug Payment Model rule.

Should you have any questions or to discuss our views further, please contact Jenny Carey, CLSA’s vice president of federal government relations and alliance development (jcarey@californiabiotech.org) or 202.743.7559.

Sincerely,

[Signatures]

S & CEO, CLSA

G & CEO, Connect

Jo & CEO, Biocom

& CEO, SoCalBio
Examining Congressional comments regarding Medicare's Part B pilot proposal

Raina H. Jain
Coral L. Atoria
Renee L. Gemmell
Peter B. Bach

May 16, 2016
Evidence-Driven Drug Pricing Project

Overview: In four recent letters to CMS, Members of Congress provided conflicting forecasts regarding how the agency’s proposed pilot program of Part B drug payment might affect many aspects of Medicare beneficiary care. We conducted a data driven assessment of these predictions, focusing on those that could be empirically reformulated into hypotheses. As in our prior report, we focused on the area of medical oncology care, which is the dominant category of drug spending in Part B, and on the marginal impact of the reimbursement formula change. We also assumed that CMS would true up their flat fee payment by specialty so that each specialty group was kept budget neutral. Our prior analyses, and those from Avalere and MEDPAC, suggest that the flat fee should be higher than originally proposed for some specialties such as oncology, and lower for others.

Findings:

1) Predictions and concerns regarding the new payment formula leading to acquisition problems for certain Part B drugs seems to ignore the impact of pharmaceutical companies choices about how quickly to raise prices, or distributors decisions about how extensively to price discriminate between doctors’ offices. Those are the choices that will determine if the payment formula leads doctors to be ‘under waser’ on certain drugs, not the formula itself.

2) Predictions regarding the payment formula causing a shift in care of cancer patients from doctor’s offices to hospital outpatient departments seem unsupported. We base this on the observation that in 2013, cancer doctors warned that due to budget sequestration there would be a massive shift of patients from offices to hospitals, and moving of patients for their expensive treatment to hospitals causing discontinuity of care. But when we examined care patterns before and after sequestration, we saw no such effects, and sequestration involved an actual reimbursement reduction, while CMS’ pilot formula reallocates payments but does not cut total payment, assuming the flat fee is calculated to achieve budget neutrality for each specialty.

3) Concerns that the pilot formula will accelerate consolidation of practices into hospitals do not seem supportable. Under the current formula, the reduction in reimbursement for hospitals will be more severe than for physician offices, reducing the arbitrage between the two care settings. This will make acquiring physician offices very slightly less, but certainly not more, attractive to hospitals.
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Domain #1: Access will be limited from drugs going 'under water'</td>
<td>The combined effect of sequestration and the proposed changes to the ASP-based payment methodology may result in some physicians facing acquisition costs that exceed the Medicare payment...</td>
<td>Phase 1... would harm beneficiary access to vital drugs as many providers would face acquisition costs that exceed the Medicare payment amount.</td>
<td>Phase 1... will severely harm patient access to needed drugs... numerous physicians would face acquisition costs that exceed the Medicare payment amount... will especially hurt seniors who depend on doctors in smaller practices or those who live in rural areas.</td>
<td>We do not believe that the model's proposed changes... will adversely impact beneficiary access to needed care... this does not limit a doctor's ability to prescribe what they believe to be the most appropriate therapy.</td>
</tr>
<tr>
<td>Domain #2: Patients will be sent to hospital outpatient departments from doctor's offices</td>
<td>Community-based physicians may refer their patients to hospital outpatient departments (HOPDs) to receive Part B medications.</td>
<td>Physicians who have trouble accessing drugs at the reduced ASP payment would likely refer patients to the hospital outpatient department (HOPD).</td>
<td>CMSS proposed Medicare drug experiment would also lead physicians to refer patients to a hospital outpatient department (HOPD).</td>
<td></td>
</tr>
<tr>
<td>Domain #3: Payment change will accelerate consolidation of doctors' offices into hospitals</td>
<td>Driving care to a less-convenient, more costly setting would reduce beneficiary choice, increase costs, and likely further hospital-physician practice consolidation</td>
<td>Driving care to a less-convenient, more costly setting makes it more challenging for beneficiaries to access needed care and increases overall Medicare costs. This will lead to further consolidation and less choice for seniors.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Experiencing Congressional comments regarding Part B payment proposal www.drugprices.org
Domain #1: Limiting Access from doctors being ‘under water’ for some drugs under the new payment model:

Letters 1, 2 and 3 all expressed some type of concern that the alternative payment formula would lead to a reduction in access to some medications for Medicare beneficiaries, while letter 4 stated that there was no such imminent concern. This concern may rest on some assumptions that are not viable.

Assuming doctors will go ‘under water’ under a new formula means assuming that drug companies will continue to raise the prices of existing products as rapidly as they have been:

As we detailed in our report on Phase I of the pilot, steady price hikes imposed by pharmaceutical companies average 1.7% every two quarters, which consumes nearly half of the 4.3% mark-up Medicare provides for Part B drugs. This is because Medicare reimburses drugs based on their sales prices from two quarters earlier. So if a drug sells for $1 in the first quarter of a year, it will be reimbursed at $1.043 in the third quarter of the year. But when companies raise prices over that time period the acquisition price in the third quarter is higher than the cost basis on which Medicare bases reimbursement. At an average price hike of 1.7%, acquisition of a vial that cost $1 in the first quarter costs $1.017 by the third quarter, meaning doctors only have around $0.026 cents cushion between Medicare’s reimbursement and drug companies new pricing ($1.043-$1.017). Our graph of the inflationary patterns for major Part B cancer drugs over the past 11 years is reproduced to the right – for a full description see our report.

Since these price hikes are not a natural phenomena, but rather occur because they can be accommodated by the reimbursement margin, it is reasonable to postulate that a smaller margin add-on, as Medicare contemplates, might lead to lower rates of price inflation for Part B drugs.
Slowing price inflation of pharmaceutical products is a means by which Medicare and patients could save money over the long term without any change in prescribing patterns, and thus may be a beneficial effect of the alternative payment formula. But it should be noted that this will only occur if the pilot has sufficient scope that the net impact is to discourage price inflation.

Assuming some doctors will go ‘under water’ under a new formula means assuming that intermediary distributors will continue to price discriminate in the marketplace as they have been:

Along with an assumption of ongoing price inflation, the letters contain an assumption that variation in acquisition price, where some physicians end up under water and others do not, is a naturally occurring phenomenon. But in the case of expensive cancer drugs, even the smallest doctors’ offices are still buying hundreds of thousands of dollars in drug per year per doctor, and they come in small packages that are easy and inexpensive to transport. So in truth there are no natural economies of scale favoring larger buyers. Rather, price discrimination is imposed by distributors, coupled with off-invoice volume based rebates in many cases, in order to enhance market share and earn fees from manufacturers. In other words, the intermediary distributors do not need to price discriminate, but they have an interest in doing so when they can.

Empiric evidence from a recent MEDPAC report supports the view that price discrimination is being accommodated by the margin Medicare provides on Part B drug. MEDPAC found that when that margin was abruptly reduced, the upper end of the acquisition price for Part B drugs fell in lockstep. In other words, a smaller reimbursement cushion led to a reduction in the magnitude of price discrimination. The example comes from budget sequestration, where in
Evidence-Driven Drug Pricing Project

April 2013 Medicare reimbursement for Part B drugs fell by 2% – the formula reduced payment from 106% of ASP to 104.3% of ASP, or 1.7%. As shown (above), the upper range of acquisition prices, as shown by the 75th percentile value, fell by nearly the same amount, around 1.7%. In other words, a reduction in reimbursement margin reduced price discrimination. In our view, even without these data policymakers can safely assume that distributors will find ways to accommodate a narrower reimbursement margin so as to not lose large segments of their distribution channel.

Assuming doctors will go ‘under water’ under a new formula means assuming that the best way to assess a reallocation of funding for buy and bill drugs is at the drug level rather than the book of business level. But doing so ignores the cumulative revenue impact of the flat fee.

Letters 1, 2, and 3, but not letter 4, appear to anchor much of the concerns around whether particular drugs might in some cases have higher acquisition costs than reimbursement rates for some providers, rather than looking at payment overall for drugs overall. As Medicare has noted, the two alternative payment formulas are intended to be budget neutral. This is achieved in the pilot formula by counter-balancing a lower percentage based add-on with a flat fee payment per treatment. The math is intended to lead doctors to earn the same total amount under either arrangement if their prescribing patterns are the average. But by definition they will not earn the same amount on each drug under the two formula – they will earn more for lower priced drugs (under $480 per treatment), less for higher priced ones (over $480 per treatment). The concern from Members of Congress about some drugs being underwater seems to ignore the fact that the structure of the reimbursement formula is specifically to have the total revenues from flat fees collectively make-up for any particular shortfalls within the Medicare book of business for doctors.

Assuming rural doctors will go ‘under water’ assumes those doctors face higher acquisition prices

Letters 1 and 3 also delve into the question of whether doctors in rural settings are particularly vulnerable to facing higher than reimbursed acquisition prices. We are unaware of any data on differences in acquisition prices for Part B drugs in rural or urban settings.
MEDPAC's analysis examining the impact of payment changes in hospitals, not doctor's offices, separate rural from urban but projected the same degree of change in both settings. These analyses did not include data on acquisition prices either.

Therefore the only way we have to gauge whether rural physicians would be particularly harmed by the cuts is to look at the problem indirectly, examining whether the decline in reimbursement rates due to sequestration affected rural and urban oncologists differently. The hypothesis here is that if rural oncologists were facing higher acquisition prices than urban providers, then the decline in reimbursement margin from sequestration would have had a disproportionately negative impact on rural providers, and as a consequence would stop participating in Medicare more frequently. Yet from 2012 to 2016 (a time period that bridges the 2013 sequestration) we found the same proportion of cancer doctors in rural and urban settings, 8%, stopped participating in the Medicare program. Analyses not shown include an examination whether population density as a continuous variable predicted disenrollment (it didn’t), or if other specialties less affected by Part B drug reimbursement (gastroenterology and rehabilitation medicine) disenrolled at different rates than oncologists (they didn’t, and they did not differ by rural/urban status either).

Domain #2: Patients will be sent to hospital outpatient departments from doctor’s offices

Letters 1, 2 and 3 raised concerns that the payment formula might lead doctors to send their patients to hospital outpatient departments, which Members of Congress characterized as less convenient and more expensive.

Assuming some doctors will send patients to the hospital outpatient department from their offices requires that a budget neutral reimbursement change alters finances so severely that they forego revenue generating business;

While the finances of private practice offices are not public, this particular concern was raised before, under the specter of an actual reimbursement cut that was not reimbursed, so observing
whether doctors followed through on transferring care to hospitals can provide indirect guidance on the possible impact of the payment formula change. Specifically, in 2013 the Community Oncology Alliance, a lobbying group for cancer doctors, warned that the sequestration cut would force 72% of practices to stop treating new Medicare patients, and also stated that community doctors would ‘split’ care of patients into the hospital outpatient department for drugs where community practices were ‘under water’. Given this prediction, we analyzed 2013 Medicare claims to see if this occurred after budgetary sequestration:

Did the migration of care to the hospital outpatient department from the doctor office accelerate as a result of sequestration?

a. Answer: NO, the pace of migration appeared to proceed at the same pace before and after sequestration. The figure shows the ratio of encounters for cancer treatment that were in doctors’ offices and hospital outpatient departments.

b) Did the fraction of patients getting care in both settings rise, fall, or remain unchanged as a result of sequestration?

Answer: NO, the percent of patients receiving care in both settings was very small (around 0.5%, or 1 in 200) and unchanged over the year.

c) Did patients receiving care in both settings tend to get more expensive drugs in the hospital outpatient department than in the doctor office?

Answer: NO, over the year there was an even split of which setting patients received more expensive treatments.
Conclusions regarding Domain #2 concerns:

There is no evidence that the reimbursement formula change that Medicare proposes implementing will lead community cancer doctors to send patients to hospital outpatient departments. We base this on the observation that warnings that this would occur from budget sequestration in 2013 did not come to fruition, and sequestration was an actual cut in reimbursement while the payment formula modification is not (assuming appropriate flat fee at implementation).

Domain #3: Payment change will accelerate consolidation of doctors’ offices into hospitals

Letters 2 and 3 expressed concern that the payment formula change would accelerate consolidation of doctor office practices into hospital systems. While that trend is strong, that is distinct from knowing how the new payment formula will alter it.

Assuming the payment formula will accelerate consolidation means assuming that physician offices will become more attractive acquisitions to hospitals under the new formula:

As highlighted in our first report, a major driver of consolidation is that a sub-category of hospitals under the 340B program can obtain deep discounts when they acquire Part B drugs but still obtain identical reimbursement from Medicare as hospitals and doctors that do not obtain those discounts. This creates an arbitrage opportunity – the doctors’ offices are more valuable to 340B hospitals than to the doctors. But as detailed in our first report, hospitals actually see larger revenue declines than doctors’ offices under the pilot formula (Table, right).

<table>
<thead>
<tr>
<th>Change to reimbursement with pilot formula in cancer care</th>
<th>Doctor’s office</th>
<th>Hospital outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mark-up/profit only</td>
<td>-24.2%</td>
<td>-60.5%</td>
</tr>
<tr>
<td>Total drug reimbursement</td>
<td>-1.0%</td>
<td>-2.8%</td>
</tr>
<tr>
<td>Drug and infusion fee</td>
<td>-0.9%</td>
<td>-2.6%</td>
</tr>
</tbody>
</table>

Conclusion regarding Domain #3 concerns:

Under the proposed formula the gap between the profits doctors make compared to hospitals is slightly narrowed, which would slow consolidation slightly.
Appendix:

Methods

A. Domain 1: Shift-of-care analysis

A 5% random sample of 2013 Medicare Part B claims was used to identify the site of care for chemotherapy drugs (HCPCS J8521-J9999). Claims from the Carrier file were classified as doctor office and claims from the Outpatient file were classified as HOPD.

For each calendar month in 2013 we calculated and graphed (1) the ratio of chemotherapy days in doctor offices versus HOPD, (2) the proportion of patients who received chemotherapy in both doctor office and HOPD and, (3) of the patients receiving treatment in both doctor office and HOPD, the proportion whose treatments were higher priced in HOPD than doctor office. A reference line is included on the graphs signifying the date under sequester (April 1, 2013) when a 2% reduction in Medicare payment began.

For the calculation of Medicare payments in (3) we excluded drugs that receive no additional payment in HOPD, as payment is rolled into the APC.

B. Domain 2: Rural/urban analysis

Provider enrollment data was obtained from the CMS publicly available Medicare Fee-For-Service Public Provider Enrollment Data for 2012\(^1\) and 2016\(^2\). All providers with a specialty code of 82(Hematology), 83(Hem/Onc), or 90(Medical Oncology) were categorized as hematology, hem/onc & oncology providers for the sake of this analysis. Rural/Urban status was determined by population density. Population density by zip code was based on population counts from 2010 census data and square footage by Census-defined zip code tabulation areas (ZCTA) from the 2013 US Gazetteer File\(^3\). Zip code tabulation areas are used by the US Census to generally represent USPS zip code service areas.\(^4\) Providers in zip codes with no matching ZCTA had unknown population density and were excluded from the analysis. To keep in line

---

\(^1\) 2012 data available at [https://data.cms.gov/Medicare/Medicare-Providers-2012/ibt-hst-cj54](https://data.cms.gov/Medicare/Medicare-Providers-2012/ibt-hst-cj54)


Evidence-Driven Drug Pricing Project

with the Census Bureau’s definition of an urbanized area, zip codes with a population density of at least 1,000 people per square mile were considered urban. All other zip codes with a known population density less than 1,000 per square mile were considered rural. Disenrollment was defined as providers present in the 2012 Medicare provider file who were not present in the 2016 provider file. Providers were identified across the two datasets by NPI. A chi-square test was used to determine the association between urban/rural status and provider disenrollment from 2012 to 2016.

C. Domain 3: Net impact of payment formula

Data Sources
This analysis used data from CMS’s October 2014 ASP file and Summary Data for 2014 MPFS Drug Codes used in the Part B Drug Payment Model. From the ASP file, we used the HCPCS code dosage information and the Average Sales Price (ASP) payment limit (ASP+6%). The Summary Data for the Part B Drug Payment Model includes information by HCPCS on utilization, charge and payment. In our analyses we used number of encounters, units and Medicare payment information for the MPFS setting. This file includes total payments of ASP+6%.

We considered only Part B cancer-related drugs, including all chemotherapy drugs (J8521-J9999) and other cancer-supportive, non-chemotherapeutic drugs (J0207, J0461, J0594, J0640, J0641, J0850, J0882, J0894, J0897, J1100, J1190, J1200, J1260, J1442, J1446, J1453, J1455, J1569, J1650, J2353, J2405, J2425, J2765, J2780, J3489, J7511, J7517, J7525, J7527) that we selected based on our clinical knowledge of cancer care. Drugs were further excluded from analyses if they were not included in either of our sources of data or had zero encounters or Medicare payments in 2014 in the physician setting. This comprised the denominator for all analyses (n=100 HCPCS).

We then adjusted the volume of drugs for which there are uses outside of oncology. Examples of such drugs include bevacizumab for eye disease, rituximab for rheumatoid arthritis, and dexamethasone that has numerous uses. Overall we examined all drugs that have non-cancer

---


6 ASP October 2014 (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McPartBDrugAvgSalesPrice/2014ASPFiles.html)

Evidence-Driven Drug Pricing Project

uses and resulted in a change of payments of $1 million or more. To do so we analyzed the 5% random sample of 2013 Medicare Part B physician claims to adjust volumes by determining the proportion of doses and average doses of uses that were for cancer and for other indications.

Analyses

For each HCPCS, we calculated the total payment to physician under four scenarios: 1) current reimbursement, 2) current reimbursement under sequestration, 3) proposed reimbursement (from CMS Part B Proposed Rule) and 4) proposed reimbursement under sequestration.

\[ \text{Units per Encounter} = \frac{\# \text{ Units}}{\# \text{ Encounters}} \]

Dose per encounter = Units per Encounter \* HCPCS code dosage

Payment per encounter:

1) \( ASP + 6\% = \text{Units per Encounter} \times \text{ASP Payment Limit Oct 2014} \)

2) \( ASP + 4.3\% = \text{Units per Encounter} \times \left( \frac{\text{ASP Payment Limit}}{1.06} \times 1.043 \right) \)

3) \( (ASP + 2.5\%) + 16.80 = \text{Units per Encounter} \times \left( \frac{\text{ASP Payment Limit}}{1.06} \times 1.025 \right) + 16.8 \)

4) \( (ASP + 0.9\%) + 16.46 = \text{Units per Encounter} \times \left( \frac{\text{ASP Payment Limit}}{1.06} \times 1.009 \right) + 16.46 \)

Part B Proposal Impact

Based on the proposed reimbursement of \( (ASP + 2.5\%) + 16.80 \) per encounter, we determined which drugs, on a per encounter basis, that doctors will be above/below current \( ASP + 6\% \) payment; drugs that doctors will lose or gain profits on.
\[ \text{ASP} \times 0.06 = \text{ASP} \times 0.025 + 16.8 \]

Budget Neutral ASP = \( \frac{\$480}{\text{Encounter}} \)

This net gain/loss under the Proposed Rule is represented in the plot by the two different color dots (green indicating gain, red indicating loss) on the cumulative percent of payment line.

We then repeated this analysis assuming the proposed reimbursement under sequestration of (ASP + 0.9%) + $16.46 per encounter, we determined which drugs on a per encounter basis that doctors will be above/below the current sequestration ASP + 4.3% reimbursement.

Budget Neutral ASP under Sequestration = \( \frac{\$484}{\text{Encounter}} \)

**Impact on Profits for Doctors and Hospitals**

For each HCPCS, we calculated the change in profits for doctors both annually and per encounter for each proposal. For each of the four scenarios, we calculated profits as:

\[
\text{Profits Per Encounter}^{\text{Scenario}} = \left( \frac{\text{Payment}^{\text{Scenario}}}{\text{Encounter}} - \frac{\text{ASP Payment Limit}}{1.06} \right)
\]

\[
\text{Total Profits}^{\text{Scenario}} = \# \text{ Encounters} \times \left( \frac{\text{Payment}^{\text{Scenario}}}{\text{Encounter}} - \frac{\text{ASP Payment Limit}}{1.06} \right)
\]

And change in profits as the difference in the proposed versus current scenarios:

Change in Profits = \( \text{Profits}^{\text{PROPOSED}} - \text{Profits}^{\text{CURRENT}} \)

We also calculated the impact on doctors profits overall for each proposal:

\[
\% \text{ Profit Change} = \frac{\sum_{\text{HCPCS}} (\text{Change in Total Profits})}{\sum_{\text{HCPCS}} (\text{Total Profits}^{\text{CURRENT}})}
\]

**Impact on Revenue**
Evidence-Driven Drug Pricing Project

The impact on revenue for Part B cancer-related drugs was calculated based on the sum of the difference in payment, weighted by the number of encounters, and divided by the 2014 Medicare payments for these drugs:

\[
\text{\% Revenue Change} = \frac{\sum_{\text{HCPCS}} \left( \frac{\text{Payment}_{\text{PROPOSED}} - \text{Payment}_{\text{CURRENT}}}{\text{Encounter}} \right) \times \# \text{Encounters}}{\sum_{\text{HCPCS}} \text{Medicare Payments}_{\text{CURRENT}}}
\]

Note: For calculation of impact on profit/revenue, administration fees were included. Fees were collected from 5% sample of 2013 Medicare claims, and were added to the denominator of each formula. HCPCS for chemotherapy administration included the following: 96401, 96402, 96405, 96406, 96409, 96411, 96413, 96415, 96416, 96417, 96420, 96422, 96423, 96425, 96440, 96445, 96450, 96542, and 96549.
June 17, 2016

Ms. Marcia Boyle
President and Founder
Immunodeficiency Foundation
110 West Road
Towson, MD 21204

Dear Ms. Boyle:

Thank you for appearing before the Subcommittee on Health on May 17, 2016, to testify at the hearing entitled “The Obama Administration’s Medicare Drug Experiment: The Patient and Doctor Perspective.”

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on July 1, 2016. Your responses should be mailed to Graham Pitman, Legislative Clerk, Committee on Energy and Commerce, 2123 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to graham.pitman@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment
Responses to Questions for the Record

Subcommittee on Health
May 17, 2016 hearing
“The Obama Administration’s Medicare Drug Experiment: The Patient and Doctor Perspective”

Mareia Boyle, President and Founder
Immune Deficiency Foundation

Questions Submitted by the Honorable Leonard Lance

As Chair of the Congressional Rare Disease Caucus, I am particularly concerned about those patients with rare diseases, a vulnerable population that already experience lengthy journeys to accurate diagnosis, only to be presented with limited therapeutic options – if any – for effective treatment.

These same at-risk patients have great difficulty locating providers who can appropriately treat their rare and complex disease. To equate their medical condition with one that has multiple therapies available puts their access to these providers at risk.

Further, as we look to encourage the adoption of personalized medicine, Congress has taken particular care to recognize that a “one-size-fits-all” approach does not respect the acute needs of rare disease patients and other unique populations.

1. Ms. Boyle, can you elaborate on the struggles rare disease patients and their families must endure and the unique needs of this population that CMS must keep in mind?

Representative Lance, the Immune Deficiency Foundation thanks you for your leadership as a champion of rare diseases issues. We greatly appreciate your recognition that a “one-size-fits-all” approach does not recognize the needs of individuals with rare diseases. It is imperative that the Centers for Medicare and Medicaid Services (CMS) keep in mind that any disruption or delay in access to treatment may cause serious health problems for patients.

Primary immunodeficiency, or PI, represents a group of more than 250 rare, chronic genetic diseases in which part of the body’s immune system is missing or functions improperly, resulting in a decreased ability to fight off infection. Throughout their lives, people with PI are more susceptible to infections, endure frequent health problems, including a number of other comorbidities, and can develop serious and debilitating illnesses.

Approximately 250,000 people are diagnosed with PI in the U.S. Depending upon the type of PI, treatments can include prophylactic antibiotic therapy, bone marrow transplantation, enzyme replacement, interferon gamma and antifungals. Patients with PI who have a lack of and/or impaired antibody function require lifelong, lifesaving treatment with immunoglobulin replacement therapy (Ig therapy), partly replacing what the body should be making and protecting them from infection. Today, with early diagnosis and appropriate therapies, such as Ig, many patients diagnosed with PI can live healthy, productive lives.
Patients with rare diseases and their families not only face the challenges that come with a serious, chronic health condition, but also face high out-of-pocket costs, difficulty being correctly diagnosed, difficulty finding providers experienced to treat their particular condition, greater chance of infection and illness, challenges with coverage of their treatment, and missed work. Many times, these challenges are compounded for families because PI is a genetic disease and multiple family members may be affected.

There are several effective medical therapies available for patients with PI which optimize their health, improve their quality of life and allow them to be productive members of society. However, it is important to understand that the Ig that is given partly replaces what the body should be making, but it does not stimulate the patient’s own immune system to make more Ig. Since Ig only replaces the missing end product, but does not correct the patient’s defect in antibody production, Ig replacement is usually necessary at regular intervals for the patient’s lifetime.

The IDF urges CMS to be aware that any disruption or delay in access to treatment may cause serious health consequences.

2. Have you heard of these concerns from the patients in your organization? Can you comment on the impact of any potential delay or interruption in treatment for these patients?

Yes, the Immune Deficiency Foundation (IDF) regularly hears from patients regarding their coverage problems or difficulty finding a provider for their regular infusions. In fact, our experience in this area was greatly intensified after the implementation of the Medicare Modernization Act of 2003 (MMA). At that time, our patient population experienced firsthand the impact of treatment delays and disruptions due to serious access problems.

Starting in 2005, patients with primary immunodeficiency (PI) saw significant reductions in reimbursement as a result of the MMA, which changed Part B drug reimbursement from the Average Wholesale Price (AWP) to Average Sales Price (ASP) plus 6%. Two studies by the Health and Human Services Office of Inspector General (OIG) (http://oig.hhs.gov/oei/reports/oei-53-05-00404.pdf) and the Assistant Secretary for Planning and Evaluation (ASPE) (https://aspe.hhs.gov/ospe-reports/2007/6081.pdf) reported in 2007 the difficulties physicians and specialty pharmacies had obtaining immunoglobulin (Ig) products at the Medicare reimbursed price and the impact on patients’ ability to obtain their infusions. The HHS OIG reported to Congress that, “Sixty-one percent of responding physicians indicated that they had sent patients to hospitals for IVIG treatment because of their inability to acquire adequate amounts of IVIG or problems with Medicare payment.”

Some of our patients had to go without treatment because they had difficulty identifying a provider who would continue to infuse them when they could no longer purchase IVIG at the Medicare reimbursed rate. The Office of the Inspector General’s (OIG) April 2007 report, Intravenous Immune Globulin: Medicare Payment and Availability, found that that Medicare reimbursement for intravenous immunoglobulin (IVIG) was inadequate to cover the cost many providers must pay for the product. During the third quarter of 2006, 44% of IVIG sales to hospitals and 41% of sales to physicians by the three largest distributors occurred at prices above
Medicare payment amounts. Earlier in the year, after price increases by manufacturers at the beginning of the year, 77% of IVIG sales to hospitals and 96% of sales to physicians occurred at prices above Medicare payment amounts. The result was that our patients struggled to find providers or had to miss or delay treatments. Some had to travel great distances, including crossing state lines, to access care. This infusion is typically given over several hours, so when you combine the travel time each way, the infusion time, and the recovery time, it means a patient could regularly miss a couple days of work or other activity for a regular infusion and incur travel costs.

Following the reduction in Medicare reimbursement for IVIG in 2005, the IDF commissioned three national surveys to better quantify the effect on patient access to care for PI patients.

The IDF survey found that substantial numbers of Medicare patients had their treatments postponed and/or reduced in frequency following the change to ASP+6%. More than 4 out of 10 Medicare patients (41%) reported postponed treatments and one-quarter of all Medicare patients suffered multiple treatment postponements. Eighteen percent of Medicare patients indicated that the time interval between infusions had increased since the end of 2004/beginning of 2005.

In addition, those surveyed reported that as a result of postponed treatments and increases in intervals between treatments, 26% of PI patients on Medicare reported suffering negative health consequences, including more infections generally (21%), increased use of antibiotics (19%), bronchitis (14%), and pneumonia (7%).

The IDF urges CMS to ensure that any reimbursement changes do not result in delay or interruption in treatment.

The Agency fails to recognize the reality that, for some conditions, there is no appropriate alternative treatment other than an orphan drug. The Proposed Rule all but acknowledges its disproportionate impact on beneficiaries with rare disorders in its discussion of budget neutrality and acknowledgement that the Model would shift Part B drug payments from specialists (treating the majority of rare disorders) to primary care providers, without furthering CMS’ stated goal of encouraging use of lower-cost treatment options.

3. Can you speak to the impact of having to switch physicians for the rare disease patients you represent?

Our patients’ disorders are rare and complex, and there are a limited number of major medical centers and physician offices that know how to manage them. Patients with a serious, chronic condition develop a long-term relationship with their physician. It is very difficult for a patient to change physicians, especially when it is not their choice to do so.

The Immune Deficiency Foundation (IDF) estimates that the average length of time between onset of symptoms and diagnosis is between nine and 15 years. Once a patient has a correct diagnosis and physician to oversee their treatment, any disruptions in that continuity of care are difficult for the patient, but also can jeopardize his or her health.
As the IDF's patients have experienced, access is compromised when physicians cannot purchase drugs at the Medicare reimbursed rate. It's not about making money off the patient—it's about being able to sustain infusions for patients—especially those with chronic conditions that require treatment in regular intervals. For our patients, intravenous immunoglobulin (IVIG) is given every 3 to 4 weeks and more frequently for subcutaneous immunoglobulin (Ig). If providers can't break even, they don't provide the treatment to our patients.

In 2007, the HHS OIG reported that 61% of responding physicians indicated that they had sent patients to hospitals for IVIG treatment, largely because of their inability to purchase IVIG at prices below the Medicare payment amounts. In addition, OIG found that some physicians had stopped providing IVIG to Medicare beneficiaries altogether.

In 2007, IDF commissioned a national survey of immunologists, conducted with the American Academy of Asthma, Allergy and Immunology (AAAAI). Fifty-one percent (51%) of physicians reported having patients change their site of IVIG therapy because of reimbursement. Thirty-six percent (36%) of physicians treating PI patients with IVIG reported their IVIG-using patients have experienced additional or more severe health problems since the beginning of 2005 because of reductions in Medicare reimbursement. Nearly half of the doctors with IVIG-using PI patients believe current Medicare reimbursement rules for IVIG pose an extreme or serious risk to the health of their patients. Three-quarters of physicians were of the opinion that current reimbursement poses at least a moderate risk to the health of their PIDD patients.

Sending patients with compromised immune systems to the hospital for treatment is dangerous and actually more expensive for the Medicare program. From experience, the IDF knows that there are few hospitals in every state that have the capacity to treat and provide IVIG to patients with PI (Two examples; only 2 in Connecticut—Yale and Hartford; and only two in Maryland---both in Baltimore) making it a geographical challenge for patients. In addition, not all sites of care are appropriate for all patients so access to the most appropriate site is crucial.

As a result of the Medicare Modernization Act of 2003 (MMA) cuts, IVIG in the physician’s office was nearly eliminated because physicians could not afford to administer infusions. Even though Medicare covered home infusions, the reimbursement became so low that specialty pharmacies could not afford to provide the items and services necessary for IVIG in the home. Congress responded by passing the Medicare IVIG Access Act (P.L. 112-242) with overwhelming support (401-3 in the House; unanimously in the Senate). This demonstration is currently underway, and IDF anticipates it will lead to a permanent fix in the current Medicare home infusion benefit for IVIG. (See https://innovation.cms.gov/initiatives/IVIG/index.html.) Our fear is that the proposed Part B demonstration, which explicitly includes the current Medicare IVIG Access demonstration, will undercut the IVIG demo. Specialty pharmacies already complain that they are close to underwater now with ASP+6 and low payment for the items and services needed for infusions in the home.

It's important to ensure access to the most appropriate and medically indicated setting. Patients with rare diseases must not lose access to their physicians and sites of care.

1 Assessing the Impact of Changes in Reimbursement Regulations and Product Availability on Access to Intravenous Immunoglobulin Treatment Among Primary Immune Deficiency Patients, The Immune Deficiency Foundation, November 28, 2005